Practice Management

Hsc
Home Study Course

Home Study Course

Section 2
November 2017

AMERICAN ACADEMY OF OTOLARYNGOLOGY–HEAD AND NECK SURGERY FOUNDATION

THE
HOME STUDY COURSE
IN
OTOLARYNGOLOGY -- HEAD AND NECK SURGERY

SECTION 2

Practice Management

November 2017

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2017 credit exam submission deadline: December 31, 2017
Section 2 suggested exam deadline: January 2, 2018
Expiration Date: August 7, 2018; CME credit not available after that date

Introduction
The Home Study Course is designed to provide relevant and timely clinical information for physicians in training and current practitioners in otolaryngology - head and neck surgery. The course, spanning four sections, allows participants the opportunity to explore current and cutting-edge perspectives within each of the core specialty areas of otolaryngology.

The **Selected Recent Material** represents primary fundamentals, evidence-based research, and state of the art technologies in practice management. The scientific literature included in this activity forms the basis of the assessment examination.

The number and length of articles selected are limited by editorial production schedules and copyright permission issues, and should not be considered an exhaustive compilation of knowledge on practice management.

The **Additional Reference Material** is provided as an educational supplement to guide individual learning. This material is not included in the course examination and reprints are not provided.

Needs Assessment
AAO-HNSF's education activities are designed to improve healthcare provider competence through lifelong learning. The Foundation focuses its education activities on the needs of providers within the specialized scope of practice of otolaryngologists. Emphasis is placed on practice gaps and education needs identified within eight subspecialties. The *Home Study Course* selects content that addresses these gaps and needs within all subspecialties.

Target Audience
The primary audience for this activity is physicians and physicians-in-training who specialize in otolaryngology-head and neck surgery.

Outcomes Objectives

The participant who has successfully completed this section should be able to:

1. Recognize the changing nature of physician reimbursement systems, the structure of the otolaryngology workforce, and how these will affect the future of the specialty.
2. Discuss how performance metrics and electronic health records may be utilized to improve quality of care.
3. Identify those aspects of common otolaryngic care most susceptible to litigation and learn possible steps to reduce this risk.
4. Review current methods that can be utilized to improve communication in the healthcare setting as a means of error reduction.
5. Explain the concept of quality of care and how its measurement will affect physician compensation in the future.
6. Discuss the key elements of team medical care and the essential patient care handoff and understand the implications in potentially reducing medical errors.
7. Restate the essential issues involved when encountering the impaired or disruptive physician and learn strategies to successfully manage these challenging situations.
8. Review the factors associated with physician burnout and learn about existing tools and strategies designed to increase physician well-being and job-related satisfaction.

Medium Used
The Home Study Course is available in electronic or print format. The activity includes a review of outcome objectives, selected scientific literature, and a self-assessment examination.

Method of Physician Participation in the Learning Process
The physician learner will read the selected scientific literature, reflect on what they have read, and complete the self-assessment exam. After completing this section, participants should have a greater understanding of practice management as well as useful information for clinical application.

Estimated time to complete this activity: 40.0 hours

Accreditation Statement
The American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Credit Designation
The AAO-HNSF designates this enduring material for 40.0 *AMA PRA Category 1 Credit(s)*™. Physicians should claim credit commensurate with the extent of their participation in the activity.

ALL PARTICIPANTS must achieve a **post-test score of 70%** or higher for a passing completion to be recorded and a transcript to be produced. Residents' results will be provided to the Training Program Director.

PHYSICIANS ONLY: In order to receive *Credit* for this activity a **post-test score of 70%** or higher is required. Two retest opportunities will automatically be available if a minimum of 70% is not achieved.

Disclosure
The American Academy of Otolaryngology Head and Neck Surgery/Foundation (AAO-HNS/F) supports fair and unbiased participation of our volunteers in Academy/Foundation activities. All individuals who may be in a position to control an activity's content must disclose all relevant financial relationships or disclose that no relevant financial relationships exist. All relevant financial relationships with commercial interests[1] that directly impact and/or might conflict with Academy/Foundation activities must be disclosed. Any real or potential conflicts of interest[2] must be identified, managed, and disclosed to the learners. In addition, disclosure must be made of presentations on drugs or devices, or uses of drugs or devices that have not been approved by the Food and Drug Administration. This policy is intended to openly identify any potential conflict so that participants in an activity are able to form their own judgments about the presentation.

[1] A "Commercial interest" is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

[2] "Conflict of interest" is defined as any real or potential situation that has competing professional or personal interests that would make it difficult to be unbiased. Conflicts of interest occur when an individual has an opportunity to affect education content about products or services of a commercial interest with which they have a financial relationship. **A conflict of interest depends on the situation and not on the character of the individual.**

2017 Section 2: PRACTICE MANAGEMENT FACULTY

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Stephanie Wilson, Stephanie Wilson Consulting, LLC; Production Manager	No relationships to disclose
Richard V. Smith, MD, chair, AAO-HNSF Education Steering Committee	Expert Witness: various legal firms
Brendan C. Stack, Jr., MD, chair, AAO-HNSF Core Otolaryngology & Practice Management Education Committee	Consulting Fee: Hollingsworth LLP; Shire Pharmaceuticals; Genentech Other Financial: Davies, Humphreys, Horton & Rees, PLC; Wright, Lindsey, Jennings, LLP

This 2017-18 Home Study Course Section 2 does not include discussion of any drugs and devices that have not been approved by the United States Food and Drug Administration.

Disclaimer
The information contained in this activity represents the views of those who created it and does not necessarily represent the official view or recommendations of the American Academy of Otolaryngology – Head and Neck Surgery Foundation.

August 7, 2018: Deadline for all 2017-18 exams to be received; course closed August 8, 2018.

EVIDENCE BASED MEDICINE

The AAO-HNSF Education Advisory Committee approved the assignment of the appropriate level of evidence to support each clinical and/or scientific journal reference used to authenticate a continuing medical education activity. Noted at the end of each reference, the level of evidence is displayed in this format: **[EBM Level 3]**.

Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001)	
Level 1	Randomized[1] controlled trials[2] or a systematic review[3] (meta-analysis[4]) of randomized controlled trials[5].
Level 2	Prospective (cohort[6] or outcomes) study[7] with an internal control group or a systematic review of prospective, controlled trials.
Level 3	Retrospective (case-control[8]) study[9] with an internal control group or a systematic review of retrospective, controlled trials.
Level 4	Case series[10] without an internal control group (retrospective reviews; uncontrolled cohort or outcome studies).
Level 5	Expert opinion without explicit critical appraisal, or recommendation based on physiology/bench research.

Two *additional ratings* to be used for articles that do not fall into the above scale. Articles that are informational only can be rated N/A , and articles that are a review of an article can be rated as Review. All definitions adapted from Glossary of Terms, Evidence Based Emergency Medicine at New York Academy of Medicine at www.ebem.org.

[1] A technique which gives every patient an equal chance of being assigned to any particular arm of a controlled clinical trial.
[2] Any study which compares two groups by virtue of different therapies or exposures fulfills this definition.
[3] A formal review of a focused clinical question based on a comprehensive search strategy and structure critical appraisal.
[4] A review of a focused clinical question following rigorous methodological criteria and employing statistical techniques to combine data from independently performed studies on that question.
[5] A controlled clinical trial in which the study groups are created through randomizations.
[6] This design follows a group of patients, called a "cohort", over time to determine general outcomes as well as outcomes of different subgroups.
[7] Any study done forward in time. This is particularly important in studies on therapy, prognosis or harm, where retrospective studies make hidden biases very likely.
[8] This might be considered a randomized controlled trial played backwards. People who get sick or have a bad outcome are identified and "matched" with people who did better. Then, the effects of the therapy or harmful exposure which might have been administered at the start of the trial are evaluated.
[9] Any study in which the outcomes have already occurred before the study has begun.
[10] This includes single case reports and published case series.

OUTLINE
Section 2: Practice Management
November 2017

I. Practice Management
   A. Quality measures (definition, PQRS)
   B. Physician reimbursement (MACRA, MIPS)
   C. Otolaryngology workforce composition

II. Professionalism
   A. Physician burnout
   B. Impaired physician
   C. Disruptive physician

III. Communication
   A. Informed consent
   B. Telemedicine

IV. Systems-Based Practice
   A. Electronic medical record
   B. Role of physician extenders (nurse practitioner, physician assistant)
   C. Team-based medicine (multi-disciplinary teams, handoffs)

V. Practice-Based Learning
   A. Maintenance of certification
   B. Litigation data, lessons learned
   C. Role of mediation in resolving litigation

TABLE OF CONTENTS
Selected Recent Materials - Reproduced in this Study Guide

SECTION 2: PRACTICE MANAGEMENT
November 2017

C. Otolaryngology workforce composition
Hughes CA, McMenamin P, Mehta V, et al. Otolaryngology workforce analysis. *Laryngoscope*. 2016; 126 Suppl 9:S5-S11. EBM level NA.....17-23

Summary: This article evaluates several database sources regarding the supply and demand of otolaryngologists in the United States. The article concludes that the available workforce is below the forecasted needs in future years for the U.S. population. The demographics of the workforce and data reporting the most common diagnoses reported during otolaryngology visits are also presented.

II. Professionalism

A. Physician burnout
Fletcher AM, Pagedar N, Smith RJ. Factors correlating with burnout in practicing otolaryngologists. *Otolaryngol Head Neck Surg*. 2012; 146(2):234-239. EBM level 4.....24-29

Summary: This is a comprehensive study of burnout among practicing ENTs, and is not just focused on academic ENTs. The study showed that younger age, hours worked per week, and fewer years in practice were the most significant predictors of burnout, whereas length of time in marriage was protective. Similar to other studies, findings indicated having children in the family also contributed to burnout.

Shanafelt TD, Kaups KL, Nelson H, et al. An interactive individualized intervention to promote behavioral change to increase personal well-being in US surgeons. *Ann Surg*. 2014; 259(1):82-88. EBM level 4.....30-36

Summary: Surgeons do not self-assess their distress level well. Validated self-assessment tools may help promote changes to improve personal well-being.

B. Impaired physician
DesRoaches CM, Rao SR, Fromson JA, et al. Physicians' perceptions, preparedness for reporting, and experiences related to impaired and incompetent colleagues. *JAMA*. 2010; 304(2):187-193. EBM level 4.....37-43

Summary: Self-policing of physicians is a keystone mechanism for the profession in identifying and managing impaired or incompetent providers. This large survey study found that more than 40% of physicians did not completely agree with the professional responsibility to report. While a majority of respondents (64%) felt well prepared to address an impaired colleague, 17% report having failed to report direct knowledge of an impaired or incompetent physician in the last 3 years. The report indicated the need to better educate physicians on the importance of reporting impaired colleagues as a patient safety issue and to reduce concerns of retribution or personal loss from reporting. This is an older paper, but high quality.

C. Disruptive physician

Cochran A, Elder WB. A model of disruptive surgeon behavior in the perioperative environment. *J Am Coll Surg*. 2014; 219(3):390-398. EBM level 4.....44-52

Summary: This paper presents a study at a single institution involving several types of operating room participants regarding disruptive surgeon behavior. The article focuses on characterizing types of disruptive behavior. The authors found situational stress tended to increase disruptive behavior.

Grogan MJ, Knechtges P. The disruptive physician: a legal perspective. *Acad Radiol*. 2013; 20(9):1069-1073. EBM level 5.....53-57

Summary: Disruptive behavior has cascading effects in the functioning and safety of the medical care team. Loss of privileges is a reasonable action by hospitals faced by disruptive physician behavior, but such action must follow some key policies.

Overton AR, Lowry AC. Conflict management: difficult conversations with difficult people. *Clin Colon Rectal Surg*. 2013; 26(4):259-264. EBM level NA.....58-63

Summary: This article provides strategies on how to deal with conflict within the workplace. It discusses approaches to preparing for the conflict discussion, proceeding with the discussion, and responding to conflict management. The authors also describe how to deal with the disruptive physician.

III. Communication

A. Informed consent

Childers R, Lipsett PA, Pawlik TM. Informed consent and the surgeon. *J Am Coll Surg*. 2009; 208(4):627-634. EBM level 5.....64-71

Summary: While this article is older, it provides a great overview of the key components and concepts in informed consent as it applies to the surgeon. Several key common challenges to full informed consent are discussed and options are reviewed.

Kraft SA, Constantine M, Magnus D, et al. A randomized study of multimedia informational aids for research on medical practices: implications for informed consent. *Clin Trials*. 2017; 14(1):94-102. EBM level 1.....72-80

Summary: Understanding of research issues and concepts are important for participants' understanding of the research and proper consent. This study evaluates the use of multimedia aids vs. text-only information on these concepts. Text-only information performed worst amongst options for information conveyance. While the article is geared to clinical research informed consent, some applicability also likely exists in clinical informed consent.

Pianosi K, Gorodzinsky AY, Chorney JM, et al. Informed consent in pediatric otolaryngology: what risks and benefits do parents recall? *Otolaryngol Head Neck Surg*. 2016; 155(2):332-339. EBM level 4.....81-88

Summary: This article presents results of a study of how well parents recalled informed consent regarding tonsillectomy, adenoidectomy, and tube placement 2 weeks after the in-office discussion. Both the in-office discussion and the phone call with the recall questions were recorded and compared. Although there was significant variability among providers as to what was included in the informed consent, it was noted that parents electing surgery tended to remember more benefits than risks. Additionally, there were parents who recalled risks and benefits that were not discussed, suggesting that they were seeking outside sources in addition to the office visit.

B. Telemedicine

Beswick DM, Vashi A, Song Y, et al. Consultation via telemedicine and access to operative care for patients with head and neck cancer in a Veterans Health Administration population. *Head Neck*. 2016; 38(6):925-929. EBM level 3.....89-93

Summary: Telemedicine is increasingly being utilized as a healthcare delivery model for complex subspecialty care in remote patient populations. Head and neck cancer is a complex disease that is optimally treated with a multidisciplinary care team and a well-developed infrastructure. Therefore, telemedicine has been proposed as a mechanism to facilitate treatment of head and neck cancer for patients who reside at a significant distance from such a center. It has been noted that in addition to facilitating timely access to subspecialty surgical care, the developed telemedicine protocol enabled significant travel-related time savings and financial savings for patients.

Hasan H, Ali F, Barker P, et al. Evaluating handoffs in the context of a communication framework. *Surgery*. 2017; 161(3):861-868. EBM level 2b.....94-101

Summary: Handoffs refer to the transfer of patient care between healthcare providers. Changes in residency work hours have resulted in an increased number of handoffs. This study examines factors that can negatively impact the handoff. Also, the information from the study allows for targeted interventions to improve the handoff process and hopefully patient care.

Irizarry T, DeVito Dabbs A, Curran CR. Patient portals and patient engagement: a state of the science review. *J Med Internet Res*. 2015; 17(6) e148. EBM level 5.....102-116

Summary: This is review article on patient portals. The article reviews factors that influence patient use of patient portals. Studies on patient portals were grouped into one of five categories: patient adoption, provider endorsement, health literacy, usability, and utility. Principal findings revealed that the CMS and Medicaid EHR incentive program is the major driver of patient portal development. The study concludes that adoption by patients and providers will come when existing patient portal features align with the needs of patients and providers.

B. Litigation data, lessons learned

Stevenson AN, Myer CM 3rd, Shuler MD, Singer PS. Complications and legal outcomes of tonsillectomy malpractice claims. *Laryngoscope*. 2012; 122(1):71-74. EBM level 4.....192-195

Summary: This article reports on the contents of the LexisNexis legal database regarding tonsillectomy cases that were litigated or settled from 1984 to 2010. Verdicts and monetary awards were analyzed for trends and common themes in the causes of complications, litigation, and outcome. The article then presents key learning points for the otolaryngologist to avoid or reduce the risk of future litigation involving tonsillectomy patients.

Svider PF, Carron MA, Zuliani GF, et al. Lasers and losers in the eyes of the law: liability for head and neck procedures. *JAMA Facial Plast Surg*. 2014; 16(4):277-283. EBM level 4.....196-202

Summary: Procedures using lasers represent a potential target for malpractice litigation when an adverse event occurs. Although otolaryngologists were more likely to be named as physician defendants when lasers were used in head and neck interventions, cases in this analysis included cutaneous/cosmetic procedures as well. The importance of the informed consent process was emphasized.

Winford TW, Wallin JL, Clinger JD, Graham AM. Malpractice in treatment of sinonasal disease by otolaryngologists: a review of the past 10 years. *Otolaryngol Head Neck Surg*. 2015; 152(3):536-540. EBM level 4.....203-207

Summary: Otolaryngologists should be knowledgeable of the reasons for litigation in the treatment of sinonasal disease as well as the importance of informed consent. This article reviews the recent trends and causes for litigation, outcomes of such suits, and legal requirements in a medical malpractice case.

C. Role of mediation in resolving litigation

Sohn DH, Bal BS. Medical malpractice reform: the role of alternative dispute resolution. *Clin Orthop Relat Res*. 2012; 470(5):1370-1378. EBM level 4.....208-216

Summary: The U.S. healthcare system needs reform. The current tort system is extremely expensive. This article explores alternative dispute resolution (ADR) as a technique to help reform the current tort system. ADR has an excellent track record of avoiding litigation, decreasing overall cost, and increasing satisfaction among both plaintiffs and defendants.

2017-18 SECTION 2: PRACTICE MANAGEMENT ADDITIONAL REFERENCES

Anoushiravani AA, Patton J, Sayeed Z, et al. Big data, big research: implementing population health-based research models and integrating care to reduce cost and improve outcomes. *Orthop Clin North Am*. 2016; 47(4):717-724.

Awad SS, Fagan SP, Bellows C, et al. Bridging the communication gap in the operating room with medical team training. *Am J Surg*. 2005; 190(5):770-774.

Ban VS, Madden CJ, Browning T, et al. A novel use of the discrete templated notes within an electronic health record software to monitor resident supervision. *J Am Med Inform Assoc*. 2017; 24(e1):e2-e8.

Barinaga G, Chambers MC, El-Othmani MM, et al. Affordable care organizations and bundled pricing: a new philosophy of care. *Orthop Clin North Am*. 2016; 47(4):707-716.

Batra PS. Evidence-based practice: balloon catheter dilation in rhinology. *Otolaryngol Clin North Am*. 2012; 45(5):993-1004.

Boyd JW. Deciding whether to refer a colleague to a physician health program. *AMA J Ethics*. 2015; 17(10):888-893.

Camp MW, Mattingly DA, Gross AE, et al. Patients' views on surgeons' financial conflicts of interest. *J Bone Joint Surg Am*. 2013; 95(2):e9 1-8.

Casalino LP, Wu FM, Ryan AM, et al. Independent practice associations and physician-hospital organizations can improve care management for smaller practices. *Health Aff (Millwood)*. 2013; 32(8):1376-1382.

Catchpole KR, Dale TJ, Hirst DG, et al. A multicenter trial of aviation-style training for surgical teams. *J Patient Saf*. 2010; 6(3):180-186.

Chang CWD, Mills JC. Effects of a reward system on resident research productivity. *JAMA Otolaryngol Head Neck Surg*. 2013; 139(12):1285-1290.

Choudhri AF, Chatterjee AR, Javan R, et al. Security issues for mobile medical imaging: a primer. *Radiographics*. 2015; 35(6):1814-1824.

Cochran A, Elder WB. Effects of disruptive surgeon behavior in the operating room. *Am J Surg*. 2015; 209(1):65-70.

Colla CH, Lewis VA, Shortell SM, Fisher ES. First national survey of ACOs finds that physicians are playing strong leadership and ownership roles. *Health Aff (Millwood)*. 2014; 33(6):964-971.

Contrera KJ, Ishii LE, Setzen G, Berkowitz SA. Accountable care organizations and otolaryngology. *Otolaryngol Head Neck Surg*. 2015; 153(2):170-174.

Date DF, Sanfey H, Mellinger J, Dunnington G. Handoffs in general surgery residency, an observation of intern and senior residents. *Am J Surg*. 2013; 206(5):693-697.

Delisle M, Grymonpre R, Whitley R, Wirtzfeld D. Crucial conversations: an interprofessional learning opportunity for senior healthcare students. *J Interprof Care*. 2016; 30(6):777-786.

Dewa CS, Loong D, Bonato S, et al. How does burnout affect physician productivity? A systematic literature review. *BMC Health Serv Res*. 2014; 14:325.

Dupree JM, Patel K, Singer SJ, et al. Attention to surgeons and surgical care is largely missing from early Medicare accountable care organizations. *Health Aff (Millwood)*. 2014; 33(6):972-979.

Dyrbye LN, West CP, Satele D, et al. A national study of medical students' attitudes toward self-prescribing and responsibility to report impaired colleagues. *Acad Med*. 2015; 90(4):485-493.

Evidence-Based Medicine Working Group. Evidence-based medicine: a new approach to teaching the practice of medicine. *JAMA*. 1992; 268(17):2420-2425.

Espinel AG, Shah RK, Beach MC, Boss EF. What parents say about their child's surgeon: parent-reported experiences with pediatric surgical physicians. *JAMA Otolaryngol Head Neck Surg*. 2014; 140(5):397-402.

Falcone JL, Claxton RN, Marshall GT. Communication skills training in surgical residency: a needs assessment and metacognition analysis of a difficult conversation objective structured clinical examination. *J Surg Educ*. 2014; 71(3):309-315.

Fischer T, Brothers KB, Erdmann P, Langanke M. Clinical decision-making and secondary findings in systems medicine. *BMC Med Ethics*. 2016; 17(1):32-44.

Furukawa MF, King J, Patel V, et al. Despite substantial progress in EHR adoption, health information exchange and patient engagement remain low in office settings. *Health Aff (Millwood)*. 2014; 33(6):1672-1679.

Grady C. Enduring and emerging challenges of informed consent. *N Engl J Med*. 2015; 372(9):855-862.

Haider AH, Obirieze A, Velopulos CG, et al. Incremental cost of emergency versus elective surgery. *Ann Surg*. 2015; 262(2):260-266.

Harle CA, Cook RL, Kinsell HS, Harman JS. Opioid prescribing by physicians with and without electronic health records. *J Med Syst*. 2014; 38(11):138-144.

Higgins A, Veselovskiy G, McKown L. Provider performance measures in private and public programs: achieving meaningful alignment with flexibility to innovate. *Health Aff (Millwood)*. 2013; 32(8):1453-1461.

Khoshbin A, Lingard L, Wright JG. Evaluation of preoperative and perioperative operating room briefings at the Hospital for Sick Children. *Can J Surg*. 2009; 52(4):309-315.

Kim JS, Cooper RA, Kennedy DW. Otolaryngology-head and neck surgery physician work force issues: an analysis for future specialty planning. *Otolaryngol Head Neck Surg*. 2012; 146(2):196-202.

Koltov MK, Damle NS. Health policy basics: Physician Quality Reporting System. *Ann Intern Med*. 2014; 161(5):365-367.

Lamba S, Tyrie LS, Bryczkowski S, Nagurka R. Teaching surgery residents the skills to communicate difficult news to patient and family members: a literature review. *J Palliat Med*. 2016; 19(1):101-107.

Langerman A, Angelos P, Siegler M. The "call for help": intraoperative consultation and the surgeon-patient relationship. *J Am Coll Surg*. 2014; 219(6):1181-1186.

Lango MN, Handorf E, Arjmand E. The geographic distribution of the otolaryngology workforce in the United States. *Laryngoscope*. 2017; 127(1):95-101.

Lifchez SD, Redett RJ 3rd. A standardized patient model to teach and assess professionalism and communication skills: the effect of personality type on performance. *J Surg Educ*. 2014; 71(3):297-301.

Mahboubi H, Salibian AA, Wu EC, et al. Contributing factors to adoption of electronic medical records in otolaryngology offices. *Laryngoscope*. 2013; 123(11):2658-2663.

Mahboubi H, Salibian AA, Wu EC, et al. The role and utilization of electronic medical records in ambulatory otolaryngology. *Laryngoscope*. 2013; 123(10):2418-2422.

Michalski A, Stopa M, Miśkowiak B. Use of multimedia technology in the doctor-patient relationship for obtaining patient informed consent. *Med Sci Monit*. 2016; 22:3994-3999.

Miller ME, Diegler M, Angelos P. Ethical issues in surgical innovation. *World J Surg*. 2014; 38(7):1638-1643.

Mills P, Neily J, Dunn E. Teamwork and communication in surgical teams: implications for patient safety. *J Am Coll Surg*. 2008; 206(1):107-112.

Mohorek M, Webb TP. Establishing a conceptual framework for handoffs using communication theory. *J Surg Educ*. 2015; 72(3):402-409.

Newcomb AB, Trickey AW, Porrey M, et al. Talk the talk: implementing a communication curriculum for surgical residents. *J Surg Educ*. 2017; 74(2):319-328.

Newton L, Sulman C. A pilot program: using text messaging to improve timely communication to tonsillectomy patients. *ORL Head Neck Nurs*. 2016; 34(2):6-10.

Ochieng J, Buwembo W, Munabi I, et al. Informed consent in clinical practice: patients' experiences and perspectives following surgery. *BMC Res Notes*. 2015; 8:765.

Prochazka AV, Fink AS, Bartenfeld D, et al. Patient perceptions of surgical informed consent: is repeat back helpful or harmful? *J Patient Saf*. 2014; 10(3):140-145.

Pugliese OT, Solari JL, Ferreres AR. The extent of surgical patients' understanding. *World J Surg*. 2014; 38(7):1605-1609.

Rehim SA, DeMoor S, Olmsted R, et al. Tools for assessment of communication skills of hospital action teams: a systematic review. *J Surg Educ*. 2017; 74(2):341-351.

Reinke CE, Kelz RR, Baillie CA, et al. Timeliness and quality of surgical discharge summaries after the implementation of an electronic format. *Am J Surg*. 2014; 207(1):7-16.

Rose C, Svider PF, Sheyn A, et al. Protecting the most vulnerable: litigation from pediatric otolaryngologic procedures and conditions. *Laryngoscope*. 2014; 124(9):2161-2166.

Russ S, Rout S, Sevdalis N, et al. Do safety checklists improve teamwork and communication in the operating room? A systematic review. *Ann Surg*. 2013; 258(6):856-871.

Shaha SH, Sayeed Z, Anoushiravani AA, et al. Big data, big problems: incorporating mission, values, and culture in provider affiliations. *Orthop Clin North Am*. 2016; 47(4):725-732.

Shanafelt TD, Hasan O, Dyrbye LN, et al. Changes in burnout and satisfaction with work-life balance in physicians and the general US working population between 2011 and 2014. *Mayo Clin Proc*. 2015; 90(12):1600-1613.

Song SA, Tolisano AM, Camacho M. Laryngology litigation in the United States: thirty years in review. *Laryngoscope*. 2016; 126(10):2301-2304.

Spatz ES, Krumholz HM, Moulton BW. The new era of informed consent: getting to a reasonable-patient standard through shared decision making. *JAMA*. 2016; 315(19):2063-2064.

Steehler KR, Steehler MK, Pierce ML, Harley EH. Social media's role in otolaryngology–head and neck surgery: informing clinicians, empowering patients. *Otolaryngol Head Neck Surg*. 2013; 149(4):521-524.

Steehler MK, Chu EE, Na H, et al. Teaching and assessing endoscopic sinus surgery skills on a validated low-cost task trainer. *Laryngoscope*. 2013; 123(4):841-844.

Svider PF, Eloy JA, Baredes S, et al. Expert witness testimony guidelines: identifying areas for improvement. *Otolaryngol Head Neck Surg*. 2015; 152(2):207-210.

Svider PF, Pashkova AA, Folbe AJ, et al. Obstructive sleep apnea: strategies for minimizing liability and enhancing patient safety. *Otolaryngol Head Neck Surg*. 2013; 149(6):947-953.

Tapia NM, Fallon SC, Brandt ML, et al. Assessment and standardization of resident handoff practices: PACT project. *J Surg Res*. 2013; 184(1):71-77.

Victores AJ, Coggins K, Takashima M. Electronic health records and resident workflow: a time-motion study of otolaryngology residents. *Laryngoscope*. 2015; 125(3):594-598.

Whittemore AD. The competent surgeon: individual accountability in the era of "systems" failure. *Ann Surg*. 2009; 250(3):357-362.

Yao CM, Fernandes VT, Palmer JN, Lee JM. Educational value of a preoperative CT sinus checklist: a resident's perspective. *J Surg Educ*. 2013; 70(5):585-587.

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The present and future of quality measures and public reporting in neurosurgery

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Quality measurement and public reporting are intended to facilitate targeted outcome improvement, practice-based learning, shared decision making, and effective resource utilization. However, regulatory implementation has created a complex network of reporting requirements for physicians and medical practices. These include Medicare's Physician Quality Reporting System, Electronic Health Records Meaningful Use, and Value-Based Payment Modifier programs. The common denominator of all these initiatives is that to avoid penalties, physicians must meet "generic" quality standards that, in the case of neurosurgery and many other specialties, are not pertinent to everyday clinical practice and hold specialists accountable for care decisions outside of their direct control.

The Centers for Medicare and Medicaid Services has recently authorized alternative quality reporting mechanisms for the Physician Quality Reporting System, which allow registries to become subspecialty-reporting mechanisms under the Qualified Clinical Data Registry (QCDR) program. These programs further give subspecialties latitude to develop measures of health care quality that are relevant to the care provided. As such, these programs amplify the power of clinical registries by allowing more accurate assessment of practice patterns, patient experiences, and overall health care value. Neurosurgery has been at the forefront of these developments, leveraging the experience of the National Neurosurgery Quality and Outcomes Database to create one of the first specialty-specific QCDRs.

Recent legislative reform has continued to change this landscape and has fueled optimism that registries (including QCDRs) and other specialty-driven quality measures will be a prominent feature of federal and private sector quality improvement initiatives. These physician- and patient-driven methods will allow neurosurgery to underscore the value of interventions, contribute to the development of sustainable health care solutions, and actively participate in meaningful quality initiatives for the benefit of the patients served.

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ABBREVIATIONS CEHRT = certified EHR technology; CMS = Centers for Medicare and Medicaid Services; EHR = electronic health record; EP = eligible professional; MACRA = Medicare Access and CHIP Reauthorization Act; MIPS = Merit-Based Incentive Payment System; NQF = National Quality Forum; N²QOD = National Neurosurgery Quality and Outcomes Database; PQRS = Physician Quality Reporting System; QCDR = Qualified Clinical Data Registry; VM = Value-Based Payment Modifier.

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Quality measurement has taken on an increasingly central role in our rapidly evolving health care landscape.[7] As the practice of medicine shifts from individual authority to societal accountability, the quality of medical interventions will be under increasing and continuous scrutiny by patients, peers, payers, and policy makers.[7]

If executed appropriately, quality measurement can empower all members of the health care equation.[7] First, the accumulation of high-quality, risk-adjusted data advances the objective of patient-centered health care by giving patients the tools to participate more meaningfully in shared decision making. Second, physicians and other health care professionals will be able to use these data to facilitate targeted quality improvement, practice-based learning, and effective resource utilization. Third, the data will allow policy makers and payers to more easily and accurately understand the true value of clinical interventions, an essential consideration in resource-intensive fields such as neurosurgery. In the end, better data will allow these various stakeholders to reward clinical excellence in an objective and evidence-based manner.

The Importance of Quality Measurement in Medicine

Now more than ever, there is increasing regulatory pressure to create a standardized framework for quality measurement across all areas of medicine. The Centers for Medicare and Medicaid Services (CMS) developed and released the CMS quality strategy in 2013[13] in alignment with the National Quality Strategy.[1] The CMS quality programs address care provided across the continuum, encourage quality improvement through the use of payment incentives and reductions, and promote transparency. Although these goals are well intentioned, most national quality metrics developed to date have been generic and do not reflect the needs of specialty medicine or meaningfully improve care. Furthermore, measures often rely solely on administrative (claims) data, which for specialties such as neurosurgery lack specificity due to coding limitations. In this environment, neurosurgery can play a pivotal role in the advancement of health care quality and safety through the creation of more robust, data-driven, specialty-specific measures.

We present here an overview of the current quality measurement and reporting landscape with an emphasis on new regulatory and legislative developments, such as the Physician Quality Reporting System (PQRS) Qualified Clinical Data Registry (QCDR) reporting option. We highlight the role of neurosurgery and new opportunities in this rapidly changing field.

Quality Measures

Quality measures are used to determine the value of care provided by physicians; they are tools that help quantify health care processes, outcomes, patient perceptions, organizational structure, and systems of care. Measures are meant to reflect the ability of physicians and clinical teams to provide high-quality care. The CMS has established that quality measures should relate to one or more of the following goals: effective, safe, efficient, patient-centered, equitable, and timely care.[17]

The types of measures reported change yearly.[17] They generally vary by specialty and focus on quality areas such as clinical outcomes, care coordination, patient safety and engagement, clinical processes, effectiveness of care, and population/public health. They can also vary by reporting method. In order for quality measures to be considered relevant to specific clinical conditions and to be selected for use, the following factors are considered: type of care delivered (e.g., preventive, chronic, acute); clinical setting in which care is delivered (e.g., office, emergency department, operating room); quality improvement goals for the given year; as well as other quality reporting programs in use.[17]

The most common measure types are outcome, process, and structural measures. They are defined as follows:[17] 1) outcome measure: a measure that assesses the results of health care experienced by patients such as clinical events, recovery and health status, experiences in the health system, and efficiency/costs of care; 2) process measure: a measure that focuses on steps that should be followed to provide good care—these measures are predicated upon the belief that a scientific basis exists to support the conclusion that the process, when executed according to design, will increase the probability of achieving a desired outcome; and 3) structural measure: a measure that assesses features of a health care organization or clinician relevant to the capacity to provide quality health care. These measures address the resources and capabilities available for patient care.

Quality Measure Development

There are several ways new quality measures may become accepted. National or regional organizations, private or public vendors, and professional societies or associations are all actively participating in the development process. Measure validation and approval by expert multidisciplinary panels lie at the core of creating high-quality metrics. Some of the highest standards for the development and maintenance of quality metrics have been set by the National Quality Forum (NQF).[28] Most developers must put their measures through a rigorous evaluation process long before the NQF considers them for endorsement. This organization's careful review and assessment gathers input from stakeholders across the health care enterprise and develops consensus about which measures warrant endorsement as "best in class." The NQF uses 4 criteria to assess a measure for endorsement. Proposed measures should be 1) important to report, 2) scientifically acceptable, 3) useable and relevant, and 4) feasible to collect.[28]

Despite its rigor, the NQF process can be lengthy and expensive. The NQF review process typically occurs on a 3-year schedule.[26] Every 3 years, endorsed measures in a topical area, as well as newly submitted measures, undergo a 9-step consensus development process, including review against updated NQF evaluation criteria, to ensure that the measure specifications are current, accurate, and

harmonized with other measures.[26] The development and maintenance of a single measure through this process can cost up to $250,000, based on some estimates.[9] The length and cost of this process make NQF endorsement prohibitive for smaller medical societies.

In recognition that the health care community is increasingly asking for more visible and faster progress in improving quality, the NQF has recently taken steps to change its approach to measure development and endorsement, with the goal to be more strategic and efficient. Much of this work has focused on streamlining its 8-step Consensus Development Process,[7] which is the primary method by which the organization evaluates and endorses consensus standards, including performance measures, best practices, frameworks, and reporting guidelines. Whether the NQF will achieve its objective of accelerating its processes to address the need to "get to better measures faster" remains to be determined.

Although CMS is required to consider NQF-endorsed measures for its federal reporting programs (where they exist), it has the authority to adopt non–NQF-endorsed measures when they target measure gaps or high-priority areas. Private payers may regard NQF-endorsed measures highly, but at present there is no mechanism to mandate use in the private sector.

The adoption of quality measures by CMS is a similarly prolonged, complicated, and expensive process. CMS relies on a standardized approach, known as the Measures Management System, for developing and maintaining measures used in its various quality programs.[12] CMS uses this framework to identify measure gaps and determine which measure development projects to fund. Funded measure developers (i.e., contractors) are then expected to adhere to these standards when developing and implementing these measures.

These and other sources have resulted in more than 1600 measures used across 33 different quality programs under Medicare alone. A study of almost 30 private health plans identified approximately 550 distinct measures in use, with little overlap between the measures used by private and public programs.[27]

Physician Quality Reporting System: Requirements for Satisfactory Reporting

Under the PQRS, individual eligible professionals (EPs) and group practices must report quality measure data to CMS on an annual basis to avoid a payment penalty. Physicians and other EPs who satisfactorily report PQRS measures data to CMS in 2015 can avoid a payment adjustment of –2%, which would apply to all 2017 Medicare Part B–covered professional services. This same penalty will apply to 2018 payments based on 2016 reporting.

The PQRS offers EPs several reporting mechanisms.[17] These options, and their associated requirements, differ slightly depending on whether they are being used by individuals or group practices. However, they generally include claims-based reporting, electronic health record (EHR) options, web interfaces, CMS-certified survey vendors, PQRS-qualified registries, and (new as of 2014) participation via a QCDR.[17]

Preliminary results from the application of PQRS to individual physicians have demonstrated that the modest incentives (which were initially part of this program, but ended after 2014) are significantly offset by the implementation and maintenance costs of the program.[8] CMS recently reported that 76.9% of the 2889 neurosurgeons who participated in PQRS in 2013 were eligible for incentive payments, which averaged only $731.[11]

Unfortunately, the majority of measures that are included in the traditional CMS-approved PQRS measure set are generic and process oriented, and concerns have been raised about their relevance to true clinical quality.[36] Existing PQRS measures often do not apply to procedural fields and acute conditions and are particularly irrelevant to surgical specialties, such as neurosurgery. The paucity of clinically relevant PQRS measures means that neurosurgeons have very little opportunity to participate in the program meaningfully and are faced with Hobson's choice—either accept increasing payment penalties or report simply for the sake of reporting. Neither achieves the quality improvement goals of the nation.

Qualified Clinical Data Registry Reporting

Fortunately, new opportunities for meaningful neurosurgical participation in quality reporting have recently been created through the Congressional authorization of QCDRs in 2014. The QCDR is an alternative to traditional PQRS reporting methods that allows participants to satisfy PQRS requirements by reporting measures that have been developed and validated by the registry entity. CMS-approved QCDR entities may include a registry, certification board, or another collaborative effort that collects medical and/or clinical data for the purpose of patient and disease tracking with an ultimate goal to foster improvement in the quality of care provided to patients.[16] The data submitted to CMS via a QCDR covers quality measures across multiple payers and is not limited to Medicare beneficiaries.

A QCDR is different from a PQRS "qualified registry" in that it is not limited to only reporting measures approved under the traditional PQRS set. This allows for the development and inclusion of measures tailored to specialty care, such as neurosurgery. A QCDR may contain measures from one or more of the following categories: Clinician & Group–Consumer Assessment of Healthcare Providers and Systems; NQF-endorsed measures; current PQRS measures; measures used by boards or specialty societies; or measures used in regional quality collaborations.

However, a QCDR entity can only offer its participants a maximum of 20 non-PQRS measures to choose from for purposes of qualifying for the PQRS.

Amplifying the Power of Clinical Registries

Clinical registries have seen explosive growth in recent years and represent a reliable clinical outcomes platform that can allow head-to-head comparison of treatment techniques.[7] Additionally, through accurate risk adjustment (to account for the sicker patients treated in some centers of excellence, or the tendency to treat patients who have

more comorbidities with less invasive options), registries allow for the evaluation of individual practitioners, practice groups, and hospital performance, as well as assessments of patient experience. These programs will supplement national efforts to minimize disparities and reward excellence. Registry programs will also facilitate targeted quality improvement, practice-based learning, shared decision making, and effective resource utilization.[7] In summary, specialty-specific quality registries are reliable tools for patients, physicians, hospitals, and payers who wish to define and promote value in therapeutic interventions. Among all the available public reporting methods, QCDRs are particularly well suited to harness the power of registries to create disease- and treatment-specific measures that reflect realistic and relevant quality targets for neurosurgery and other medical specialties.

The Complexity Continues

Despite the obvious value of quality measurement and reporting, physicians are currently faced with a cacophony of conflicting regulatory requirements. In addition to participation in PQRS,[15] physician groups are also mandated to gradually participate in 2 additional quality initiatives. First, the EHR Incentive Program, also known as meaningful use, aims to assess if physician groups are using federally certified EHR technology (CEHRT) in a meaningful manner to improve patient care.[14] Under this program, physicians are assessed for the use of CEHRTs to verify drug-drug and drug-allergy interactions, to computerize order entries for medications and laboratory orders, and to create and transmit summary of care documents.

Physicians are even held accountable for actions beyond their control, such as ensuring that a patient views, downloads, or transmits health information to a third party. Although this program initially offered more than $30 billion in incentive payments to physicians and hospitals that were meaningful users of CEHRTs, the program has now transitioned to penalties only. Medicare providers who do not meet federal meaningful use standards in 2016 will face a 3% cut in Medicare payments in 2018.[14] This "stick-based" approach is driving both hospitals and physician practices to undergo major restructuring of their budgets to increase the emphasis on information technology.[29]

The Value-Based Payment Modifier (VM) is an additional mandate that results in differential payments to physician group practices and solo practitioners under the Medicare Physician Fee Schedule based on an evaluation of performance on a composite of quality and cost-of-care measures.[18] This program is being applied gradually, depending on the size of the provider group. Noncompliance, as well as poor performance, can result in Medicare pay cuts as high as 4%.[18] Quality composite scores are based on PQRS measures reported (including non–first-year QCDRs), as well as 3 outcomes measures automatically calculated by CMS based on administrative claims. The cost composite consists of total per capita spending measures and a measure that looks at spending related to a patient's entire hospital episode (including 3 days prior to and 30 days after the hospitalization). These measures are not only irrelevant to specialty care, but they also may result in neurosurgeons being held accountable for care decisions and spending outside of their control. Although high-value care can be rewarded under this program, recent evidence has shown that the program is not having a major impact on patient outcomes[22] and that only a small minority of providers will experience financial benefits.[31]

Although the cumulative effect of all of these penalties is concerning, bigger concerns have been raised about the true impact of these initiatives on patient outcomes. The literature demonstrates modest benefits when using EHRs,[2,10,32] but no association between meaningful use and improved outcomes has been identified.[33] (Meaningful use is using CEHRT to improve the quality, safety, and efficiency of care. The CMS meaningful use program sets specific objectives that eligible professionals and hospitals must achieve to qualify for CMS EHR Incentive Programs.)

Similarly, only modest gains have been observed in the preliminary implementation of pay-for-performance initiatives,[6] and there has been significant criticism about the current structure and effectiveness of the VM.[19,34] There is a need to coordinate these quality programs and return control to the medical profession and its relevant clinical experts to determine the most accurate and meaningful ways to measure and improve the quality of subspecialty care. Neurosurgeons should not face penalties for the inability to achieve generic standards that are not relevant to their practices. Congressional initiatives are underway[4] with proposed legislation to reform aspects of the EHR Incentive Program. This includes more stringent requirements on EHR vendors to ensure that their systems are interoperable and can actually be used to seamlessly transmit health information and improve care.[24]

Public Reporting

Adding to the complexity and perversity of the current quality improvement enterprise is the fact that CMS (and private payers and other stakeholders) have begun to publicly report data that they believe reflect true quality. Last year, CMS announced plans to publicly report quality measure performance data collected on all physicians via its Physician Compare website[19] by 2016, if technically feasible. Concerns have been raised about the validity of performance data, especially in regard to the rigor of risk adjustment, appropriateness of patient attribution to providers,[21] and the role of hospital administrators in the accurate reporting of data.[20] The closely related Hospital Compare website (https://www.medicare.gov/hospitalcompare/search.html), which displays hospital quality metrics, has been criticized recently for the validity of the publicly reported data.[5] As CMS continues to increase the data available for public consumption, questions remain about whether consumers actually find such data useful and whether they are using it for health care decision making.

The Future for Quality Reporting

Recent legislation passed by the US Congress (the Medi-

care Access and CHIP Reauthorization Act [MACRA])[23] repealed Medicare's sustainable growth rate payment formula and replaced it with a new streamlined value-based incentive payment system called the Merit-Based Incentive Payment System (MIPS). The MIPS consolidates the 3 existing Medicare incentive programs (PQRS, meaningful use, and VM), repeals their existing penalty structure, and replaces it with a new system that will give physicians the opportunity to earn incentive payments for high performance. The MIPS payments, incentives, and negative adjustments will slowly increase over the coming years. Because MIPS is designed to be budget neutral, meaning that bonus payments must be offset by negative payment adjustments, it is difficult to predict actual payments until the program begins. However, Congress has budgeted an additional $500 million bonus pool each year to provide incentive payments to the highest performers.

MACRA offers higher annual Medicare fee schedule payment updates to physicians who participate in and receive a significant portion of their revenue from alternative payment models (e.g., accountable care organizations, bundled payment initiatives, and patient-centered medical homes). Under the alternative payment model system, in addition to financial rewards from the underlying shared-savings model, physicians have the opportunity to earn an additional 5% annual bonus from 2019 to 2025.

As noted, MIPS eliminates the existing penalties for PQRS, the EHR, and VM programs at the end of 2018.[23] Starting in 2019, physicians will receive bonuses or penalties that are determined by a composite score, ranging from 0 to 100. The score consolidates the existing quality programs as follows: 30% quality, 30% resource use, 25% meaningful use of EHRs, and 15% for a new component that will recognize clinical practice improvement activities that may be more relevant to a specialty, but are not recognized under the current system (this could include reporting to a QCDR, American Board of Medical Specialties Program for Maintenance of Certification, and other activities). Physicians will only be assessed on measures that are relevant to their practice. Also, scoring weights may be adjusted as necessary to ensure that individuals are measured equitably, based on the comorbidity profile of their patients. However, risk adjustment of these measures is critical to ensure that the quality and resource-utilization measures are accurate assessments of physician performance. The biggest challenge is to protect neurosurgeons from a system that unfairly penalizes those who take on risk in their practice.

Lest neurosurgeons question the overall commitment of payers to aggressively link objective measures of quality to reimbursement, it should be noted that in January 2015, only a few months before MACRA passed and authorized all of the previously mentioned changes, the Secretary of the US Department of Health and Human Services set an explicit timetable to more rapidly shift Medicare reimbursements from volume to value, setting out to tie 85% of all Medicare fee for service payments to quality or value by 2016, and 90% by 2018. In parallel to this effort, the private sector formed an alliance and announced the goal of tying 75% of their payment models to quality and lowering health care costs by 2020.

MACRA is a major step toward combining and updating existing quality programs. The role of QCDRs was prominently featured in the legislation, making clear that registries will continue to be an essential component of public reporting moving forward. Furthermore, the new law directs CMS to make the quality programs more clinically relevant and insists that physicians be meaningfully involved in the design of reporting systems. Physician specialty societies will have an enhanced opportunity to identify and submit quality measures (particularly if developed for use in QCDRs) that are relevant to their specialties, without having to first pass through the NQF or other long and costly endorsement processes. Most importantly, this congressional mandate may create significant opportunities for neurosurgery to influence the changing quality measures landscape.

Qualified Clinical Data Registry in Neurosurgery

Neurosurgery has been at the forefront of the new developments for QCDRs and the creation of specialty-specific quality measures. The development of the National Neurosurgery Quality and Outcomes Database ([N^{2}QOD] http://www.neuropoint.org/NPA%20N2QOD.html) by the NeuroPoint Alliance[25] provided the specialty with the data that allowed the development of the first neurosurgery-specific QCDR and associated quality metrics. This initial project focused on lumbar spine surgery, because the lumbar module of the N^{2}QOD was the most fully developed component of the registry.[3] A detailed report of neurosurgery's first QCDR, as well as a review of the newly created measures, is offered in a companion article.[30] As more subspecialty modules are implemented in N^{2}QOD, their data will be used to develop additional subspecialty-specific QCDRs.

The initiatives taken by organized neurosurgery demonstrate a commitment on behalf of our specialty to maintain a leading role in developing meaningful quality improvement and health care transparency projects. By using granular registries, such as the N^{2}QOD, we are confident that we can highlight the value of neurosurgical procedures and ultimately, improve patient outcomes.[35] Our goal is to facilitate these developments and empower all the stakeholders in health care (physicians, patients, policy makers, and payers) to make appropriate decisions based on neurosurgery-specific data.

Conclusions

Quality measurement and public reporting are intended to facilitate targeted outcome improvement, practice-based learning, shared decision making, and effective resource utilization in health care. Regulatory pressures have created a complex network of quality requirements to be met by physicians and practices. However, recent legislative reform is changing this landscape and fueling optimism that QCDRs specifically, and registries in general, will be the main quality-reporting avenues in the near future. Neurosurgery has been at the forefront of these developments and has leveraged the experience of

the N²QOD to develop one of the first specialty-specific QCDRs. This program will allow neurosurgeons to objectively demonstrate the value of our interventions and actively participate in meaningful quality initiatives, to the benefit of our patients, as well as the purchasers of health care services.

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References

1. Agency for Healthcare Quality and Research: **The National Quality Strategy (NQS).** (http://www.ahrq.gov/workingforquality/about.htm) [Accessed October 15, 2015]
2. Ancker JS, Kern LM, Edwards A, Nosal S, Stein DM, Hauser D, et al: Associations between healthcare quality and use of electronic health record functions in ambulatory care. **J Am Med Inform Assoc 22:**864–871, 2015
3. Asher AL, Speroff T, Dittus RS, Parker SL, Davies JM, Selden N, et al: The National Neurosurgery Quality and Outcomes Database (N2QOD): a collaborative North American outcomes registry to advance value-based spine care. **Spine (Phila Pa 1976) 39 (22 Suppl 1):**S106–S116, 2014
4. Atkinson M, Jeffries J: Alexander, Murray announce working group to identify ways to improve electronic health records. **US Senate Committee on Health, Education, Labor & Pensions Newsroom.** April 29, 2015. (http://www.help.senate.gov/chair/newsroom/press/alexander-murray-announce-working-group-to-identify-ways-to-improve-electronic-health-records) [Accessed October 15, 2015]
5. Austin JM, Jha AK, Romano PS, Singer SJ, Vogus TJ, Wachter RM, et al: National hospital ratings systems share few common scores and may generate confusion instead of clarity. **Health Aff (Millwood) 34:**423–430, 2015
6. Bardach NS, Wang JJ, De Leon SF, Shih SC, Boscardin WJ, Goldman LE, et al: Effect of pay-for-performance incentives on quality of care in small practices with electronic health records: a randomized trial. **JAMA 310:**1051–1059, 2013
7. Bekelis K, Goodney RP, Dzebisashvili N, Goodman DC, Bronner KK: Variation in the care of surgical conditions: cerebral aneurysms, in Goodney PR, Dzebisashvili N, Goodman DC, et al. (eds): **Variations in the Care of Surgical Conditions: A Dartmouth Atlas of Health Care Series.** Lebanon, NH: Dartmouth College, 2014
8. Berman B, Pracilio VP, Crawford A, Behm WR, Jacoby R, Nash DB, et al: Implementing the physician quality reporting system in an academic multispecialty group practice: lessons learned and policy implications. **Am J Med Qual 28:**464–471, 2013
9. Booz Allen Hamilton: **Hospital Quality Reporting in the United States: A Cost Analysis for the Hospital Quality Alliance.** Washington, DC: The Hospital Quality Alliance, 2006
10. Carter JT: Electronic medical records and quality improvement. **Neurosurg Clin N Am 26:**245–251, ix, 2015
11. Centers for Medicare and Medicaid Services: **Analysis and Payment.** (https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/pqrs/analysisandpayment.html) [October 15, 2015]
12. Centers for Medicare and Medicaid Services: **A Blueprint for the CMS Measures Management System.** (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MeasuresManagementSystemBlueprint.html) [October 15, 2015]
13. Centers for Medicare and Medicaid Services: **CMS Quality Strategy 2013—Beyond.** (https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/qualityinitiativesgeninfo/downloads/cms-quality-strategy.pdf) [Accessed October 15, 2015]
14. Centers for Medicare and Medicaid Services: **Eligible Professional Meaningful Use. Stage 1 (2014 Definition).** (https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/downloads/ep_mu_tableofcontents.pdf) [Accessed October 15, 2015]
15. Centers for Medicare and Medicaid Services: **Physician Quality Reporting System.** (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html?redirect=/pqri/) [Accessed October 15, 2015]
16. Centers for Medicare and Medicaid Services: **Qualified Clinical Data Registry Reporting.** (https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/pqrs/qualified-clinical-data-registry-reporting.html) [Accessed October 15, 2015]
17. Centers for Medicare and Medicaid Services: **Quality Measures**. (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/index.html) [Accessed October 15, 2015]
18. Centers for Medicare and Medicaid Services: **Value-Based Payment Modifier**. (https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeedbackprogram/valuebasedpaymentmodifier.html) [Accessed October 15, 2015]
19. Chien AT, Rosenthal MB: Medicare's physician value-based payment modifier—will the tectonic shift create waves? **N Engl J Med 369:**2076–2078, 2013
20. Coulam R, Kralewski J, Dowd B, Gans D: The role of medical group practice administrators in the adoption and implementation of Medicare's physician quality reporting system. **Health Care Manage**. **Rev Mar** [epub ahead of print], 2015
21. Dowd B, Li CH, Swenson T, Coulam R, Levy J: Medicare's Physician Quality Reporting System (PQRS): quality measurement and beneficiary attribution. **Medicare Medicaid Res Rev 4:**mmrr2014.2004.2002.a2004, 2014
22. Greene J, Hibbard JH, Overton V: Large performance incentives had the greatest impact on providers whose quality metrics were lowest at baseline. **Health Aff (Millwood) 34:**673–680, 2015
23. Medicare Access and CHIP Reauthorization Act of 2015, Pub L 114-10
24. Landro L: Electronic medical records get a boost. **Wall Street Journal.** February 16, 2015. (http://www.wsj.com/articles/electronic-medical-records-get-a-boost-1424145649) [Accessed October 15, 2015]
25. McGirt MJ, Speroff T, Dittus RS, Harrell FE Jr, Asher AL: The National Neurosurgery Quality and Outcomes Database (N²QOD): general overview and pilot-year project description. **Neurosurg Focus 34(1):**E6, 2013
26. National Quality Forum: **Consensus Development Process.** Washington, DC: National Quality Forum (http://www.qualityforum.org/Measuring_Performance/Consensus_Development_Process.aspx) [Accessed October]
27. National Quality Forum: **MAP 2015 Considerations for Implementing Measures in Federal Programs.** Washington, DC: National Quality Forum (http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=79068) [Accessed October 15, 2015]
28. National Quality Forum: **Measure Evaluation Criteria and Guidance for Evaluation Measures for Endorsement.** Washington, DC: National Quality Forum (http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=79434) [Accessed October 15, 2015]
29. Neumeier H, Berner ES, Burke DE, Azuero A: Hospital

budget increase for information technology during phase 1 meaningful use. **Health Care Manag (Frederick) 34:**157–165, 2015
30. Parker SL, McGirt MJ, Bekelis K, Holland CM, Davies J, Devin CJ, et al: The National Neurosurgery Quality and Outcomes Database Qualified Clinical Data Registry: 2015 measure specifications and rationale. **Neurosurg Focus 39(6):**E4, 2015
31. Rau J: Medicare is stingy in first year of doctor bonuses. **Kaiser Health News.** April 6, 2015. (http://khn.org/news/medicare-is-stingy-in-first-year-of-doctor-bonuses/) [Accessed October 15, 2015]
32. Reed M, Huang J, Brand R, Graetz I, Neugebauer R, Fireman B, et al: Implementation of an outpatient electronic health record and emergency department visits, hospitalizations, and office visits among patients with diabetes. **JAMA 310:**1060–1065, 2013
33. Samal L, Wright A, Healey MJ, Linder JA, Bates DW: Meaningful use and quality of care. **JAMA Intern Med 174:**997–998, 2014
34. VanLare JM, Blum JD, Conway PH: Linking performance with payment: implementing the Physician Value-Based Payment Modifier. **JAMA 308:**2089–2090, 2012
35. Ziewacz JE, McGirt MJ, Chewning SJJ Jr: Adverse events in neurosurgery and their relationship to quality improvement. **Neurosurg Clin N Am 26:**157–165, vii, 2015
36. Zimlich R: The PQRS challenge: Will quality metrics improve care or create more reimbursement red tape? **Med Econ 90:**18–20, 26–28, 2013

Disclosures

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Author Contributions

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Review

Understanding Quality Measures in Otolaryngology–Head and Neck Surgery

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As health care reimbursements based on pay-for-performance models become more common, there is an unprecedented demand for ways to measure health care quality and demonstrate value. Performance measures, a type of quality measure, are unique tools in a health care delivery system that allow objective monitoring of adherence to specific goals and tracking of outcomes. We sought to provide information on the development of quality measures in otolaryngology–head and neck surgery, as well as the goals of performance measurement at a national level and for our specialty. The historical development, various types, and approach to creating effective performance measures are discussed. The primary methods of developing performance measures (using clinical practice guidelines, clinical registries, and alternative methods) are also discussed. Performance measures are an important tool that can aid otolaryngologists in achieving effective, efficient, equitable, timely, safe, and patient-centered care as outlined by the Institute of Medicine.

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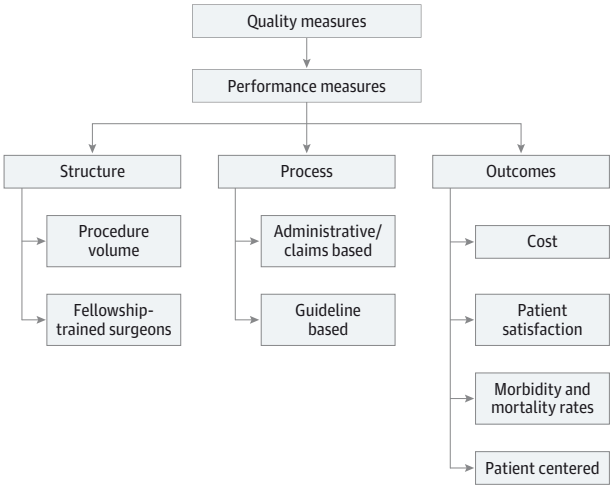
A significant component of health care reform in the United States has been the pursuit of high-quality and high-value health care. As health care reimbursements increasingly follow pay-for-performance models, there is an unprecedented demand for ways to measure health care quality and demonstrate value. As recently as January 2015, the Department of Health and Human Services mandated that, by 2018, up to 90% of Medicare payments be linked to a quality measure.[1] However, the discipline of otolaryngology–head and neck surgery is in the early stages of defining quality measures, and further work is necessary to perfect these measures.

Figure 1. Types of Performance Measures



Examples shown encompass the various domains used to measure the quality of health care delivery.

The Institute of Medicine defines quality care as being effective, efficient, equitable, timely, safe, and patient centered.[2] Another earlier definition of quality from the Institute of Medicine is "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."[3(p21)] It is important that physicians, policymakers, payers, and patients share a common definition of quality regarding the delivery of health care. To define robust quality measures and reduce variation, many agencies, including the Centers for Medicare & Medicaid Services and the Agency for Health Care Research and Quality, have turned to performance measures.

Performance measures are a unique tool to demonstrate value and quality in a health care delivery system by objectively monitoring adherence to specific goals and tracking outcomes. The Institute of Medicine defines performance measures as a "numeric quantification of healthcare quality." Alternatively, the American College of Cardiology/American Heart Association Task Force on Performance Measures describes performance measures as a subset of quality metrics that are "specifically suitable for public reporting, external comparisons, and possibly pay-for-performance programs."[4(p2113)] The term *performance measure* is reserved for those quality metrics only with "...attributes rendering them suitable for public reporting and for explicit comparisons of care between institutions and/or healthcare providers."[4(p2114)]

Donabedian[5] first described performance measurement as applied to health care as a way to measure the various domains of care delivery and focused on structural, process, and outcome measures. Birkmeyer et al[6] later discussed applying this paradigm specifically to surgical care. Performance measurement in surgery has

continued to evolve (**Figure 1**).[7] Currently, quality measures in use by the Department of Health and Human Services are available. For example, measure HMIS 000608, "timing of antibiotic prophylaxis (prophylactic antibiotic initiated within 1 hour prior to surgical incision) in surgery,"[8(p63)] is a measure of the number of patients aged 18 years or older who undergo procedures with indications for prophylactic parenteral antibiotics and are given the antibiotic within an hour prior to incision. The objective of this review is to provide information on quality measures in otolaryngology–head and neck surgery, the goals of performance measurement at a national level and within our specialty, and how quality and performance measures are developed.

Goal of Performance Measurement

In general, the purposes of performance measurement are to (1) define the outcome of an intervention, (2) measure an improvement in outcomes caused by a modification of a treatment or care process, and (3) compare the quality of care delivered by various entities, including hospitals, medical groups, or physicians.[9] However, it is important to consider the alternative side of performance measurement from the payer's perspective.

In otolaryngology, patient safety and quality improvement are sometimes seen as interchangeable; however, the 2 factors are slightly different in an important way. The patient safety movement is primarily focused on identifying how adverse events occur and subsequently implementing changes to reduce their occurrence. To use the paradigm of the Oxford Center for Evidence-Based Medicine Levels of Evidence[10] that span diagnosis, prognosis, screening, treatment benefits, and harms, only treatment harms and errors of diagnosis are usually addressed by patient safety initiatives. Although this method is fundamentally important for reducing adverse events and should be continued, performance measurement as a method of quality improvement, in contrast, is more broadly focused.

Performance measurement is a way to examine positive outcomes as well as adverse events, and thus incentivize best practices. Rather than focusing on the avoidance of practices associated with a higher risk of adverse events, performance measurement aims to take the best possible characteristics, processes, and outcomes within a discipline and translate them into actionable goals. The **Table** reports examples of current performance measures in use via the Physician Quality Reporting System in otolaryngology.[11]

Historical Background

The first national program devoted to the reporting of quality measures in medicine (ORYX Initiative) was launched in 1997 by The Joint Commission. This initiative was driven by "continuous and increasing pressure for cost containment and quality improvement."[12(p63)] For a hospital to be accredited, it was required to report data on 2 of 4 core performance measure sets, including acute myocardial infarction, heart failure, pneumonia, and pregnancy.[13] Initially, there was no consensus on the kinds of performance measures for reporting, and none of the measures submitted to The Joint Commission were publicly available.

Numerous important changes occurred in 2004. First, The Joint Commission began making the reported data from previous years available to the public, which today can be found online.[14] Second, the Centers for Medicare & Medicaid Services began reducing payments to hospitals that did not report the previously mentioned Joint Commission measures and instituted their own public reporting system the following year. At present, The Joint Commission requires health care facilities to report 6 sets of performance measures to maintain accreditation.[15] The Centers for Medicare & Medicaid Services also requires reporting via the Physician Quality Reporting System to avoid a negative 2% payment adjustment in 2017.[16]

Table. Existing Performance Measures in Otolaryngology–Head and Neck Surgery in Current Use by the Physician Quality Reporting System[a]

Diagnosis	Type	Measure
AOE		
Topical therapy	Process	Percentage of patients aged ≥2 y with AOE who received prescriptions for topical preparations
Systemic antimicrobial therapy (avoidance of inappropriate use)	Process	Percentage of patients aged ≥2 y with AOE who did not receive prescriptions for systemic antimicrobial therapy
Adult sinusitis		
Antibiotic prescribed for acute sinusitis (appropriate use)	Process	Percentage of patients aged ≥18 y with acute sinusitis who received prescriptions for an antibiotic within 7 d of diagnosis or within 10 d after onset of symptoms
Appropriate choice of antibiotic: amoxicillin prescribed for patients with acute bacterial sinusitis (appropriate use)	Process	Percentage of patients aged ≥18 y with acute bacterial sinusitis who received prescriptions for amoxicillin, with or without clavulanate, as a first-line antibiotic at the time of diagnosis
CT scan for acute sinusitis (overuse)	Outcome	Percentage of patients aged ≥18 y with acute sinusitis who received a CT scan of the paranasal sinuses at the time of diagnosis or within 28 d after date of diagnosis
>1 CT scan within 90 d for chronic sinusitis (overuse)	Outcome	Percentage of patients aged ≥18 y with chronic sinusitis who received >1 CT scan of the paranasal sinuses at the time of diagnosis or within 90 d after the date of diagnosis

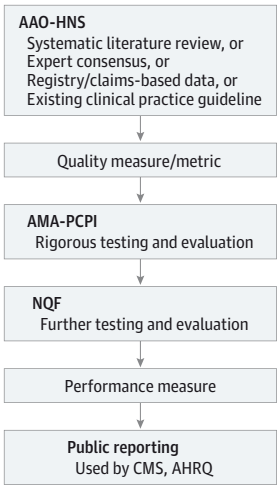
Abbreviations: AOE, acute otitis externa; CT, computed tomography.

[a] Information obtained from the Centers for Medicare & Medicaid Services.[11]

Components of a Good Performance Measure

It is important for physicians to not focus narrowly on maximizing scores on quality measures and forget the overall needs of the patient.[17] The use of performance measures to improve quality of care should thus be held to rigorous criteria to avoid unintended adverse consequences. Chassin et al[18] have proposed 4 accountability measures to which process measures should adhere: (1) there is a strong evidence base showing that the care process leads to improved outcomes, (2) the measure accurately captures whether the evidence-based care process has been provided, (3) the measure addresses a process that has few intervening care actions that must occur before the improved outcome is realized, and (4) implementation of the measure has little or no chance of inducing unintended adverse consequences.

Figure 2. Potential Pathway of Quality and Performance Measure Development



AAO-HNS indicates American Academy of Otolaryngology–Head and Neck Surgery; AHRQ, Agency for Healthcare Research and Quality; AMA-PCPI, American Medical Association–Physician Consortium for Performance Improvement; CMS, Centers for Medicare & Medicaid Services; and NQF, National Quality Forum.

Choosing a Topic for Performance Measure Development

The American Academy of Otolaryngology–Head and Neck Surgery[19] has outlined a list of 28 individual Physician Quality Reporting System performance measures and 3 measure groups that may be applicable to an otolaryngology practice. However, if otolaryngologists are to use the full potential of performance measures to improve quality of care, we must continue to carefully develop quality measures. Areas of particular interest are procedures with high morbidity and mortality, such as laryngectomy[20]; high resource utilization, such as cochlear implantation[21]; and high volume, such as tympanostomy tube insertion in children.[22]

Performance Measure Development

Currently, performance measures are primarily developed by committees in subspecialty organizations working with national organizations, such as the Agency for Healthcare Research and Quality and the Physician Consortium for Performance Improvement of the American Medical Association (AMA-PCPI). These 2 organizations represent the first layer of rigorous testing and evaluation beyond the subspecialist expert committee. When a set of performance measures is finalized, the measures can be turned over to the National Quality Forum, which then subjects the measures to a rigorous testing phase and allows for open comments from all stakeholders, including patient advocates. National Quality Forum approval of a measure is generally considered the pinnacle of performance measure quality and validation. In the following sections, we discuss various methods of developing performance measures (**Figure 2**).

Clinical Practice Guidelines as Process Measures

Within otolaryngology, past performance measures have come from translating clinical practice guidelines into process measures. When a clinical practice guideline establishes a best practice, the performance measure then becomes determining how often this practice is followed. Similar to a statistical regression analysis of actual vs expected outcomes, a practice guideline is the clinical correlate.[23] Specifically, strong recommendations from clinical practice guidelines can be converted to effective performance measures.[24]

One example of a performance measure in otolaryngology that has been developed using a clinical practice guideline is the use of tympanometry to diagnose otitis media with effusion in children. The key action statement from this guideline, a "strong recommendation to use tympanometry or pneumatic otoscopy in diagnosis of [otitis media with effusion]," was converted to a process measure (ie, how often this procedure was followed).[25(p598)] Using this performance measure, Lannon et al[26] were able to show that only 33% of pediatric clinics were following this strongly recommended practice. This finding may be the result, in part, of a failure in documentation since this study was conducted by using a review of medical records. However, a study by Patel et al[27] that surveyed otolaryngologists on how they diagnosed otitis media with effusion found that 25 of 29 of the respondents (86.2%) reported using pneumatic otoscopy or tympanometry to make the diagnosis, meaning that at least 1 of 10 otolaryngologists surveyed did not follow the guidelines. This is but one example of how performance measures may highlight areas in which we are not following our own evidence-based guidelines.[28]

One advantage of using clinical practice guidelines as process measures is that the bulk of the data collection has already been done. Thus, enforcing the adoption of an action carrying a strong recommendation from a guideline is relatively straightforward. A disadvantage of this method is that there are relatively few procedures for which guidelines exist, and guideline development will always lag years behind new procedures, since they require robust evidence for their endorsement. When guidelines do not exist for a procedure, alternative methods of quality measure development must be sought.

Using Clinical Registries for Performance Measures

Clinical registries are an excellent source of data from which to develop performance measures because the data can be of very high quality and prospectively collected. Having a large collection of patients in a focused registry allows for comparison of patients going through similar care pathways. Both process and outcome measures can then be developed from these data and subsequently tested.

Our cardiology colleagues have served as outstanding role models. By encouraging participation in the Get With the Guidelines–Stroke program, Schwamm et al[29] were able to show improvement in 8 separate performance measures in a sample of 790 hospitals within the United States. For example, the percentage of patients presenting within 2 hours of stroke symptom onset who received intravenous tissue plasminogen activator within 3 hours of symptom onset increased from 42% at baseline to 73% across the entire sample of 322 847 patients after 5 years of participation in the program. With strong process measures, it may be possible to encourage similar changes in otolaryngology.

An advantage of using clinical registries for performance measure development is that much larger numbers of patients can be studied than possible in single-center or even multicenter studies

in academic centers. A disadvantage of this method is that the quality of the data are dependent on the level of detail recorded in the registry. As seen in studies based on administrative data, at times the conclusions may be quite limited, as seen in studies of thyroidectomy from the National Inpatient Sample.[30]

Other Methods of Developing Performance Measures

We should not preclude developing quality measures for procedures for which there are no existing clinical practice guidelines or registries. Although these quality measures may not be as robust as performance measures (and thus not suitable for public reporting), solo or group practices, academic departments, and hospitals may still benefit from tracking quality measures internally. Furthermore, by starting the process of developing and tracking quality measures, we begin the long process of performance measure development by presenting evidence to organizations such as the AMA-PCPI to conduct more rigorous testing.[31]

There is compelling evidence for provider volume as a quality measure. A study[32] of the National Inpatient Sample showed that, for certain procedures (eg, pancreatectomy), the postoperative mortality rate varied from 3.8% in high-volume centers to 16.3% in low-volume centers after adjusting for patient age, sex, race, procedure year, urgency of admission, Charlson score, and socioeconomic status. However, the use of provider volume as a quality measure is controversial. Although differences in mortality across low- vs high-volume hospitals are observed on the aggregate level, provider volume is not a good predictor of individual hospital mortality rates. In addition, not all procedures are associated with a difference in provider experience.[6] Thus, we must be careful not to overuse this measure by assuming it to be true of all surgical procedures and also not unfairly penalize high-performing hospitals regardless of their volume. However, for selected procedures, including pancreatectomy and esophagectomy,[33] provider volume can be an effective performance measure.[34]

The development of patient-centered outcome measures should be a priority for otolaryngologists. Although performance measures focused on morbidity and mortality are well suited for high-risk procedures, low-risk procedures require patient-centered outcome measures, especially when the goal of the intervention is to improve quality of life.[6] An example of such a procedure is cochlear implantation[21]; the risk of mortality is low, but the effect on quality of life from a poor outcome can be tremendous, preventing a child from attending mainstream schools or an adult from continuing to work.

An advantage of alternative forms of performance measure development other than using guidelines or registries is that almost any topic can be targeted within reason. The combination of a systematic review and an expert panel can provide a similar framework to guideline development and result in the creation of high-quality performance measures.[35] A disadvantage of this method is that there are added steps in advancing from a quality measure to a publicly reportable performance measure because endorsement by the American Academy of Otolaryngology–Head and Neck Surgery must be obtained prior to submitting to national quality organizations, such as the AMA-PCPI.

Conclusions

Performance measures are an important tool that can aid otolaryngologists in achieving effective, efficient, equitable, timely, safe, and patient-centered care as outlined by the Institute of Medicine. The use of performance measurement, both for quality improvement and cost containment, is here to stay. As experts in our specialty, we must take the lead in creating well-developed quality and performance measures.

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REFERENCES

1. Burwell SM. Setting value-based payment goals—HHS efforts to improve US health care. *N Engl J Med*. 2015;372(10):897-899.

2. Institute of Medicine, Committee on Quality of Health Care in America. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: National Academy Press; 2001.

3. Lohr KN, ed. *A Strategy for Quality Assurance*. Vol. 1. Washington, DC: Institute of Medicine, National Academy Press; 1990.

4. Bonow RO, Masoudi FA, Rumsfeld JS, et al; American College of Cardiology; American Heart Association Task Force on Performance Measures. ACC/AHA classification of care metrics: performance measures and quality metrics: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures. *J Am Coll Cardiol*. 2008;52(24):2113-2117.

5. Donabedian A. Evaluating the quality of medical care. *Milbank Mem Fund Q*. 1966;44(3)(suppl):166-206.

6. Birkmeyer JD, Dimick JB, Birkmeyer NJ. Measuring the quality of surgical care: structure, process, or outcomes? *J Am Coll Surg*. 2004;198(4):626-632.

7. Nielsen DR. Evidence-based performance measurement. In: Flint PW, Haughey BH, Lund VJ, et al, eds. *Cummings Otolaryngology–Head and Neck Surgery*. 6th ed. Philadelphia, PA: Elsevier Saunders; 2015:28-42.

8. US Department of Health & Human Services. Agency for Healthcare Research and Quality. Measures inventory. http://www.qualitymeasures.ahrq.gov/hhs/index.aspx. Accessed May 15, 2015.

9. Eddy DM. Performance measurement: problems and solutions. *Health Aff (Millwood)*. 1998;17(4):7-25.

10. Oxford Center for Evidence-Based Medicine Levels of Evidence Working Group. The Oxford 2011 levels of evidence. http://www.cebm.net/index.aspx?o=5653. Published 2011. Accessed March 20, 2015.

11. Centers for Medicare & Medicaid Services. Measures codes. https://www.cms.gov/medicare

/quality-initiatives-patient-assessment-instruments/pqrs/measurescodes.html. Modified October 7, 2015. Accessed May 15, 2015.

12. Lee KY, Loeb JM, Nadzam DM, Hanold LS. Special report: an overview of the Joint Commission's ORYX Initiative and proposed statistical methods. *Health Serv Outcomes Res Methodol*. 2000;1(1):63-73.

13. Williams SC, Schmaltz SP, Morton DJ, Koss RG, Loeb JM. Quality of care in US hospitals as reflected by standardized measures, 2002-2004. *N Engl J Med*. 2005;353(3):255-264.

14. Joint Commission. Quality check. http://www.qualitycheck.org/. Published 2015. Accessed March 31, 2015.

15. Joint Commission. Joint Commission online: performance measurement. http://www.jointcommission.org/assets/1/23/jconline_September_24_14.pdf. Published September 24, 2014. Accessed March 31, 2015.

16. Centers for Medicare & Medicaid Services. How to report once for 2015 Medicare quality reporting programs. http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2015HowtoReportOnce.pdf. Revised March 2015. Accessed March 31, 2015.

17. Casalino LP. The unintended consequences of measuring quality on the quality of medical care. *N Engl J Med*. 1999;341(15):1147-1150.

18. Chassin MR, Loeb JM, Schmaltz SP, Wachter RM. Accountability measures—using measurement to promote quality improvement. *N Engl J Med*. 2010;363(7):683-688.

19. American Academy of Otolaryngology–Head and Neck Surgery. 2014 PQRS quality measures. http://www.entnet.org/content/2014-pqrs-quality-measures. Published 2015. Accessed March 31, 2015.

20. Gourin CG, Frick KD, Blackford AL, et al. Quality indicators of laryngeal cancer care in the elderly. *Laryngoscope*. 2014;124(9):2049-2056.

21. Vila PM, Hullar TE, Buchman CA, Lieu JE. Is there a need for performance measures for cochlear implant centers? *Otolaryngol Head Neck Surg*. 2015;153(4):484-487.

22. Rosenfeld RM, Schwartz SR, Pynnonen MA, et al. Clinical practice guideline: tympanostomy tubes in children. *Otolaryngol Head Neck Surg*. 2013;149(1)(suppl):S1-S35.

23. Garrett KE. *The Measurement of Health Care Performance: A Primer for Physicians*. Chicago, IL: Council of Medical Specialty Societies; 2007.

24. Rosenfeld RM, Shiffman RN, Robertson P. Clinical Practice Guideline Development Manual, Third Edition: a quality-driven approach for translating evidence into action. *Otolaryngol Head Neck Surg*. 2013;148(1)(suppl):S1-S55.

25. Rosenfeld RM, Culpepper L, Doyle KJ, et al. Clinical practice guideline: otitis media with effusion. *Otolaryngol Head Neck Surg*. 2004;130(5)(suppl):S95-S118.

26. Lannon C, Peterson LE, Goudie A. Quality measures for the care of children with otitis media with effusion. *Pediatrics*. 2011;127(6):e1490-e1497.

27. Patel MM, Eisenberg L, Witsell D, Schulz KA. Assessment of acute otitis externa and otitis media with effusion performance measures in otolaryngology practices. *Otolaryngol Head Neck Surg*. 2008;139(4):490-494.

28. Neely JG, Graboyes E, Paniello RC, Sequeira SM, Grindler DJ. Practical guide to understanding the need for clinical practice guidelines. *Otolaryngol Head Neck Surg*. 2013;149(1):1-7.

29. Schwamm LH, Fonarow GC, Reeves MJ, et al. Get With the Guidelines–Stroke is associated with sustained improvement in care for patients hospitalized with acute stroke or transient ischemic attack. *Circulation*. 2009;119(1):107-115.

30. Chung TK, Rosenthal EL, Porterfield JR, Carroll WR, Richman J, Hawn MT. Examining national outcomes after thyroidectomy with nerve monitoring. *J Am Coll Surg*. 2014;219(4):765-770.

31. Gourin CG, Couch ME. Defining quality in the era of health care reform. *JAMA Otolaryngol Head Neck Surg*. 2014;140(11):997-998.

32. Birkmeyer JD, Siewers AE, Finlayson EV, et al. Hospital volume and surgical mortality in the United States. *N Engl J Med*. 2002;346(15):1128-1137.

33. Dudley RA, Johansen KL, Brand R, Rennie DJ, Milstein A. Selective referral to high-volume hospitals: estimating potentially avoidable deaths. *JAMA*. 2000;283(9):1159-1166.

34. Dimick JB, Birkmeyer JD, Upchurch GR Jr. Measuring surgical quality: what's the role of provider volume? *World J Surg*. 2005;29(10):1217-1221.

35. Spertus JA, Eagle KA, Krumholz HM, Mitchell KR, Normand SL; American College of Cardiology; American Heart Association Task Force on Performance Measures. American College of Cardiology and American Heart Association methodology for the selection and creation of performance measures for quantifying the quality of cardiovascular care. *Circulation*. 2005;111(13):1703-1712.

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Physician Reimbursement: From Fee-for-Service to MACRA, MIPS and APMs

Phillip Miller* and Kurt Mosley†

To a significant degree, "healthcare reform" is a movement to change how both physicians and healthcare facilities are compensated, with value replacing volume as the key compensation metric. The goal of this movement has not yet been accomplished, but the process is accelerating. In this article, we track how the arc of physician compensation is bending, how the Medicare Access and CHIP Reauthorization Act will drive further changes to physician compensation models, and how these changes may affect physician practice patterns and physician staffing in the future.

KEY WORDS: Physician compensation; fee-for-service; value-based physician reimbursement; Merit-Based Incentive Payment System; alternative payment models; Medicare Access and CHIP Reauthorization Act; MACRA; physician recruiting.

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In 1880, the average daily cost of keeping a patient in New York's St. John's Hospital was 80 cents, or about $14 in today's money. Healthcare was cheap, and the remuneration that physicians and hospitals earned was correspondingly minimal. The average annual salary for a house physician at St. John's that year was $300, while the hospital's total annual budget was $4689.[1]

In the 20th century, however, the picture changed as it became necessary for hospitals to bear the cost of maintaining sterile conditions, purchasing more sophisticated equipment, and maintaining more highly trained clinical staffs. The cost of hospital stays rose accordingly. In response to publication of *The Flexner Report* in 1910, which cast a highly critical eye on U.S. medical education, the number of U.S. medical schools dropped from 162 in 1906 to 85 in 1919. Physician-to-population ratios also declined, from 157 per 100,000 population in 1900 to 125 per 100,000 population in 1930.[2] With the advent of more complex physician training and a reduction of competition among doctors, physician fees also rose. Soon consumers began to feel the financial pinch of paying physicians and hospitals more for care, and talk of health insurance began.

In a "back to the future" moment, national health insurance was incorporated into the Progressive Party's presidential platform as early as 1912, and in 1927, "the inability to pay the cost of modern scientific medicine" was the first item on the agenda at the American Medical Association (AMA) convention.[2]

Table 1. U.S. Healthcare Expenditures in 1929

Total	$3.6 billion
Paid by consumers	$2.9 billion
Paid by public sources	$485 million
Paid by philanthropy	$217 million

Data from reference 2.

Nevertheless, patients continued to pay directly for medical care. In 1929, medical expenditures in the United States (as estimated by the AMA) were $3.6 billion, or 4% of the GDP[2] (today they are about $3 trillion, or 18% of the GDP, an 83000% increase). Of this, patients paid 80.6% (Table 1).

THIRD-PARTY PAYERS AND "ORIGINAL SIN"

Eventually, the alternative to direct payments for care became third-party payments, made through private insurance plans such as Blue Cross and Blue Shield; employer-sponsored insurance, pioneered by Kaiser Steel and other large employers who were strapped for labor during World War II; and the government, via Medicare and Medicaid. By 1958, 75% of Americans had thirty-party health insurance, a number that stands at 89% today.[2]

The Blues and, subsequently, Medicare and Medicaid instituted the "pay as you go" model of reimbursement for

individual policy holders, which, from a cost perspective, can be viewed as the healthcare system's "original sin." Unlike home insurance, where home owners are paid a lump sum by insurance companies in the event of a disaster and then pay contractors to rebuild their homes, third parties paid the physician or the hospital directly, not the insured patient. All services were paid for, even routine, easily affordable services. There were no deductibles and no copays.

Predictably, the effect of this fee-for-service model has been to increase utilization and hence costs, as neither the patient nor the provider has a stake in limiting services or expenses. If home insurance paid for routine upgrades such as new curtains to replace faded ones, or new appliances to replace old ones, the effect on utilization and costs would no doubt be similar.

The history of healthcare since the post-Medicare cost curve rise has largely been the story of efforts to somehow rein in or otherwise reshape the fee-for-service model. These efforts include prospective payments, Diagnostic Related Groups (DRGs), capitation/managed care, CPT codes, the Resource-Based Relative Value Scale (RBRVS), the Physician Quality Reporting System (PQRS), the Group Practice Reporting Option (GPRO), Value-Based Purchasing (VBP), Recovery Audit Contractors (RACs), bundled payments, and the Sustainable Growth Rate (SGR) formula.

MACRA MEANS PHYSICIANS MUST MAKE A CHOICE

On April 16, 2015, another major step occurred in the evolution of fee-for-service reimbursement. The Medicare Access and CHIP Reauthorization Act (MACRA) repealed the SGR mechanism of Medicare payments to physicians. In doing so, it made the fee-for-service model less attractive in an attempt to move physicians to a fee-for-value model.

Under the new model, Medicare payments to physicians will increase by 0.5% a year from July 2015 to December 2018. In January 2019, a new replacement Medicare formula will require physicians to pick from two ways to participate in Medicare's payment system:

1. **Merit-Based Incentive Payment System (MIPS).** MIPS combines PQRS, the Value-Based Modifier, and Meaningful Use into one larger program that gives doctors a quality score. If their scores are above the average, their reimbursement rates will go up; if they are at the average, there will be no adjustment; and if below the average, Medicare payment will be cut.
2. **Alternative Payment Models (APMs).** APMs require a group of physicians to band together and take a lump sum of money to care for a group of patients. If they can provide the care for less—and hit certain quality metrics—they get to keep some of the leftover cash. The hope is that these models will persuade physicians to be vigilant against wasteful care, since they will have a financial incentive to spend less than their lump sum amount. Physicians who are eligible and who choose to participate in a qualifying APM will receive a 5% bonus each year from 2019 through 2024 on top of all their other Medicare payments. Beginning in 2026, they will qualify for a 0.75% increase in their payments each year. APMs must place material financial risk for monetary losses on physicians and other clinicians, use quality measures comparable to MIPS, and use certified electronic health record (EHR) technology.

The law requires that the Centers for Medicare & Medicaid Services report on the number of doctors dropping out of Medicare.

Under both payment models, physicians will still be provided with a fee-for-service payment based on the Physician Fee Schedule (PFS). From 2020 to 2025, existing Medicare fee-for-service rates will remain at 2019 levels with no updates. By retaining a fee-for-service component it is hoped that physicians will remain productive, as they will continue to be rewarded for volume of patients seen or volume of work done as measured by relative value units (RVUs). Realizing that these payment systems may not appeal to some physicians, the law requires that CMS report on the number of doctors dropping out of Medicare.

PAYMENT SCORES UNDER MIPS

The MIPS program will assess physicians in four categories. Physicians will receive a score of 0 to 100, according to their performance in each of the four categories:

- Quality of their care (30%);
- EHR Meaningful Use (25%);
- Use of healthcare resources (30%); and
- Activities undertaken to improve clinical practice (15%).

Medicare will compare a physician's composite score with a performance threshold that will be the mean of the scores for all clinicians subject to MIPS. Clinicians who score above this threshold will receive bonuses funded by the penalties imposed on physicians who fall below the threshold. Physicians at the threshold will receive no payment adjustment. Scores will be publicly available through "Physician Compare." Adoption of telehealth and remote patient monitoring by physicians participating in MIPS are specifically named as potential score-boosters. From 2020 to 2025 Medicare fee-for-service rates will remain at 2019 levels with no updates; it is these scores, therefore, that will determine the total amount physicians participating in MIPS earn from Medicare payments.

MIPS scores will impact physician Medicare payments as follows:

- ±4% in 2019;
- ±7% in 2020; and
- ±9% in 2021.

An additional incentive payment for "superstars" will be available, capped at an aggregate amount of $500 million for each of the years 2018 through 2023.

Low MIPS scores could undermine the financial viability of many practices.

Hypothetically, in 2021 a MIPS participating physician could receive a $100 fee-for-service payment for treating a particular Medicare patient. With a high MIPS score, that payment could increase to $109. With an average MIPS score it would remain $100. With a poor MIPS score it could decrease to $91. Given current profit margins for many physician practices, low MIPS scores could undermine the financial viability of many practices.

WHAT IS AN ALTERNATIVE PAYMENT MODEL?

If a physician or healthcare organization chooses to opt out of MIPS and participate in an APM, they have another choice to make—which type of APM? Participation in Accountable Care Organizations (ACOs), a Patient-Centered Medical Home (PCMH), or a bundled payment model will qualify as an APM under MACRA.

Accountable Care Organizations

One way physicians can participate in an ACO is through the Medicare Shared Savings Program (MSSP). Like other ACO models, the MSSP rewards ACOs that keep increases in healthcare costs low while meeting performance standards on quality of care. To become part of the program, eligible providers can create or participate in an ACO.

Participants must meet quality performance measures from four domains: patient/caregiver experience; preventive health; care coordination/patient safety; and at-risk populations. Much like MIPS, providers must meet a threshold (at least the 30th percentile) to be eligible for the shared savings. Paying for performance will be phased in over subsequent years.

Patient-Centered Medical Home

Another option for an APM is the PCMH model. Research from the Patient-Centered Primary Care Collaborative indicates that PCMHs reduce visits to the emergency department by 57% and readmissions by 29%. In addition, a 57% reduction in cost provides evidence that PCMHs may prove to be extremely effective.

However, experts say that the PCMH model requires significant upfront investment, and costs for continued support can be very expensive as well. The time, effort, and spending it takes to produce a substantial return may signify that the model is not as universally applicable as may be desired.

Bundled Payments

Beginning in 2012, the ACA-founded Medicare and Medicaid Innovation Center established Bundled Payments for Care Improvement to assess the ability of a variety of payment models to improve patient care and lower costs to Medicare. Participation has been voluntary, and the models ultimately lead to a prospectively determined payment for all hospital, physician and other clinician services for an episode of care.

WHAT WILL PHYSICIANS DO?

How will physicians react to these changes? Will they align with larger entities, try to maintain their status as independent practice owners, retire, or pursue some other course?

Given the complexities of payment models such as MIPS, it is likely that even more physicians will embrace employment and join APMs, which virtually by definition must be large, integrated entities employing physicians.

Physicians may choose to circumvent third-party payers and practice on a direct-pay/concierge basis.

About 28% of physicians (~225,000 doctors) are 60 years old or older, and partly in response to new payment models, many of these doctors, who grew up in the fee-for-service era, can be expected to retire as soon as they have the means to do so. Other physicians may choose to circumvent third-party payers and practice on a direct-pay/concierge basis. A growing number also can be expected to forego full-time practice and work on a temporary ("locum tenens") basis, accept nonclinical roles, or switch to part-time practice. The types of physicians medical groups and hospitals seek also may change, from entrepreneurial, high revenue–generating, solo-minded physicians who are typically favored in the fee-for-service model, to collaborative, resource-minded physicians likely to succeed in value-based models.

The reality is that reimbursement in healthcare is dramatically more convoluted and arcane than in almost any other sector of the economy, in which professionals

or businesses generally determine their price, submit a bill to the recipient of the goods or services provided, and are paid by the recipient the amount they invoiced. The ability of practice managers and physicians to understand and adapt to pending reimbursement changes will largely determine their professional satisfaction and success.

REFERENCES

1. Crossen C. When hospitals were places only the poor could afford to enter. *The Wall Street Journal*. March 3, 2004; www.wsj.com/articles/SB107826755202744576.
2. Gorman L. The history of health care costs and health insurance. *Wisconsin Policy Research Institute Report*. 2006;19(10):1-31; www.wpri.org/WPRI-Files/Special-Reports/Reports-Documents/Vol19no10.pdf.

The Laryngoscope

TRIOLOGICAL SOCIETY CANDIDATE THESIS

Otolaryngology Workforce Analysis

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Objectives/Hypothesis: The number of trained otolaryngologists available is insufficient to supply current and projected US health care needs. The goal of this study was to assess available databases and present accurate data on the current otolaryngology workforce, examine methods for prediction of future health care needs, and explore potential issues with forecasting methods and policy implementation based on these predictions.

Study Design: Retrospective analysis of research databases, public use files, and claims data.

Methods: The total number of otolaryngologists and current practices in the United States was tabulated using the databases of the American Academy of Otolaryngology–Head and Neck Surgery, American Medical Association, American Board of Otolaryngology, American College of Surgeons, Association of American Medical Colleges, National Center for Health Statistics, and Department of Health and Human Services. Otolaryngologists were identified as surgeons and classified into surgical groups using a combination of AMA primary and secondary self-reported specialties and American Board of Medical Specialties certifications. Data gathered were cross-referenced to rule out duplications to assess total practicing otolaryngologists. Data analyzed included type of practice: 1) academic versus private and 2) general versus specialty; and demographics: 1) urban versus rural, 2) patient age, 3) reason for visit (referral, new, established, surgical follow-up), 4) reason for visit (diagnosis), and 5) payer type.

Results: Analysis from the above resources estimates the total number of otolaryngologists practicing in the United States in 2011 to be 12,609, with approximately 10,522 fully trained practicing physicians (9,232–10,654) and 2,087 in training (1,318 residents and 769 fellows/others). Based on 2011 data, workforce projections would place the fully trained and practicing otolaryngology workforce at 11,088 in 2015 and 12,084 in 2025 unless changes in training occur. The AAO-HNS Physicians Resource Committee performed an extensive analysis of collated data from multiple sources in 2014 and identified 10,800 practicing otolaryngologists and 2,087 in training. It is estimated that the current attrition rate is approximately 306 otolaryngologists per year. Percentage distribution of office visits by patient age was found to be 20% $<$15 years old, 7% 15 to 24 years old, 21% 25 to 44 years old, 32% 45 to 64 years old, 11% 65 to 74 years old, and 10% $\geq$75 years old. Reason for visit was 34% new, 29% chronic, 17% chronic with exacerbation, and 15% pre- or postsurgical follow-up. The top diagnoses consisted of otitis media, chronic sinusitis, and impacted cerumen. Payer mix consisted of 59% private insurance, 19% Medicare, and 12% Medicaid/Children's Health Insurance Program.

Conclusions: Despite past findings and predictions of 8,000 to 8,500 otolaryngologists practicing in the United States, collated data from above resources places the total at 12,887, with 10,800 fully trained and practicing in 2014. This 30% to 50% underestimation of the otolaryngology workforce has an impact on future predictions and resource utilization analysis. Even when this correction is considered, the available trained otolaryngologists required to serve the otolaryngologic health care needs of the US population are still insufficient and understaffed. The impact of an aging population and the estimated 30 to 47 million newly insured citizens under the 2010 Patient Protection and Affordable Care Act are also unprecedented variables that must be considered. Further analysis of differences in physician productivity and geographic population density, and model formation of current otolaryngology workforce utilization, are needed to predict future public health needs.

Key Words: Public heath, otolaryngology workforce, physician shortage, resident training, specialty planning, physician supply, health care reform.

Level of Evidence: NA

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This article was accepted as a Triological Society Thesis under the sponsorship of Stil Kountakis, MD, PhD and David Terris, MD.

This article is a synthesis of years of work and the efforts of many people. The subject of workforce analysis is a complex issue. The task of defining a point in time for a moving target and of digesting both objective data and subjective opinions on what is most relevant and important is difficult at best. In 2014, the American Academy of Otolaryngology–Head and Neck Surgery Physicians Resource Committee led by David Kennedy, MD completed an analysis of practicing US otolaryngologists. The findings of this committee as well as the findings of "Triological Society Thesis: Otolaryngology Workforce 2015, Public Health Resource Requirements" by C.A.H. are presented in this article. We hope this document accomplishes the desired goal of establishing an accurate and meaningful baseline and a tool for future discussion and analysis.

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INTRODUCTION

To produce a health care workforce of sufficient size and skill to meet the US population's health care needs requires accurate data on the current workforce and a thorough understanding of how changes in the population and health policy will affect future demand. Accurate projections of future health care supply and demand advise stakeholders and policymakers about the implications of expected changes in the health care environment and allow planned adjustments to be developed, discussed, and implemented. The number of trained otolaryngologists available is believed to be insufficient to supply current and projected US health care needs.[1,2]

Physician workforce planning is essential to ensure an adequate and appropriate supply of well-trained physicians to meet the US population's future health care needs. Additionally, the impact of an aging population and 47 million newly insured citizens under the Patient Protection and Affordable Care Act (ACA) are unprecedented variables that will certainly exacerbate this shortage.

The goal of this project is to access available databases and present accurate data on the current otolaryngology workforce, examine methods for prediction of future health care needs, and explore potential issues with forecasting methods and policy implementation based on these predictions.

MATERIALS AND METHODS

To accurately calculate the current practicing otolaryngology workforce, the total number of practicing otolaryngologists and current practices in the United States were tabulated using a number of research databases, public use files, and claims data. Research databases included the American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS), American Medical Association (AMA), American Board of Otolaryngology (ABO), American College of Surgeons (ACS), Association of American Medical Colleges (AAMC), National Center for Health Statistics (NCHS), and Department of Health and Human Services (HHS).

Otolaryngologists were identified as surgeons and classified into surgical groups using a combination of AMA primary and secondary self-reported specialties and American Board of Medical Specialties (ABMS) certifications. This analysis only included active, nonresident, nonfederal surgeons. Active surgeons are defined as those younger than 80 years who report working in administration, direct patient care, medical research, medical teaching, or other nonpatient care activities, or who have an unclassified activity status. Active surgeons exclude those who are classified as retired, semiretired, temporarily not in practice, or not active for other reasons. Once collected, results were cross-tabulated to remove any duplication. These data were obtained in close communication and cooperation with the Physicians Resource Committee of the AAO-HNS. These data represent raw numbers and do not reflect productivity, type of practice, location, or age/gender-based analysis.

To examine methods for prediction of future health care needs and to validate the best research tools to determine physician workforce issues, demographics, current practices, and future projected public health needs, an extensive review of available literature was performed. Interviews were conducted with leaders from various specialties and disciplines to understand available tools and their inherent strengths and weaknesses.

A review of the available pertinent otolaryngology literature was also performed, and interviews were conducted with leaders within otolaryngology to assess the current state of otolaryngology. Public use files were utilized to quantify current otolaryngology practice demographics and to help form models for future needs.

RESULTS

Current Otolaryngology Workforce

To accurately calculate the current practicing otolaryngology workforce, the total number of practicing otolaryngologists and current practices in the United States was tabulated using a number of research databases, public use files, and claims data. Otolaryngologists were identified as surgeons and classified into surgical groups using a combination of AMA primary and secondary self-reported specialties and ABMS certifications.

The results for actively practicing fully trained otolaryngologists are: AAO-HNS, 10,102 (2010 data), 10,389 (2011 data), 10,800 (2014 data); ABO, 10,136 (2010 data), 10,654 (2014 data); NCHS, 9,989 (2010 data); HHS, 10,067 (2010 data); AMA, 9,882 (2010 data); ACS, 10,002 (2009 data), 10,008 (2011 data); AAMC, 9,232 (2009 data).

In 2014, based on the work of the AAO-HNS Physicians Resource Committee (PRC), there were 1,318 residents training in 103 Accreditation Council for Graduate Medical Education (ACGME)-accredited otolaryngology residency programs in the United States, producing 271 trained otolaryngologists per year. In addition to these allopathic programs, 25 otolaryngology residents per year graduate from osteopathic programs, giving a total of 296 fully trained otolaryngologists per year entering the workforce.

Based on the original Triological Society thesis, the 2011 AAO-HNS and ABO data appeared to be the most up to date and complete. The AAO-HNS data show 10,389 whereas the ABO data show 10,654 completely trained otolaryngologists in the workforce in 2011. If these two numbers are averaged, the approximate number of trained otolaryngologists in the workforce in 2011 is 10,522. To these numbers one could add the 1,318 residents in training and the 769 individuals designated as fellows or others, giving a total of 12,609 active and training otolaryngologists in the workforce in 2011. These numbers do not, however, gauge physician productivity or differences across category of employment (full-time equivalent, full time, or part time), number of patients seen, academic versus private, area distribution (urban vs. rural), and types of surgery done (general vs. fellowship-trained specialty care).

The average attrition rate of otolaryngologists is not believed to differ from that of other medical specialties. The overall annual attrition rate from clinical practice, including estimated death rate, is approximately 1.7% based on the AMA's Physician Masterfile,[3] which includes data on all physicians who have ever obtained a medical license in at least one US state.

To deduce future workforce numbers, this average number of 10,522 completely trained otolaryngologists in 2011 was extrapolated by using the Clinical Specialty Supply Model formula. Using this formula, $Ct = C0 + Ent - (C0 \times A0)$, where *Ct* represents the projected clinician supply, *C0* represents the current supply of clinicians, *Ent* represents the number of new trainee entrants, and *A0* represents the attrition rate, this extrapolation gives 11,088 trained otolaryngologists in 2015 and 12,084 trained otolaryngologists in 2025. The 2014 findings of the AAO-HNS PRC estimated practicing otolaryngologists in the United States at approximately 10,800, with an additional 1,318 residents and 769 fellows (AAO-HNS Physicians Resource Committee, September 20, 2014, personal communication not subject to external validation). The difference in these numbers illustrates the complexity and difficulty of forecast methods and highlights that multiple forecast methods with accurate baseline data are necessary to predict and prepare for future workforce needs.

In 2015 otolaryngology matched 299 residents; if this remains stable, we would have 1,495 residents in training. Fellowships are also increasing. The 2014 attrition rate, based on available data, was estimated at 316 per year, an increase from 2011 estimates of 256 per year (September 20, 2014). There is debate as to what is a sufficient number of practicing US otolaryngologists. The current 10,800 otolaryngologists (1:27,000 population) is low compared to other countries and to current and future forecasted needs of the US population (AAO-HNS Physicians Resource Committee, May 20, 2015, personal commuication not subject to external validation).

These numbers were essentially stabilized by the Congressional Budget Act of 1997, which froze graduate medical education (GME) funding. There is currently much debate on this subject, and changes to otolaryngology programs have occurred. According to the 2014–2015 ACGME data book, there are 106 ACGME otolaryngology training programs, with a total of 1,506 residents in training. Additionally, they recognize 28 neurotology fellows and 34 pediatric otolaryngology fellows. The otolaryngology match matched 299 residents in 2015 and 302 residents in 2016.[4]

Current Otolaryngology Demographics

Current otolaryngology demographics databases were reviewed. The ACS Health Policy Research Institute (HPRI) data were found to be the most comprehensive. According to the ACS HPRI reports, the number of otolaryngologists in active practice in the United States (excluding residents in training) increased 60% between 1981 and 2009. However, the ratio of otolaryngologists per 100,000 population increased from 1981 until 2001, was stable between 2001 and 2006, and then began to decline between 2006 and 2009.

According to ACGME data, from 2001 to 2009, the number of otolaryngology residents in training increased by 23%, although the number of otolaryngology training programs remained at 103 during this period.[5]

We do not find this increase in ABO and AAO-HNS data and are unclear as to the accuracy of these data. However, even if this increase is considered, the databases agree that geographic distribution has become more challenging in that between 2004 and 2009, one in five US counties lost otolaryngologists relative to population.[6]

The representative age and gender distribution of the otolaryngology workforce has also changed over time. In 2009, the average age of otolaryngologists in active practice was 51.4 years, with 15.1% older than 65 years. This represents a >4% increase compared to 1981 (10.8%). Women have been increasingly entering the otolaryngology workforce since 1981, with the number of female otolaryngologists increasing from 111 to 1,158. However, men continue to account for the majority of otolaryngologists (88.4%).[7]

Otolaryngology practice demographics have also continued to change. The proportion of the otolaryngologist workforce in group practice increased from 37.8% in 2001 to 53.4% in 2009. In 2001, slightly more than 30.1% of otolaryngologists were in solo practice compared with 25.1% in 2009. The percentage of otolaryngologists employed by health maintenance organizations, nonhospital government, and other entities also declined substantially between 2001 and 2009. Additionally, within this timeframe, otolaryngologists in solo practices were found to be 6.7 years older than otolaryngologists in group practice.[8]

Current Otolaryngology Practice

According to the Centers for Disease Control and Prevention's National Ambulatory Medical Care Survey, in 2010 there were an estimated 20 million visits to nonfederal, employed, office-based otolaryngologists in the United States. Percentage distribution of office visits by patient age was 20% <15 years old, 7% 15 to 24 years old, 21% 25 to 44 years old, 32% 45 to 64 years old, 11% 65 to 74 years old, and 10% ≥75 years old.

Reason for visit was 34% new, 29% chronic, 17% chronic with exacerbation, and 15% pre- or postsurgical follow-up. The top diagnoses consisted of otitis media, chronic sinusitis, and impacted cerumen. Payer mix consisted of 59% private insurance, 19% Medicare, and 12% Medicaid/Children's Health Insurance Program.

The 2014 AAO-HNS PRC looked at socioeconomic data from a number of sources to illustrate current practice. These findings suggest that the average practicing otolaryngologist in the United States is a 52-year-old man (84% male vs. 16% female), who works 51 hours per week for 48 weeks per year (2,448 hr/yr) and plans to retire at age 68 years. He works 30.0 hours in the office and 11.4 hours in the operating room or roughly 3.8 days in the clinic, 1.4 days in the operating room (AAO-HNS Physicians Resource Committee, May 20, 2015, personal communication not subject to external validation).

Other statistics include: new patients/wk, 26.4 (median); established patients/wk, 49.5 (median); average wait for new appointment, 2.0 weeks (median); 8.5% intend to retire within 3 years (up from 6.9% in 2011); 3% intend to close their practice to new patients; 23% intend to increase patient load; and there are twice as many female otolaryngologists who are <45 years old (25%) than are >45 years old (12%).

DISCUSSION

Physician Workforce Analysis and Reform

Physician workforce analysis and reform presents extraordinary challenges. To begin to address these challenges, we need to know where we currently are in terms of supply, demand, and infrastructure to deliver these services. Although debate continues, most believe that we currently have a gap between the supply of otolaryngologists and patient demand; it is further believed that the underservice gap is increasing over time. There is also agreement that our current health care infrastructure is inadequate to meet current demand, and even more inadequate if we consider the additional demand of an aging population and the predicted effects of the ACA.

Division exists on the size of this underservice gap and how best to mitigate future deficiencies. In discussions with otolaryngology leaders, Michael Maves MD, MBA (past Executive Vice President of the AAO-HNS and past Chief Executive Officer and Executive Vice President of the AMA) believes the otolaryngology workforce is markedly underserving current US need and that this situation, under existing policy, will only worsen. "What is currently needed is a true snapshot of current services to guide our future endeavors" (M. Maves, personal communication, January 29, 2014).

David Kennedy, MD (former Chair of the AAO-HNS PRC) believes that we, as a specialty, cannot afford to wait for perfect data. He believes the data have been derived from the most recognized sources and the primary issues are not the absolute numbers but whether the current otolaryngologists to population ratio and the current scope of practice are correct for the US health care system. He is concerned that this ratio is decreasing, especially in the face of an aging population, and is concerned by the effect the ACA will have on that ratio. Evidence from multiple data sources indicates that this ratio has decreased and that this trend will continue. "Under all scenarios, a shortage of otolaryngologists by 2025 is predicted, even allowing for the expectation that mid-level providers will provide lower intensity services within the specialty."[9] He agrees that generational lifestyle preferences, an aging workforce, payment changes, and potential downstream effects of resident work hour limitations are difficult to quantify, but certainly need to be considered when future projections are prepared. He also believes that this gap cannot be corrected by increasing residency training alone, but that increase should be coupled with changes to the structure of current residency training through shortening the length of training or earlier subspecialization.[10]

Harold Pillsbury, MD (past President of the Triological Society and the ABO) has grave concerns regarding diluting our otolaryngology residency programs by potentially developing a two-tiered residency or a primary certificate program. He notes that "funding for residents encompasses only five years or first certification. It would be difficult to envision how we could support a five year residency with the present paradigm of funding from the Centers for Medicare and Medicaid Services."[11] His second concern involves the present resident workforce, in that "young people are emphasizing lifestyle more than they did previously". Additionally, regulations on resident work hours have decreased productivity compared to past generations.[11] Although debate exists, other authors have voiced concerns that decreasing resident work hours can impact surgical training experience.[12–14] Dr. Pillsbury is also concerned that some forces within our specialty tend to overestimate the size of our group to increase our perceived political power on the federal policy level. He believes this is short-sighted and only serves to hurt our specialty by reducing our actual numbers and decreases our ability to train future residents. Dr. Pillsbury agrees that the future supply of otolaryngologists will be less than adequate and improvements in technology and surgical applications will only increase demand and make this shortage more acute (H. Pillsbury, personal communication, February 3, 2014). To highlight the importance of these issues, the National Ambulatory Medical Care Survey added a set of questions examining physician workforce issues in 2013. "Fueled in part by changes in the delivery system, there is strong interest in understanding the dynamics of practice redesign and how team-based medical care is actually delivered."[15]

National workforce study databases project future supply and demand for physicians, and most conclude that there is currently a shortage of physicians in the United States and also conclude that the deficiency is increasing. Factors cited that exacerbate this shortage include increased population growth, an aging population, and economic and health policy factors. This issue is made more complex by changes in physician demographics, trends in retirement, and medical student and resident training capacity. An additional unknown is what the future role and scope of nonphysician health care providers such as advanced practice registered nurses and physician assistants (PAs) will be.

Physician workforce analysis and reform are challenging. Political, socioeconomic, and physician autonomy issues all interact to complicate the discussion of what represents the optimal or even an adequate physician workforce. Questions pertaining to what is a full-time practice and what constitutes a part-time practice, comparisons of academic and private practices, male as opposed to female physician lifetime productivity, and the perceived generalist–specialist imbalance[12] all polarize the debate. The major focus of workforce reforms should be to optimize the training of the future workforce within any given specialty and guide leaders to increase emphasis on areas for which more background and training are warranted and create policies to incentivize a more optimal distribution of care.[16]

The US health care system, with the passage of the ACA, is evolving at an increasingly rapid pace. In general, the structure of health care delivery is moving toward larger and more integrated systems. The traditional independent physician's practice is being replaced by contractual arrangements among hospitals or large groups of clinicians. The financing of medical care is changing due to federal legislation, meaningful use, and

pressures from payers to remain competitive. Reimbursement systems are changing under the Current Procedural Terminology and International Classification of Diseases systems toward bundling procedures and disease-based and/or patient outcome strategies.[17]

The practice of otolaryngology and many other surgical specialties continues to rapidly change. New procedures, not anticipated even 20 years ago, are now performed by a variety of surgical specialists. The practices of head and neck oncologic and endocrine surgery, skull base surgery, neuro-otology, and pediatric otolaryngology have continued to develop, increasing the scope and demand for otolaryngologists. New technology and procedures, along with changes in surgical training pathways and certification, have resulted in changing referral patterns and a redistribution of surgical specialties.

This rapidly changing landscape requires a comprehensive systematic analysis to assess the current strength of the otolaryngology workforce, not only in sheer numbers but in type of practice, distribution, and productivity. The current patient need for otolaryngology services must be assessed, and the current infrastructure of health care delivery and patient access must be analyzed. These are the building blocks to begin to make predictions of future need. The use of predictive models can then be developed and tested to guide us in the numbers needed and the way we train our students and residents. The goal is to guarantee our ability to deliver quality otolaryngology health care to the US population.

Models for Future Prediction

This article elected to use the Clinical Specialty Supply Model to estimate otolaryngology future workforce numbers. This is arguably one of the simpler formulas to use and is not the only way a specialty should assess their future workforce. Kim et al.[9] proposed three models to calculate demand to make a "best estimate" for the future. The first two methods used data obtained from the ACS Health Policy Research Institute's publication, *The Surgical Workforce in the United States*, which draws mainly from the AMA Physician Master File and AAMC Data Warehouse.

Method 1: Demand was extrapolated into the future based on a continuation of the number of otolaryngologists per 100,000 population over the period 2004–2008 (current demand ratio). It depended solely on population growth.

Method 2: Demand was estimated by maintaining the per capita supply of otolaryngologists from the past 5 years (2004–2008) but only for the insured population (current insured demand ratio). It assumed a gradual increase in coverage, achieving full coverage in 2020, as the Congressional Budget Office assumes a reduction in the uninsured population by 32 million by 2019.[18]

Method 3: Demand was extrapolated using two models described by Cooper et al.[19,20] The first was based on the established historical relationship between gross domestic product (GDP) and health care spending. They assumed that for every 1.0% growth in inflation-adjusted GDP, the demand for physician services would increase by 0.5%. GDP was extrapolated at a historical average growth rate of 4.4%. The second model was constructed based on predicted demand of the stated health care reform goals (growth to decline from its historic level of 2.5% above GDP to 1.0% above GDP between 2010 and 2020).

Regardless of which model is used, there is a significant gap between supply and demand for all years, with an increasing gap through 2025. This gap persisted despite manipulation of the extrapolation data to include an increase in number of residents trained, decreased resident training time, adjustments to current physician workload, or the addition of nurse practitioners and PAs. The gap increased markedly when expansion of care secondary to the ACA was factored.

A number of online tools have been developed to forecast the future workforce. Examples are the AMA's Health Workforce Mapper (http://www.ama-assn.org/ama/pub/advocacy/state-advocacy-arc/health-workforce-mapper.page) and the FutureDocs Forecasting Tool (https://www2.shepscenter.unc.edu/workforce/). These tools give the user the ability to manipulate estimates of supply and demand for health care services for many types of services for different geographic regions at varied future periods.

Forecasting Methods and Implementing Policy Based on These Predictions

The work of forecasting the future heath care needs of a population is complex. Many unknowns conspire to make this process a difficult task, but physician input and accurate workforce planning are essential to ensure a supply of physicians adequate to meet the US population's future health care needs.

Two unprecedented unknowns are the effects of the ACA and America's aging population. The ACA is expected to expand health insurance coverage to an estimated 30 to 47 million previously uninsured persons over the next few years.[21] At the same time, physician shortages are expected to worsen across the nation. According to the AAMC, a shortage of more than 90,000 doctors, including 45,000 primary care physicians and 46,000 surgeons and specialists, is likely to occur in the next 10 years.

It is estimated that approximately one-third of physicians could retire in the next decade, contributing to the concern that the current supply of physicians will not be able to meet the growing demand for care.[22]

It is also believed that the US population is expecting and using health care more than in the past. Workforce planning today must take into account the increasing demand on health care services per capita. In an analysis in *Health Affairs*,[23] Grover and Niecko-Najjum predict that physician workforce proposals that rely exclusively on implementing new models of care or changing the distribution of medical specialties to address shortages are likely to fail in meeting the health care needs of a growing, aging population unless the number of physicians is increased. The authors believe

health care workforce projections have been unreliable because they are often based upon idealized future delivery systems rather than current identifiable utilization trends.

The shortage of physicians is expected to grow as the US population expands and advances in care are realized. This growing population lives longer, suffers from multiple illnesses, and uses more than double the health care services at age 65 years as younger adults. "With looming changes in health care treatments, technology, finance, and delivery, researchers and policy makers must understand that an adequate supply of physicians will have to be achieved both through more efficient health care delivery models and through an increased number of GME training positions.... Current attempts at payment and delivery system reform must be complemented with an adequate supply of physicians and other health professionals in primary care and in medical and surgical specialties."[24]

Complex changes such as improving efficiency, reconfiguring the way services are delivered, and making more effective use of physicians will certainly be required, but an increase in the number of well-trained physicians is also essential. It is estimated that if current proposals before Congress to lift the cap on the number of residency positions that Medicare partially supports are accepted, an additional 4,000 physicians per year could be trained, an expansion of approximately 15% over current training levels. However, this would only meet 30% of expected shortages.[25,26] If our specialty does not take an aggressive lead in this process, other policy makers may determine our future pathway.

If physician supply and use patterns stay the same, the United States is expected to experience a shortage of 124,000 full-time physicians by 2025.[26] To address the predicted shortage, the AAMC recommended an increase in medical school enrollment, although a corresponding number of residency slots for these graduates have yet to be assessed or developed. According to the AMA Wire in 2015, a "record-breaking 20,630 students enrolled in medical school for the first time, contributing to a 25 percent increase in medical school enrollment since 2002. Medical student enrollment in U.S. osteopathic medical schools also increased by 3.5 percent over 2014 enrollment, with 7,025 students enrolling this year, according to the American Association of Colleges of Osteopathic Medicine."[27] AAMC President and Chief Executive Officer Darrell Kirch, MD stated "these numbers underscore a dire need for Congress to increase funding for graduate medical education, so students can continue to succeed in training and meet demands.... To ensure that we have enough physicians to care for our growing, aging population in the face of a real and significant doctor shortage in the coming decade, Congress also must increase federal support for residency training.... Unless lawmakers act without delay, patients may not have access to the care they need in the future."[26]

Although this increase is necessary, it will not be sufficient to meet predicted patient needs and demand. Simply educating and training more physicians will not be enough to address these shortages. To be successful, complex changes such as improving efficiency, reconfiguring the way services are delivered, and making better use of our physicians will be required.

CONCLUSION

Despite past findings and predictions of 8,000 to 8,500 otolaryngologists practicing in the United States, this study places the total at 12,609, with 10,522 fully trained and practicing in 2011. The 2014 findings of the AAO-HNS Physicians Resource Committee, September 20, 2014, personal communication not subject to external validation, placed practicing otolaryngologists in the United States at approximately 10,800, with an additional 1,318 residents and 769 fellows.

Even when this correction is considered, the available trained otolaryngologists required to serve the otolaryngologic health care needs of the US population are still insufficient. All current forecast models predict a continued shortage of otolaryngologists to 2025. Policy changes, if instituted, will take a decade to be even partially realized. A comprehensive, systematic analysis to assess the current strength of the otolaryngology workforce, the current patient need for otolaryngology services, and the current infrastructure of health care delivery and patient access is required to make accurate future predictions. To guarantee our ability to deliver quality otolaryngology health care to the US population, we must guarantee an adequate, well-trained workforce supply. This requires we plan appropriately and form the necessary policies to educate our future otolaryngologists. The impact of an aging population and 47 million newly insured citizens under the ACA are unprecedented variables that must be considered. Further analysis of differences in physician productivity and geographic population density are needed to predict future public health needs. Additional model formation of current workforce utilization is also needed to predict the effects of our aging population and the influx of 47 million newly insured US citizens.

It is imperative that we as a specialty address these issues, because our members and leaders have the best grasp of the pertinent issues and possible solutions. It is our obligation to provide access and serve our patients' health care needs. We must accept this responsibility for the future of our specialty.

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BIBLIOGRAPHY

1. Cooper RA. There's a shortage of specialists: is anyone listening? *Acad Med* 2002;77:761–766.
2. Association of American Medical Colleges. The complexities of physician supply and demand: projections from 2013 to 2025. 2015. Available at: https://www.aamc.org/download/426242/data/ihsreportdownload.pdf?cm_mmc=AAMC-_-ScientificAffairs-_-PDF-_-ihsreport. Accessed on 6 February 2016.

3. American Medical Association. AMA physician masterfile. Available at: http://www.ama-assn.org/ama/pub/about-ama/physician-data-resources/physician-masterfile.page. Accessed on 6 February 2016.
4. National Resident Matching Program. Charting outcomes in the match. 2014. Available at: http://www.nrmp.org/wp-content/uploads/2014/09/Charting-Outcomes-2014-Final.pdf. Accessed on 6 February 2016.
5. Brotherton SE, Etzel SI. Graduate medical education, 2008–2009. *JAMA* 2009;302:1357.
6. Association of American Medical Colleges Center for Workforce Studies. 2012 physician specialty data book. 2012. Available at: https://www.aamc.org/download/313228/data/2012physicianspecialtydatabook.pdf. Accessed on 6 February 2016.
7. Accreditation Council for Graduate Medical Education. Data resource book. Available at: https://apps.acgme.org/connect/login?ReturnUrl=%252fconnect%252fissue%252fwsfed%253fwa%253dwsignin1.0%2526wtrealm%253dhttps%25253a%25252f%25252fapps.acgme.org%25252fads%25252f%2526wctx%253drm%25253d0%252526id%25253dpassive%252526ru%25253d%2525252fads%2525252f%2526whr%253dacgme-us. Accessed on 6 February 2016.
8. Neuwahl S, Fraher E, Pillsbury H III, Weissler MC, Ricketts T, Gaul K. Trends in the otolaryngology workforce in the U.S. *Bull Am Coll Surg* 2012;97:30–34.
9. Kim JSC, Cooper RA, Kennedy DW. Otolaryngology–Head and Neck Surgery Physician Work Force issues an analysis for future specialty planning. *Otolaryngol Head Neck Surg* 2012;146:196–202.
10. Kim JSC, Cooper RA, Kennedy DW. Response to "Analysis of the workforce and otolaryngology specialty planning" by Pillsbury. *Otolaryngol Head Neck Surg* 2012;146:340–341.
11. Pillsbury HC III. Analysis of the workforce and otolaryngology specialty planning. *Otolaryngol Head Neck Surg* 2012;146:340.
12. Moalem J, Salzman P, Ruan DT, et al. Should all duty hours be the same? Results of a national survey of surgical trainees. *J Am Coll Surg* 2009; 209:47–54.
13. Hutter M, Kellogg KC, Ferguson CM, Abbott W, Warshaw A. The impact of the 80-hour resident workweek on surgical residents and attending surgeons. *Ann Surg* 2006;243:864–875.
14. Bilimoria KY, Chung JW, Hedges LV, et al. National cluster-randomized trial of duty-hour flexibility in surgical training. *N Engl J Med* 2016; 374:713–727.
15. Centers for Disease Control and Prevention National Center for Health Statistics. Ambulatory health care data. Available at: http://www.cdc.gov/nchs/ahcd/namcs_participant.htm. Accessed on 6 February 2016.
16. Pillsbury HC III, Cannon CR, Sedory Holzer SE, et al. The workforce in otolaryngology-head and neck surgery: moving into the next millennium. *Otolaryngol Head Neck Surg* 2000;123:341–356.
17. Neuwahl S, Fraher E, Pillsbury H III, Weissler M, Ricketts T, Gaul K. Trends in the otolaryngology workforce in the US. *Bull Am Coll Surg* 2012;97:30–34.
18. Henry Kaiser Family Foundation. The uninsured: a primer—key facts about health insurance on the eve of coverage expansions. 2013. Available at: http://kff.org/uninsured/report/the-uninsured-a-primer-key-facts-about-health-insurance-on-the-eve-of-coverage-expansions/. Accessed April 5, 2014.
19. Cooper RA. Weighing the evidence for expanding physician supply. *Ann Intern Med* 2004;141:705–714.
20. Cooper RA, Getzen TE, McKee HJ, Laud P. Economic and demographic trends signal an impending physician shortage. *Health Affairs* 2002;21: 140–154.
21. Congressional Budget Office. Estimates for the insurance coverage provisions of the Affordable Care Act updated for the recent Supreme Court decision. 2012. Available at: http://www.cbo.gov/publication/43472. Accessed on 6 February 2016.
22. Association of American Medical Colleges. Physician shortages to worsen without increases in residency training. 2011. Available at: https://www.aamc.org/download/150584/data/physician_shortages_factsheet.pdf. Accessed on 6 February 2016.
23. Grover A, Niecko-Najjum LM. Building a health care workforce for the future: more physicians, professional reforms and technological advances. *Health Affairs* 2013;32:1922–1927.
24. Association of American Medical Colleges. AAMC physician workforce policy recommendations. 2012. Available at: https://www.aamc.org/download/304026/data/2012aamcworkforcepolicyrecommendations.pdf. Accessed on 6 February 2016.
25. Dill MJ, Salsberg ES. The complexities of physician supply and demand: projections through 2025. 2008. Available at: http://www.innovationlabs.com/pa_future/1/background_docs/AAMC%20Complexities%20of%20physician%20demand,%202008.pdf. Accessed on 6 February 2016.
26. Association of American Medical Colleges. Recent studies and reports on physician shortages in the US. 2012. Available at: https://www.aamc.org/download/100598/data/. Accessed on 6 February 2016.
27. Vassar L. Here's what this year's medical class looks like. AMA Wire. 2015. Available at: http://www.ama-assn.org/ama/ama-wire/post/heres-this-years-medical-class-looks-like. Accessed on 6 February 2016.

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Factors Correlating with Burnout in Practicing Otolaryngologists

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Abstract

Objective. This study sought to determine which demographic and practice characteristics were predictive of professional burnout in otolaryngologists.

Study Design. Cross-sectional survey.

Setting. Tertiary care hospital.

Subjects and Methods. Postal mailings, including the Maslach Burnout Inventory (MBI), were sent to alumni of the University of Iowa Hospitals and Clinics otolaryngology program. Participants completed the MBI according to the enclosed instructions. In addition, they answered a brief questionnaire comprising 8 items designed to collect demographic information. The MBI was then scored and subjects were classified according to their degree of burnout. Statistical analysis was then performed, and correlations were used to summarize associations between continuous variables.

Results. This study had a response rate of 49% to the survey. Of the respondents, 3.5% met criteria for burnout syndrome, and 16% were classified as having high levels of burnout according to the MBI. Young age, number of hours worked per week, and length of time in practice were found to be statistically significant predictors of burnout. In addition, the length of time married and the presence of children in the home were also significant predictors of burnout.

Conclusion. The authors report an investigation of burnout in practicing otolaryngologists using a validated instrument with correlation to potentially modifiable risk factors. The experience of burnout was found to correlate significantly with both personal and professional factors, each of which can potentially be addressed to curb the incidence of burnout. Further understanding of the potential risk factors for burnout is necessary to minimize and prevent burnout among practicing otolaryngologists.

Keywords

burnout, burnout syndrome, practicing otolaryngologist

The syndrome of physician burnout is a serious problem in modern health care. Because of its many potential impacts on the health care landscape, burnout has become one of the most commonly analyzed manifestations of stress in physicians. Recent studies have attempted to quantify and characterize burnout in many medical and surgical subspecialties.[1-4] In the field of otolaryngology–head and neck surgery, several studies have begun to examine the myriad contributory factors that lead to burnout in residents,[5,6] academic faculty,[7] academic chairpersons,[8] and subspecialists.[9] These studies have started to demonstrate the critical role that personal and professional-related stressors play in the development of burnout. Many of these stressors are potentially modifiable. As such, attempts to understand how these stressors correlate with burnout are of paramount importance to reducing the incidence of this phenomenon. Herein we report the results of a study that attempts to quantify demographic and practice characteristics that correlate with burnout in practicing otolaryngologists.

Burnout is a syndrome characterized by a high degree of emotional exhaustion (EE) and depersonalization (DP) and a low degree of personal accomplishment (PA).[10] The most commonly used and rigorously validated instrument for measuring burnout is the Maslach Burnout Inventory–Human Services Study (MBI-HSS). The MBI-HSS measures each of these 3 aspects of burnout on a subscale related to the frequency of their occurrence. The EE subscale measures feelings that result from being emotionally overextended or exhausted by one's work; the DP subscale measures cynicism and callous responses toward recipients of one's service, care, treatment, or instruction; and the PA subscale assesses feelings of satisfaction with one's job-related achievements. Numeric scores are generated; however, there is no particular

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cutoff point at which a subject is considered ''burned out.'' Rather, scores are compared to normative data and grouped into low, average, and high degrees of EE, DP, and PA, reflecting a continuum of potential responses to work-related stress. Although the syndrome of burnout is readily identified with the MBI-HSS, the value of the survey is its ability to assess a subject's place along a spectrum of responses to stress ranging from low to high degrees of burnout, in contrast to a dichotomous characterization of burnout as either ''present'' or ''absent.''

In the present study, we measured burnout in alumni of the University of Iowa Hospitals and Clinics (UIHC) residency program in otolaryngology using the MBI-HSS. In conjunction with the survey, we also collected demographic information from survey participants, and correlation between demographic data and burnout was assessed.

Materials and Methods

Study Design and Participants

The design of this investigation was a questionnaire-based study of alumni of the UIHC otolaryngology program who were registered with our alumni relations office as of 2008. The survey was distributed to a total of 236 alumni.

Survey Administration

A single postal mailing containing the MBI-HSS and a demographic data sheet was sent. Each mailing included the survey, the demographic data sheet, a postage-paid return envelope, an instruction sheet, and a cover letter broadly explaining the study's purpose. To maintain confidentiality, survey participants were instructed not to mark any identifying information on the survey or return envelope. Participation in the study was completely voluntary. Completed surveys were returned by mail and stored anonymously by secretarial staff otherwise uninvolved with the study. The study protocol, survey instrument, and demographic survey were reviewed and approved by the University of Iowa Institutional Review Board.

MBI-HSS

The MBI-HSS evaluates the 3 subjective components of burnout—namely, PA, EE, and DP—through a brief 22-item inventory. We administered the full MBI-HSS, including all 22 questions, among 3 subscales: 9 questions assess emotional exhaustion, 8 evaluate personal accomplishment, and 5 score depersonalization. Questions regarding emotional exhaustion include ''I feel like I am at the end of my rope,'' and ''I feel burned out from my work.'' Questions such as ''I have accomplished many worthwhile things in this job'' assess personal accomplishment, whereas questions such as ''I feel I treat some of my faculty and residents as if they were impersonal objects'' measure depersonalization. The items are listed in no particular order, and respondents are instructed to assign a frequency to these feelings on a scale ranging from *never* to *once a day*. Survey respondents link each statement to a score on a 6-point Likert scale (0 = *never;* 1 = *a few times a year or less;* 2 = *once a month or less;* 3 = *a few times a month;* 4 = *once a week;* 5 = *a few times a week;* 6 = *every day*), relating the statement or feeling to the incidence of its perception. In scoring the survey, responses were grouped according to category (EE, DP, and PA) based on a key and added together to generate a score for each category.

Table 1. Maslach Burnout Inventory Subscale Stratification (% of Subjects in Each Stratum)

	Low	Moderate	High
Emotional exhaustion	71	15	19
Depersonalization	56	17	21
Personal accomplishment	10	24	57

Demographic Data Survey

The demographic data survey consisted of a total of 8 questions. The survey was designed to collect basic demographic information, including age (by decade), marital status, length of time married, and number of children in the home. It also collected information about the survey participants' practice, including type of practice (academic vs private, group vs solo, single vs multispecialty group), number of hours worked per week, and number of years in practice. One question addressed spirituality by asking respondents to indicate how religious they are on a 7-point Likert scale (1 = *very religious;* 7 = *not at all religious*).

Statistical Analysis

Statistical analysis was performed using SAS version 9.1 for Windows (SAS Institute, Cary, North Carolina). Pearson correlation coefficients were used to summarize associations between continuous variables. Univariate and multivariate linear regression was used to measure crude and adjusted associations for categorical and continuous risk factors for burnout. Associations and comparisons of means were considered statistically significant if $P \leq .05$.

Results

Demographic Information

Of 236 surveys distributed, 115 were returned completed (49% participation rate). Of note, 94% of the study population indicated that they were married, with the average number of years married being 16.3 (range, 1-57 years), and 56% (64/115) of participants indicated that they had children living with them. Only 14% (16/115) were younger than age 40, and equal proportions of respondents were in their fourth and fifth decades: 23% (27/115) aged 41 to 50 years and 23% (26/115) aged 51 to 60 years. The majority of the study population was in private practice 56% (64/115) with 34% (39/115) in academic medicine.

MBI-HSS

Percentages of subjects stratified into low, moderate, and high levels for each subscale are listed in **Table 1**. Levels

Table 2. Percentage of Participants Meeting Criteria for Burnout

Burnout	No. (%)
↑ EE/DP	19/115 (16)
↑ EE/DP, ↓ PA	4/115 (3.5)

Abbreviations: EE, emotional exhaustion; DP, depersonalization; PA, personal accomplishment, ↑, high level; ↓, low level.

Table 3. Mean Maslach Burnout Inventory Subscores for Survey Participants

	Mean	Standard Deviation	Range
Emotional exhaustion	16.5	11.5	Low
Depersonalization	6.2	5.4	Moderate
Personal accomplishment	41.2	5.8	Low

of EE were low in most participants (71%), with 15% and 19% indicating moderate and high levels, respectively. Levels of DP were also low in the majority (56%), with 17% exhibiting moderate and 21% with high levels. Results are listed in **Table 2** for the number of respondents meeting criteria for the true syndrome of burnout characterized by high levels of EE and DP combined with low levels of PA, as well as those with high EE and DP alone, irrespective of PA. Both have been used in the literature to classify individuals as demonstrating high levels of burnout.[2,11,12] The use of the EE and DP indices to measure burnout independent of PA is based on findings from the development of the MBI-HSS showing strong correlation between levels of EE and DP regardless of PA.[10] On the basis of these 2 criteria, 3.5% exhibited burnout syndrome and 16% demonstrated high levels of burnout. **Table 3** lists the mean MBI-HSS subscores for our survey participants. The mean (SD) EE score fell into the low range at 16.5 (11.5), the mean (SD) DP score was moderate at 6.2 (5.4), and the mean (SD) PA score was high at 41.2 (5.8) (scale: low EE $\leq$18, high EE $\geq$27; low DP $\leq$5, high DP $\geq$10; high PA $\geq$40, low PA $\leq$33).

Correlation and linear regression modeling were performed to determine predictors of burnout. In keeping with similar studies of burnout,[3,13] our analysis concentrated on EE and DP, which had the strongest associations among the 3 burnout subscales. **Table 4** summarizes significant results. Age showed an inverse relationship with EE ($r = –0.39$, $P < .0001$) and DP ($r = –0.28$, $P < .0041$). The length of time married also showed similar negative correlations with EE ($r = –0.33$, $P = .0007$) and DP ($r = –0.33$, $P = .0045$). The number of children in the home was correlated with EE ($r = 0.22$, $P = .0275$) and DP ($r = 0.23$, $P = .0235$).

With regard to practice-related factors, the number of hours worked per week showed an association with EE ($r = 0.31$, $P = .0016$). Likewise, the number of years on the job was also related with EE but showed an inverse relationship ($r = –0.25$, $P = .0108$). There was no statistically significant relationship between practice setting (ie, academic or private, solo or group) and EE or DP.

Discussion

Physician burnout continues to be a widespread problem with many deleterious sequelae. The negative impacts of physician burnout on the health care landscape are well documented and include such effects as dissatisfied and less compliant patients, riskier prescribing profiles, lower productivity, and increases in medical errors, to name a few.[14-18] Although several studies have recently begun to address this phenomenon in otolaryngologists,[7,8,19] we have yet to attain a thorough understanding of the risk factors leading to its occurrence. Herein we report a study of burnout in practicing otolaryngologists with correlation to potentially modifiable risk factors.

Burnout was not very prevalent in our survey population. Of those surveyed, only 3.5% experienced the composite syndrome of burnout with high scores on all 3 indices, and 16% had burnout according to subscale measurements of EE and DP. In addition, analysis of the subscale results shows a more favorable picture of practicing otolaryngologists' health with respect to burnout. Both emotional exhaustion and depersonalization scores on average were in the low range. High levels of EE and DP were found in only 19% and 21% of respondents, respectively. These results are in contrast to other published surveys of burnout in academic otolaryngologists and department chairs, which showed moderate levels of burnout in the majority of respondents.[7,8] Prior studies[7] have also demonstrated lower levels of burnout among otolaryngologists when compared to other surgical specialties such as general surgery and OB/GYN, and our results are in keeping with this. Our respondents also had lower mean burnout scores than were reported in the normative data for the medicine subscale of the MBI-HSS, which showed mean (SD) EE, DP, and PA levels of 22.19 (9.53), 7.12 (5.22), and 36.53 (7.34), respectively.[10] When compared to large surveys of burnout such as the one by Shanafelt et al[20] of 7905 members of the American College of Surgeons, our population also had a lower level and degree of burnout. This may reflect a sampling bias of our study in that those surgeons experiencing higher levels of burnout may have been less likely to complete and return our survey because of a lack of interest or time. Therefore, it is possible that the extent of burnout was underreported in our study population. The study population in Shanafelt et al also comprised 41% general surgeons compared to 4.7% otolaryngologists. This difference in study population may account for the observed difference in burnout reported, in light of the fact that the general surgery population tends to have higher degrees of burnout than otolaryngology.

Both the prevention and treatment of burnout rely heavily on the recognition of its manifestations. Recognition can be difficult in professionals with high stress such as physicians, who frequently demonstrate poor insight into their own mental and professional health.[21] This has contributed

Table 4. Significant Predictors of Burnout

Covariate	Predictor	Regression Coefficient (β)	Standard Error	95% Confidence Interval (of β)	R^2	*P* Value
Age	EE	−3.28	0.77	−4.80 to −1.76	0.15	<.0001
	DP	−1.05	0.36	−1.75 to −0.34	0.08	.0041
No. of years married	EE	−0.24	0.069	−0.38 to −0.11	0.11	.0007
	DP	−0.09	0.032	−0.16 to −0.03	0.08	.0045
Presence of children in the home	EE	1.93	0.86	0.22 to 3.64	0.05	.0275
	DP	0.88	0.38	0.12 to 1.64	0.05	.0235
Hours worked/wk	EE	0.15	0.047	0.06 to 2.24	0.10	.0016
No. years on the job	EE	−0.27	0.11	−0.49 to −0.07	0.06	.0108

Abbreviations: EE, emotional exhaustion; DP, depersonalization.

to the immense underrecognition of burnout in physicians. The ability to quantify burnout using a validated instrument (MBI-HSS) has enhanced our capacity to detect burnout and to understand the factors associated with it. Studies that have used the MBI-HSS have shown lower levels of burnout in otolaryngologists when compared with other surgical specialties.[1,13] Studies have also shown that burnout in otolaryngologists varies based on level of training. In a 2007 study, Golub et al[5] found high levels of burnout in 10% of residents surveyed, whereas Hill and Smith[6] found that 31% of residents experienced high levels of burnout. This is in comparison to a survey of academic faculty demonstrating high levels of burnout in 4% and a separate study of department chairs that had high levels in only 3%.[7,8] Our investigation further bears this out, with burnout syndrome demonstrated in only 3.5% of practicing otolaryngologists surveyed.

This difference is thought to be the result of the higher work hour demands placed on residents, who, despite the recent reduction in work hours mandated by the Accreditation Council for Graduate Medical Education, are still working more hours per week than their attending counterparts. Indeed, in many studies, the number of hours worked per week has consistently been shown to be one of the strongest predictors of physician burnout.[1,7,22,23] This was also the case in the present study, which demonstrated a significant correlation between the number of hours worked per week and one's level of EE. Given the demanding nature of the medical field, this is not surprising; yet if a reduction in the level of burnout is to be expected with one's career advancement, perhaps efforts to curb burnout are best targeted toward residents in training. These interventions may alleviate burnout stemming from overwork, but they would not obviate the search for modifiable risk factors to curb the incidence of burnout deriving from other sources.

Our understanding of the risk factors that contribute to burnout is still emerging. In a recent survey of academic faculty in otolaryngology, Golub et al[7] found that dissatisfaction with the balance between personal and professional life was one of the strongest predictors of burnout. A similar survey of academic chairs in otolaryngology found that burnout was correlated with low spousal support, the loss of key faculty, and disputes with the medical school dean.[8] These findings shed light on one of the key elements of burnout: the sense of losing control of one's professional life. In fact, a strong sense of control of one's environment has been shown to be of paramount importance to attenuating symptoms of burnout.[4,24,25]

In the current study, younger age and fewer years in practice were significant predictors of burnout. This is in keeping with previously published data in otolaryngologists and other surgical specialties.[7,26] This may be explained by the perceived lack of control of one's professional environment at the early stages of one's career when new and often unfamiliar stressors are brought to bear. Physicians who have been in practice longer have most likely adapted coping mechanisms that are protective against burnout. Experience also allows for maturity and increased confidence, both of which provide an improved sense of control over professional matters. It is also somewhat more difficult to determine the optimal professional/personal balance earlier in one's career, thus increasing the strain of each. Interestingly, practice setting did not correlate with burnout, thus highlighting the importance of personal coping skills as a more important determinant of response to stress than work environment. We also found no significant correlation between religious beliefs and EE or DP.

The quality of interpersonal relationships and personal support systems has been highlighted as having a significant impact on the development of professional burnout.[15,18,23] The presence of work-home conflicts has also been shown to be a major contributing factor to surgeon burnout.[25] Our present analysis demonstrates an inverse relationship between the number of years married and both EE and DP. One explanation is that the experience and maturity acquired through years of marriage improve one's adaptability to its demands and insulates against the development of EE and DP. Certainly, the personal stresses of a new marriage can be challenging, and when compounded with the constant emotional and psychological demands of patient care, this may significantly increase one's risk of burnout. Our study also found that having more children in the home was significantly correlated with both EE and DP. Given the constant demands of childrearing, this is not surprising. Yet the complex interplay of these demands with one's professional aspirations may also contribute to

these findings. One recent study found that 23.4% of surgeons felt that their commitment to childrearing slowed their career advancement.[25] Perhaps lacking sense of control and flexibility as childrearing encroaches upon professional demands and ambition increases the likelihood of burnout in this population.

Our study suffers from a few limitations. First, the 49% response rate, although comparable to similar published studies,[5,25] opens the possibility of response bias. It may also have decreased the power of our study to detect other correlations between burnout and the risk factors of interest. Additional selection bias may have been introduced by limiting our survey to alumni, who may have a tendency to embellish their survey responses so as to not appear inferior to their former faculty mentors. Third is the self-reported nature of the gathered data, which may not reflect each participant's actual behavior. Last, the cross-sectional design of the survey prohibits our ability to determine cause-and-effect relationships and the potential direction of causality. Despite these limitations, we believe that the data presented here may serve to further enhance our understanding of the complex interplay of factors (both personal and professional) leading to physician burnout. Further study is needed to determine where best to direct efforts to reduce the incidence of burnout in physicians.

Conclusion

Most practicing otolaryngologists surveyed experience low levels of burnout. Factors directly correlating with burnout include number of hours worked per week and number of children in the home. Inverse relationships were noted between burnout and age, the number of years in practice, and number of years married. There was no significant correlation between practice setting and burnout. As these study results were obtained through a survey of graduates of a single otolaryngology program, they cannot be extrapolated to represent the experience of all US otolaryngologists. However, these findings may help practicing otolaryngologists understand and target potentially modifiable personal and professional factors that contribute to burnout.

Author Contributions

Aaron M. Fletcher, preparation of manuscript, interpretation of data; **Nitin Pagedar**, preparation of manuscript, statistical analysis, interpretation of data; **Richard J. H. Smith**, preparation of manuscript, study design, interpretation of data.

Disclosures

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References

1. Campbell DA Jr, Sonnad SS, Eckhauser FE, Campbell KK, Greenfield LJ. Burnout among American surgeons. *Surgery*. 2001;130:696-705.
2. Gabbe SG, Melville J, Mandel L, Walker E. Burnout in chairs of obstetrics and gynecology: diagnosis, treatment, and prevention. *Am J Obstet Gynecol*. 2002;186:601-612.
3. Cruz OA, Pole CJ, Thomas SM. Burnout in chairs of academic departments of ophthalmology. *Ophthalmology*. 2007;114:2350-2355.
4. Shanafelt TD, West CP, Sloan JA, et al. Career fit and burnout among academic faculty. *Arch Intern Med*. 2009;169:990-995.
5. Golub JS, Weiss PS, Ramesh AK, Ossoff RH, Johns MM III. Burnout in residents of otolaryngology–head and neck surgery: a national inquiry into the health of residency training. *Acad Med*. 2007;82:596-601.
6. Hill JD, Smith RJ. Monitoring stress levels in postgraduate medical training. *Laryngoscope*. 2009;119:75-78.
7. Golub JS, Johns MM III, Weiss PS, Ramesh AK, Ossoff RH. Burnout in academic faculty of otolaryngology–head and neck surgery. *Laryngoscope*. 2008;118:1951-1956.
8. Johns MM III, Ossoff RH. Burnout in academic chairs of otolaryngology: head and neck surgery. *Laryngoscope*. 2005;115:2056-2061.
9. Contag SP, Golub JS, Teknos TN, et al. Professional burnout among microvascular and reconstructive free-flap head and neck surgeons in the United States. *Arch Otolaryngol Head Neck Surg*. 2010;136:950-956.
10. Maslach C, Leiter MP. *Maslach Burnout Inventory Manual*. Palo Alto, CA: Consulting Psychologists Press; 1996.
11. Balch CM, Shanafelt TD, Sloan J, Satele DV, Kuerer HM. Burnout and career satisfaction among surgical oncologists compared with other surgical specialties. *Ann Surg Oncol*. 2011;18:16-25.
12. West CP, Dyrbye LN, Sloan JA, Shanafelt TD. Single item measures of emotional exhaustion and depersonalization are useful for assessing burnout in medical professionals. *J Gen Intern Med*. 2009;24:1318-1321.
13. Balch CM, Shanafelt TD. Burnout among surgeons: whether specialty makes a difference. *Arch Surg*. 2011;146:385-386.
14. Shanafelt TD, Balch CM, Bechamps G, et al. Burnout and medical errors among American surgeons. *Ann Surg*. 2010;251:995-1000.
15. Mingote Adan JC, Moreno Jimenez B, Galvez Herrer M. Burnout and the health of the medical professionals: review and preventive options. *Med Clin (Barc)*. 2004;123:265-270.
16. Balch CM, Freischlag JA, Shanafelt TD. Stress and burnout among surgeons: understanding and managing the syndrome and avoiding the adverse consequences. *Arch Surg*. 2009;144:371-376.
17. Prins JT, van der Heijden FM, Hoekstra-Weebers JE, et al. Burnout, engagement and resident physicians' self-reported errors. *Psychol Health Med*. 2009;14:654-666.
18. Rosenstein AH, Mudge-Riley M. The impact of stress and burnout on physician satisfaction and behaviors. *Physician Exec*. 2010;36:16-18, 20, 22-23.
19. Johnson JT, Wagner RL, Rueger RM, Goepfert H. Professional burnout among head and neck surgeons: results of a survey. *Head Neck*. 1993;15:557-560.
20. Shanafelt T, Balch C, Bechamps G, et al. Burnout and career satisfaction among American surgeons. *Ann Surg*. 2009;250:463-471.

21. Balch CM, Shanafelt T. Combating stress and burnout in surgical practice: a review. *Thorac Surg Clin*. 2011;21:417-430.
22. Embriaco N, Azoulay E, Barrau K, et al. High level of burnout in intensivists: prevalence and associated factors. *Am J Respir Crit Care Med*. 2007;175:686-692.
23. Pejuskovic B, Lecic-Tosevski D, Priebe S. Burnout in psychiatrists, general practitioners and surgeons. *World Psychiatry*. 2011;10:78.
24. Meldrum H. Exemplary physicians' strategies for avoiding burnout. *Health Care Manag (Frederick)*. 2010;29:324-331.
25. Wurlitzer F. Other contributing factors to burnout among American surgeons. *Ann Surg*. 2010;252:707.
26. Dyrbye LN, Shanafelt TD, Balch CM, Satele D, Sloan J, Freischlag J. Relationship between work-home conflicts and burnout among American surgeons: a comparison by sex. *Arch Surg*. 2011;146:211-217.

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ORIGINAL ARTICLE

An Interactive Individualized Intervention to Promote Behavioral Change to Increase Personal Well-Being in US Surgeons

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Objective: Evaluate the utility of a computer-based, interactive, and individualized intervention for promoting well-being in US surgeons.

Background: Distress and burnout are common among US surgeons. Surgeons experiencing distress are unlikely to seek help on their own initiative. A belief that distress and burnout are a normal part of being a physician and lack of awareness of distress level relative to colleagues may contribute to this problem.

Methods: Surgeons who were members of the American College of Surgeons were invited to participate in an intervention study. Participating surgeons completed a 3-step, interactive, electronic intervention. First, surgeons subjectively assessed their well-being relative to colleagues. Second, surgeons completed the 7-item Mayo Clinic Physician Well-Being Index and received objective, individualized feedback about their well-being relative to national physician norms. Third, surgeons evaluated the usefulness of the feedback and whether they intended to make specific changes as a result.

Results: A total of 1150 US surgeons volunteered to participate in the study. Surgeons' subjective assessment of their well-being relative to colleagues was poor. A majority of surgeons (89.2%) believed that their well-being was at or above average, including 70.5% with scores in the bottom 30% relative to national norms. After receiving objective, individualized feedback based on the Mayo Clinic Physician Well-Being Index score, 46.6% of surgeons indicated that they intended to make specific changes as a result. Surgeons with lower well-being scores were more likely to make changes in each dimension assessed (all Ps < 0.001).

Conclusions: US surgeons do not reliably calibrate their level of distress. After self-assessment and individualized feedback using the Mayo Clinic Physician Well-Being Index, half of participating surgeons reported that they were contemplating behavioral changes to improve personal well-being.

Keywords: behavioral change, burnout, intervention, Physician Well-Being Index, physician

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Studies during the last decade have demonstrated high rates of distress and burnout among US physicians.[1–4] Physician distress may manifest itself in a variety of ways, including stress, depression, fatigue, and low career satisfaction.[5,6] Burnout appears to be one of the most common manifestations of distress, with recent studies indicating that 30% to 45% of US physicians are experiencing burnout.[2–5,7,8] Burnout is a syndrome of emotional exhaustion and depersonalization that leads to decreased effectiveness at work.[9] In addition to potential personal consequences, physician distress can affect physicians' satisfaction with their work and the quality of medical care they provide.[10–15]

A series of studies conducted by the American College of Surgeons (ACS) since 2008 have provided insight into the experience and repercussions of distress among US surgeons.[2,15–24] This effort has characterized the prevalence of burnout and distress among US surgeons[2] and explored correlations with work hours,[16] area of subspecialization,[21,25] malpractice suits,[26] and practice setting.[2,25] These studies have also identified potential personal consequences of distress among surgeons, including problematic alcohol use,[23] strained personal relationships,[17,20] and suicidal ideation.[27] From a professional standpoint, surgeon distress seems both to contribute to medical errors[15] and to cause surgeons to consider reducing their clinical workload and/or to pursue early retirement.[3,28]

Other than descriptive information on the habits and self-care strategies of thriving surgeons,[24] there is limited information on what steps surgeons can take to reduce distress. Like other physicians,[29] surgeons experiencing distress are unlikely to seek help of their own initiative.[27] A variety of factors likely contribute to this fact, including concerns about repercussions for licensure, the belief that distress and burnout are normal parts of being a physician, and a professional culture that minimizes distress until it reaches dangerous levels.[27,29,30]

Several barriers have also prevented proactive screening for physician distress, including the lack of a brief screening instrument that evaluates the relevant dimensions of distress, the complex scoring systems required for the available tools, a lack of physician-specific normative data, and no information regarding what level of distress results in clinically relevant outcomes. Through a 5-year iterative process, we developed and validated a brief 7-item self-assessment tool [Mayo Clinic Physician Well-Being Index (MPWBI) Table 1] to evaluate the dimensions of distress commonly experienced by physicians.[31–33] A recent validation study among approximately 7000 US physicians confirmed the utility of the MPWBI and indicated that the index was able to stratify an individual physician's risk of experiencing adverse personal and professional consequences (eg, makeing medical error, intent to leave practice, suicidal ideation).[31]

Although the best strategy to help individuals improve their well-being is unknown, computer-based, interactive, and individualized interventions have been shown to be an effective approach to promote behavioral change.[34,35] In this study, conducted as part of the ongoing ACS effort to promote surgeon well-being, we tested the utility of an interactive and individualized intervention based on the MPWBI in approximately 1100 US surgeons. After answering baseline questions regarding how they believed their well-being compared with their colleagues, participating surgeons completed an online version of the MPWBI after which they received immediate, individualized feedback. Surgeons were then asked a series of follow-up questions regarding the utility of the feedback and whether they planned to make specific changes based on the information provided.

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Disclosure: T. Shanafelt and L. Dyrbye developed both the Medical Student Well-Being Index and Mayo Clinic Physician Well-Being Index. Mayo Clinic holds the copyright on these technologies and accordingly Mayo Clinic and Drs Shanafelt and Dyrbye have a potential financial interest in these technologies. The Medical Student Well-Being Index has been licensed to a commercial entity, although no royalties have been received to date. To obtain permission to use the index, please contact the corresponding author. The authors declare no conflicts of interest.

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TABLE 1. Mayo Clinic Physician Well-Being Index*

During the past month . . .
- have you felt burned out from your work?
- have you worried that your work is hardening you emotionally?
- have you often been bothered by feeling down, depressed, or hopeless?
- have you fallen asleep while stopped in traffic or driving?
- have you felt that all the things you had to do were piling up so high that you could not overcome them?
- have you been bothered by emotional problems (such as feeling anxious, depressed, or irritable)?
- has your physical health interfered with your ability to do your daily work at home and/or away from home?

*Each question is answered using a yes/no scale. Basic scoring systems and weighted scoring approaches that may improve sensitivity and specificity for predicting specific outcomes (eg, mental quality of life; suicidal ideation) are reviewed in reference 31.

METHODS

Participants

Study eligibility and the electronic participation process were similar to our 2008 and 2010 ACS studies.[2,15–24] A random sample of 8000 surgeons who were members of the ACS, had an e-mail address on file with the ACS, and permitted their e-mail to be used for correspondence with the ACS were notified of the study. Participation was voluntary, and all responses were anonymous. The ACS Governor's Committee on Physician Competency and Health commissioned the study, and institutional review board oversight for protection of human subjects was provided by the Mayo Clinic institutional review board. Surgeons received 2 e-mails notifying them of the study and inviting them to participate. Surgeons who volunteered to participate completed the study electronically in March to April 2013.

Physician Well-Being Index

The 7-item MPWBI evaluates the dimensions of distress commonly experienced by physicians [eg, burnout (emotional exhaustion, depersonalization), depression, fatigue, mental quality of life, physical quality of life]. The robust, iterative process to develop and validate the MPWBI is described in previous publications.[31–33] After initial development and validation in medical students,[32,33] the MPWBI was subsequently adapted and tested in a national sample of approximately 7000 US physicians.[31] That study confirmed the utility of the MPWBI for assessing multiple dimensions of physician distress, defined the normative scores for US physicians,[31] and indicated that the index is associated with clinically relevant personal and professional endpoints (eg, medical errors,[15] intent to leave practice,[22] suicidal ideation[36]). For the present study, a Web-based version of the MPWBI was created along with automated scoring reports that provided immediate, individualized feedback based on the MPWBI score. This feedback informed physicians how their level of distress compared with national physician norms[31] and also provided dashboards that gave participating surgeons specific data on how their degree of distress may impact them personally and professionally in 6 dimensions. The feedback to all participants also included the phone number for the National Suicide Prevention hotline.

Intervention and Data Collection

It should be emphasized that this study was not a survey but a multistep electronic intervention. The cover letter stated that the purpose of the study was to evaluate the utility of a validated online self-assessment tool that would provide individualized feedback on the individual's well-being relative to that of other physicians/surgeons. Although the entire process was designed to take 5 minutes or less, the intervention had 3 phases. First, surgeons provided baseline information regarding demographic characteristics (age, sex, practice setting, years in practice) and their assessment of personal well-being relative to other physicians. Response options for this latter question included: "poor" (bottom 30% of physicians), "below average" (31st–40th percentile), "average" (41st–60th percentile), "above average" (61st–70th percentile), and "excellent" (top 30% of physicians). These options were designed to represent an intuitive distribution and allow assessment of the accuracy of self-calibration relative to actual objective benchmarking using the MPWBI (scores of 0 represent the top 27.4% of physicians nationally; scores $\geq$4 represent the bottom 29.3% of physicians nationally).[31]

Second, surgeons completed the 7-item MPWBI and subsequently received immediate, individualized feedback (Fig. 1). This feedback informed the participants how their well-being compared with national physician norms[31] and provided information on risk in 6 specific dimensions (fatigue, career satisfaction, meaning in work, risk of suicidal ideation, risk degree of distress may contribute to errors, and mental quality of life). Third, surgeons answered follow-up questions evaluating the usefulness of the information provided and indicating whether they intended to make any specific changes "as a result of reviewing the feedback" to (i) reduce burnout, (ii) reduce fatigue, (iii) promote work-life balance, or (iv) promote career satisfaction.

Statistical Analysis

Standard descriptive statistics were used to characterize responding surgeons. Associations between variables were evaluated using the Kruskal-Wallis test (continuous variables) or χ^2 test (categorical variables) as appropriate. All tests were 2-sided, with type I error rates of 0.05. All analyses were done using SAS, version 9 (SAS Institute, Inc, Cary, NC).

RESULTS

Of the 8000 fellows and associate fellows of the ACS notified of the study by e-mail, 1150 volunteered to participate. The basic demographic and practice characteristics of study participants are shown in Table 2. The median age of volunteers was 53 years, and 84.2% were men. Participating surgeons had been in practice a median of 20 years, and most were in either private practice (46.7%) or academic practice (36.7%). When asked to subjectively assess their well-being relative to other physicians, 993 surgeons (89.2%) believed that their well-being was at or above average. Only 25 surgeons (2.2%) believed that their well-being was in the bottom 30% relative to other physicians (Table 2).

The distribution of scores on the MPWBI is shown in Figure 2. Scores of participating surgeons were consistent with that expected on the basis of national physician normative data, with 28.9% of surgeons scoring into the top 30% relative to national norms and 24% scoring in the bottom 30% relative to national norms.[31]

Surgeons' ability to subjectively assess their own well-being relative to other physicians was poor. Among the 275 surgeons with an MPWBI score of 4 or more (eg, in the bottom ~30% relative to national physician norms), 194 (70.5%) believed that their well-being was at or above average, including 66 (24.0%) who believed that their well-being was above average relative to other physicians. Similarly, among the 332 surgeons with an MPWBI score of 0 (eg, top ~30% relative to national physician norms), 40 (13.6%) believed that their well-being was at or below average.

Surgeons were next asked to subjectively "indicate whether the individualized feedback from the online self-assessment tool was helpful for calibrating personal well-being relative to your colleagues" (Table 3). Collectively, 546 surgeons (49.5%) rated the feedback "somewhat" to "extremely" helpful (highest 3 choices on a 5-point

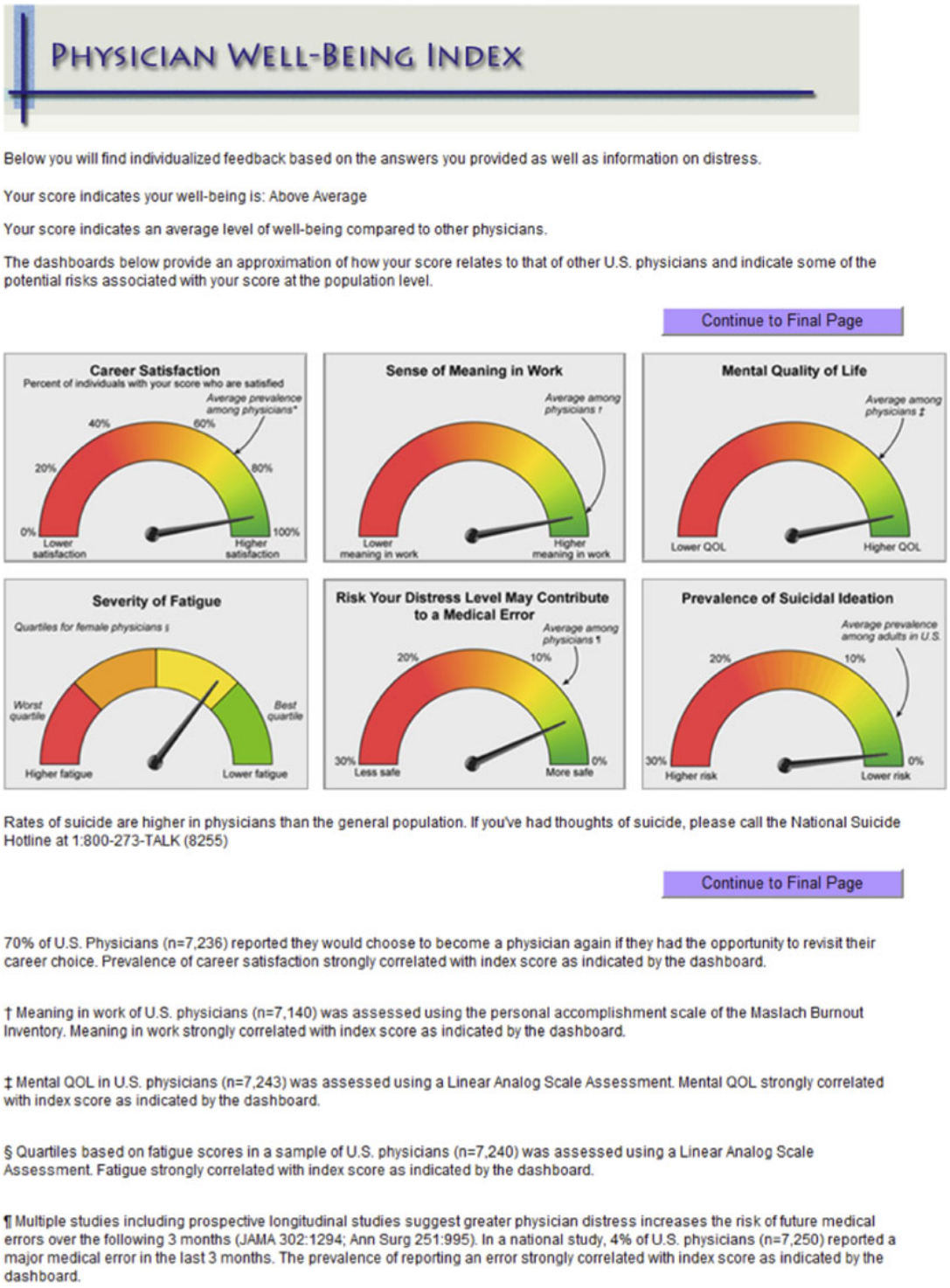

FIGURE 1. Example of individualized feedback provided to surgeons completing the online self-assessment using the MPWBI. QOL indicates quality of life.

scale), 257 (23.3%) reported that the information was only slightly helpful, and 301 (27.3%) reported that the feedback was not helpful. Surgeons with better well-being scores on the MPWBI were as or more likely to report that they found the feedback helpful as those with lower well-being scores (Table 3).

Finally, surgeons were asked whether they were considering making a change in any of 4 specific dimensions (eg, to reduce burnout, to reduce fatigue, to promote work-life balance, and to promote career satisfaction) as a direct result of the feedback on how their well-being compared with other physicians (Table 3). As a direct

TABLE 2. Demographic and Practice Characteristics

Age, yr	
Median	53 (10.6)
<40	120 (11.3%)
40–49	288 (27.2%)
50–59	369 (34.8%)
60+	283 (26.7%)
Missing	90
Sex	
Women	176 (15.8%)
Men	937 (84.2%)
Missing	37
Years in practice	
Median	20
<10	215 (20.8%)
10–19	290 (28.0%)
≥20	530 (51.2%)
Missing	115
Practice setting	
Private practice	520 (46.7%)
Academic practice	408 (36.7%)
Military	18 (1.6%)
Veterans	15 (1.4%)
Other*	152 (9.7%)
How do you think your well-being compares with other physicians?	
Poor (bottom 30% of physicians)	25 (2.2%)
Below average (31st–40th percentile)	95 (8.5%)
Average (41st–60th percentile)	329 (29.6%)
Above average (61st–70th percentile)	325 (29.2%)
Excellent (top 30% of physicians)	339 (30.5%)
Missing	37

Values given are number (percentage) unless indicated otherwise.
*Other category includes those working in other practice settings, other areas (eg, industry), or retired.

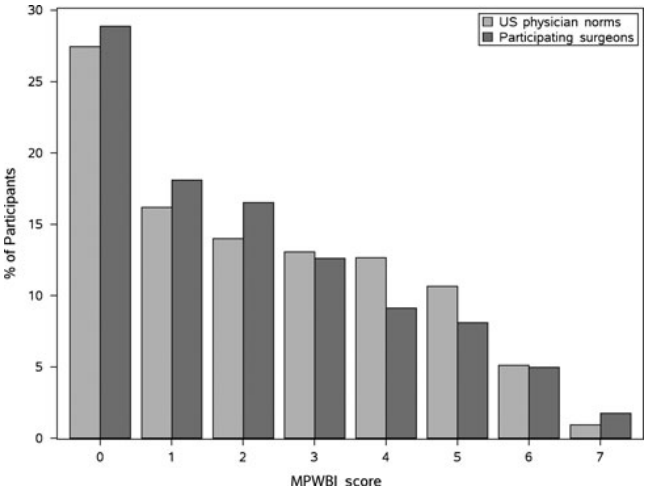

FIGURE 2. Distribution of MPWBI scores. The figure shows the distribution of MPWBI scores (*x* axis) of the participating surgeons (dark gray bars; n = 1150) relative to a normative sample of approximately 7000 US physicians (light gray bars).[31] Higher scores indicate greater levels of distress. MPWBI indicates Mayo Physician Well-Being Index.

TABLE 3. Subjective Assessment of Feedback Utility and Intent to Make Changes as a Direct Result of the Feedback

	Proportion of Surgeons Rating Feedback "Somewhat" to "Extremely Helpful"
MPWBI score*	
0	65.0%
1	49.0%
2	43.6%
3	41.0%
4	36.5%
≥5	44.6%
Proportion of surgeons reporting they were considering making a change as a direct result of feedback to:	N = 1150
Reduce burnout	296 (26.7%)
Reduce fatigue	302 (27.3%)
Promote work-life balance	437 (39.2%)
Promote career satisfaction	380 (34.2%)
≥1 of above	529 (46.6%)

*Lower scores indicate less distress and higher well-being.

result of the individualized feedback, 296 participants (26.7%) reported that they intended to make changes to reduce burnout, 302 (27.3%) to reduce fatigue, 437 (39.2%) to promote work-life balance, and 380 (34.2%) to promote career satisfaction. Collectively, 529 (46.6%) indicated that they were considering making a change in at least 1 of these dimensions as a result of the individualized feedback. A strong dose-response relationship was observed between feedback that an individual's well-being was lower than physician norms and intent to make a change. In each of the 4 dimensions evaluated, surgeons having lower well-being were more likely to be considering making a change (Figs. 3A–D). The proportion of surgeons considering making at least 1 change (Fig. 4A) and the number of changes being considered (Fig. 4B) also increased on the basis of the feedback surgeon's received regarding how their well-being compared with physician norms on the MPWBI.

DISCUSSION

Despite the high prevalence of distress among US physicians, few physicians seek help of their own initiative.[27,29,30] In the present study of more than 1000 US surgeons, physicians' ability to reliably calibrate their level of distress relative to colleagues was poor. The high prevalence of burnout among physicians may lead some individuals with severe distress to believe that their experience is simply a normal part of being a physician. Likewise, physicians may compare their experience with a limited circle of colleagues they interact with regularly but who may not be a representative sample. Among surgeons whose well-being was in the lowest 30% relative to national physician norms, the majority (>70%) believed that their well-being was at or above average, including approximately 25% who believed that their well-being was above average. These findings illustrate poor calibration and lack of awareness—both of which may be important barriers to physicians taking steps to promote personal health and well-being.

Behavioral change is believed to be a multistep process characterized by at least 6 phases: precontemplation (no intent to make changes; may not be aware of the need for change), contemplation (aware of the need for a change and considering making a change in near future), preparation (ready to take action and have begun making plans to change), action (have taken action and changed their behavior), maintenance (sustain new habits avoid regression to old ways), and termination (certainty that able to preserve healthy approaches rather than reverting to old unhealthy habits).[34] The poor self-calibration of well-being likely results in many surgeons being at

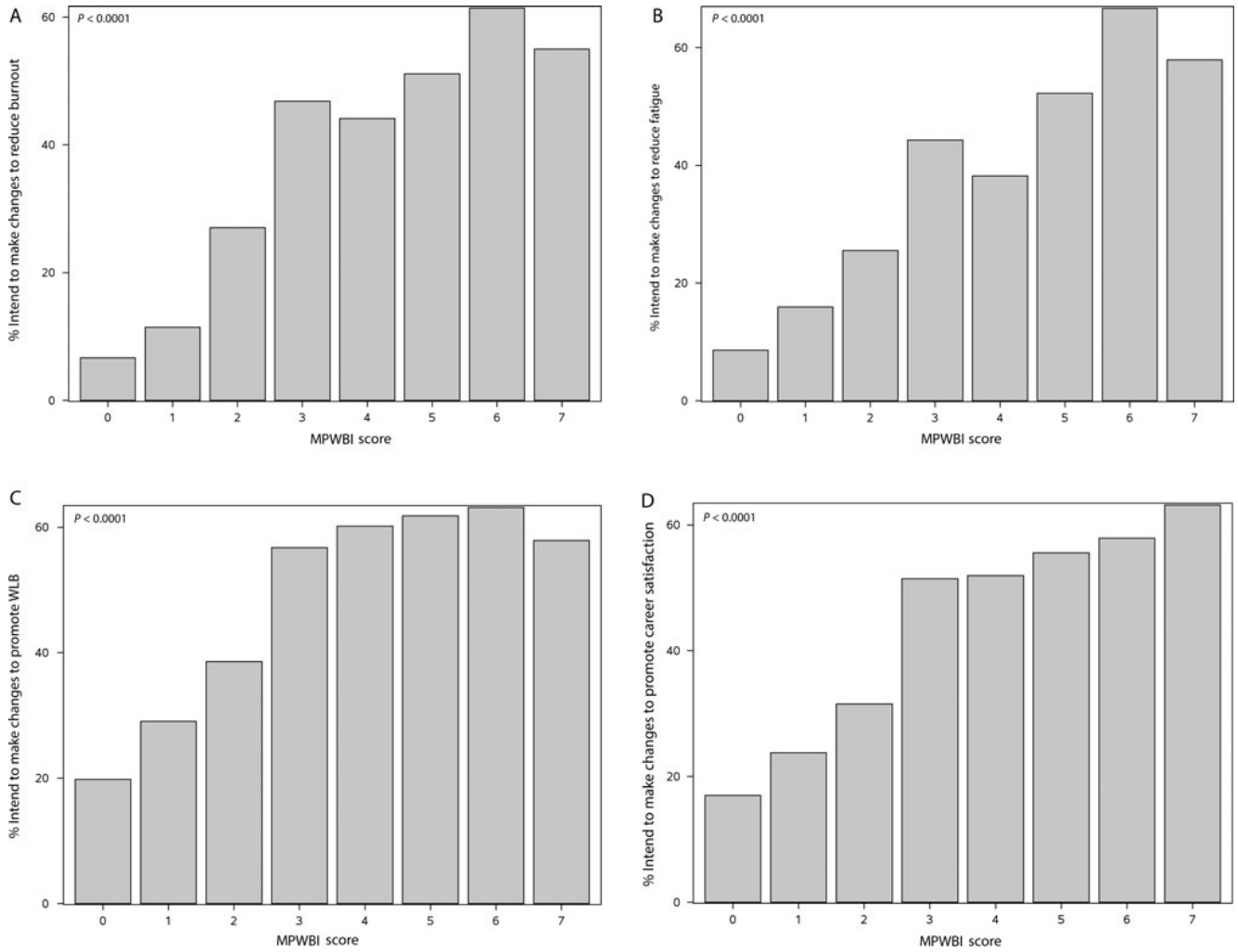

FIGURE 3. Feedback regarding well-being relative other physicians and intent to make changes to promote well-being. MPWBI scores are shown on the *x* axis (higher scores indicate greater levels of distress). The proportion of surgeons who indicated they were considering making changes to reduce burnout (A), reduce fatigue (B), promote work-life balance (C), and promote career satisfaction (D) as a direct result of the individualized feedback received is shown on the *y* axis of each figure. Feedback of higher levels of distress relative to physician norms was correlated with higher likelihood of considering making changes in each dimension. MPWBI indicates Mayo Physician Well-Being Index; WLB, work-life balance.

the precontemplation stage of this process, unaware of the need for a change to promote resilience and improve career satisfaction.

The intervention phase of this study provides encouraging results. When surgeons received objective, individualized feedback on how their well-being compared with normative samples of physicians and potential personal and professional risks (Fig. 1), they recognized the need for a change. Nearly half of the study participants indicated that they were considering making at least 1 change to reduce burnout, reduce fatigue, promote work-life balance, or promote career satisfaction as a direct result of the individualized feedback. Strikingly, the individualized feedback on distress level as stratified by the MPWBI was strongly associated with intent to make a change in each of the 4 dimensions assessed. Those with greater distress were also considering a greater number of changes as a result of the feedback. Because physicians have reached their standing by being high achievers, feedback to those in distress on how their well-being relates to peers may leverage their competitive nature and desire to be successful to help promote changes to improve well-being.

These observations provide evidence that the specific feedback provided to those most in need of a change helped them progress from the precontemplation phase to the contemplation phase. The graded, incremental increase in the proportion intending to make a change and the number of changes they were considering as distress level increased also indicates that the feedback effectively conveyed stratified information to participating surgeons. Surgeons whose well-being was only slightly below average planned to make more limited adjustments in a fewer number of domains, suggesting that the feedback may have helped these individuals promote early intervention and prevention before more severe distress developed. Notably, although physicians with the highest levels of well-being were appropriately less likely to report that they were considering making changes, they were as or more likely to report that they found the individualized feedback helpful. This observation may indicate that physicians' confidence in the accuracy of their self-calibration is low (although they think that their well-being is above average they are not certain) and that the objective information helped affirm

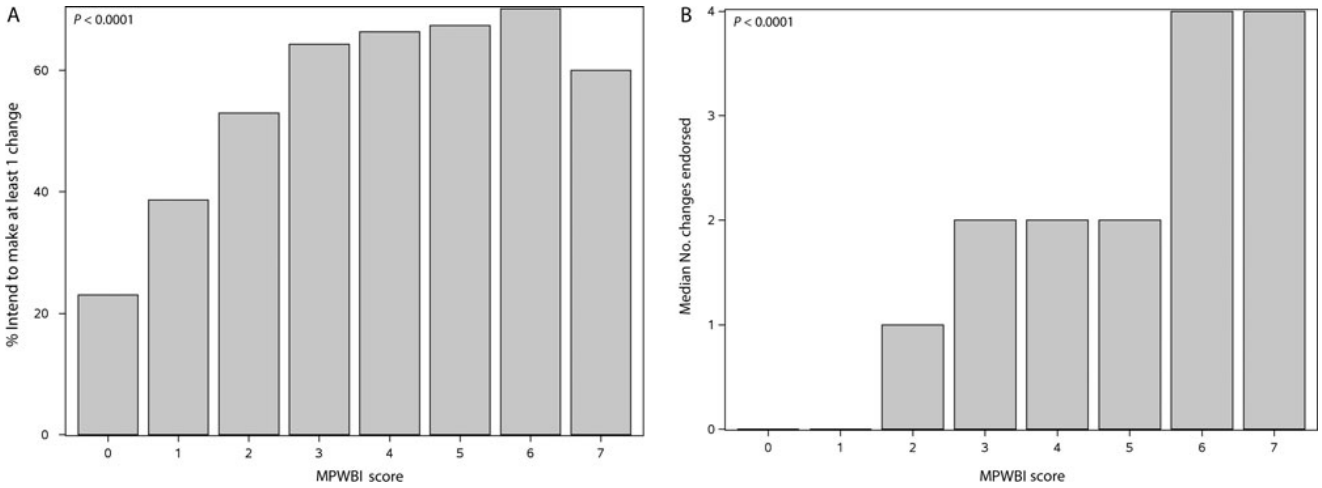

FIGURE 4. MPWBI score and intent to make changes. MPWBI scores are shown on the *x* axis (higher scores indicate greater levels of distress) of each figure. A, The proportion of surgeons who indicated they were considering making changes in at least 1 of the 4 dimensions assessed (Fig. 3) as a direct result of the individualized feedback they received is shown on the *y* axis. B, The median number of changes (range = 1–4) being considered is shown on the *y* axis. MPWBI indicates Mayo Physician Well-Being Index.

and reassure those with high well-being. Collectively, these findings suggest that periodic assessment and feedback may have relatively universal benefit for physicians because it seems to provide useful information both to those who are doing well (affirmation and reassurance) and to encourage behavioral change to those who are struggling.

Our study is subject to several limitations. Considering making a change to promote well-being is one step in the process of behavioral change and will not result in an actual change in many cases. Nonetheless, the intervention tested helped a large proportion of surgeons move from the precontemplation phase of behavioral change to the contemplation phase, which is the necessary first step to a meaningful change. Longitudinal studies are needed to see how many physicians proceed to the preparation and action phases. Combining the interactive electronic intervention tested here in conjunction with follow-up initiatives may increase the proportion of physicians proceeding to the action phase.[34] For example, applying an interactive version of the MPWBI to assess well-being and provide individualized feedback may be a useful first step that helps bring physicians to the point they are ready to consider a change. Physicians could then be offered a menu of specific activities to reduce burnout and fatigue or to promote work-life balance and career satisfaction.[34,35] Several publications have reviewed strategies surgeons can take to promote their well-being.[5,24,37–40]

It is unknown whether the study participants are representative of surgeons in general. Although the sample size was large and study volunteers were drawn from a random, national sample of surgeons who are members of the ACS, only approximately 14% of those notified about the study volunteered to participate. Participation rates are a well-recognized problem in medical research trials in the United States.[41,42] The age, sex, practice setting, and years in practice of volunteers seem similar to surgeons in prior studies of the ACS membership,[2,23] suggesting that the participating surgeons are likely representative. Nonetheless, replication of these findings in other samples will be important.

CONCLUSIONS

US surgeons do not reliably calibrate their level of distress. After interactive, self-assessment with individualized feedback based on the MPWBI, nearly half of surgeons reported that they were contemplating behavioral changes to improve personal well-being. Surgeons with greater distress were more likely to be considering making changes to promote well-being and to be contemplating changes in a greater number of dimensions. The interactive electronic intervention tested here seems to provide useful information to surgeons and to help those with greater degrees of distress move from the precontemplation phase to the contemplation phase of making changes to promote personal well-being.

REFERENCES

1. Shanafelt TD, Boone S, Tan L, et al. Burnout and satisfaction with work-life balance among US physicians relative to the general US population. *Arch Intern Med*. 2012;172:1377–1385, 1–9.
2. Shanafelt TD, Balch CM, Bechamps GJ, et al. Burnout and career satisfaction among American surgeons. *Ann Surg*. 2009;250:463–471.
3. Campbell DA, Jr, Sonnad SS, Eckhauser FE, et al. Burnout among American surgeons. *Surgery*. 2001;130:696–702; discussion 702–705.
4. Kuerer HM, Eberlein TJ, Pollock RE, et al. Career satisfaction, practice patterns and burnout among surgical oncologists: report on the quality of life of members of the Society of Surgical Oncology. *Ann Surg Oncol*. 2007;14:3043–3053.
5. Shanafelt T, Sloan J, Habermann T. The well-being of physicians. *Am J Med*. 2003;114:513–517.
6. Dyrbye LN, Harper W, Durning S, et al. Patterns of distress in US medical students. *Med Teach*. 2011;33:834–839.
7. Bertges Yost W, Eshelman A, Raoufi M, et al. A national study of burnout among American transplant surgeons. *Transplant Proc*. 2005;37:1399–1401.
8. Allegra C, Hall R, Yothers G. Prevalence of burnout in the U.S. oncology community: results of a 2003 survey. *J Oncol Pract*. 2005;1:140–147.
9. Maslach C, Jackson S, Leiter M. *Maslach Burnout Inventory Manual*. 3rd ed. Palo Alto, CA: Consulting Psychologists Press; 1996.
10. Shanafelt TD, Bradley KA, Wipf JE, et al. Burnout and self-reported patient care in an internal medicine residency program. *Ann Intern Med*. 2002;136:358–367.
11. Firth-Cozens J, Greenhalgh J. Doctors' perceptions of the links between stress and lowered clinical care. *Soc Sci Med*. 1997;44:1017–1022.
12. West CP, Huschka MM, Novotny PJ, et al. Association of perceived medical errors with resident distress and empathy: a prospective longitudinal study. *JAMA*. 2006;296:1071–1078.
13. West CP, Tan AD, Habermann TM, et al. Association of resident fatigue and distress with perceived medical errors. *JAMA*. 2009;302:1294–1300.

14. Williams ES, Manwell LB, Konrad TR, et al. The relationship of organizational culture, stress, satisfaction, and burnout with physician-reported error and suboptimal patient care: results from the MEMO study. *Health Care Manage Rev*. 2007;32:203–212.
15. Shanafelt TD, Balch CM, Bechamps G, et al. Burnout and medical errors among American surgeons. *Ann Surg*. 2010;251:995–1000.
16. Balch CM, Shanafelt TD, Dyrbye L, et al. Surgeon distress as calibrated by hours worked and nights on call. *J Am Coll Surg*. 2010;211: 609–619.
17. Dyrbye LN, Shanafelt TD, Balch CM, et al. Physicians married or partnered to physicians: a comparative study in the American College of Surgeons. *J Am Coll Surg*. 2010;211:663–671.
18. Balch CM, Shanafelt TD. Burnout among surgeons: whether specialty makes a difference. *Arch Surg*. 2011;146:385–386.
19. Balch CH, Oreskovich MR, Dyrbye LN, et al. Personal consequences of malpractice lawsuits on American surgeons. *J Am Coll Surg*. 2011;213: 657–667.
20. Dyrbye LN, Shanafelt TD, Balch CM, et al. Relationship between work-home conflicts and burnout among American surgeons: a comparison by sex. *Arch Surg*. 2011;146:211–217.
21. Balch CM, Shanafelt TD, Sloan J, et al. Burnout and career satisfaction among surgical oncologists compared with other surgical specialties. *Ann Surg Oncol*. 2011;18:16–25.
22. Shanafelt T, Sloan J, Satele D, et al. Why do surgeons consider leaving practice? *J Am Coll Surg*. 2011;212:421–422.
23. Oreskovich MR, Kaups KL, Balch CM, et al. Prevalence of alcohol use disorders among American surgeons. *Arch Surg*. 2012;147:168–174.
24. Shanafelt TD, Oreskovich MR, Dyrbye LN, et al. Avoiding burnout: the personal health habits and wellness practices of US surgeons. *Ann Surg*. 2012;255:625–633.
25. Balch CM, Shanafelt TD, Sloan JA, et al. Distress and career satisfaction among 14 surgical specialties, comparing academic and private practice settings. *Ann Surg*. 2011;254:558–568.
26. Balch CM, Oreskovich MR, Dyrbye LN, et al. Personal consequences of malpractice lawsuits on American surgeons. *J Am Coll Surg*. 2011;213: 657–667.
27. Shanafelt TD, Balch C, Dyrbye LN, et al. Special report: suicidal ideation among American surgeons. *Arch Surg*. 2011;146:54–62.
28. Kent GG, Johnson AG. Conflicting demands in surgical practice. *Ann R Coll Surg Engl*. 1995;77:235–238.
29. Center C, Davis M, Detre T, et al. Confronting depression and suicide in physicians: a consensus statement. *JAMA*. 2003;289:3161–3166.
30. Balch CM, Shanafelt TS. Dynamic tension between success in a surgical career and personal wellness: how can we succeed in a stressful environment and a "culture of bravado"? *Ann Surg Oncol*. 2011;18:1213–1216.
31. Dyrbye LN, Satele D, Sloan J, et al. Utility of a brief screening tool to identify physicians in distress. *J Gen Intern Med.* 2013;28:421–427.
32. Dyrbye LN, Szydlo DW, Downing SM, et al. Development and preliminary psychometric properties of a well-being index for medical students. *BMC Med Educ*. 2010;10:8.
33. Dyrbye LN, Schwartz A, Downing SM, et al. Efficacy of a brief screening tool to identify medical students in distress. *Acad Med*. 2011;86:907–914.
34. Prochaska JO, Velicer WF. The transtheoretical model of health behavior change. *Am J Health Promot*. 1997;12:38–48.
35. Velicer WF, Prochaska JO, Bellis JM, et al. An expert system intervention for smoking cessation. *Addict Behav*. 1993;18:269–290.
36. Shanafelt TD, Balch CM, Dyrbye L, et al. Special report: suicidal ideation among American surgeons. *Arch Surg*. 2011;146:54–62.
37. Balch CM, Shanafelt T. Combating stress and burnout in surgical practice: a review. *Adv Surg*. 2010;44:29–47.
38. Balch CM, Freischlag JA, Shanafelt TD. Stress and burnout among surgeons: understanding and managing the syndrome and avoiding the adverse consequences. *Arch Surg*. 2009;144:371–376.
39. Shanafelt T. A career in surgical oncology: finding meaning, balance, and personal satisfaction. *Ann Surg Oncol*. 2008;15:400–406.
40. Kuerer HM, Breslin T, Shanafelt TD, et al. Road map for maintaining career satisfaction and balance in surgical oncology. *J Am Coll Surg*. 2008;207: 435–442.
41. Murthy VH, Krumholz HM, Gross CP. Participation in cancer clinical trials: race-, sex-, and age-based disparities. *JAMA*. 2004;291:2720–2726.
42. Galea S, Tracy M. Participation rates in epidemiologic studies. *Ann Epidemiol*. 2007;17:643–653.

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ORIGINAL CONTRIBUTION

Physicians' Perceptions, Preparedness for Reporting, and Experiences Related to Impaired and Incompetent Colleagues

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Context Peer monitoring and reporting are the primary mechanisms for identifying physicians who are impaired or otherwise incompetent to practice, but data suggest that the rate of such reporting is lower than it should be.

Objective To understand physicians' beliefs, preparedness, and actual experiences related to colleagues who are impaired or incompetent to practice medicine.

Design, Setting, and Participants Nationally representative survey of 2938 eligible physicians practicing in the United States in 2009 in anesthesiology, cardiology, family practice, general surgery, internal medicine, pediatrics, and psychiatry. Overall, 1891 physicians (64.4%) responded.

Main Outcome Measures Beliefs about and preparedness for reporting and experiences with colleagues who practice medicine while impaired or who are incompetent in their medical practice.

Results Sixty-four percent (n=1120) of surveyed physicians agreed with the professional commitment to report physicians who are significantly impaired or otherwise incompetent to practice. Nonetheless, only 69% (n=1208) of physicians reported being prepared to effectively deal with impaired colleagues in their medical practice, and 64% (n=1126) reported being so prepared to deal with incompetent colleagues. Seventeen percent (n=309) of physicians had direct personal knowledge of a physician colleague who was incompetent to practice medicine in their hospital, group, or practice. Of those with this knowledge, 67% (n=204) reported this colleague to the relevant authority. Underrepresented minorities and graduates of non-US medical schools were less likely than their counterparts to report, and physicians working in hospitals or medical schools were most likely to report. The most frequently cited reason for taking no action was the belief that someone else was taking care of the problem (19% [n=58]), followed by the belief that nothing would happen as a result of the report (15% [n=46]) and fear of retribution (12% [n=36]).

Conclusion Overall, physicians support the professional commitment to report all instances of impaired or incompetent colleagues in their medical practice to a relevant authority; however, when faced with these situations, many do not report.

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WHILE SYSTEM-LEVEL FACtors cause many of the medical errors that harm patients, some of these incidents are attributable to the judgment and actions of individual physicians.[1] Various factors can impair physicians' judgment, including mental health conditions, alcoholism, drug use, and failure to maintain technical competence.[2] Many states have mandatory reporting statutes, requiring physicians and other health care professionals to report to appropriate authorities those physicians whose ability to practice medicine is impaired by alcohol or drug use or by physical or mental illness.[3] The American Medical Association (AMA), the Charter on Medical Professionalism, and the European Federation of Internal Medicine go further, stating that physicians have an "ethical obligation to report" and are expected to "participate in the process of self-regulation."[2,4-6]

For editorial comment see p 210.

A 1999 Institute of Medicine report[7] and periodic media accounts have heightened public awareness of egregious physician behaviors (eg, surgeons leaving midway through operations) and medical

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errors (eg, wrong-site surgery).[8] Despite increased attention, data suggest that the rate of reporting by physicians is far lower than it should be, given the estimated numbers of physicians who become impaired or who are otherwise incompetent to practice at some point in their careers.[9-15]

In this article, analyses from a large national survey of physicians are presented examining (1) beliefs about the commitment to self-regulation through reporting significantly impaired or incompetent colleagues, (2) preparedness to report, (3) personal experiences with these difficult situations, and (4) actions taken when confronted with impaired or incompetent colleagues.

METHODS

Survey Design and Testing

For this 2009 survey, we revised the professionalism questionnaire that we had administered in 2004.[9,16] The revisions added items focused specifically on physician behaviors when confronted with a colleague who was impaired or otherwise incompetent to practice. We also revised specific survey items that had not adequately discriminated among respondents (ie, had ceiling effects whereby almost all physicians agreed with a given statement). We based revisions on findings from 4 focus groups involving 40 total physicians and recommendations from an interdisciplinary expert advisory group with 15 members. We conducted a pretest, mailing the survey to 21 physicians to ensure that the survey administration process worked appropriately. The final survey was 7 pages long and contained 110 individual survey items (the survey is available from the authors by request). The Massachusetts General Hospital institutional review board approved the final survey.

Sample

Using the AMA 2008 Masterfile, all US physicians in primary care (family practice, internal medicine, and pediatrics) and 4 non–primary care specialties (anesthesiology, cardiology, general surgery, and psychiatry) were identified. Excluded were all osteopathic physicians, resident physicians, and physicians in federally owned hospitals; those with no address; those who requested not to be contacted; and those who were retired. From this pool of eligible participants, we randomly selected 500 physicians within each of the 7 specialties (total sample, 3500).

Survey Administration

The questionnaire was administered by the Center for Survey Research at the University of Massachusetts–Boston. The center sent the initial survey packet by Priority Mail in May 2009 and included a cover letter, fact sheet, questionnaire with a sticker on the back containing the random participant identification number, postage-paid return envelope, and a $20 incentive. The center made telephone calls to all nonrespondents to solicit participation, and 2 additional mailings were sent to all nonrespondents.

Dependent Variables

Physicians' beliefs about reporting were assessed using the question, "Please rate the extent to which you agree with the following statement . . . Physicians should report all instances of significantly impaired or incompetent colleagues to their professional society, hospital, clinic, and/or other relevant authorities." Response categories were "completely agree," "somewhat agree," "somewhat disagree," or "completely disagree." For the multivariable analysis described below, a new dichotomous variable was created that compared physicians who "completely agree" with physicians who gave any other response. We focused on the "completely agree" response because the AMA Code of Ethics, the Charter on Medical Professionalism, and many state mandates require physicians to report all instances of colleagues whose practice of medicine is significantly impaired or incompetent.

Two survey items were used to assess physicians' preparedness for dealing with impaired or incompetent colleagues. Physicians were asked to rate the extent to which "you feel prepared to deal with colleagues who practice medicine while they are impaired" and "you feel prepared to deal with colleagues who are incompetent in their medical practice." Response categories were "very prepared," "somewhat prepared," "very unprepared," and "somewhat unprepared." For the multivariable analysis described herein, a new dichotomous variable was created that combined "very prepared" and "somewhat prepared" into one group and "very unprepared" and "somewhat unprepared" into another.

Two survey items were used to examine physician behavior about reporting colleagues: "In the last three years, have you had direct, personal knowledge of a physician who was impaired or incompetent to practice medicine in your hospital, group, or practice?" and "In the most recent case, did you report that physician to a hospital clinic, professional society, or other relevant authority?" Response categories were "yes" and "no."

The survey further asked physicians with direct, personal knowledge of an impaired or incompetent colleague to report whether there had been a time in the past 3 years when they did not report because of any of the following reasons or beliefs: "someone else was taking care of the problem," "nothing would happen as a result of the report," "the physician would be excessively punished," "it could easily happen to you," and "it was not your responsibility." The survey also asked if physicians did not report because of fear of retribution or lack of knowledge about how to report. All physicians were asked to respond "yes" or "no" for each of the items.

Independent Variables

The study hypothesis was that the dependent variables described above could be affected by the following physician and practice characteristics: physician sex, race/ethnicity (self-reported as African American [non-

Hispanic], Asian, Hispanic, Native American, Pacific Islander, white [non-Hispanic], or other, with white and Asian combined into a "not underrepresented minority" category, other categorized on a case-by-case basis, and the remainder combined into an "underrepresented minority" category), specialty, graduate of a US medical school (yes/no), number of years in practice (<10, 10-19, 20-29, ≥30), and practice organization (hospital or clinic, university or medical school, group practice, solo or 2-person practice, other).

Another hypothesis was that the malpractice environment in which physicians practice may affect beliefs, preparedness, and reporting behaviors. As a proxy for this, data from the 2009 National Practitioner Database were used to calculate the total malpractice claims paid per physician per state. These data were grouped into tertiles (eg, low, medium, and high) for the multivariable analysis.[17]

Analyses

Univariate and bivariate relationships in the data were examined. To test for significant differences between groups, 2-sided *t* tests (continuous variables) or χ^2 tests (categorical variables) were used as appropriate. A multivariable model was constructed based on the bivariate analysis.

Separate multivariable logistic regression models were fitted to evaluate the association of outcomes (beliefs about reporting; preparedness to deal with, knowledge of, and reporting of impaired or incompetent colleagues) with the independent variables described above. Adjusted percentages and standard errors were obtained from these models.[18]

Further examination included the reasons for not reporting an impaired or incompetent colleague to relevant authorities among those who said they did not report. Multivariable analysis of reasons for not reporting were not conducted, owing to small sample sizes. All analyses used weights that accounted for the sampling design and nonresponse and were conducted in SAS version 9.2 (SAS institute Inc, Cary, North Carolina) and SUDAAN version 10.0.1 (RTI International, Research Triangle Park, North Carolina).

RESULTS

Of the 3500 sampled physicians, 562 were ineligible because they were deceased, out of the country, practicing a nonsampled specialty, on leave, or not currently providing patient care. Of the remaining 2938 eligible physicians, 1891 completed the survey, yielding an overall response rate of 64.4%. Response rates by physician specialty were 72.7% (pediatrics), 67.5% (family practice), 65.1% (surgery), 64.6% (anesthesiology), 64.0% (psychiatry), 60.8% (internal medicine), and 50.6% (cardiology).

TABLE 1 shows characteristics of the survey respondents. Based on weighted data, 67% of respondents were men, and 10% were underrepresented minorities. Twelve percent of respondents had been in practice for less than 10 years, 28% for 10 to 19 years, 31% for 20 to 29 years, and 29% for 30 years or longer. In terms of primary practice type, 40% worked in group practices (more than 2 persons), 22% in solo or 2-person practices, 19% in hospitals or

Table 1. Characteristics of Respondents (N=1891)[a]

Characteristic	No.	%	
		Unweighted	Weighted[b]
Sex			
Men	1284	70	67
Women	539	30	33
Race/ethnicity[c]			
Not underrepresented minority	1648	91	90
Underrepresented minority	168	9	10
Specialty			
Anesthesiology	259	14	11
Cardiology	218	12	6
Family practice	269	15	22
General surgery	263	14	7
Internal medicine	249	14	29
Pediatrics	297	16	15
Psychiatry	255	14	10
Type of medical school graduate			
US	1331	73	72
International	494	27	28
Years in practice			
<10	210	11	12
10-19	464	25	28
20-29	569	31	31
≥30	579	32	29
Practice organization			
Hospital or clinic	343	19	19
University or medical school	117	6	5
Group	744	41	40
Solo or 2-person	401	22	22
Other	223	12	13
Total malpractice claims paid per practicing physician in state in which physician practices			
Low (0.003-≤0.007)	629	34	35
Medium (0.008-<0.011)	582	32	33
High (≥0.011)	619	34	32

[a] Not all respondents answered all questions.
[b] Estimates obtained using weights that account for sampling design and nonresponse.
[c] See "Methods."

clinics, and 5% in a university faculty practice plan or medical school.

Beliefs About the Commitment to Report Impaired or Incompetent Colleagues

TABLE 2 presents regression-adjusted percentages of physicians who completely agree with the statement "physicians should report all instances of significantly impaired or incompetent colleagues to their professional society, hospital, clinic and/or other relevant authority." Overall, 64% of physicians completely agreed with this statement. Women physicians were significantly more likely than men to completely agree, as were graduates of US medical schools compared with those graduating from non-US medical schools. Years in practice were significantly associated with beliefs; however, this association was not linear. Rather, the trend was S-shaped, with those in practice for 10 to 19 years and those in practice for more than 30 years being less likely than other physicians to completely support reporting.

Practice organization was significantly associated with complete agreement about reporting impaired and incompetent colleagues. Physicians practicing in hospitals or clinics were most likely to completely endorse reporting, followed by those practicing in a university or medical school. Physicians in solo or 2-person practices and in group practices were least likely to completely support reporting.

The malpractice environment was also significantly associated with beliefs about reporting. Physicians practicing in areas with low numbers of malpractice claims were significantly more likely than those practicing in areas with medium or high numbers to com-

Table 2. Beliefs About and Preparedness for Dealing With Impaired or Incompetent Colleagues

Characteristic	Completely Agree Physicians Should Report All Impaired or Incompetent Colleagues		Very or Somewhat Prepared to Deal With Impaired Colleagues		Very or Somewhat Prepared to Deal With Incompetent Colleagues	
	No. (%) [95% CI][a]	*P* Value	No. (%) [95% CI][a]	*P* Value	No. (%) [95% CI][a]	*P* Value
Total	1120 (64)		1208 (69)		1126 (64)	
Sex						
Men	759 (61) [58-64]	.02	894 (69) [66-73]	.07	839 (65) [62-68]	.01
Women	361 (68) [64-73]		314 (64) [59-69]		287 (58) [53-63]	
Race/ethnicity[b]						
Not underrepresented minority	1024 (64) [61-67]	.21	1095 (67) [65-70]	.57	1022 (63) [60-65]	.64
Underrepresented minority	96 (58) [50-67]		113 (70) [62-78]		104 (65) [56-73]	
Specialty						
Anesthesiology	163 (65) [59-71]	.94	191 (76) [70-81]	<.001	193 (77) [71-82]	<.001
Cardiology	121 (63) [56-69]		140 (63) [56-70]		136 (63) [56-70]	
Family practice	163 (63) [57-69]		163 (65) [59-71]		143 (57) [51-63]	
General surgery	165 (65) [59-71]		187 (71) [65-76]		175 (66) [60-72]	
Internal medicine	150 (62) [56-68]		167 (68) [62-74]		157 (6) [58-70]	
Pediatrics	196 (66) [61-72]		167 (59) [54-65]		160 (58) [52-64]	
Psychiatry	162 (63) [57-69]		193 (76) [70-81]		162 (62) [56-69]	
Type of medical school graduate						
US	870 (67) [64-70]	<.001	871 (67) [64-70]	.57	800 (62) [58-64]	.14
International	250 (56) [51-61]		337 (69) [64-74]		326 (66) [61-71]	
Years in practice						
<10	147 (71) [63-78]	.02	134 (69) [62-76]	.009	131 (68) [61-75]	.001
10-19	295 (62) [57-67]		273 (61) [56-66]		248 (55) [50-60]	
20-29	364 (67) [62-71]		381 (67) [63-72]		363 (64) [59-69]	
≥30	314 (59) [54-64]		420 (73) [69-78]		384 (67) [62-72]	
Practice organization						
Hospital or clinic	231 (70) [65-76]	.01	230 (69) [63-74]	.04	215 (63) [57-69]	.13
University or medical school	79 (66) [56-77]		88 (80) [73-88]		82 (72) [63-81]	
Group	450 (61) [57-65]		480 (66) [62-70]		439 (59) [55-64]	
Solo or 2-person	216 (58) [53-64]		273 (69) [63-74]		258 (66) [60-71]	
Other	144 (70) [63-76]		137 (64) [57-71]		132 (64) [57-71]	
Total claims paid per practicing physician						
Low (0.003-≤0.007)	415 (68) [64-72]	.03	402 (67) [62-71]	.82	374 (63) [59-67]	.98
Medium (0.008 < –0.011)	338 (60) [55-64]		393 (68) [64-72]		364 (62) [58-67]	
High (≥0.011)	367 (63) [58-67]		413 (68) [64-73]		388 (63) [58-67]	

Abbreviation: CI, confidence interval.
[a] Numbers are unadjusted; all percentages are adjusted. All estimates were obtained using multivariable analysis controlling for all variables shown in the table.
[b] See "Methods."

pletely agree that physicians should report all instances of impaired or incompetent colleagues.

Preparedness to Deal With Impaired or Incompetent Colleagues

Table 2 shows the ratings by physicians of their own preparedness to deal with impaired colleagues. Overall, 69% of physicians said they were very or somewhat prepared. Among the specialties, anesthesiologists and psychiatrists were most likely and pediatricians were the least likely to feel very or somewhat prepared. Physicians practicing in medical school and university settings were significantly more likely to report being prepared than those in other practice settings.

Table 2 also shows ratings by physicians of their own preparedness to deal with incompetent colleagues. Similar to the data concerning impaired colleagues, 64% of physicians overall reported being prepared to deal with colleagues who were incompetent in their medical practice, and preparedness varied by specialty and professional age. However, unlike preparedness to deal with impaired colleagues, for which no significant difference was found between men and women physicians, women were significantly less likely than men to report being prepared to deal with incompetent colleagues.

Experiences With Impaired and Incompetent Colleagues

Seventeen percent (n=309) of physicians reported having direct personal knowledge of an impaired or incompetent physician colleague in their hospital, group, or practice in the last 3 years. Only physician specialty was significantly associated with direct personal knowledge (TABLE 3), with anesthesiologists being the most likely and pediatricians being the least likely to report such knowledge.

As shown in Table 3, 67% of physicians with knowledge of an impaired or incompetent colleague reported that individual to a hospital, clinic, professional society, or other relevant authority. Underrepresented minority physicians were significantly less likely than other physicians to report, as were international medical graduates compared with graduates of US medical schools.

Practice organization was significantly associated with reporting. Seventy-six percent of physicians practicing in hospitals and 77% of those in universities or medical schools who had knowledge of an impaired or incompetent colleague reported that colleague to the relevant authority. In contrast, only 44% of physicians with such knowledge in solo or 2-person practices reported that colleague.

Reasons for Failing to Report

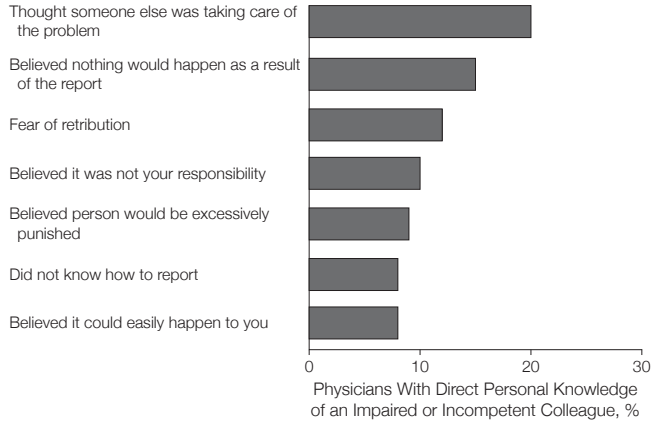
The FIGURE shows the reasons why physicians did not report an impaired or incompetent colleague at least once in the past 3 years. Among the 309 with such knowledge, the most frequently cited reason for not reporting was the belief that some-

Table 3. Experiences With Impaired or Incompetent Colleagues

Characteristic	Had Direct Personal Knowledge of a Physician Who Was Impaired or Incompetent to Practice Medicine in Hospital, Group, or Practice		Reported Impaired or Incompetent Colleague to a Hospital, Clinic, Professional Society, or Other Relevant Authority	
	No. (%) [95% CI][a]	*P* Value	No. (%) [95% CI][a]	*P* Value
Total	309 (17)		204 (67)	
Sex				
Men	240 (17) [15-19]	.40	156 (66) [59-73]	.84
Women	69 (15) [12-19]		48 (67) [55-80]	
Race/ethnicity[b]				
Not underrepresented minority	282 (16) [14-18]	.85	190 (68) [62-74]	.02
Underrepresented minority	27 (17) [10-24]		14 (47) [28-66]	
Specialty				
Anesthesiology	72 (26) [20-31]	<.001	52 (67) [56-79]	.32
Cardiology	37 (17) [11-22]		21 (68) [53-83]	
Family practice	43 (17) [12-21]		32 (71) [59-83]	
General surgery	51 (19) [14-24]		33 (71) [56-85]	
Internal medicine	37 (16) [11-20]		21 (59) [44-73]	
Pediatrics	25 (9) [6-12]		13 (54) [35-73]	
Psychiatry	44 (18) [13-23]		32 (77) [66-87]	
Type of medical school graduate				
US	236 (18) [15-20]	.13	175 (73) [66-79]	<.001
International	73 (14) [10-18]		29 (45) [32-58]	
Years in practice				
<10	29 (14) [9-20]	.14	25 (79) [61-96]	.14
10-19	60 (15) [11-19]		38 (66) [53-78]	
20-29	127 (20) [16-23]		88 (70) [61-79]	
≥30	93 (15) [12-18]		53 (57) [46-69]	
Practice organization				
Hospital or clinic	65 (19) [14-24]	.24	49 (76) [63-88]	.002
University or medical school	24 (20) [12-29]		18 (77) [59-94]	
Group	131 (17) [14-20]		90 (71) [63-80]	
Solo or 2-person	63 (16) [11-20]		29 (44) [30-57]	
Other	26 (11) [7-16]		18 (62) [42-82]	
Total claims paid per practicing physician				
Low (0.003-≤0.007)	113 (18) [15-22]	.37	80 (67) [58-77]	.91
Medium (0.008-0 < .011)	98 (16) [12-19]		63 (64) [54-75]	
High (≥0.011)	98 (15) [12-19]		61 (66) [57-76]	

Abbreviation: CI, confidence interval.
[a] Numbers are unadjusted; all percentages are adjusted. All estimates were obtained using multivariable analysis controlling for all variables shown in the table.
[b] See "Methods."

Figure. Reasons for Failing to Report an Impaired or Incompetent Colleague in Last 3 Years



Percentages are unadjusted. All physicians reporting direct personal knowledge of an impaired or incompetent colleague (n=309) were asked to respond "yes" or "no" to each item; percentages will not sum to 100%.

one else was taking care of the problem (19% [n=58]), followed by the belief that nothing would happen as a result of the report (15% [n=46]). Other reasons for failing to report included fear of retribution (12% [n=36]), the belief that reporting was not their responsibility (10% [n=30]), or that the physician would be excessively punished (9% [n=27]).

COMMENT

These national data regarding physicians' beliefs, preparedness, and actual experiences related to impaired and incompetent colleagues raise important questions about the ability of medicine to self-regulate. More than one-third of physicians do not completely support the fundamental belief that physicians should report colleagues who are impaired or incompetent in their medical practice. This finding is troubling, because peer monitoring and reporting are the prime mechanisms for identifying physicians whose knowledge, skills, or attitudes are compromised. Similar to suspected cases of child or spousal abuse, in which physicians are legally mandated to alert relevant authorities, physicians are required by the AMA Code of Ethics to report colleagues whom they suspect are unable to practice medicine safely because of impairment or incompetence. Clearly, additional efforts on the part of medical societies, specialty and accrediting organizations, and hospitals are needed to reinforce the responsibilities of the medical community and to prepare physicians to deal with these difficult situations.

Physician education around reporting may be most needed among physicians in solo and dual practices, in which more than 40% of respondents did not completely agree with the professional responsibility to report impaired or incompetent colleagues. Moreover, whereas physicians in this group were no less likely than those in other practice organizations to have direct knowledge of an impaired colleague, fewer than half reported that colleague to an authority. The isolation of solo or dual practice may make it difficult for physicians in such practices to know about reporting procedures. Another possibility is that these physicians are heavily dependent on referrals and fear either retribution or a loss of reputation. Further study is needed to understand how this practice dynamic affects physicians' beliefs about self-regulation and the best methods for ensuring that physicians in small practices can access reporting mechanisms when necessary.

The findings also support and extend prior research concerning physicians who are outside the majority (ie, underrepresented minorities and international medical school graduates). For these physicians, reporting an impaired or incompetent colleague may pose particular challenges. Underrepresented minority physicians are equally likely to endorse the commitment to report, to feel prepared to deal with impaired or incompetent colleagues, or to have encountered such colleagues—yet more than half of these physicians did not report. International medical graduates demonstrated a similar pattern, although they are also less likely than US graduates to endorse reporting. Further research should examine whether these physicians feel particularly vulnerable to retribution or loss of reputation because of their "outsider" status.

These data on why physicians do not report colleagues have practical implications for improving physician reporting systems. First, it is clear that a reliance on self-regulation is not sufficient to ensure that reporting will occur. This suggests the need for stronger external regulation. Organizations that might play a much more significant role in managing reporting and remediation may include professional societies, licensing groups, hospitals, and patient groups. Second, reporting systems must be designed and maintained to protect the confidentiality of the reporting physicians. Given that physicians outside the majority or heavily dependent on referrals are less likely to report, it is critical that their fears of retaliation be adequately addressed to increase the likelihood that they will feel able to report when necessary. Third, some underreporting appears related to physicians' beliefs that nothing will happen as a result of the report. One way to address this is to provide physician reporters with confidential feedback about the outcomes of any actions taken based on the report. These changes would likely address several

of the more frequent reasons for nonreporting.

This study has several limitations. First, because of reliance on voluntary disclosure of failure to report impaired and incompetent colleagues, these failures may be viewed as negative, and the results likely represent a lower-bound estimate of the actual frequency of nonreporting. Second, although the response rate was relatively high for a physician survey, nonresponse bias might exist. Attempts were made to adjust for the possible bias through weighting, but such adjustments are imperfect. Third, the accuracy of the respondents' beliefs about whether their colleagues were, in fact, impaired or incompetent cannot be verified. Physicians may have made erroneous judgments about their colleagues' functioning and competence. It is possible that what a physician reported as incompetence may have been, for example, a difference of opinion regarding a diagnosis or treatment plan. Survey methods do not allow determination of exactly how often this misclassification happens.

Overall, this study calls into question the willingness and ability of physicians to identify and report colleagues whose ability to practice medicine is impaired by alcohol or drug use or by physical or mental illness, as well as those incompetent to practice because of deficits in knowledge and skills. These findings further suggest that a large number of practicing physicians do not support the current process of self-regulation: it is underused and appears to have several major shortcomings, including a perceived lack of anonymity and efficacy. All health care professionals, from administrative leaders to those providing clinical care, must understand the urgency of preventing impaired or incompetent colleagues from injuring patients and the need to help these physicians confront and resolve their problems. The system of reporting must facilitate, rather than impede, this process. Reliance on the current process results in patients being exposed to unacceptable levels of risk and in impaired and incompetent physicians possibly not receiving the help they need.

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Study concept and design: DesRoches, Fromson, Birnbaum, Iezzoni, Campbell.
Acquisition of data: DesRoches, Campbell.
Analysis and interpretation of data: DesRoches, Rao, Fromson, Birnbaum, Iezzoni, Vogeli, Campbell.
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Statistical analysis: DesRoches, Rao.
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REFERENCES

1. Leape LL, Fromson JA. Problem doctors: is there a system-level solution? *Ann Intern Med*. 2006;144(2):107-115.
2. American Medical Association (AMA). Code of Medical Ethics. AMA Web site. http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics.shtml. Accessed February 16, 2010.
3. Massachusetts General Laws, chapter 112, §5F. State of Massachusetts Web site. http://www.mass.gov/legis/laws/mgl/112-5f.htm. Accessed February 16, 2010.
4. ABIM Foundation, ACP-ASIM Foundation, European Federation of Internal Medicine. Medical professionalism in the new millennium: a physician charter. *Ann Intern Med*. 2002;136(3):243-246.
5. Kurlander JE, Morin K, Wynia MK. The social-contract model of professionalism: baby or bath water? *Am J Bioeth*. 2004;4(2):33-36.
6. Wynia MK. The short history and tenuous future of medical professionalism: the erosion of medicine's social contract. *Perspect Biol Med*. 2008;51(4):565-578.
7. Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academies Press; 2000.
8. Swidey N. The revolutionary. *The Boston Globe*. http://www.boston.com/news/globe/reprints/010404_the_revolutionary/. January 4, 2004. Accessed February 16, 2010.
9. Campbell EG, Regan S, Gruen RL, et al. Professionalism in medicine: results of a national survey of physicians. *Ann Intern Med*. 2007;147(11):795-802.
10. Neff KE. Understanding and managing physicians with disruptive behavior. In: Ransom SB, Pinsky WW, Tropman JE, eds. *Enhancing Physician Performance: Advanced Principles of Medical Management*. Tampa, FL: American College of Physician Executives; 2000:45-72.
11. Barnard A. Doctors' behavior gets new scrutiny. *The Boston Globe*. August 18, 2002:A1.
12. Papadakis MA, Hodgson CS, Teherani A, Kohatsu ND. Unprofessional behavior in medical school is associated with subsequent disciplinary action by a state medical board. *Acad Med*. 2004;79(3):244-249.
13. Samkoff JS, McDermott RW. The hospital and the impaired physician. *Pa Med*. 1990;93(2):40-42.
14. Sharpe VA, Faden AI. *Medical Harm: Historical, Conceptual, and Ethical Dimensions of Iatrogenic Illness*. New York, NY: Cambridge University Press; 1998.
15. Fromson J. Addressing clinician performance problems as a systems issue. In: Youngberg B, Hatlie MJ, eds. *The Patient Safety Handbook*. Boston, MA: Jones & Bartlett; 2004:423-430.
16. Campbell EG, Gruen RL, Mountford J, Miller LG, Cleary PD, Blumenthal D. A national survey of physician-industry relationships. *N Engl J Med*. 2007;356(17):1742-1750.
17. Number of paid medical malpractice claims, 2008. The Henry J. Kaiser Family Foundation Web site. http://www.statehealthfacts.org/comparemaptable.jsp?ind=436&cat=8&sort=a&gsa=2. Accessed June 8, 2010.
18. Korn EL, Graubard BI. *Analysis of Health Surveys*. New York, NY: John Wiley & Sons Inc; 1999.

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A Model of Disruptive Surgeon Behavior in the Perioperative Environment

Amalia Cochran, MD, FACS, William B Elder, PhD

BACKGROUND: Surgeons are the physicians with the highest rates of documented disruptive behavior. We hypothesized that a unified conceptual model of disruptive surgeon behavior could be developed based on specific individual and system factors in the perioperative environment.

STUDY DESIGN: Semi-structured interviews were conducted with 19 operating room staff of diverse occupations at a single institution. Interviews were analyzed using grounded theory methods.

RESULTS: Participants described episodes of disruptive surgeon behavior, personality traits of perpetrators, environmental conditions of power, and situations when disruptive behavior was demonstrated. Verbal hostility and throwing or hitting objects were the most commonly described disruptive behaviors. Participants indicated that surgical training attracts and creates individuals with particular personality traits, including a sense of shame. Interviewees stated this behavior is tolerated because surgeons have unchecked power, have strong money-making capabilities for the institution, and tend to direct disruptive behavior toward the least powerful employees. The most frequent situational stressors were when something went wrong during an operation and working with unfamiliar team members. Each factor group (ie, situational stressors, cultural conditions, and personality factors) was viewed as being necessary, but none of them alone were sufficient to catalyze disruptive behavior events.

CONCLUSIONS: Disruptive physician behavior has strong implications for the work environment and patient safety. This model can be used by hospitals to better conceptualize conditions that facilitate disruptive surgeon behavior and to establish programs to mitigate conduct that threatens patient safety and employee satisfaction. (J Am Coll Surg 2014;219:390−398. © 2014 by the American College of Surgeons)

Disruptive conduct by physicians is increasingly cited as a problem in health care systems. The American Medical Association has defined disruptive physician behavior as "Conduct, whether verbal or physical, that negatively affects or that potentially may negatively affect patient care disruptive behavior. (This includes but is not limited to conduct that interferes with one's ability to work with other members of the health care team)."[1]

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Disruptive behavior can be overtly intimidating, such as inappropriate anger or threats, or passive conduct, such as avoiding assignments or demonstrating an uncooperative attitude toward work tasks. This behavior can be intentional or might occur with lack of awareness of its effects. Health care professionals in positions of power often exhibit these behaviors, and surgeons in particular have been documented as frequent offenders by both coworkers and patients.[2,3] The downstream effects of disruptive and intimidating physician behaviors are protean, and include decreased patient satisfaction, increased risk of patient harm, increased rates of staff attrition, and increased rates of litigation.

Although surgeons are most commonly identified as the perpetrators of disruptive behavior in the health care environment, no study has described the different modalities of disruptive behaviors that are commonly exhibited. In addition, no unifying model provides a framework for the occurrence of disruptive behaviors by surgeons. We hypothesized that semi-structured interviews and grounded theory analysis would generate a

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robust description of disruptive surgeon behavior, including catalysts for this behavior.

METHODS

The research design selected for this qualitative project followed a grounded theory methodological approach.[4-6] As defined by Strauss, this theory stresses extensive use of interviews in conducting research, highlighting the need for data immersion by the researcher to understand processes.[5] The aim of grounded theory methods was to produce innovative theory that is "grounded" in data collected from participants on the basis of the complexities of their lived experiences in a social context. The goal of this research project was to generate theory about the types and causes of disruptive surgeon behavior in the perioperative environment from the collected data. Use of the grounded theory process allowed us to explain how those that work in the operating room perceive disruptive surgeon behavior.

Participants

After receiving IRB approval, the study's participants were recruited at a single academic hospital setting through email requests for participants for a study on disruptive behavior by surgeons in the operating room. The final number of participants was determined by data saturation, and maximum variation of interviewees was sought to gather a wide range of experiences. Maximum variation was accomplished in the study by selecting participants from among those who responded to email to gather data from participants from a wide range of experiences. Participants were sought until information gathered from interviews no longer deepened or contradicted previous data.[4] Participants were purposively sampled with an eye to achieving maximum variation with respect to age, sex, and occupation to increase the likelihood that the findings would incorporate different perspectives.[7]

Data acquisition

A single interviewer with no personal or professional ties to the interviewees conducted all of the semi-structured interviews confidentially (WBE). Two broad questions addressing interviewees' experiences with disruptive surgeons and the meaning they made of those experiences guided the individual interviews. The first question was, "Can you tell me about a time when you saw a surgeon demonstrate disruptive behavior?" The participants spent 10 to 20 minutes responding to this question. The second question, which took 30 to 40 minutes to discuss, was, "Please explain why you believe the surgeon behaved in this way." More specific auxiliary questions focused participants' answers on particular concerns raised in the context of interviewee responses. The interviews were audiorecorded and transcribed. After the interview, each participant had the opportunity to review and approve his or her transcript for accuracy as a way to perform "member checking;" that is, to achieve trustworthiness and ensure that the data honored the meaning as conceived by the participants.[8,9] Both investigators had access to and reviewed all interview transcripts.

Study participants chose their own pseudonyms. The investigators removed education, religious affiliation, vocation, marital status, and names of any institution from transcripts to protect the confidentiality of participants. After the interview, each participant had the opportunity to review and approve his or her transcript for accuracy of content. This allowed them to confirm that any identifying information was removed, as well as to allow them to add, remove, or modify any portion of the transcript.

Throughout data collection, the investigators recorded impressions and ideas in journals. These notes were analyzed as well. Therefore, multiple sources provided confirmation of data, enhancing the study's rigor.[10]

Data analysis

Grounded theory methodology is based on the process of analyzing the narratives of interviewees, then developing codes, categories, and themes that are grounded in their descriptions, and, finally, generating hypotheses about how these themes interplay.[4,10] Throughout the study, the authors maintained self-reflective journals, as well as analytic and theoretical memos according to the principles of grounded theory design.[6,11-13] This procedure created documentation of observations during data collection, including how data were organized into categories, connections made between pieces of data, processes that developed, and identification of various themes expressed by the participants. The two authors met regularly to analyze data, including providing feedback, challenging one another's data analysis, adding to emerging thoughts, consulting for ongoing feedback on codes and emerging themes, and bringing to light one another's own subjectivities as researchers. The credibility of this qualitative study was achieved through a triangulation of data sources, including participant checking, peer debriefing, and audit trails.[14]

In accordance with grounded theory analysis, data were analyzed using open, axial, and selective coding.[6] First, in open coding, the data were organized into pieces of meaning formed by phrases, sentences, or paragraphs in which the participants expressed their experiences. These verbal elements were then organized into theme-based categories. Second, in axial coding, these categories were compared to determine inter-relationships.[15] The categories were continually revised as new data were obtained

and analysis became more complex (eg, categories were redefined to include various subcategories). The categories evolved, eventually forming a theory of participants' experiences.[15] Finally, in selective coding, an overarching theory was determined, based on a core category that subsumed all others, and on the relationships between different participants' experiences.[6,15] The result was a 4-component model of these experiences.

RESULTS

All 19 participants worked in the perioperative environment of the same academic medical center at the time of their interview in 2012. In terms of occupation, 5 participants were medical students, 4 were anesthesiology faculty members, 4 were general surgery residents, 4 were perioperative nurses, and 2 were scrub technicians. Demographics of participants are documented in Table 1.

The following 4 themes about the disruptive behavior of surgeons were indicated through data analysis, participant checking, peer debriefing, and examination of the audit trail: categories of disruptive behavior, situational stressors, cultural conditions, and personality traits.

Categories of disruptive behavior

Participants observed a range of behaviors that were disruptive to the surgical environment, the most common of which was verbal hostility (see Table 2). Fifteen interviewees reported instances in which they witnessed a surgeon demonstrate verbal hostility by "yelling," "swearing," making "offensive comments," "blaming" others for difficulties, "threatening," or making "disparaging remarks" about others' capacities. Interviewees described the aim of this hostility was to berate, intimidate, cause a feeling of deficiency, or evoke a sense of shame. For example, 3 interviewees described being told, "You're killing the patient!" and 3 mentioned instances when surgeons had said to them, "You're an idiot!" Interviewees reported that these verbal outbursts and comments created anxiety and discomfort in the operating environment, as well as fear of escalated behavior.

Physical tantrums, manifested by throwing of objects or hitting or kicking walls or equipment (eg, buckets, tray stands, etc), were another common form of disruptive behavior and reported by 12 participants. Throwing was typically preceded by yelling, with subsequent throwing of a nearby object or an object already in the surgeon's hands. For example, interviewees recounted instances when frustrated surgeons threw cell phones, pagers, scalpels, or medical supplies into the air, toward the wall, or on the floor. Participants also described instances when these objects veered or bounced and inadvertently hit others in the room. Respondents perceived tantrum throwing as resulting in more errors in a surgical procedure and escalating demonstrations of anger. In the most grievous reports, 7 participants described cases of physical assault, including being pushed, grabbed, jabbed, hit, or having objects thrown directly at them. These descriptions involved being yelled at when being grabbed by the arm, or yelled at and then hit on the back or side.

Nine interviewees described situations in which their concern for patient safety directly conflicted with the desire of the surgeon to efficiently complete the case. This included times when staff was concerned the patient was at a high risk for morbidity and/or harm, when there was doubt as to whether the case should proceed as planned, or when taking precautions that the surgeons believed were unjustified. Interviewees reported being in a difficult position when they wanted to stand up for the patient in the face of opposition from the surgeon who was preoccupied with time pressures. For example, all anesthesiologists reported being pressured to administer more anesthetic than was safe or necessary during moments when surgeons attributed difficulties to a need for additional sedation. Participants also described occasions when surgeons insisted that multiple cases could be done simultaneously and that they, therefore, should have access to more than one operating room and team.

Another form of disruptive behavior was refusal to work with unfamiliar staff or with staff in training. Seven interviewees reported that surgeons demanded to work with the same staff each day, and when new staff was assigned to the operating room, surgeons would berate them, resist their help, or stop the surgery. Interviewees indicated that they believed that working with established staff allowed for greater familiarity, expediency of communication, and avoided the additional effort of training by the surgeons.

Table 1. Interviewee Demographics

Demographics	
Age, y, median (IQR)	33 (28–44)
Sex, n	
Male	9
Female	9
Race, n	
White	13
Asian American	4
Hispanic	1
African American	1
Highest level of education, n	
Some college/associate's degree	2
Bachelor's degree	9
MD	8

IQR, interquartile range.

Table 2. Disruptive Behavior Descriptions

Variants	Representative comments
Verbal hostility	"There is a scrub, and he is Latino. This surgeon will tell him derogatory things. Like, "What? Did you just cross the river? Is your green card still fresh?" "I can't understand what they heck you're saying. Are you like, one of those brown people?" And he'll use cuss words. "
Physical tantrum	"He was very angry, yelling at her [the nurse] across the desk, and then he came around the desk and actually pinned her up against the wall and had his hand on her throat while saying, "You can't take my room away." People pulled him off."
Threat to patient safety	"So we run out, we meet the patient, we get the IV started, we come into the room, I am pushing the propofol, putting the patient to sleep, and there's a whack between my shoulder blades, which, by the way, when I'm giving a drug is probably not a good thing to do."
Refusal to work with new/different team members	"If … I'm not in his room, he goes to my coordinator and yells at her about why I'm not in his room. And so there's nothing I can really do. It makes me mad …. Just being in his room is hard."

Situational stressors fostering disruptive behavior

Interviewees provided several factors that are consistent with situational stressors (Table 3). Inappropriate conduct by surgeons most often occurred when an unexpected complication arose during surgery. Ten interviewees explained that during these unpredictable moments, surgeons might believe they are not in control, and the risk of patient morbidity and mortality escalates. They might also perceive additional stress because they believe they are acting alone to find a solution and will ultimately be blamed should the situation escalate or not resolve. Disruptive behavior can result from a surgeon believing that, despite best efforts, there is nothing he or she can do to prevent patient deterioration.

Working with unfamiliar staff was also mentioned frequently as a source of frustration for surgeons. Eight participants mentioned that disruptive surgeons were known to escalate their behavior when working with staff that were not his or her normal operating room team. Interviewees explained that the technical difficulty of surgery is ameliorated by the routine of having expectations for the rhythm of a procedure. Familiarity of staff with a surgeon's patterns allows them to anticipate steps in a procedure and the instruments that are required at a given moment. When this rhythm is disrupted, the frustration can build during the course of a case until a disruptive incident occurs.

The third most-often mentioned situational stressor for disruptive behavior was the dual responsibility of training learners and providing the best care for a patient. This challenge applied to the training of surgical residents and medical students, as well as to trainees in the other perioperative disciplines. Five interviewees said that teaching when performing surgery is demanding because of the risk that the trainee might make a mistake that results in major complications. Interviewees explained that watching someone struggle with a complicated maneuver that you can perform yourself with proficiency can be frustrating and can lead to outbursts. In addition, the inclusion of a circulating nurse trainee or scrub student can disrupt a surgeon's normal expectations and result in a struggle about appropriate levels of autonomy for these individuals as they learn how to perform their job.

Cultural conditions fostering a tolerant environment

The power dynamics of the hospital environment that privileged surgeons and allowed them to behave

Table 3. Situational Stressors

Factors	Representative comments
Complications during surgery	"It's high stress anyway, and then the slightest thing [complication] takes it to super high stress. But if we make mistakes, people really die. You basically have nobody to blame but yourself at the end if somebody's hurt by what you're doing. And that's a huge burden to bear."
Working with unfamiliar staff	"I work with this one surgeon. He's very difficult. I'm definitely his security blanket. As long as I'm in the room … there are some times when I can mess up or not have an instrument fast enough or whatever and he never really gets mad at me, but he will get mad at everyone else in the room. So when I have students in there, he gets very defensive. He will tell them that they're no good, that they'll never be as good as me. "
Responsibilities associated with training	"The way you teach someone … is you allow them to operate … but you still are putting a resident in a position where they can hurt your patient … so there's a fairly low threshold to tolerate … errors."

disruptively generated an additional theme (Table 4). The most often mentioned reason given for the tolerance of difficult behavior was the considerable amount of money surgeons earned for the institution. Eleven participants explained that surgeons were viewed as consumers of the hospital resources and that staff was responsible to provide the services necessary to keep surgeons satisfied, even if it meant tolerating disruptive behavior. One interviewee explained that behavior of disruptive surgeons deteriorates during the course of their careers from less severe (eg, yelling, threatening, blaming) to major disturbances (eg, throwing objects, physical contact, leaving the room), for which they incur no negative repercussions from the institution because of their money-making capacity. Participants also explained that the more money a surgical specialty made, the more disruptive behavior was tolerated; neurosurgeons and cardiac surgeons were most frequently described in these discussions.

Ten participants reported that surgeons demonstrated disruptive behavior most frequently and most intensely toward those with the least amounts of power in the hierarchical structure of the perioperative environment, particularly nurses and surgical scrub technicians. These participants agreed that surgical technicians were especially vulnerable because their position obligates them to attend to the surgeon's needs, because they were on the bottom of the power hierarchy, and because they tended to work with the same staff in the same setting.

Those in positions of less power were frequently women and staff of color. Eight participants reported that men were favored in the operating room by both male and female surgeons. Attractive women were less frequently seen as the victims of disruptive behavior, regardless of their level of skill or vocation, and several interviewees reported male doctors preferred to work with attractive female staff. Female participants described being called derogatory names, being hit, and witnessing physical violence perpetrated by male surgeons toward female staff. Five interviewees reported they had witnessed racial discrimination perpetrated by white male surgeons toward staff of color. Most commonly reported were incidents when surgeons had made comments to staff, including telling people to return to their country of origin, asking them about their residency status, or telling them that their surgical skills were deficient because of their ethnic background. For example, one participant of color reported being told, "Maybe it's because you're black that you can't [do this] right."

Nine participants explained that the surgeon is traditionally in a position of near-absolute power in the operating room; the surgeon orchestrates all activities and no one checks his or her power or reprimands them when they misbehave. Participants reported they had witnessed more frequent disruptive behavior in academic hospitals than in private institutions and within American hospitals more frequently than in hospitals in other countries where they had worked. This was attributed to the fact that in the study institution's academic setting, surgeons are employed by the medical school rather than the hospital and have fewer potential consequences from the hospital for disruptive behavior. Participants also reported their belief that disruptive behavior is more common in states where nurses are not unionized because with union support a nurse might be more likely to pursue an issue of disruptive behavior by a surgeon.

Personality factors of those who most commonly behave disruptively

Those who behave in a disruptive manner manifested common personality factors (Table 5). Sixteen interviewees reported that some surgeons were consistently disruptive and acknowledged that others were consistently kind and professional in their interactions. Surgeons who frequently perpetrated disruptive behavior had an interpersonal pattern of intimidating and demeaning behavior that became particularly prominent in stressful situations. It was these surgeons of a particularly abrasive personality style, described as "compulsive," "arrogant," "detached," "emotionless," and "self-interested," who were seen as being the most apt to be triggered by situational stressors and to take advantage of the power they hold in hospitals.

Surgery training was viewed as attracting this type of disruptive personality. Twelve interviewees explained that because the training process is intensive and marked

Table 4. Cultural Conditions

Factors	Representative comments
Surgeons make money for the hospital	"The institution gives them the signal, 'You know what, you bring a lot of money to the institution, and you can do whatever you like.' And so they do …. The institution turns its head because to fire a surgeon … you're probably talking tens of millions of dollars."
Exhibition of power vs least powerful	"The further you go down in the power structure, the less inhibited the disruptive behavior by surgeons. They think of those people as expendable and invisible."
Unchecked surgeon power	"The more disruptive the surgeon was … the more they got. If they whined and complained and made a fuss, they had the power and they would get rewarded."

Table 5. Personality Factors

Factors	Representative comments
Maladaptive personalities attracted to surgical training and careers	"This behavior is more common in surgery than in some other specialties. If you have a difficult personality, if you're a contentious person, you're not going to go into something where one of the markers of success is high emotional intelligence. Those dysfunctional personalities … are more likely to go into something where they don't have to have one-on-one contact."
Maladaptive behaviors fostered by surgical training	"The training … is high stress … no one gives you good coping skills. You're very rarely praised for doing a good job, but you're always criticized for doing a poor job. You're trying to hold it in and not react to your attending."
Internalized sense of shame/failure to "measure up"	"When things start going wrong you feel that inadequacy and you think, "My God …. Maybe I'm not good enough to do this." And I think that's very scary … that maybe you're not competent enough to do it."

by constant stress and criticism, those more likely to succeed in surgical training were seen as perfectionistic, self-assured people who were unperturbed by the lack of positive reinforcement and thrived in the face of constant challenge. Surgery training was thought to attract individuals who aspired to high-powered careers and unquestioned authority in a situation that required little empathy or emotional connection with patients. Interviewees made the distinction that it was not necessary to have this type of personality to be proficient at technical surgical skills; however, it was beneficial to have this personality type to succeed in surgical training and to "fit in" with surgical culture. Although some medical student interviewees stated that they were initially drawn to surgery, they ultimately decided not to enter into the field because they did not want to become like the personalities they perceived were a result of surgical training.

These same participants explained that this difficult style of interacting was reinforced during surgery training, which was seen as a process that made trainees feel worthless to make them malleable, responsive to the favor of the instructor, and dependent on the instructor's ideas rather than their own intuition. In the course of an ongoing sense of inadequacy and failure, social isolation, and lack of social support, a trainee became accustomed to a style of learning characterized by intense criticism and hostility. Because this was the interpersonal style by which they were trained, surgeons were seen as recreating the same intimidation, verbal abuse, and shaming to teach others.

Nine interviewees believed that surgeons who were especially disruptive are those with an internalized sense of shame or self-doubt as a result of interpersonal trauma during their lives or because the training and socialization into the surgery profession was traumatic. These surgeons were especially volatile because they were struggling with their own insecurities and fear that mistakes or complications indicated that they were poor clinicians. They reacted to mistakes or complications with blame for others and anger because of their desire to externalize self-doubt. Other participants pointed out that surgeons often acted angrily because they worried about being thought of as possessing deficient skills and did not handle complications well in part because of a fear that poor outcomes would confirm their fears of inadequacy.

Grounded theory model

Figure 1 shows the model of disruptive behavior of surgeons that emerged from thematic analysis. The figure illustrates the interactions among the themes described by the interviewees. One interviewee suggested this model when asked to describe why disruptive behavior occurs: "I think it's a combination of someone's underlying personality traits, a culture that tolerates that type of behavior, and specific situational stressors."

DISCUSSION

Disruptive behaviors occur across the spectrum of health care disciplines.[16,17] However, when asked which specialties were more inclined to display disruptive and intimidating behavior, the most frequent response to one survey was general surgery.[2] The culture of Departments of Surgery might be most accustomed to an overall acceptance in health care of intimidating and disruptive behaviors.[18] Previous studies have highlighted a number

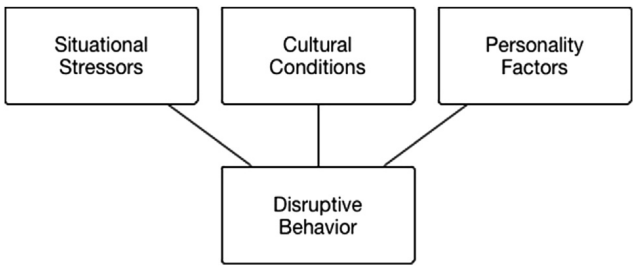

Figure 1. Model of disruptive surgeon behavior.

of stressors surgeons face, namely, pressure from productivity demands, costs, and the threat of litigation, a hierarchical system that privileges physicians because of their clinical role, and the strain of very emotional situations.[2,19] Although disruptive behaviors have been tolerated historically for all of these reasons, this acquiescence is no longer acceptable in light of recent evidence of the complex impact on the greater health care system of disruptive physician behavior. Disruptive behaviors have been found to result in harm to patients, poor patient satisfaction, increased cost of care, and loss of staff.[16,20,21] For colleagues of intimidating physicians, disruptive events increase stress, frustration, loss of concentration, and are damaging to teamwork and communication.[2]

This study provides the first qualitative description of disruptive surgeon behavior in the perioperative environment. Grounded theory analysis was used to generate descriptions of the spectrum of disruptive surgeon behaviors using the meaning ascribed by those most affected by the behaviors. Expounding specifically on incidents described by interviewees allowed us to delineate perceived characteristics and conditions that enable disruptive behaviors by surgeons in the operating room. The profound impact that experiences, cultural factors, and determination of why surgeons behave as they do emphasizes the need for descriptions that use the words of those who work in these environments and who have experienced these effects. With this approach, the conceptualization of disruptive behavior emerged entirely from interviewees' input. This methodology allows the meaning participants have made of their experiences to be elicited without the use of preconceived constructs to interpret the data.[4,6,11]

Participants explained that aggressive personalities were historically drawn to surgery, where a disruptive interpersonal pattern might be reinforced in training through a culture of shame. Medical students described a reticence to pursue a career in surgery precisely because of concerns about this sort of culture being prevalent and expressed a desire to not become a disruptive physician. Many interviewees believed that hospitals tolerated surgeons' intimidation of staff because their services were lucrative for the institution. In short, despite increasing attention to disruptive physician behavior and external mandates that it be addressed, those who are subject to this behavior projected an air of pessimism that change will occur.

Previous studies of safety culture have described disparities of opinion about the cause of tension in the operating room and have therefore provided diverse solutions. Communication failures in the operating room are a key source of interpersonal tension, and these communication failures relate directly to the concept of the "inciting event" described by our interviewees.[22] Evaluation of teamwork in the operating room using both quantitative and qualitative methods has demonstrated that the quality of collaboration and communication is perceived very differently by surgeons and other team members.[23,24] Those incongruent perspectives provide a critical nidus for communication failures.

Negative emotions generated as responses to and consequences of conflict are destructive in development of a cohesive group identity.[25,26] The myriad perspectives on sources of tension in the operating room and the importance of shared group purpose in high-reliability teams highlights the importance of interprofessional education activities, particularly for novices who are learning to navigate this complex culture.[24,27] These same interprofessional training exercises might also serve as reflective opportunities for more established staff, resulting in improved group dynamics and cohesiveness.

Participants described verbal hostility as a common form of disruptive behavior. Control of emotions is central to preventing escalation of potential inciting events in the perioperative environment; misattribution and harsh language, both behaviors described by interviewees in this study, commonly result in transformation of task conflict to relational conflict.[25,26] Although verbal hostility is likely a result of both learned and intrinsic personality traits, conflict management training can mitigate this factor.[25,28] Recent work by Sanfey and colleagues, identified the need for early identification of problem residents and remediation of their undesirable behaviors using a program based on the highly successful model of Vanderbilt's Center for Patient and Professional Advocacy.[29] Our findings would support similar proposals for a reporting and remediation system for faculty as well, recognizing that altering deeply ingrained, long-held behaviors can present a more extensive challenge.

Our study is not without limitations. First and foremost, all participants worked in the perioperative setting at a single institution. Although some of them had experiences at other institutions and in other clinical settings, this did not apply to all. Therefore, some findings might be unique to the institutional environment, highlighting the importance of attempting to replicate these findings. An additional shortcoming was our ability to recruit surgical scrub technicians to participate in the interview process. Although multiple attempts were made to invite individuals in this role to participate, we simply were not successful in completing an interview with more than two. One of the clear themes from the completed interviews with scrub technicians was the impact of the power differential between the scrub technician and the surgeon, as well as potential apprehension surrounding

being identified as a study participant, despite our efforts to maintain confidentiality. The authors attribute the inability to recruit scrub technicians to the study to a sense of disempowerment expressed by the two who were successfully interviewed. This also highlights the limitation of selection bias because participants sought the opportunity for their interviews after receiving a recruitment email; those who chose to participate might be individuals who had a particular interest in or specific experiences with disruptive surgeon behavior.

As with any research design, limitations are also inherent in qualitative methods. These limitations include the ability to generalize findings, variations in interpretation of the data, and the interpretative power of the data.[14] It will be important over time to replicate the findings of this research, including the use of quantitative approaches that would do justice to the complexity of disruptive behavior. Mixed methods could be used to facilitate an improved understanding and generate new theory about disruptive physician behaviors and causes.

Credibility in a qualitative study is established through triangulation of data sources.[14] In this study, techniques for triangulation included:

1. Participant checking: This was done through sending the transcripts to participants to verify their words and allowing them to modify any of their interview materials.
2. Peer debriefing: In the case of this research, the investigators met regularly as a peer research team, challenging one another's data analysis, adding to emerging thoughts, raising insight into factors not previously considered, and bringing to light subjectivities as researchers. The emerging analysis was iteratively revisited for ongoing feedback on codes and emerging themes, as well as the final conceptual model.
3. Audit trails: This included notes generated during data analysis, writing down which participants mentioned each theme, documenting which themes were ultimately not included, and categorization of quotes into concept families. This complex process provides verification of the integrity of the analytical process.

The model generated from this study has a variety of potential applications in an environment seeking to address disruptive surgeon behaviors. Although situational stressors are subject to considerable individual variability, they can be addressed at both the system and the individual level. Team member training has been identified by surgeons as a key method for improving patient safety, and would likely contribute to increased stability of operating room teams, creation of shared mental models, and increased individual investment in overall team function.[23,30] Redress of inciting events at an individual level dovetails with need for addressing personality factors and speaks again to the relevance of conflict-management training for surgeons and those who work in the operative environment. As previously described by Rogers and colleagues, conflict-management training for surgeons would ideally foster acquisition of effective behaviors and enhance understanding of ineffective behaviors.[25,28] Finally, buy-in for correction of cultural conditions that permit disruptive surgeon behavior must come from the top; although cultural transformation can initiate at any level, ultimately hospital and medical center leadership will have to accept responsibility for creation of a safe learning environment that includes a reporting system predicated on a clear code of conduct.[31] At the authors' institution, a new program was implemented in the 2013 to 2014 academic year that meets the criteria described by Leape and colleagues[31] as a response to The Joint Commission; the impact of this program will be evaluated as maturation occurs but represents a resource for culture change that has been received enthusiastically by staff and students.[32]

Although disruptive behavior in health care organizations is not rare and most health care providers have experienced or witnessed disruptive behavior, 40% of clinicians do not report the intimidator or the behavior.[18,33-35] However, a culture of safety is "dependent on teamwork, positive interactions, and collaboration."[25] Health care organizations are now required to have programs in place to protect workplace culture and to promote safety for the health care team and patients. Tolerating disruptive behavior might appear to be endorsed by not taking complaints seriously, which can compromise staff morale and patient care.[26] However, the single most malleable factor in the model generated by our interviews was the presence of a culture that tolerates disruptive behaviors; by simply altering this one area, a major change in traditional surgical culture could happen quickly. If, however, we continue to turn a blind eye to tantrums, threats, and intimidation, and the factors that underlie those behaviors, little can or will change.

Author Contributions

Study conception and design: Cochran, Elder
Acquisition of data: Elder
Analysis and interpretation of data: Cochran, Elder
Drafting of manuscript: Cochran, Elder
Critical revision: Elder

REFERENCES

1. American Medical Association. Report of the Council on Ethical and Judicial Affairs: Physicians with Disruptive Behavior. 2002.

Available at: http://www.ama-assn.org/resources/doc/code-medical-ethics/9045a.pdf. Accessed January 15, 2014.
2. Rosenstein AH, O'Daniel M. A survey of the impact of disruptive behaviors and communication defects on patient safety. Jt Comm J Qual Patient Saf 2008;34:464–471.
3. Hickson GB. Patient complaints and malpractice risk. JAMA 2002;287:2951.
4. Glaser BG, Strauss AL. The Discovery of Grounded Theory: Strategies for Qualitative Research. New York: Aldine; 1967.
5. Strauss AL. Qualitative Analysis for Social Scientists. Cambridge: Cambridge University Press; 1987.
6. Strauss AL, Corbin J. Basics of Qualitative Research: Grounded Theory Procedures and Techniques. 3rd ed. Los Angeles, CA: Sage Publications, Inc.; 2008.
7. Patton MQ. Qualitative Evaluation and Research Methods. 3rd ed. Los Angeles, CA: Sage Publications, Inc.; 2001.
8. Lincoln YS, Guba EG. Naturalistic Inquiry. Los Angeles, CA: Sage Publications, Inc.; 1985.
9. Williams E, Morrow S. Achieving trustworthiness in qualitative research: a pan-paradigmatic perspective. Psychother Res 2009;19:576–582.
10. Morrow S, Smith M. Qualitative research for counseling psychology. In: Brown S, Lent R, eds. Handbook of Counseling Psychology. 3rd ed. New York: Wiley; 2000:199–230.
11. Charmaz K. Constructing Grounded Theory: A Practical Guide Through Qualitative Analysis. London: Sage; 2006.
12. Ponterotto J. Qualitative research in counseling psychology: a primer on research paradigms and philosophy of science. J Couns Psychol 2005;52:126–136.
13. Morrow S. Quality and trustworthiness in qualitative research in counseling psychology. J Couns Psychol 2005;52:250–260.
14. Marshall C, Rossman GB. Designing Qualitative Research. 5th ed. Los Angeles, CA: Sage Publications, Inc.; 2010.
15. Fassinger R. Paradigms, praxis, problems, and promise: grounded theory in counseling psychology research. J Couns Psychol 2005;52:156–166.
16. Rosenstein AH, O'Daniel M. Disruptive behavior and clinical outcomes: perceptions of nurses and physicians. Am J Nurs 2005;105:54–64. quiz 64–65.
17. Institute for Safe Medication Practices. Unresolved Disrespectful Behavior in Healthcare: Practitioners Speak Up (Again)—Part I. 2013. Available at: http://www.ismp.org/Newsletters/acutecare/showarticle.asp?id=60. Accessed January 15, 2014.
18. Porto G, Lauve R. Disruptive Clinician Behavior: A Persistent Threat to Patient Safety. Patient Safety & Quality Healthcare. 2006. Available at: http://www.psqh.com/julaug06/disruptive.html. Accessed January 15, 2014.
19. Keogh T, Martin W. Managing unmanageable physicians: leadership, stewardship and disruptive behavior. Physician Exec 2004;30:18–22.
20. Morrissey J. Encyclopedia of errors. Growing database of medication errors allows hospitals to compare their track records with facilities nationwide in a nonpunitive setting. Mod Healthc 2003;33. 40, 42.
21. Rosenstein AH. Original research: nurse-physician relationships: impact on nurse satisfaction and retention. Am J Nurs 2002;102:26–34.
22. Lingard L, Espin S, Whyte S, et al. Communication failures in the operating room: an observational classification of recurrent types and effects. Qual Saf Health Care 2004;13:330–334.
23. Makary M, Sexton JB, Freischlag J, et al. Operating room teamwork among physicians and nurses: teamwork in the eye of the beholder. J Am Coll Surg 2006;202:746–752.
24. Lingard L, Regehr G, Espin S, et al. Perceptions of operating room tension across professions: building generalizable evidence and educational resources. Acad Med 2005;80[Suppl]:S75–S79.
25. Rogers D, Lingard L, Boehler ML, et al. Teaching operating room conflict management to surgeons: clarifying the optimal approach. Med Educ 2011;45:939–945.
26. Rogers DA, Lingard L. Surgeons managing conflict: a framework for understanding the challenge. J Am Coll Surg 2006;203:568–574.
27. Rogers DA, Lingard L, Boehler ML, et al. Foundations for teaching surgeons to address the contributions of systems to operating room team conflict. Am J Surg 2013;206:428–432.
28. Rogers DA, Lingard L, Boehler ML, et al. Surgeons managing conflict in the operating room: defining the educational need and identifying effective behaviors. Am J Surg 2013;205:125–130.
29. Sanfey H, Darosa DA, Hickson GB, et al. Pursuing professional accountability: an evidence-based approach to addressing residents with behavioral problems. Arch Surg 2012;147:642–647.
30. Manser T. Teamwork and patient safety in dynamic domains of healthcare: a review of the literature. Acta Anaesthesiol Scand 2009;53:143–151.
31. Leape LL, Shore MF, Dienstag JL, et al. Perspective: a culture of respect, part 2: creating a culture of respect. Acad Med 2012;87:853–858.
32. The Joint Commission. Sentinel Event Alert, Issue 40: Behaviors that undermine a culture of safety; 2010. Available at http://www.jointcommission.org/assets/1/18/SEA_40.PDF. Accessed April 6, 2014.
33. Eberlein TJ. Shaping a modern academic department of surgery: honoring the past; focusing on the future. Ann Surg 2012;256:395–401.
34. Leape LL, Fromson JA. Improving patient care problem doctors: is there a system-level solution? Ann Intern Med 2006;144:107–116.
35. Weber DO. Poll results: doctors' disruptive behavior disturbs physician leaders. Physician Exec 2004;30:6–14.

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The Disruptive Physician:

A Legal Perspective

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Rationale and Objectives: This article addresses the medical and legal implications of disruptive physician behavior. In addition, this article will address the appropriate use of due process in peer review of disruptive physician behavior.

Conclusions: While most hospitals and even national organizations, like the American Medical Association, have definitions for what constitutes disruptive physician behavior, these definitions have been further examined and clarified in court rulings. These court rulings not only further clarify what constitutes disruptive behavior but also establish a threshold for revocation/nonrenewal of a physician's hospital privileges.

Key Words: Disruptive physician behavior; professionalism; medical-legal issues.

All physicians experience pressures and frustrations in their careers ranging from, literally, making life-and-death decisions in medical management to declining income and increasing regulatory burdens (1–3). In this high-pressure setting, events and circumstances may be enough to "test a saint" (3). Anger, frustration, and even the occasional swear can be normal human responses when confronted with the broad range of stressors and responsibilities in a physician's career. However, there is a point where a physician's behavior can cross the line from expected emotional responses to disruptive behavior.

Professionalism has long been seen as an "Aunt Minnie" (eg, you know it when you see it). The same can be said about unprofessional behavior. Unfortunately, such subjective descriptions are of limited value when writing hospital policy, evaluating a physician's behavior, or trying a case in a court of law. Subsequently, this article will explore the legal precedents set by court rulings in which physician behavior was deemed a legitimate reason to revoke or refuse renewal of physician staff privileges.

While harassment, of any form, is certainly disruptive behavior, in terms of legal precedent, this is typically addressed under Title IV of the 1964 Civil Rights Act and Title IX of the Education Amendments of 1972 (4). Instead, the focus of this article will be the other unprofessional behaviors covered under the increasing well-defined legal precedents defining "disruptive behavior."

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DEFINITION AND PREVALENCE DISRUPTIVE BEHAVIOR

As medical professionals, we have an instinctive understanding of what constitutes disruptive physician behavior. Many of us may be able to recall an example of a disruptive physician from our training and subsequent careers:

"They're out there … browbeating nurses and pharmacists, dressing down hapless staff, belittling patients to their faces, swearing at the tops of their voices, muttering ominous threats, dripping sarcasm and snide innuendo, slouching in late day after day, raging, sulking, hurling surgical instruments, blowing off appointments, sabotaging meetings, sneering at administrators, insulting their colleagues, refusing to answer pages, addling their judgment with drink or drugs, breaching sexual boundaries…" (3).

Disruptive behavior is a common problem, with 18% of physician executives stating they encounter disruptive behavior on a monthly basis in their organization and another 14% dealing with it on a weekly basis (3). The Alabama, Kentucky, and Wisconsin state medical societies have published data showing disruptive behavior encompasses 30% of their complaints (5). The estimated prevalence of disruptive behavior among all US physicians is 5% (3). Usually the disruptive behavior results from conflict between a physician and a nurse.

The American Medical Association (AMA) states, "Personal conduct, whether verbal or physical, that negatively affects or that potentially may negatively affect patient care constitutes disruptive behavior. (This includes but is not limited to conduct that interferes with one's ability to work with other members of the health care team.) However, criticism that is offered in good faith with the aim of improving patient care should not be construed as disruptive behavior" (6). Disruptive behavior includes verbal assaults that are personal, irrelevant, rude, insulting, or otherwise

inappropriate or unprofessional. Throwing instruments, damaging property, or unprofessional outbursts of anger have been determined to be disruptive. Some say hostile, angry, abusive, aggressive, or confrontational voice or body language is disruptive. Most agree that language or criticism directed to the recipient in such a way as to ridicule, intimidate, undermine confidence, or belittle is disruptive behavior.

LESSONS FROM CASE LAW

Court after court has held disruptive behavior as a legitimate reason to revoke or refuse renewal of staff privileges as has been evidenced in several landmark cases (7–9). Case law varies slightly from state to state; however, the aforementioned cases and other subsequent cases have laid the groundwork for the Federal Healthcare Quality Improvement Act of 1986 (10).

For example, one case involved a physician who told a nurse that "she should get off her ass" and that she was a "wrench in the works, she was obstructing patient care" (11). His privileges were revoked and he sued the hospital. That court held, "So, essentially, disruptive is to interrupt the ordinary course of things, the normal course of things, is disruptive. And, as defined in the Duquesne Law Review, the disruptive practitioner is by definition contentious, threatening, unreachable, insulting and frequently litigious. He will not, or cannot, play by the rules, nor is he able to relate to or work well with others," (12).

Another case involved a surgeon who had an angry exchange with two anesthesiologists when an operation began 3 minutes behind schedule (13). When the anesthesiologists attempted to explain why they were taking a few minutes to reexamine the patient's medical records before administering the anesthesia to the patient on the operating table, he told them that he "didn't give a damn about incompetent people's excuses." According to the anesthesiologists, he then launched into a tirade of insults in loud and angry tones in front of the still-conscious patient. His disruptive behavior continued when he falsely reported to a nurse supervisor that one of her patients had just hanged himself in their hospital room; in fact, the patient was fine. He explained that he had intended the episode as a "joke" to teach the nurse "responsibility." On another occasion, he slapped a surgical technician's hands, apparently as a reprimand for a perceived mistake in handling a catheter, while she was assisting him in an operation. His privileges were revoked. He sued to get them back and lost.

Another physician interfered with a lymph node biopsy being performed by his archrival, another obstetrician/gynecologist (14). He strode into the operating room suite and demanded that a nurse, who was the operating room coordinator, stop another physician's operation. He did not follow the appropriate procedure of complaining before the surgery to the chief of surgery or to the chief of the medical staff. He lost his privileges. He, too, sued and lost.

Therefore, virtually all courts uphold the right of a hospital to act whenever the physician's disruptive conduct, in the expert opinion of the hospital authorities, "may" or "could" adversely affect patient care. This majority view is consistent with the Federal Health Care Quality Improvement Act of 1986, which states disruptive behavior "affects or could affect adversely the health or welfare of a patient or patients" (10). The potential effect on patient care may not be presumed but must be shown by the evidence. But a hospital need not wait for a disruptive physician to harm a patient before revoking a medical staff member's privileges (15).

What is not disruptive behavior? One court has said, "Doctors, like other people, have quirks, and some doctors are more disagreeable than others. The mere fact that a doctor is irascible, however, does not constitute good cause for termination of his or her hospital privileges" (16). On similar grounds, another court concludes, "The mere fact that a physician is irascible, however, or that he or she generally annoys other physicians, nurses or administrators does not constitute sufficient cause for termination of his or her hospital privileges" (14). Criticism that is offered in good faith with the aim of improving patient care should not be construed as disruptive behavior (17). However, the right to criticize constructively "is not a right to malign" (18). It has been made very clear that "a doctor should not be cut off from staff membership merely because he or she has criticized hospital practices and other doctors" (18).

Courts generally defer to hospitals' peer review process when a decision to revoke or refusal to renew staff privileges occurs. This position is supported by the AMA, which has argued, "The vast majority of lawsuits challenging peer review proceedings should be dismissed at the summary judgment stage. Suits against peer reviewers should be allowed to go forward only when the plaintiff has rebutted the presumption that the peer review proceeding was reasonable and fair" (18). "Any lesser standard would deter physicians from serving as peer reviewers and would therefore undermine the purpose of the HCQIA" (18).

Rarely, courts side with the physician. One physician lost his privileges because he complained to governing bodies about his hospital's practices being outside the norm (19). Specifically, he argued the hospital did not follow appropriate procedures in posting random on-call schedules, provided deficient child psychiatric care, and had policies requiring premature patient discharge when patients ran out of insurance to cover their care. He was able to prove that his privileges were not revoked in a reasonable belief of furthering the quality of health care. In another case, the Tenth Circuit upheld a district court's finding that the peer review board lacked immunity because the board investigated only two patient charts before deciding to revoke the physician's privileges, which was not a reasonable effort to obtain facts (20).

POTENTIAL CAUSES OF DISRUPTIVE PHYSICIAN BEHAVIOR

In general, physicians need to have a consistent track record of prosocial behavior to gain acceptance into medical school,

to complete their training, and to obtain licensure and Drug Enforcement Agency certification. Subsequently, it is reasonable to ask what factors may trigger disruptive behavior in this group of individuals.

One can cite many "common sense" reasons such as overwork, family strife, a dysfunctional working environment, supervisor pressure, and anxiety. Some authors believe that the "normal" stress of medical practice has been compounded by large educational debt loads for graduating physicians, increasing malpractice premiums, decreasing reimbursement, and the pressure to see more patients in a shorter amount of time (2). According to one recent survey, "This is a difficult time for physicians with flat or declining income, rising expectations, rising office overhead, and diminished autonomy. Physicians are depressed about their loss of control and enormously frustrated by the complexity of the health care system. They bristle at the need for regulatory oversight and have a great deal of difficulty with any non-physicians mandating any kind of activity or behavior, clinical or otherwise. Their frustration boils over all too easily" (3).

An underlying physical, mental, or behavioral disorder causing physician impairment may provide an explanation for new-onset disruptive physician behavior. The AMA defines *physician impairment* as, "any physical, mental or behavioral disorder that interferes with ability to engage safely in professional activities" (21). The 2000 AMA Report of the Council on Ethical and Judicial Affairs addresses the subject of disruptive behavior and physician impairment (22). It states, "Whether the disruptive behavior is the manifestation of an underlying pathology or not, it is important that it be addressed. In some instances, processes that already are established for grievances or for dealing with impaired workers may be expanded or may serve as models to address disruptive physicians" (22). Of note, the term *physician impairment* has sometimes been inappropriately applied to physicians who have returned to good health, are substance-free and in a monitoring program, or have successfully completed a knowledge or skill remediation course. Subsequently, it is not appropriate to label these physicians either impaired or disruptive.

Understanding the triggers for disruptive behavior has the potential to prevent or ameliorate such behaviors when managing the high stress medical environment. Moreover, identifying underlying physical or behavioral disorders can address treatable causes of disruptive behavior.

IMPACT OF DISRUPTIVE BEHAVIOR

Disruptive physician behavior can result in significant medical, economic, and emotional consequences. Examples include disharmony and poor morale, increased staff turnover, incomplete and dysfunctional communication, heightened financial risk and litigation, reduced self-esteem among staff, reduced public image of hospital, and unhealthy and dysfunctional work environment (2,5).

The Joint Commission states, "Intimidating and disruptive behaviors can foster medical errors, contribute to poor patient satisfaction and to preventable adverse outcomes, increase the cost of care, and cause qualified clinicians, administrators and managers to seek new positions in more professional environments. Safety and quality of patient care is dependent on teamwork, communication, and a collaborative work environment" (23).

One should not underestimate the impact of disruptive behavior on morale. If the coworkers of the disruptive physician see the behavior continue, they assume there was no punishment. This is severely disheartening to those who work hard, follow the rules, and are routinely professional.

Most important, problem behaviors can threaten the performance of the health care team and subsequently can adversely affect the safety and quality of patient care (24).

TABLE 1. Essential Steps that an Organization Should Take to Deal with Disruptive Behaviors as Outlined by the American Medical Association.

- Clearly state which behaviors will not be tolerated.
- Adopt bylaw provisions or policies for intervening in situations where a physician's behavior is identified as disruptive.
- Establish a process to review or verify reports of disruptive physician behavior.
- Establish a process to notify a physician whose behavior is disruptive that a complaint has been made, allow the disruptive physician to respond to the complaint, and monitor for improvement after intervention.

Accessed at https://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion9045.page. Last accessed July 12, 2013.

ADDRESSING DISRUPTIVE BEHAVIOR

The AMA provides the essential steps an organization should take to deal with disruptive behavior (6). (Table 1) The Joint Commission suggests 11 actions for addressing disruptive behavior, including adopting a zero tolerance policy (25) (Table 2).

Once the ground rules have been established, the hospital's peer review process must abide by three principles (Table 3).

First, they must operate with a reasonable belief that they are improving the quality of patient care (26). Second, they must only make their decision to revoke or refuse renewal of staff privileges after a reasonable effort to obtain the facts (27). The relevant inquiry under the second element "is whether 'the totality of the process leading up to the professional review action evidenced a reasonable effort to obtain the facts,'" not a perfect effort (28). Last, they must provide a fair hearing. This includes proper notice of the hearing, the reasons for the proposed action and a summary of the physician's rights at the hearing. The hearing shall be held before an arbitrator mutually acceptable to the physician and the health care entity, before a hearing officer who is appointed by the entity and who is not in direct economic competition with the physician involved, or before a panel of individuals who are appointed by the entity and are not in direct

TABLE 2. Suggested Actions for Dealing with Disruptive Behavior from The Joint Commission.

1. Educate all team members—both physicians and non-physician staff—on appropriate professional behavior defined by the organization's code of conduct. The code and education should emphasize respect. Include training in basic business etiquette (particularly phone skills) and people skills.
2. Hold all team members accountable for modeling desirable behaviors, and enforce the code consistently and equitably among all staff regardless of seniority or clinical discipline in a positive fashion through reinforcement as well as punishment.
3. Develop and implement policies and procedures/processes appropriate for the organization that address:
   a. "Zero tolerance" for intimidating and/or disruptive behaviors, especially the most egregious instances of disruptive behavior such as assault and other criminal acts. Incorporate the zero tolerance policy into medical staff bylaws and employment agreements as well as administrative policies.
   b. Medical staff policies regarding intimidating and/or disruptive behaviors of physicians within a health care organization should be complementary and supportive of the policies that are present in the organization for non-physician staff.
   c. Reducing fear of intimidation or retribution and protecting those who report or cooperate in the investigation of intimidating, disruptive and other unprofessional behavior. Non-retaliation clauses should be included in all policy statements that address disruptive behaviors.
   d. Responding to patients and/or their families who are involved in or witness intimidating and/or disruptive behaviors. The response should include hearing and empathizing with their concerns, thanking them for sharing those concerns, and apologizing.
   e. How and when to begin disciplinary actions (such as suspension, termination, loss of clinical privileges, reports to professional licensure bodies).
4. Develop an organizational process for addressing intimidating and disruptive behaviors that solicits and integrates substantial input from an inter-professional team including representation of medical and nursing staff, administrators and other employees.
5. Provide skills-based training and coaching for all leaders and managers in relationship-building and collaborative practice, including skills for giving feedback on unprofessional behavior, and conflict resolution. Cultural assessment tools can also be used to measure whether or not attitudes change over time.
6. Develop and implement a system for assessing staff perceptions of the seriousness and extent of instances of unprofessional behaviors and the risk of harm to patients.
7. Develop and implement a reporting/surveillance system (possibly anonymous) for detecting unprofessional behavior. Include ombuds services and patient advocates, both of which provide important feedback from patients and families who may experience intimidating or disruptive behavior from health professionals. Monitor system effectiveness through regular surveys, focus groups, peer and team member evaluations, or other methods. Have multiple and specific strategies to learn whether intimidating or disruptive behaviors exist or recur, such as through direct inquiries at routine intervals with staff, supervisors, and peers.
8. Support surveillance with tiered, non-confrontational interventional strategies, starting with informal "cup of coffee" conversations directly addressing the problem and moving toward detailed action plans and progressive discipline, if patterns persist. These interventions should initially be non-adversarial in nature, with the focus on building trust, placing accountability on and rehabilitating the offending individual, and protecting patient safety. Make use of mediators and conflict coaches when professional dispute resolution skills are needed.
9. Conduct all interventions within the context of an organizational commitment to the health and well-being of all staff, with adequate resources to support individuals whose behavior is caused or influenced by physical or mental health pathologies.
10. Encourage inter-professional dialogues across a variety of forums as a proactive way of addressing ongoing conflicts, overcoming them, and moving forward through improved collaboration and communication.
11. Document all attempts to address intimidating and disruptive behaviors.

http://www.jointcommission.org/assets/1/18/SEA_40.PDF. Last accessed July 12, 2013.

TABLE 3. Guiding Principles for Hospital's Peer Review Process of an Alleged Disruptive Physician.

- They must operate with a reasonable belief that they are improving the quality of patient care.
- They must only make their decision to revoke or refuse renewal of staff privileges after a reasonable effort to obtain the facts.
- They must provide a fair hearing.

competition with the physician involved. The physician is entitled to representation by an attorney or other person of the physician's choice, to have a record made of the proceedings, copies of which may be obtained by the physician upon payment of any reasonable charges associated with the preparation thereof, to call, examine, and cross-examine witnesses. The physician has the right to present evidence determined to be relevant by the hearing officer, regardless of its admissibility in a court of law, to submit a written statement at the close of the hearing. Upon completion of the hearing, the physician involved has the right to receive the written recommendation of the arbitrator, officer, or panel, including a statement of the basis for the recommendations, and to receive a written decision of the health care entity, including a statement of the basis for the decision.

CONCLUSION

Disruptive behavior is common and adversely impacts the quality of patient care. Disruptive behavior, by definition, is

a violation of social and professional norms that interferes with patient care. Subsequently, it is imperative that each organization clearly defines and communicates what constitutes inappropriate behavior in order to establish normative behavior for the work environment.

It is equally important that the process for addressing disruptive behavior be transparent, predicable, and fair (ie, follows due process). Following the procedural requirements of due process benefits all involved. The hospital and those involved in peer review are protected from liability. The accused physician can be protected from disciplinary actions that are motivated by other concerns than quality of care.

Once an organization defines disruptive behavior and subsequently establishes and enforces a process for managing it, then the necessary culture changes can begin to minimize and/or prevent such behaviors.

REFERENCES

1. Medical professionalism in the new millennium: a physician charter. Ann Intern Med 2002; 136(3):243–246.
2. Rosenstein AH, O'Daniel M. Impact and implications of disruptive behavior in the perioperative arena. J Am Coll Surg 2006; 203(1):96–105.
3. Weber D. Poll results: doctors' disruptive behavior disturbs physician leaders. Phys Exec 2004(September-October);6–14.
4. Berlin L. Sexual harassment. AJR Am J Roentgenol 2006; 187(2):288–293.
5. Samenow C, Swiggart W, Spickard A. A CME course aimed at addressing disruptive physician behavior. Phys Exec 2008;(1):27–28.
6. American Medical Association opinion 9.045-Physicians with disruptive behavior. Available at: http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion9045.page. Accessed July 12, 2013.
7. Even v.Longmont United Hospital Association, 629 P.2d 1100, 1103 (Colo. Ct. App. 1981) Available at: http://scholar.google.com/scholar_case?case=4214755260184158 43&q=%22disruptive+physician%22&hl=en&as_sdt=2. Accessed July 12, 2013.
8. Ladenheim v. Union County Hospital District, 76 Ill. App. 3d 90, 98, 31 Ill. Dec. 568, 574, 394 N.E. 2d 770, 776 (1979). Available at: http://www.state.il.us/court/Opinions/AppellateCourt/1996/1stDistrict/September/WP/1950368.doc. Accessed July 11, 2013.
9. Yarnell v. Sisters of St. Francis Health Services, Inc., 446 N.E. 2d 359, 363 (Ind. Ct. App. 1983). Available at: http://www.leagle.com/xmlResult.aspx?xmldoc=1983805446NE2d359_1789.xml&docbase=CSLWAR1-1950-1985. Accessed July 12, 2013.
10. Health Care Quality Improvement Act of 1986. 42 U.S.C. § 11151(9) (1988). Available at: http://www.ssa.gov/OP_Home/comp2/F099-660.html. Accessed July 12, 2013.
11. Gordon v. Lewistown Hospital, 714 A. 2d 539-Pa: Commonwealth Court. 1998 Available at: http://caselaw.findlaw.com/us-3rd-circuit/1265356.html. Accessed July 12, 2013.
12. Gordon v. Lewistown Hospital, 714 A. 2d 539-Pa: Commonwealth Court 1998 See N.T., Dr. Fishter's Testimony, 2/16/93, pp. 97–98. Available at: http://caselaw.findlaw.com/us-3rd-circuit/1265356.html. Accessed July 12, 2013.
13. Bryan v. James E. Holmes Regional Medical Center, 33 F. 3d 1318 Ct of App, 11th Ct 1994. Available at: https://bulk.resource.org/courts.gov/c/F3/33/33.F3d.1318.92-2963.html. Accessed July 12, 2013.
14. Mahmoodian v. United Hosp. Center, Inc., 404 SE 2d 750-W Va: Supreme Court of Appeals 1991 @ 761. Available at: http://wv.findacase.com/research/wfrmDocViewer.aspx/xq/fac.19910425_9996.WV.htm/qx. Accessed July 12, 2013.
15. Nanavati, 107 N.J. at 254, 526 A. 2d at 704. Available at: http://scholar.google.com/scholar_case?case=8717450390906093469&q=%22disruptive+physician%22&hl=en&as_sdt=2. Accessed July 12, 2013.
16. McElhinney v. William Booth Memorial Hosp., 544 2d 216, 218 (Ky. 1977). Available at: http://scholar.google.com/scholar_case?case=18139559487535384215&q=%22disruptive+physician%22&hl=en&as_sdt=2. Accessed July 12, 2013.
17. Lapenta S. Disruptive behavior and the law. Phys Exec 2004(September-October);27–29.
18. Sussman v. Overlook Hosp. Ass'n, supra, 95 N.J. Super. at 495 (valid and constructive criticism of hospital practices should not be equated with potential disharmony); Health Care Law, supra, § 15.04[2][c] at 15-30. Available at: http://scholar.google.com/scholar_case?case=14360292466732114920&q=%22disruptive+physician%22&hl=en&as_sdt=2. Accessed July 12, 2013.
19. Clark v. Columbia/HCA Info. Servs., 25 P. 3d 215-Nev: Supreme Court 2001. Available at: http://scholar.google.com/scholar_case?case=6116276865515422600&q=Clark+v.+Columbia/HCA+Info.+Servs.+25+P.+3d+215+-+Nv:+Supreme+Court+2001.&hl=en&as_sdt=2. Accessed July 12, 2013.
20. Brown v. Presbyterian Healthcare Services, Nos. 95-2293, 96-2013. November 29, 1996. Available at: https://bulk.resource.org/courts.gov/c/F3/101/101.F3d.1324.95-2293.96-2013.html. Accessed July 12, 2013.
21. American Medical Association policies related to physician health. Available at: www.ama-assn.org/resources/doc/physician-health/policies-physicain-health.pdf. Accessed July 12, 2013.
22. Rakatansky H. Report of the Council on Ethical and Judicial Affairs, subject: physicians with disruptive behavior. Available at: http://search0.ama-assn.org/main/jsp/templates/primaryJSP/fullview.jsp?keyword=report+of+the+council+on+ethical+and+judicial+affairs+disruptive&FilterList=&advancedSearch=&sort=&pagination=. Accessed July 12, 2013.
23. Behaviors that undermine a culture of safety. Sentinel Event Alert 2008;(40):1.
24. Behaviors that undermine a culture of safety. Sentinel Event Alert 2008;(40):3.
25. Behaviors that undermine a culture of safety. Sentinel Event Alert 2008;(40):2.
26. Rogers v. Columbia/HCA, 971 F. Supp. 229 (W.D. La. 1997), aff'd, 140 F. 3d 1038 (5th Cir. 1998). Available at: http://scholar.google.com/scholar_case?case=17642893823341522934&q=%22disruptive+physician%22&hl=en&as_sdt=2. Accessed July 12, 2013.
27. 42 U.S.C. § 11112(a)(2).- Standards for professional review actions. [cited 2013 February 18]; Available at: http://www.gpo.gov/fdsys/granule/USCODE-2010-title42/USCODE-2010-title42-chap117-subchapI-sec11112/content-detail.html. Accessed July 12, 2013.
28. Cowell, 153 Wn. App. at 931 (quoting Morgan, 101 Wn. App. at 770). Available at: http://scholar.google.com/scholar_case?case=3317719683749263277&q=%22disruptive+physician%22&hl=en&as_sdt=2. Accessed July 12, 2013.

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Conflict Management: Difficult Conversations with Difficult People

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Abstract

Conflict occurs frequently in any workplace; health care is not an exception. The negative consequences include dysfunctional team work, decreased patient satisfaction, and increased employee turnover. Research demonstrates that training in conflict resolution skills can result in improved teamwork, productivity, and patient and employee satisfaction. Strategies to address a disruptive physician, a particularly difficult conflict situation in healthcare, are addressed.

Keywords
- conflict management
- resolution skills

Objectives: Upon completion of the article, the reader will: (1) Understand the importance of conflict resolution and management. (2) Recognize skill sets applicable to conflict management. (3) Summarize the steps necessary involved in a successful confrontational conversation.

Conflicts of various magnitudes occur frequently. You share a workspace with a colleague who consistently leaves the space disorganized and messy, which seems unprofessional to you since patients are seen in that office. Or a senior colleague insists being the first author on a research paper when you did all the work. In the preoperative area, the anesthesiologist disagrees with your surgical plan in the presence of the patient. A more extreme example would be a disruptive physician who yells or throws charts or instruments.

The frequency of conflict has been measured in several settings. In an observational study of operating rooms, conflicts were described as "high tension events"; in all surgical cases observed there was at least one and up to four high tension events.[1] Another study found on average four conflicts per operation emerged among operating room team members.[2] In a survey of 5,000 full time employees in nine different countries, 85% of employees dealt with conflict at work to some degree and 29% dealt with conflict frequently or always.[3] Another viewpoint focuses upon "toxic personalities" defined as "anyone who demonstrates a pattern of counterproductive work behaviors that debilitate individuals, teams, and even organizations over the long term."[4] Conflict occurs frequently when working with such people. In a survey, 64% of respondents experienced a toxic personality in their current work environment and 94% had worked with someone like that during their career.[4] In another study, 91% of nurses reported experiencing verbal abuse.[5] The impact of these interactions on mood is significant. In a real-time study, employees recorded interactions with a coworker or superior at four random intervals daily; the employees rated the interactions as positive or negative and recorded their mood. The negative interactions affected the employee's mood five times more strongly than positive encounters.[6]

Some would argue that conflict may be beneficial in certain situations, but in others it has negative consequences.[7] The proposed benefits of conflict include improved understanding of the task, team development, and quality of group decision making. The other line of thought suggests that conflict distracts from the immediate tasks and wastes resources on conflict resolution. Whether or not it is occasionally helpful, it is clear that many instances of conflict are harmful.

Conflict is associated with significant cost to organizations. In the study of employees from nine countries, the average number of hours spent per week on workplace conflict varied from 0.9 to 3.3 hours. In the United States, the average was 2.8

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hours.[3] The calculated expense based on average hourly earnings in 2008 was $359 billion in lost time. High rates of employee turnover and absenteeism are associated with environments where conflict is poorly managed.

Health care is a complex system that requires effective teamwork and cooperation to function well. Patient safety research reveals that patient outcomes are negatively impacted when conflict mismanagement and other dysfunctions occur.[8–10] Another consequence of poorly managed conflict is disruption of care. In a national survey of physicians, almost two-thirds of respondents reported seeing other physicians disrupt patient care at least once a month.[11] More than 10% of the respondents reported witnessing that behavior daily.

Frequent causes of conflict include lack of clarity with expectations or guidelines, poor communication, lack of clear jurisdiction, personality differences, conflicts of interest, and changes within the organization.[12] Behavior that results in conflict could include bullying, limited communication or not sharing important information, and verbal or physical violence.[13] Employees cite personality clashes, stress, heavy workloads, poor leadership at the senior and managerial levels, lack of honesty and openness, and lack of role clarity as the most frequent causes of conflict.[3]

Although conflict cannot be avoided, it can be managed. Since conflict will always be present on an individual and organizational level, it is important to develop the skills to appropriately manage a difficult conversation or interaction. Experts agree that the skills necessary can be acquired; they believe that conflict competence can be defined and learned. One definition of conflict competence is "the ability to develop and use cognitive, emotional, and behavioral skills that enhance productive outcomes of conflict while reducing the likelihood of escalation or harm."[14] The goal is to be competent in having difficult conversations. One model uses the terminology "crucial conversations and "crucial confrontations." A "crucial conversation" is defined as "a discussion between two or more people where (1) the stakes are high, (2) opinions vary, and (3) emotions run strong."[15] Confrontations are those face-to-face conversations in which someone is held accountable.[16]

Real life examples prove their statements and the benefits of improved conflict management. One group demonstrated that teaching the necessary communication skills resulted in 10% improvement in their habits of confronting difficult issues.[16] With that change, customer and employee satisfaction, productivity, and quality also improved. An information technology (IT) group found that improved communication practices resulted in 30% improvement in quality, almost 40% increase in productivity, and near 50% decrease in costs.[16] CPP Global report "Workplace Conflict and How Business Can Harness it to Thrive" study found "training does not reduce the occurrence of conflict, but it clearly has an impact on how conflict is perceived and can mitigate the negative outcomes associated with conflict."[3]

Various models of successful conflict management have been proposed.[14,16] The models typically include discussions of common responses to conflict and ways to effectively address conflict. These models will be combined and summarized in this article.

The common underlying principles of all the models are that

1. Conflict is inevitable and that both positive and negative consequences may occur depending on how the conflict is managed.
2. The results are likely to be better with active engagement rather than avoidance.
3. People must be motivated to address conflict.
4. Behavioral, cognitive, and emotional skills can be acquired.
5. Emotional skills require self-awareness.
6. The environment must be neutral and feel safe.

Response to Conflict

To begin this process, it is important to cultivate self-awareness in regards to one's physical and emotional reaction to situations involving conflict. The most common responses on approaching conflict include: avoiding, accommodating, competing, compromising, and collaborating.[17] Avoidance (or silence) refers to an individual recognizing conflict in a situation and actively deciding to not engage or deal with the problem. Avoidance may be prudent when the issue is minor in nature, as a temporary response when emotions are high or when others can resolve an issue more efficiently. This approach would be the opposite of someone whose response is to compete, which is categorized as being forcing, uncooperative, and assertive in the situation. Competition might be appropriate in emergent situations or actions known to be unpopular need to be taken on an important issue. People whose response is to accommodate others generally do not have their own needs met. Accommodation may be necessary when one is wrong, if the issue is more critical to others or if the value of harmony in the situation outweighs the benefit of a conflict. When accommodation is used, the conflict is resolved but if the pattern repeats itself frequently residual resentment may affect the relationship. Accommodation is also referred to as yielding.[18] Compromise and collaboration are both a balance of assertiveness and cooperativeness. The difference between the two is that compromise is often a negotiation between two parties with equivalent power, whereas collaboration is focused on finding a solution where all parties involved have their needs met. Compromise is focused on fixing a problem with a set amount of resources and collaboration allows for a broader view on problem solving. A combination of compromise and collaboration has also been defined as a problem-solving response.[18] Although there is not a correct response, responses characterized by open-mindedness to the ideas and perspectives of others promote positive outcomes.[17]

Conflict Management Skills

When a conflict exists, the first step is to decide whether to address it. That decision involves balancing the reward against price of addressing the issue; that balance is unique to each circumstance. Some general rules are that if the issue

is troublesome enough that it is affecting your behavior or weighing on your conscience, it should be addressed. It is important not to confuse the perceived difficulty of the conversation with determination of whether it will be beneficial and appropriate to proceed. Perceived differences in power often impact a decision to address a conflict; however, lessons from aviation and other industries illustrate the benefits of open communication and the risks of silence even in situations of different levels of authority or power.[19,20]

Once it is been decided to address the conflict, there are several steps involved in preparation for the conversation. One step is to determine the exact nature of the conflict. When considering the exact nature of the conflict, some authors offer the following guidance.[16] If the issue occurs once, it is appropriate to discuss the content of the issue; if it has occurred repeatedly, one should focus on the pattern of events. If the problem impacts your relationship with the other person or team members, then the topic should be your relationship. One pitfall of conflict management is allowing task or pattern type conflict to deteriorate to relationship conflict by overpersonalizing the issue. Another system appropriate for team conflict divides conflict into task, process, and relationship conflicts. Task conflict is similar to content conflict, while process conflict refers disagreement over team processes.[21]

One must also thoroughly understand one's own position. It is critical to gather all of the background information and any data necessary to discuss the conflict. Then one needs to achieve clarity about what is desired from the confrontation as well as what one is prepared to give up or compromise. Another key element is awareness of which outcomes one considers undesirable. Part of the preparation is consideration of one's own motivations and goals as well as the motivations and goals of the other party. This step seems obvious but is frequently not done or only superficially evaluated. Considering why a rational and ethical person would have behaved in the manner troubling you often opens an alternative view of the situation. The authors of *Crucial Confrontations* label this preparation as "mastering your story."[16] In short, it is understanding from as many vantage points as possible how the problem situation might have developed.

The level of intensity of the conflict is another consideration in determining how best to approach the issue. One model divides the intensity of conflict into five levels.[14] Level 1 is differences. Those are situations in which two or more people have different perspectives on the situation; they understand the other person's viewpoint and are comfortable with the difference. This level of conflict can be an asset for a team or organization because it allows individuals to compare or analyze without an emotional overlay. Level 2 are misunderstandings in which two people understand the situation differently. Misunderstandings are common and can be minor, but can also escalate when stakes are high. If there are negative consequences such as missed events or obligations people tend fault and accuse one another which adds negative emotions to the situation. If the misunderstandings are frequent, it may indicate problems with communication. Level 3 is disagreements; these are times when people have different viewpoints of the situation, and despite understanding the other's position they are uncomfortable with the difference. This level can also easily escalate if ignored. Level 4 is discord. In those instances, conflict results in relationship issues between the people involved even after a specific conflict is resolved. There is often constant tension between those individuals. Level 5 is polarization, which describes situations with intense negative feelings and behavior in which there is little to no hope of resolution. For those conflicts, the mandatory first step is the agreement to communicate.

Another aspect of preparation is to recognize your emotional response and how it might affect your view of the situation. Addressing a difficult situation when one is angry or frustrated is more likely to be ineffective than when one is calm. Several famous quotes illustrate the point.

> "Speak when you are angry and you will make the best speech you will ever regret."
>
> –Ambrose Bierce

It is therefore important to postpone the discussion until one is able to think more calmly and clearly. It is helpful to have an awareness of behaviors that "push your buttons." One list of possibilities comes from an assessment instrument, "Conflict Dynamic Profile (Center for Conflict Dynamics Eckerd College, St. Petersburg, FL)" that includes the following behaviors: abrasive, aloof, hostile, micromanaging, over analytical, self-centered, unappreciative, unreliable, and untrustworthy.[22] A technique to reduce tension is cognitive reappraisal or reframing which refers to looking at alternative perspectives and outcomes of the situation to "reframe" it in a different, generally positive, light. Some other suggested techniques to manage one's emotions are consciously identifying and addressing one's fears about the outcome of the conflict or possible consequences. Centering techniques, which are based on martial arts, offer a way to calm oneself and focus on the positive aspects of the situation.[14]

> "The great remedy for anger is delay"
>
> –Thomas Paine

All conflict management research confirms that setting a safe environment is a critical element in successful management of conflict. In a safe environment, all participants believe they will be respected and treated fairly. The authors of *Trust and Betrayal in the Workplace* present a model that includes three different types of necessary trust.[23] One is contractual trust or trust of character which is confidence in the intentions of others. The second is communication trust or trust of disclosures. In an environment with communication trust, everyone is comfortable that people will share information, be honest, and keep private information confidential. The final type is capability trust; when present, the

participants have confidence in others' abilities to deliver on promises. That model recognizes that trust can be harmed by betrayal, but also rebuilt.

Another description of a safe environment is one with mutual respect and mutual purpose.[16] Mutual respect involves using a tone of voice and words and facial expressions that convey respect for others as human beings. Mutual purpose is having the common goal of problem solving. Although the first model may seem difficult to achieve in all situations, mutual respect and mutual purpose are basic required elements for an effective discussion of a conflict.

How does one establish a safe environment? The conversation must be held in a private, preferably neutral, setting with enough protected time for the discussion. Some experts suggest that a potentially neutral way to establish the goal of joint problem solving is to start the discussion by describing the gap between the expected and observed behavior. Other options include asking for permission to discuss a topic or beginning with the facts from your perspective or your observations. It sets the wrong tone to start the conversation with your conclusion, particularly if it is harsh. One should share all appropriate and relevant information and avoid being vague.[16] Other tips to maintain a safe environment include asking open-ended questions, focusing initially on points of agreement and using "I" statements. Some examples of "I" statements are "I feel frustrated" and "I am concerned." One must be aware of one's body language as well as tone and volume of voice.

Common mistakes to avoid are trying to soften the message by mixing it with complimentary statements or using an overly familiar tone of voice initially before addressing the problem. Most people feel they are being manipulated or treated dishonestly when the messages are mixed. Inappropriate humor or comments disrupt the rapport needed for a safe environment. Another common error is using nonverbal hints or subtle comments with the belief they can successfully address a conflict. This technique is risky because one is never clear on the other person's interpretations of the hints or comments. It also does not work to blame someone else for a decision or request you are making. It ultimately undermines any respect or authority you may hold. Asking people to guess the reason for the meeting, essentially to read your mind, is irritating and ineffective at problem solving.

Once a decision has been made and a neutral environment decided upon for the conversation, there are key elements to conducting the conversation. One organization (CMP Resolutions) terms this first phase as scoping.[24] It includes the time to understand what is happening, each person's perspective of the conflict, and what is important to them, as well as establishing ways the involved parties can work toward a solution. The first step in the conversation is to allow all parties to state their opinions and their perspectives on the conflict. Before beginning, the ground rules regarding confidentiality and decision making should be outlined. Listening, respectively, to each participant during this step is very important. Asking clarifying questions without imposing one's own view of the situation is a skill that often requires practice. One must be aware of the tone and volume of voice to ensure that the environment remains respectful. Expressions of empathy such as "that sounds really difficult" are helpful in setting the tone and encouragement of information sharing. One should avoid judgmental or blaming statements. Listening skills are one of the primary skills to be developed when working on one's ability to manage conflict. Utilizing "AMPP" helps to remember four main listening skills that are helpful when faced with a problem.[16] "A" stands for ask which starts the conversation and allows the other person to discuss their feelings about the situation. Mirroring (M) is a tool to encourage the speaker to continue or offer more information when they seem reluctant. The technique involves statements about what you are observing (e.g., you seem down today) in the other person and then asking a question. The third technique, paraphrasing (P), is the restating of their responses in your own words which shows active listening and makes clear whether you both have the same understanding. Finally, prime (P) refers to priming the pump. It is useful when someone is clearly emotional about the issue but reluctant to talk despite the use of the first three techniques. With this method, one makes a guess out loud about what the other person might be thinking or feeling. One must choose the words carefully and use a calm tone to avoid worsening the situation. The goal is to make the other person feel comfortable speaking. Other potentially helpful acronyms to use during conflict management are seen in ►**Table 1**.

The next part of the conversation is defining the problem. A consensus on the definition of the problem is necessary for participants to be able to compare and discuss solutions. As noted earlier, the problem might be defined as the issue with one occurrence, a pattern of episodes or the working relationship. After creating a mutually agreed upon definition, the next step is to brainstorm possible solutions to the

Table 1 Helpful acronyms related to conflict management[14,16]

VALUED conflict model
Validate
Ask (open-ended questions)
Listen (to test assumptions)
Uncover interests
Explore options
Decide (on solutions)
Four main listening skills
Ask
Mirroring
Paraphrasing
Prime
TSA's four R's of conflict management
Recognize
Respond with **R**espect
Resolve and manage
Reflect

conflict. If possible, these solutions should address the needs of all parties involved.

After a list has been created of alternative solutions, each participant should discuss their preferred solution. There also needs to be a "reality check" with the decision makers. Perhaps the ideal solution is too expensive or not feasible because of existing regulation or organizational policies. The goal is finding commonality and acceptable compromises that allow for all participants to feel like their needs are met and the conflict is being addressed. Once this solution is chosen, an action plan that outlines the "who, what, and when" of fixing the problem needs to be devised. Making sure that everyone involved understands their role and tasks are an important step to accomplish the solution.

Many models suggest that reflection on ways to prevent or more effectively handle similar conflicts in the future at the end of the conversation is beneficial. A follow-up plan is critical. If a plan with timelines is not designed and implemented, the behavior will typically change for a period of time but then slip back into old patterns. Whether the plan is another meeting, completion of certain tasks, or a system of monitoring, it should be defined clearly.

A particularly complex issue in conflict management is the disruptive physician. Historically, that issue has been addressed reluctantly if at all. The physician is often a high revenue producer and organizational leaders fear the consequences of antagonizing the physician or there is concern about a potential conflict of interest. The term is defined in various ways. One definition of disruptive physician behavior is "a practice pattern of personality traits that interferes with the physicians' effective clinical performance."[25] The Ontario College of Physicians and Surgeons defined it as "inappropriate conduct whether in words or action that interferes with or has the potential to interfere with, quality health care delivery."[26] An occasional bad day or overreaction does not constitute disruptive behavior. Rather it is the pattern of repeated episodes of significant inappropriate behavior.

The typical behaviors are often divided into aggressive and passive aggressive categories. Aggressive behaviors include yelling, abusive language, intimidation, and physically aggressive actions. Passive-aggressive behaviors include intentional miscommunication, impatience with questions, racial, general or religious jokes, and implied threats. Despite estimates that only 3 to 6% of physicians qualify as disruptive physicians,[27] the negative impact on the health care system is significant. The behavior undermines morale and productivity as well as the quality of care and patient safety. For example, nurses are less likely to call physicians with a history of disruptive behavior even when they need to clarify an order or report a change in a patient's condition. According to the Joint Commission, these behaviors "can foster medical errors, contribute to poor patient satisfaction and to preventable adverse outcomes, increase the cost of care, and cause qualified clinicians, administrators, and managers to seek new positions in more professional environments."[28] In an academic environment, this behavior is associated with poor role modeling for students and trainees. Because of the impact, both the Joint Commission and the Federation of State Medical Boards addressed the issue in their standards and policies.[28,29]

If the pattern of behavior is recognized early, a conversation with a trusted colleague or physician leader using the techniques described above might be sufficient to change the pattern of behavior. One model of corrective feedback starts by preparing the physician for the meeting with advanced notice and provision of a private setting and respectful atmosphere. Often asking the physician to provide a self-assessment of their interactions with others is a good starting point that can be followed with the observations of specific disruptive behaviors. Strategies for change and improvement as well as set expectations and a monitoring program need to be discussed and articulated before concluding the meeting.[30]

There is evidence that an organization that sets standards for behavior and uses the principles of "action learning" to address variances will have desirable outcomes with disruptive physicians. Briefly, the principles of action learning, which was developed by Reginald Revans, are that the best learning occurs through active questioning and reflection rather than instruction.[31] The people involved tackle a real-life problem by asking questions, discussing alternative solutions, reflecting on change, and monitoring progress. In an interview study of independent, single-specialty surgical practices representing 350 physicians, the investigator determined whether the use of action learning principles correlated with desirable outcomes with disruptive physicians.[32] Desirable outcomes include retention of the physician with a change in the troublesome behavior. In 20 practices, action learning resulted in successful management of the problem.

However, most disruptive physicians require more intensive intervention. Reynolds argues that "constructive change in disruptive physicians comes through requiring adherence to expected behaviors while providing educational and other supports to teach the physician new coping skills for achieving the desired behaviors."[25] A comprehensive evaluation including medical, chemical, and psychiatric evaluation is the first step. It is important to identify an underlying treatable condition. A program of remediation including educational and psychological training to foster new coping skills is outlined. A critical part of the program is long-term follow-through and monitoring. For most disruptive physicians, it is the threat of imposed consequences rather than internal motivation to improve that guides their compliance with the program.[25] Several well-established programs offer resources for the training including the Physician Assessment and Clinical Education (PACE) program at the University of California School of Medicine, San Diego[33] and the Distressed Physician Program at Vanderbilt University School of Medicine in Nashville.[34] A composite case study of transformative learning to address disruptive physician behavior illustrates the process used.[35]

Conflict occurs frequently and often results in significant disruption and cost for individuals and organizations. Although often avoided or poorly managed, evidence suggests the skills for effective management of conflict can be learned.

Multiple studies confirm when conflict is successfully addressed, and multiple benefits accrue to the organization and individuals.

References

1 Saxton R. Communication skills training to address disruptive physician behavior. AORN J 2012;95(5):602–611
2 Booij LH. Conflicts in the operating theatre. Curr Opin Anaesthesiol 2007;20(2):152–156
3 Workplace Conflict and How Businesses Can Harness It to Thrive. Global Human Captial Report CPP 2008. Available at: https://www.cpp.com/pdfs/CPP_Global_Human_Capital_Report_Workplace_-Conflict.pdf
4 Kusy M, Holloway E. Toxic Workplace!. San Francisco, CA: Jossey-Bass; 2009
5 Sofield L, Salmond SW. Workplace violence. A focus on verbal abuse and intent to leave the organization. Orthop Nurs 2003; 22(4):274–283
6 Miner G, Glomb M, Hulin C. Experience sampling mood and its correlates at work. J Occup Organ Psychol 2005;78:171–193
7 Janss R, Rispens S, Segers M, Jehn KA. What is happening under the surface? Power, conflict and the performance of medical teams. Med Educ 2012;46(9):838–849
8 Catchpole KRK, Giddings AEB, Hirst DT, Peek GJ, De Leval MR. A method for measuring threats and errors in surgery. Cogn Technol Work 2008;10:295–304
9 Christian CK, Gustafson ML, Roth EM, et al. A prospective study of patient safety in the operating room. Surgery 2006;139(2):159–173
10 Gawande AA, Zinner MJ, Studdert DM, Brennan TA. Analysis of errors reported by surgeons at three teaching hospitals. Surgery 2003;133(6):614–621
11 MacDonald O. Disruptive Physician Behavior. Quantia MD, 2011. Available at: www.quantiamd.com
12 Umiker WO. Management Skills for the New Health Care Supervisor. 3rd ed. Gaithersburg, Md.: Aspen Publishers; 1998:xxiii, 423
13 Rogers-Clark C, Pearce S, Cameron M. Management of disruptive behaviour within nursing work environments: a comprehensive systematic review of the evidence. JBI Library of Systematic Reviews 2009;7(15):615–678
14 Runde C, Flanagan T. Developing Your Conflict Competence: A Hands-On Guide for Leaders, Managers, Facilitators and Teams. San Francisco, CA: Jossey-Bass; 2010
15 Patterson K, Grenny J, McMillan R, Switzler A. Crucial Conversations: Tools for Talking When Stakes Are High. New York: McGraw-Hill; 2002:xv, 240
16 Patterson K, Grenny J, McMillan R, Switzler A. Crucial Confrontations: Tools for Resolving Broken Promises, Violated Expectations, and Bad Behavior. New York: McGraw-Hill; 2005:xviii, 284
17 Quinn RE, Faerman SR, Thompson MP, McGrath M. Becoming a Master Manager. Wiley: New York; 2010:86–98
18 Greer LL, Saygi O, Aaldering H, de Dreu CK. Conflict in medical teams: opportunity or danger? Med Educ 2012;46(10):935–942
19 Gladwell M. Outliers: the Story of Success. New York, NY: Little, Brown and Co.; 2008
20 Argyris C. Skilled incompetence. In: Harvard Business Review on Effective Communication. Harvard Business School Press: Boston, MA; 1999:101–118
21 Thompson LL. Making the Team: A Guide for Managers. 4th ed. Upper Saddle River, NJ: Prentice Hall; 2011
22 Capobianco S, Mark D, Kraus L. Managing Conflict Dynamics: A Practical Approach. 5th ed. St. Petersburg, FL: Eckerd College; 2008
23 Reina DS, Reina ML. Trust and Betrayal in the Workplace: Building Effective Relationships in Your Organizations. 2nd ed. San Francisco, CA: Berrett-Koehler; 2006
24 Crawley J. I'll meet you half way. Nurs Stand 2011;25(38):64
25 Reynolds NT. Disruptive Physician Behavior: Use and Misuse of the Label. JMR 2012;98:8–19
26 Guidebook for Managing Disruptive Behavior. Toronoto, Ontario, Canada: College of Physicians and Surgeons, Ontario Hospital Association; 2008
27 Leape LL, Shore MF, Dienstag JL, et al. Perspective: a culture of respect, part 1: the nature and causes of disrespectful behavior by physicians. Acad Med 2012;87(7):845–852
28 Commission TJ. Behaviors that undermine a culture of safety. Joint Commission Sentinel Event Alert, 2008; (40). Available at: http://www.jointcommission.org/assets/1/18/SEA_40.PDF
29 Boards, F.o.S.M., Report of the Special Committee on Professional Conduct and Ethics, Section III Disruptive Behavior, Federation of State Boards of Medicine, 2000:4–7
30 Hewson MG, Little ML. Giving feedback in medical education: verification of recommended techniques. J Gen Intern Med 1998; 13(2):111–116
31 Adams M. The practical primacy of questions in action learning. In: Dilworth L, Boshyk Y, eds. Action Learning and Its Applications, Present and Future. Lambertville NJ: Palgrave Macmillan Publishers; 2010:1–11
32 Sullivan M. Disruptive doctors. In: Minnesota Physician. Minneapolis, MN: Minnesota Physician Publishing, Inc.; 2013:1,10–11,38
33 Anger Management for Healthcare Professionals Program. [cited 2013 February 26, 2013]. Available at: paceprogram.ucsd.edu
34 Program for Distressed Physicians. Center for Professional Health [cited 2013 March 3]. Available at: http://www.mc.vanderbilt.edu/root/vumc.php?site=cph&doc=36636
35 Samenow CP, Worley LL, Neufeld R, Fishel T, Swiggart WH. Transformative learning in a professional development course aimed at addressing disruptive physician behavior: a composite case study. Acad Med 2013;88(1):117–123

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ETHICS

Informed Consent and the Surgeon

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The practice of surgery entails many things, from the mastery of good clinical judgment to the cultivation of advanced technical and operative skills. Equally paramount to the practice of surgery is the ability to develop relationships with patients that instill trust and facilitate communication. During the past 50 years, the nature of the patient-surgeon relationship has undergone a significant transformation. Although certain central ethical tenets of medicine have remained unchanged, the emphasis on patient autonomy, transparency, and shared decision-making has increasingly come to the forefront of medical practice. For example, although the Hippocratic tenet of primum non nocere and the principle of beneficence continue to be central to the ethical practice of surgery, more paternalistic conceptions of the surgeon have largely been abandoned. Rather, over the past 50 years, patient autonomy and the right to individual self-determination have replaced the previous belief that "doctor knows best."

One of the earliest legal acknowledgments that physicians were too paternalistic in how they practiced and communicated with patients was the landmark 1914 New York Court of Appeals case, *Schloendorff v Society of New York Hospital*.[1] In this case, a physician who believed he was acting in the best interests of the patient and removed a malignant tumor against the wishes of his patient was found guilty of battery. In the majority opinion, presiding Justice Benjamin Cardozo observed that "a surgeon who performs an operation without a patient's consent commits an assault."[1] This decision emphasized the patient's basic right of self-determination in the context of the patient-surgeon relationship. Later court decisions, including the 1972 *Canterbury v Spence* case,[2] more formally codified and expanded on the autonomous role that patients have in their relationships with treating physicians. Specifically, in the *Canterbury v Spence* case, the justices ruled that physicians and surgeons could no longer hide behind therapeutic privilege to excuse a lack of adequate disclosure to patients.[2] Additional court decisions would follow, effectively ushering in a new era of how surgeons would need to reconceptualize the patient-physician relationship.

As the scope of the surgeon-patient relationship was changing, informed consent came to embody the shift toward a more patient-centered paradigm of care. In contrast to a past era largely characterized by a minimal exchange of information and unilateral decision-making, informed consent was held up as the legal and ethical solution to avoid previous paternalistic pitfalls.[3-5] Armed with the tool of informed consent, surgeons now were expected to have a formal mechanism both to recognize patient autonomy and to address patients as self-determining moral agents. In the routine use of informed consent, therapeutic privilege and other more paternalistic tendencies would hopefully be replaced.[3]

Informed consent serves to identify and respect a patient's best interests by giving each patient the opportunity to decide autonomously what his or her best interests are in light of the planned procedure. The informed consent process is meant to recognize the inherent ethical worth of self-determination, regardless of the content or character of the decision itself. In turn, informed consent seeks to recognize each patient's value system, and their individual life goals, and how these factors inform their decision-making. It could be argued that in its truest form, informed consent is really the process; the document is only a concrete sign that the process has occurred.

Despite inarguable advances, implementation of informed consent in the surgical setting can still represent a challenge. In daily practice, informed consent can frequently be seen as nothing more than a patient's signature, rather than an involved, deliberative process between patient and surgeon. In addition, surgeons-in-training are rarely given formal training in informed consent, so young surgeons may lack a proper understanding of how to engage patients in this important process. Surgical residents deserve the opportunity to learn the art of obtaining informed consent in the clinical setting and should be encouraged by faculty not to dismiss or modify this process in the interest of time or for any other reason. In fact, surgeons may be prone to dispense with lengthy discussions, and some studies even suggest that physicians frequently convey the "wrong" information to the patient.[5,6] These studies highlight the fact that physicians often communicate types

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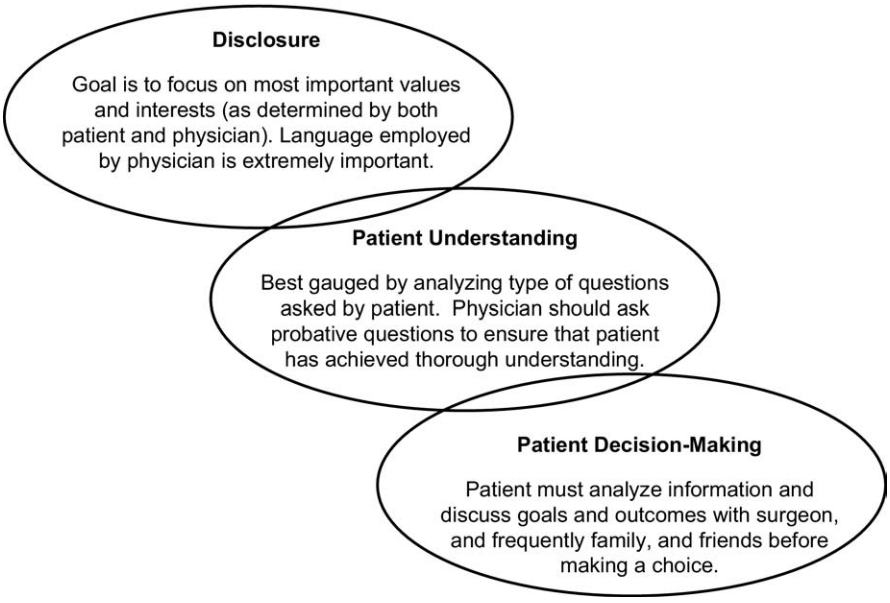

Figure 1. The major ethical requirements of informing the patient during the informed consent process. Note that the boxes represent separate components of the process, but they overlap to signify their interrelationship.

of information that patients do not perceive to be important.[7,8] Clearly, both the mechanism and content of the informed consent process can be suboptimal. This fact is reflected in empiric data that show both physician and patient dissatisfaction with how well the elements of informed consent are fulfilled.[5,6]

Informed consent is particularly important in the surgical realm. Given the procedure-based nature of surgery, informed consent must be an integral part of every surgeon's daily practice. In addition, surgical patients often need the most information and guidance because many surgical procedures are complicated and the attendant risks and benefits are unknown to patients. Patients frequently approach surgery with a wide range of emotions, from "profound distrust to unquestioned faith,"[7] further complicating the process. Insights like these solidify the importance of the informed consent process and the need for practicing physicians to reevaluate their own understanding of the components essential in this process, not to mention the need to improve resident and medical student training.

Although an understanding of informed consent can be achieved through either legal or ethical channels, it is our opinion that a purely legalistic viewpoint is too reductionistic to be of great value. Our intent is not to provide a comprehensive review of the literature on informed consent. Such an exhaustive philosophical and historical review may not be pragmatic for the practicing surgeon. Rather, we here seek to provide a perspective that focuses both on the ethical and pragmatic applications of informed consent that may be more valuable to the surgeon. In doing this, our hope is to encourage surgeons to think about informed consent not as a mandatory part of their daily clinical practice, but more importantly, as a fundamental component of cultivating the patient-physician relationship.

Informed consent: ethical and practical considerations

Informed consent is often conflated into both a single theoretical concept and a single practical endeavor. Although we often discuss informed consent as a single entity, it is helpful to deconstruct informed consent into two distinct components: "informed" and "consent." Although each of these elements is necessary, neither alone is sufficient. In addition, the skill set and ethical considerations involved with each element are somewhat distinct. As such, for illustrative purposes, we will address the elements of "informed" and "consent" in their own right.

Informing the patient

Although the process and scope of "informing" the patient has been widely debated,[2,8-10] for pragmatic purposes we will present three general steps: physician disclosure, patient understanding, and patient decision-making (Fig. 1).

Physician disclosure entails conveying relevant and germane information to the patient. The scope and nature of this information is determined, in part, by an understanding of the values and interests most significant to the pa-

tient. It is critical that surgeons bear in mind that although disclosing information may sometimes be mundane and routine to the surgeon, the process is novel and frequently confusing to the patient. As such, information should be presented as clearly as possible and include a discussion of the diagnosis, treatment options, and alternatives to treatment including nonsurgical management or nonintervention. Selective truth telling must be avoided, and surgeons should make honest admissions of variables that are not well controlled and other factors that are not well understood by the medical profession or the surgeon.[8,10]

The process of disclosure has been plagued by the ethical question of how much information the surgeon should disclose. In general, information related to the patient should include explanation of the procedure; explanation of risks, benefits, and potential consequences of the procedure; and discussion of alternatives. Few would disagree that it would be impossible to completely inform every patient in every circumstance, that is, to take the time to relay every detail of every risk, side effect, or potential outcome of a given therapeutic intervention. The imbalance in medical knowledge between the physician and patient may be prohibitive to allow full disclosure. As such, there has been much discourse about the amount of information that is necessarily adequate in the informed consent process. Over time, three main models of informed consent have emerged that attempt to articulate what an adequate disclosure of information to patients really means (Table 1).[2,3,11,12]

One model of information disclosure is the professional standard. The professional model reflects a traditional, Hippocratic approach in which physicians disclose to patients no more (and hopefully no less) than what other physicians would disclose in similar circumstances. In this model, the standard of disclosure is measured by what other competent health care professionals in similar circumstances would disclose. The professional standard model has been criticized by some as being too physician centered; in this model, information disclosure is measured by what the physician—not the patient—deems important. As such, this approach reduces individual patients to generalized clinical scenarios, and physicians similarly are reduced to performing a task that could be managed by an informative brochure or checklist.

Another model of information disclosure is the reasonable person standard. In this model, rather than the adequacy of information disclosure being measured by what the "reasonable" physician would disclose, the metric is what the "reasonable" patient would want to know. The legal standard in this model of disclosure is the "materiality" or significance of information to the patient's decision-making process. This model requires that a physician disclose any information that is "material" to a reasonable person's decision. Several court decisions in the 1970s upheld the reasonable person standard, once called the "reasonable man standard."[2,3] Despite this, many within the medical community have argued that the reasonable person standard is ambiguous and difficult to satisfy. Specifically, the concept of what constitutes a "reasonable" person has largely gone undefined, leaving indeterminate the pragmatic implications of this standard. Although this model more adequately addresses patient autonomy, it leaves open for interpretation what it means to be "reasonable."[13] In addition, what a "reasonable" person may want to know about a given medical intervention can vary depending on the unique characteristics of his or her disease, values, and life goals.

Because of the limitations of both the professional and reasonable person standards, a third information disclosure standard has been advocated by some ethicists.[14-16] This third standard is known as the subjective standard. The subjective standard requires the physician to disclose whatever information is material to the particular patient being treated. That is, the subjective standard holds that the amount of information disclosed should fit with the life plan and interests of each particular patient. Although the subjective standard has been hailed as an improvement over the professional and reasonable person standards because it values a patient's right to information specific to their personal situation, the standard has been criticized as being overly onerous to physicians. Specifically, critics have argued that it is unfair to expect physicians to be able to discern the particular values, interests, and life circum-

Table 1. Models of Informed Consent

Model	Definition and problems
Professional model	Disclosure and discussion based on what other physicians would disclose in similar circumstances
	Problem: Promotes generalizations and diminishes importance of individual patient values and interests
Reasonable model	Disclosure and discussion based on what a reasonable patient would want to know
	Problem: What is reasonable to one patient may be unreasonable to the next
Subjective model	Disclosure and discussion based solely on specific interests, values, and life plan of patient
	Problem: Difficult to know every important detail of patient's life; cumbersome to implement consistently
Balanced model: reasonable and subjective	Disclosure and discussion based on the most important and relevant interests, values, and goals of patient, as identified by both patient and physician

stances of every patient who needs informed consent. Not to mention, how can anyone but the patient really know the details of the patient's life and the full spectrum of the patient's interests?

Perhaps the best approach to information disclosure uses a model that combines elements of both the reasonable standard and the subjective standard. Although the reasonable standard has some practical advantages (it does not oblige physicians to know more about their patients than what would be "reasonably" expected), the reasonable standard alone does not go far enough in tailoring the process to patient individuality. In contrast, although the subjective standard may be overly cumbersome, it more adequately addresses patient autonomy and the mandate to address the individual needs of each patient. Combining the reasonable and subjective creates a balance between respect for patient autonomy and individual best interest, while reducing some of the practical limitations encountered in the subjective standard. Under a combined subjective and reasonable standard model, physicians would be encouraged to communicate with and learn about their patients to the greatest extent possible, but with an understanding that time limitations and a duty to other patients may prevent knowing all the details necessary to giving adequate disclosure. Adequate disclosure must be based on a patient's values and interests, but both physician and patient need to identify which values and interests take precedence over those of lesser importance to the patient, so that decisions are practically made.

Achieving adequate information disclosure is often not easy and requires the physician to be especially attentive to the language used while communicating with the patient. When disclosing information, it is not enough simply to use lay terminology, diagrams, or similar strategies to educate the patient and evaluate the patient's understanding. Rather, the specific choice of words used by the physician is critical. In disclosing information, the surgeon's word choice can exert an unintended influence over the patient's overall decision-making process, an ethically problematic process called "framing."[8] For example, telling a patient, "your quality of life will be horrible if we do not do this procedure in the near future" may reflect the honest belief or experience of the surgeon. But framing the information in this way may diminish the patient's ability to synthesize true objective data into a decision that reflects the patient's interests and values. Instead, telling a patient, "there is good evidence that patients have a lower chance of full recovery and have poor functional outcomes if they wait X amount of time before having this procedure," liberates the patient from potential bias because it allows a more objective assessment of the clinical situation. Each patient and the Gestalt that accompanies the situation at the time of such a discussion, however, have to be individualized. Although surgeons should try to avoid "overframing" the discussion, they do need to provide information based on their clinical experience and expertise to help the patient make a truly informed decision.

Framing is often unintentional, but a more intentional type of framing can occur in which the physician provides an unnecessarily negative outlook for a patient's procedure or prognosis, called "crepe hanging."[17] Although providing patients with accurate prognostic information is important, painting an unreasonably bleak picture of a patient's chances to either appear correct if the outcomes are particularly poor or exceptional if the outcomes are good should be avoided. Despite being rife with ethical peril, crepe hanging may be tempting to the rare physician who seeks protection from negative outcomes. Both this and more subtle forms of framing that can occur during the informed consent process must be avoided. In general, the language used by the physician in the information disclosure process should be as objective as possible. Of course, many patients still want their surgeon's more subjective opinion of their clinical situation. In general, it is best that the surgeon withhold an opinion until after disclosure is complete, and only on the direct request of the patient.

Information disclosure is a critical part of informed consent, but subsequent active assessment of the patient's understanding of the disseminated information is similarly important. Before the decision-making process can begin, patients need to understand fully the realm of outcomes possible with each of their therapeutic options (cognitive understanding), and fully recognize how their beliefs and values relate to the therapeutic options and associated potential outcomes (evaluative understanding).[8,10] To ensure cognitive understanding, it is often helpful for the surgeon to ask patients to reiterate in their own words their understanding of the rationale, risks, and benefits of the procedure. The idea here is not to quiz the patient, but rather to encourage an open exchange of information and encourage the patient to participate and to ask any necessary questions. If the patient is reluctant to ask questions or asks questions that suggest an incomplete or incorrect understanding of the circumstances, the surgeon should engage in further discussions with the patient to ensure that any misunderstandings are rectified and that the patient's values and interests are being respected. Surgeons should also be aware that some patients may value not asking questions, and this should be respected within reason.

Although surgeons are responsible for engaging patients in this dialog, patients have a similar ethical obligation. That is, patients should be active partners in the informed

consent process. Patients may understand the information presented, but some patients may decide not to decide and choose to rely solely on their surgeon's recommendation. In general, patients should be encouraged to be more active participants in the decision-making process, with the surgeon avoiding being the person actually making decisions for the patient. Even though recommendations are permissible, outright declarations of what "should be done" ought to be withheld.[8,10] In general, surgeons should avoid making declarations of "what to do," but surgeons can still offer clear recommendations and attempt to persuade patients about a certain course of therapy if it seems clearly in the patient's best interest to do so. This does not mean that the patient's choices will be ignored, but rather that in discussing options with patients, the surgeon can still be clear that a particular choice may appear to be a "poor" one in the surgeon's judgment.

After disclosure of information from the physician to the patient, patients must then synthesize everything they have learned from the treating surgeon, other consulting physicians, family, friends, and any independent research to make a final decision. It is important to remember that patients need adequate time to process information, reflect on their values and interests, and make an informed choice. Surgeons similarly need time to learn enough about a patient's life story, values, and priorities to help guide patients in their decisions. The time and place in which the informed consent process could be initiated include a variety of conceivable scenarios, from the outpatient clinic setting to the inpatient bedside. Depending on the type of operation for which consent is being obtained and the level of discussion that the patient requests, the process of informed consent may be best facilitated over the course of multiple preoperative visits, during which enough time can be allocated for the surgeon and patient to achieve a collaborative understanding of the patient's best interests. Because informed consent is not a static event but rather an ongoing process, several preoperative visits (or phone calls) are preferable to a single preoperative visit. In addition, viewing informed consent as an ongoing process serves to strengthen the physician-patient relationship and improves patient compliance.[8] Obviously, in the situation of a surgical emergency, much of this process may be lost because of the urgency of the situation. The surgeon should keep in mind, however, that in these situations the informing process can also occur after the operation as part of the ongoing development of the physician-patient relationship.

Obtaining consent from the patient

The second component of informed consent is the "consent" process. The consent process can technically be done without satisfying any of the essential elements of the "informed" component. Although this is clearly not desirable, it unfortunately may often be the case that patients consent to procedures or interventions without properly being informed. Having a patient simply sign an informed consent form to satisfy a legal requirement does not necessarily reflect that the patient understands the goals of care or whether these goals are aligned with their values and interests. As such, although written consent is a routine and necessary part of the informed consent process, surgeons should not overly focus on the paper while ignoring the process.

Table 2. Essential Components of Documenting Consent

1. Clear description of the planned procedure and its risks and benefits.
2. Details of possible alternative therapies, including the option of no treatment, as well as their attendant risks and benefits.
3. Documentation that patient had chance to ask questions (eg, clinic note "patient had chance to ask questions and all were answered to their satisfaction").
4. Authorization with signature of patient or surrogate decision-maker. Confirmation of patient authorization with signature of physician and witness.

Still, the patient's signature is almost always necessary for an operation to proceed, so some form of documentation must exist.[18] Sometimes the essential elements of the information disclosure are carried out before the patient signs the consent document. It is permissible for the actual signature to be obtained by residents, physician assistants, or other properly trained staff after the surgeon has properly informed the patient,[19] but it is generally preferable that both components of informed consent be carried out together. In addition, although the process ideally should occur during a preoperative clinic visit to allow adequate time for questions, the surgeon should also see the patient and personally confirm his or her consent on the day of the operation.

The actual informed consent document needs to fulfill a number of criteria (Table 2). First, the informed consent document should provide a clear description of the planned procedure and its attendant risks and benefits. Second, the document must adequately articulate anticipated outcomes, both positive and negative, in the near and distant future. Third, there should be some notation of the questions asked by the patient during the informed consent process — a particularly important element considering that for some patients, a more complete understanding is achieved only on reading the informed consent form. Similarly, the physician's response to these questions should be noted, for example, in the surgeon's preoperative clinic note. The documentation should also record the presence of all individuals involved in the informed consent process. Last, the patient must authorize the surgeon and the surgi-

cal team with his or her personal signature or the signature of the surrogate decision-maker.[8,10] This signature is of considerable import because it indicates that authorization is separate but necessary to the "consent" component.

Informed consent: other considerations

Patient refusal

There are a number of ethically problematic situations related to the informed consent process that can arise in surgery. For example, a patient may refuse an operation because he or she is unable to make a decision, despite the surgeon having engaged the patient in the informed consent process as outlined earlier. The surgeon should recognize that the patient has the right to refuse an operation, and explain to the patient that no offense has been caused as a result of the refusal.[10] The surgeon should explore with patients the reasons for refusing an operation; this gives the surgeon some insight into the patients' thought process, and demonstrates to the patients that their refusal does not mean that they lose the care or support of their surgeon. In addition, patients who refuse elective surgery should understand that their refusal does not necessarily prevent an opportunity for a later procedure.

Diminished capacity

Not infrequently, surgeons may encounter patients with diminished decision-making capacity secondary to cognitive dysfunction, psychiatric illness, etc. Surgeons should not automatically assume that these patients are incompetent and deny them a role in the informed consent process. The surgeon has a responsibility to personally engage the patient to determine the patient's level of understanding. Although the capacity to participate in decision-making can be made by a physician, determination of incompetence is more a legal issue requiring psychiatric testimony and a judicial process. If consultation with psychiatrists, lawyers, or other physicians is necessary, the surgeon should be upfront with the patient about this plan.[8] Ultimately, the goal between the surgeon and any consultant should be to improve the patient's decision-making capacity when possible, and not to simply obtain affirmation that a patient needs a proxy decision-maker.

There will be patients, however, who are incompetent to make their own decisions. Patients deemed incapable of making decisions require a proxy decision-maker. The proxy decision-maker can be someone previously chosen by the patient when the patient was in a competent state, or someone appointed by the court. Often proxy decision-makers are family members or close friends who have been chosen because they are believed to have the best perception of the patient's values and interests.[10] In those occasional circumstances in which the surgeon disagrees with the surrogate decision, the hospital ethics committee should be consulted.

Cultural and familial issues

Respect for autonomy and the judicious application of informed consent are cornerstones of modern medical practice in the United States and reflect the largely individualistic approach to patient care embodied in Western medicine. The concept of illness and how therapeutic decisions are made may differ in certain cultures. Surgeons and other physicians who practice within the Western medical paradigm can encounter difficult ethical dilemmas when caring for patients with varying cultural values. Surgeons need to pay increased attention during the informed consent process to ensure that cultural values are identified, valued, and respected.

On occasion, balancing the requirements of the traditional, Western informed consent process with the appropriate respect for the culture in question can be challenging. Perhaps one of the biggest challenges to surgeons in the United States is dealing with patients and families from cultures in which the principle of individual autonomy is not the primary driving principle of decision-making. For example, Korean Americans, Japanese Americans, and Mexican Americans are examples of cultural groups who may generally more frequently believe that terminal diagnoses and information relevant to treatment should be withheld from the patient and instead communicated only with the patient's family.[20,21] These situations raise obvious ethical dilemmas and challenges for the treating surgeon. For example, when the surgeon is asked to communicate more directly with the family rather than the individual patient, the direction of communication can be displaced away from the patient, which may prevent the surgeon from establishing an effective physician-patient relationship. Second, the surgeon loses the ability to fully assess the patient's understanding of the disease and the available therapeutic options in the context of the patient's unique values and interests. Third, and perhaps most significantly, the surgeon may have difficulty recognizing whether any given patient agrees with his loss of autonomy, or whether he is instead heteronomously acting under the pressures, values, or demands of others.[22]

There are no easy solutions to these concerns. Surgeons should approach each patient as a unique individual regardless of cultural influences, and avoid making assumptions based on race, religion, or family influences (Fig. 2).[19,22] The most effective way to approach patients from cultures in which individual autonomy may not be the dominant ethical principle involves, from the beginning, a heightened attentiveness for subtleties in the interactions between the patient and the family. Discrepancies between

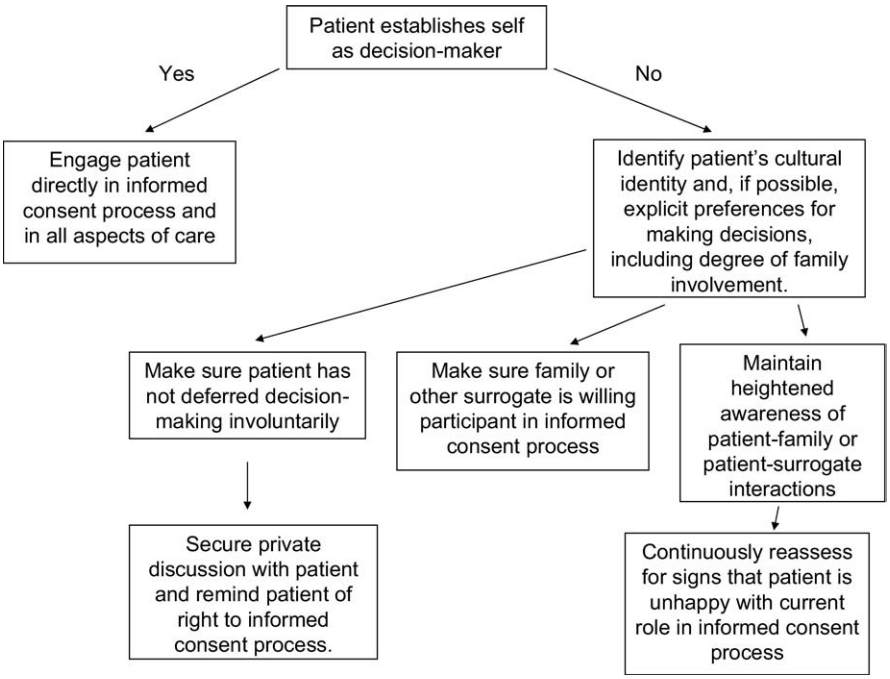

Figure 2. Navigating cultural and familial issues during the informed consent encounter.

what a patient says and how a patient behaves should be noted. The surgeon must also secure a private discussion with the patient, during which time the patient is made aware of the informed consent process and his right to it.[22] If the patient does not wish to participate in the traditional "Western" informed consent process, the surgeon should make sure that the patient does wish the family to assume the responsibility of decision-making. In this way, attention is paid to the patient's wishes, even if autonomy in its truest sense is being subjugated by other cultural values. Finally, the surgeon must ensure that the family itself agrees to make decisions on the patient's behalf that are congruent with the cultural beliefs of the patient—a difficult task because members within a family may disagree with each other over this issue.[22]

In general, individual patient autonomy and the right to fully participate in the informed consent process should be upheld unless the patient explicitly indicates that family members should be included or even be solely responsible in the decision-making process. Although surgeons should not believe that they need to protect patients from their families, physicians should ensure that when a patient defers to familial values or interests, the patient has done so willingly. Continuously encouraging patients to be candid about their familial values and interests can allow surgeons to monitor the decision-making dynamic between patient and family.[23] If a patient does seem dissatisfied or pressured by the family dynamic, a private discussion with the patient (and potentially the family) would be the first step in redefining the best interests of the patient.

In conclusion, a strong doctor-patient relationship is a critical component to the practice of good medicine. In recent decades, the ethical and legal response to the historically paternalistic doctor-patient relationship that dominated the field of medicine for centuries has evolved into the current concept of informed consent. Informed consent is best conceptualized as an ongoing process that involves both information disclosure and authorization for the procedure in question. The best approach to informed consent combines elements of the subjective and reasonable standards. Specifically, surgeons should learn as much as is reasonably possible about a patient's values and interests to provide treatment options and goals of care that align with that individual's interests and values. The surgeon should strive to disclose information, ensure patient understanding, and facilitate and empower patients to be active participants as decision-makers. When carried out properly, informed consent not only serves to respect patient autonomy but perhaps more importantly, cultivates and solidifies the patient-physician relationship.

REFERENCES

1. Schloendorff v. Society of New York Hospital. 211 NY 125 (1914).
2. Canterbury v. Spence. 464 F2d (1972).

3. Veatch RM. The basics of bioethics. Upper Saddle River, NJ: Prentice Hall; 2003.
4. Faden RR, Beauchamp TL. The concept of informed consent. In: Contemporary issues in bioethics, 6th ed. Beauchamp TL, Walters L, eds. Belmont, CA: Wadsworth Publishing, 2003.
5. Katz J. Reflections on informed consent: 40 years after its birth. J Am Coll Surg 186(1998):466–474.
6. Faden RR, Becker C, Lewis C, Freeman J, Faden AI. Disclosure of information to patients in medical care. Med Care 1981;19: 718–733.
7. McKneally MF, Ignagni E, Martin DK, D'Cruz J. The leap to trust: perspective of cholecystectomy patients on informed decision making and consent. J Am Coll Surg 2004;199:51–57.
8. Jones JW ML, Richman BW. A comprehensive primer of surgical informed consent. Surg Clin North Am 2007;87:903–918.
9. Faden RR, Beauchamp TL. A history and theory of informed consent. New York: Oxford University Press; 1986.
10. McCullough LB, Jones JW, Brody BA. Informed consent: autonomous decision making of the surgical patient. In: Surgical ethics. McCullough LB, Jones JW, Brody BA, eds. New York: Oxford University Press, 1998:15–37.
11. Salgo v. Leland Stanford Jr. University Board of Trustees (1957).
12. Natanson v. Kline. 350 p. 2d (1960).
13. Katz J. Physicians and patients: a history of silence. In: Contemporary issues in bioethics, 6th ed. Belmont: Wadsworth; 2003:141–145.
14. Beauchamp TL, Childress JF. Principles of biomedical ethics, 4th ed. New York: Oxford University Press; 1994:44–119.
15. Waisel DB, Truog RD. Informed consent. Anesthesiology 1997; 87:968–978.
16. Waisel DB, Truog RD. The benefits of the explanation of the risks of anesthesia in the day surgery patient. J Clin Anesth 1995;7:200–204.
17. Waisel DB. The hazards of "hanging crepe" or stating overly pessimistic prognoses. J Clin Ethics 2000;11:171–174.
18. Jones JW, McCullough LB, Richman BW. Informed consent: it's not just signing a form. Thorac Surg Clin 2005;15:451–460.
19. Anderson OA, Wearne IM. Informed consent for elective surgery–what is best practice? J R Soc Med 2007;100:97–100.
20. Blackhall LJ, Murphy ST, Frank G, et al. Ethnicity and attitudes toward patient autonomy. JAMA 1995;274:820–825.
21. Akabayashi A, Slingsby BT. Informed consent revisited: Japan and the U.S. Am J Bioeth 2006;6:9–14.
22. Hyun I. Waiver of informed consent, cultural sensitivity, and the problem of unjust families and traditions. Hastings Cent Rep 2002;32:14–22.
23. Kipnis K. Taking families seriously enough. Am J Bioeth 2006; 6:21–22; discussion 27–28.

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A randomized study of multimedia informational aids for research on medical practices: Implications for informed consent

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Abstract

Background/Aims: Participant understanding is a key element of informed consent for enrollment in research. However, participants often do not understand the nature, risks, benefits, or design of the studies in which they take part. Research on medical practices, which studies standard interventions rather than new treatments, has the potential to be especially confusing to participants because it is embedded within usual clinical care. Our objective in this randomized study was to compare the ability of a range of multimedia informational aids to improve participant understanding in the context of research on medical practices.

Methods: We administered a web-based survey to members of a proprietary online panel sample selected to match national US demographics. Respondents were randomized to one of five arms: four content-equivalent informational aids (animated videos, slideshows with voice-over, comics, and text) and one no-intervention control. We measured knowledge of research on medical practices using a summary knowledge score from 10 questions based on the content of the informational aids. We used analysis of variance and paired t-tests to compare knowledge scores between arms.

Results: There were 1500 completed surveys (300 in each arm). Mean knowledge scores were highest for the slideshows with voice-over (65.7%), followed by the animated videos (62.7%), comics (60.7%), text (57.2%), and control (50.3%). Differences between arms were statistically significant except between the slideshows with voice-over and animated videos and between the animated videos and comics. Informational aids that included an audio component (animated videos and slideshows with voice-over) had higher knowledge scores than those without an audio component (64.2% vs 59.0%, $p < .0001$). There was no difference between informational aids with a character-driven story component (animated videos and comics) and those without.

Conclusion: Our results show that simple multimedia aids that use a dual-channel approach, such as voice-over with visual reinforcement, can improve participant knowledge more effectively than text alone. However, the relatively low knowledge scores suggest that targeted informational aids may be needed to teach some particularly challenging concepts. Nonetheless, our results demonstrate the potential to improve informed consent for research on medical practices using multimedia aids that include simplified language and visual metaphors.

Keywords

Research on medical practices, comparative effectiveness research, pragmatic clinical trials, multimedia, video, informed consent, research ethics

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Introduction

Clinical researchers rely on the informed consent process to demonstrate respect for the autonomy of research participants. Central to this process is the assumption that research participants understand the nature, risks, benefits, and design of the study at the time they agree to participate.[1–4] Typical efforts to achieve informed consent focus on the provision of information to prospective research participants, but evidence that participants actually comprehend the disclosed information is often absent,[5,6] nor is it clear what degree of comprehension is needed to establish that a participant's consent is truly "informed." A growing body of evidence reveals that many participants do not understand the studies they join;[7–11] for example, one review found that study participants understood the concept of randomization only 50% of the time.[12] Not only does this evidence demonstrate that informed consent could be significantly improved but misunderstanding of a study's goals and processes may also result in lower participation rates.[13,14]

The growth of research on medical practices embedded within learning health care systems, which compares commonly used interventions rather than new interventions, further complicates the informed consent process.[15] Prior work in this area has revealed widespread misconceptions and confusions about this kind of research—for example, patients' beliefs that doctors always know which of several accepted medications is best or that research always includes a placebo control, as well as confusion about the goals of research versus clinical care.[16,17] Introducing prospective participants to the concept of research on medical practices may therefore be especially challenging, as it contradicts common assumptions about medical expertise and how research studies work.

There have been a number of efforts to improve informed consent in clinical research settings using multimedia informational aids. These multimedia aids sometimes include the use of an audio component and/or a character-driven story or narrative, among other enhanced features. However, there is no clear standard for how much of an improvement in understanding is needed to justify the cost of developing a multimedia aid, and reviews of the literature have shown these efforts to have mixed results.[18,19] In some studies, multimedia aids have improved participant understanding,[20,21] while others have shown no significant improvement in knowledge despite participants' reports that they found them worthwhile.[22] None of these studies have addressed understanding of research on medical practices specifically.

Our earlier work has suggested that patients perceive character-driven animated videos with an audio component to be helpful in learning about these concepts.[16,23,24] Here, we present results from a randomized study comparing four content-equivalent informational aids about research on medical practices, including our original animated videos and a control arm. We hypothesized that (1) informational aids would improve participant understanding more than the no-intervention control, (2) audio aids would improve understanding more than non-audio aids, and (3) aids based on a character-driven story would improve understanding more than aids without a character-driven story. Our findings have implications for how the characteristics of different informational aids help prospective participants learn about research and can be applied to improve the process of informed consent for research on medical practices.

Methods

Study design

We conducted a self-administered, web-based survey using an experimental between-group design to compare the effects of four informational aids on respondents' understanding of core aspects of research on medical practices, including variation in medical practice and the meaning of randomization. Respondents were randomly assigned to one of four informational aid arms or a control group, which allowed us to control for potential confounders and enabled us to draw causal inferences about the effects of the informational aids on understanding.

Study sample

Survey Sampling International (SSI) made the survey available to members of its online research panel, consisting of individuals who had previously signed up to participate in survey research. Our survey was open to English-reading US adults. SSI recruited panel members by generic emailed messages several times per week. Respondents received a small incentive as part of the panel's points-based reward program. Respondents were screened to meet quota minimums matching US population characteristics by age, gender, region, ethnicity, race, education, and income according to the 2014 US Census. Eligible respondents were randomly assigned to one of the five study arms. We used sequential enrollment until 300 respondents had completed each arm. We determined sample size based on power calculations assuming t-tests with power = .80 to detect a difference in proportion of knowledge scores of .07 with alpha = .05. Survey administration took place between 28 October and 9 November 2015.

Survey development

We based the format of this survey on our prior survey of patients' attitudes about research on medical

practices.[23,24] We followed the tailored design method for web-based surveys and adhered to basic principles of classic measurement, including multi-item operationalization, to guide question development and structure.[25,26]

We established face and content validity of the survey questions through expert review and cognitive interviews with prospective study participants. SSI panel members completed the survey in a mock-up of its online format while simultaneously explaining their answers via telephone to a study-team interviewer, who used a combination of the think-aloud and probing methods.[27] We completed a total of three rounds of interviews with 15 interviews per round, iteratively refining survey questions and response categories as well as evaluating technical functionality.

Informational aids and development

We provided respondents in all arms, including the control, with a brief definition of research on medical practices in the introduction to the survey (Figure 1). Beyond this information, the informational aids were equivalent in content but different in delivery approach, including two with an audio component and two based on a character-driven story, as described below. The content of each of the four informational aids was split into two sections, each conveying information about core concepts in research on medical practices. The first section introduced the concept of variation in usual medical practices, using the example of different doctors prescribing different antihypertensive medications and describing the multiple factors that can influence a doctor's choice to prescribe a certain medication. The second section described two approaches to research on medical practices: medical record review and randomization. It briefly described each research method and how the method can be used to compare commonly prescribed medications. The features of each informational aid are described below. The survey instrument and all informational aids are available at https://rompethics.iths.org/study-details.

Animated videos (audio, character-driven). In a previous study,[16,23] we developed whiteboard-animated videos with Booster Shot Media, a health communications multimedia production company. Whiteboard animation is a style of video that shows a time-lapse of the process of hand-drawing illustrations on a whiteboard background. These videos presented a character-driven story of several patient–doctor interactions. The two videos were 3:20 and 3:07 min long, and respondents were required to play the entirety of each video without fast-forwarding in order to advance in the survey. Further details on the development of these videos are described elsewhere.[16,23]

Slideshows with voice-over (audio, not character-driven). We developed our slideshows with voice-over by beginning with the script from the animated videos. We removed the character-driven elements from the script but otherwise maintained the factual content. We developed slides to highlight the key points from the script using Microsoft PowerPoint, including stock photos from the PowerPoint clip-art gallery. The two videos were 1:11 and 2:13 min long, and respondents were required to play the entirety of each slideshow without fast-forwarding in order to advance in the survey.

Comics (no audio, character-driven). We created the comics collaboratively with Booster Shot Media. These comics used the same hand-drawn style as the animated videos but were presented as still images with word balloons and text boxes, without any audio component. We maintained the character-driven story from the animated videos, making adjustments to the script to fit the comic strip format. The two comics comprised eight and seven rows, with one to three panels per row.

Text (no audio, not character-driven). We presented a text-only version of the scripts from the slideshows with voice-over. The two sections were 171 and 314 words long.

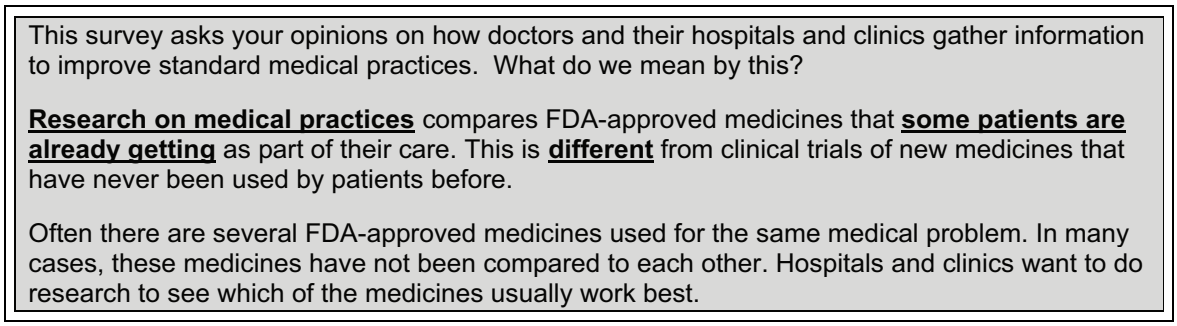

Figure 1. Definition of research on medical practices.

Measures

Our primary outcome was respondent understanding of the information about research on medical practices provided by the informational aids. A series of knowledge questions followed each section of the informational aids. Each knowledge question was presented as a statement with response options True, False, or Don't Know. We designed the knowledge questions to discriminate between basic recognition, recall, and inferential processing of information presented in all four informational aids.[28] We refined this intent through cognitive interviews. Evaluation of the discriminatory capacity of the knowledge measure is presented in the "Results" section.

In addition to the knowledge questions, the survey asked about topics related to informed consent and risk in the context of research on medical practices, as well as standard demographic questions, for a total of 39 questions. Results from those questions are not reported here. The informational aids also each had a third section about informed consent, which was followed by knowledge questions specific to consent issues; these are not included in our knowledge score because they do not address our primary outcome, knowledge of research on medical practices.

Statistical analysis

We based summary knowledge scores on the sum of the number of correct responses divided by the total number of possible correct responses (10), reported as a percentage. We used data from the 300 completed surveys per study arm for analysis, evaluating within- and across-arm differences in demographics and attrition using analysis of variance (ANOVA) and cell chi-square. We report basic descriptive statistics. We used ANOVA (generalized linear models) and Tukey's t-tests for least square difference to compare knowledge scores across arms. We performed all statistical analysis using SAS© 9.4.

Institutional review board review, informed consent, and privacy

The Stanford University, University of Washington, and University of Minnesota institutional review board (IRB) approved this study with a waiver of documentation of informed consent. SSI collected the survey data, and members of the research team only received aggregate data.

Results

Overall completion rate

Of the 2016 panel members who entered the survey portal, 1565 completed the survey and 1500 were included in final data, resulting in an overall completion rate of 74.4%. Final data excluded 65 respondents because their responses failed one or more of the following data quality parameters: (1) time to complete the survey (not counting time required for videos) was less than one-third of the median completion time or (2) there was evidence of acquiescence bias, suggested by sequential multiple-choice questions answered at the same extreme where some variation was expected. We used data from a total of 1500 completed surveys, with 300 completes per arm, for analysis.

Respondent characteristics

Despite the use of random assignment, our sample did not achieve equivalence in distribution across arms for three characteristics: Hispanic/Latino ethnicity, education, and income (Table 1). Similar distributional differences in ethnicity were also present at entry to the survey, with no discernible or interpretable pattern. No statistically significant differences in ethnicity were present in a comparison of survey completers and non-completers ($p = .8362$). Distributional differences in educational level were primarily due to a lower proportion of respondents with higher educational attainment in the animated video arm compared to the other four arms. Overall, the difference in distribution of education across survey completers and non-completers was not significant. The difference in distribution of income was significant and was also present at entry to the survey. Due to non-equivalence across arms, to isolate the effect of multimedia format on knowledge, we controlled for ethnicity, education, and income in our between-arm analysis.

Knowledge measure

The overall mean percent correct on each question across arms ranged from a low of 28.5% (Q10) to a high of 94.3% (Q1) (Online Appendix A). There was also variation between arms for most questions: the within-question variation by arm was statistically significant ($p \leq .05$) for all individual knowledge questions except Q8 ($p = .20$), providing strong support for within-arm discriminatory ability of knowledge questions (Figure 2). Furthermore, respondents who were randomized to the slideshow with voice-over arm scored higher on 6 of the 10 knowledge questions than those in all other arms.

Difference in knowledge scores across arms

The unadjusted mean knowledge scores were highest for respondents in the slideshow with voice-over arm (65.7 (standard deviation (SD) = 16.7)), followed by the animated video (62.7 (SD = 18.8)), comic (60.7

Table 1. Respondent characteristics.

	Overall	Animated videos	Slideshows with voice-over	Comics	Text	Control
Mean age (SD)	43.2 (16.5)	43.4 (16.5)	44.1 (16.8)	44.5 (16.7)	42.3 (16.5)	41.6 (15.9)
Gender (% male)	48.6	50.7	48.3	42.0	50.0	52.0
Hispanic or Latino (%)**	16.5	21.3	9.7	11.0	15.0	25.3
Race (%)						
Asian	5.0	2.7*	4.3	8.3*	6.3	3.3
Black or African American	12.0	14.7	10.3	13.0	10.3	11.7
White/Caucasian	71.0	70.0	77.0	68.3	67.3	72.3
Other	12.0	12.7	8.3*	10.3	16.0	12.7
Education*						
Less than high school	12.0	10.3	8.7*	12.0	17.7*	11.3
High school	30.0	34.7	27.0	33.7	25.3	29.3
Some college or vocational	29.0	32.3	29.7	21.3*	26.7	35.0
College graduate	19.0	16.3	21.0	19.0	20.0	18.7
Post-graduate	10.0	6.3	13.7	14.0	10.3	5.7
Income*						
Less than US$20k	17.0	18.3	10.7*	17.7	22.0*	16.3
US$20,000–US$39,999	20.9*	26.3*	23.7*	19.3	17.7	17.7
US$40,000–US$59,999	16.9	18.7	18.7	14.7	16.0	16.3
US$60,000–US$79,999	13.4	12.7	12.7	13.0	13.0	15.7
US$80,000–US$99,999	7.9	9.3	8.3	6.7	7.7	7.7
US$100,000–US$149,999	17.1*	10.7*	18.7	19.3	17.3	19.3
US$150,000 or more	6.8*	4.0*	7.3	9.3	6.3	7.0

SD: standard deviation; ANOVA: analysis of variance.
*$p < .05$; **$p < .01$, chi-square, ANOVA with multiple paired t-tests.

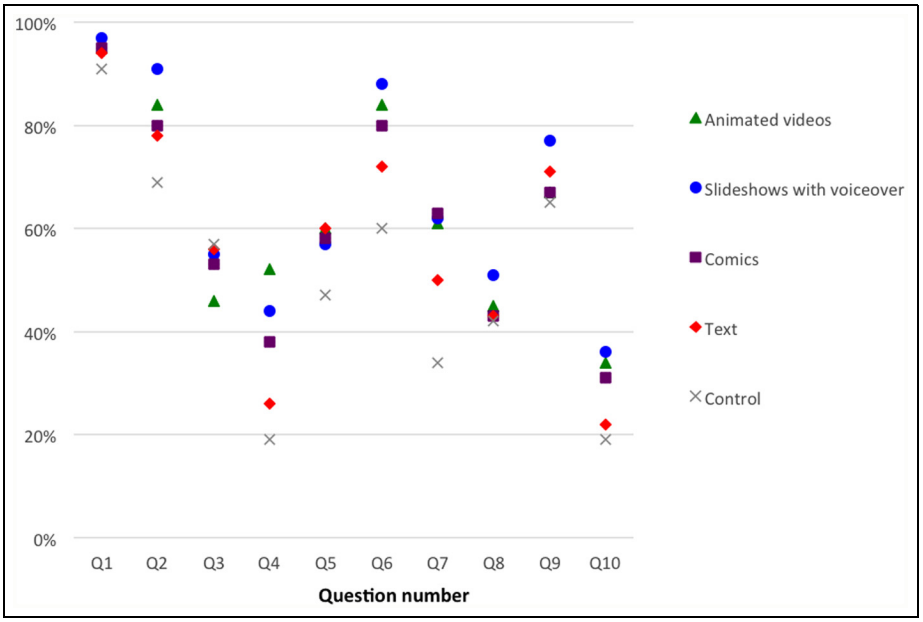

Figure 2. Individual knowledge questions: percent correct by arm.

(SD = 18.5)), text (57.2 (SD = 18.3)), and control (50.3 (SD = 16.8)) arms.

Table 2 presents the comparison and tests for difference in mean knowledge scores between arms. The statistical test used for comparison is a Tukey's t-test, comparing mean squared differences. In light of distributional differences found for ethnicity, education, and income across arms, we controlled these characteristics for the t-tests of significance. As indicated, the difference in knowledge between the control arm and each informational arm was statistically significant for all four informational aids ($p < .0001$). Differences in knowledge scores between arms were statistically significant between all arms except between the slideshows with voice-over and animated videos, and between the animated videos and comics.

Table 2. Difference in adjusted mean knowledge scores between arms.

	Animated videos	Slideshows with voice-over	Comics	Text
Slideshows with voice-over	1.6 (p = .1137)	–	–	–
Comics	1.6 (p = .1139)	3.2** (p = .0015)	–	–
Text	3.9** (p = .0001)	5.5** (p < .0001)	2.3* (p = .0215)	–
Control	8.8** (p < .0001)	10.3** (p < .0001)	7.2** (p < .0001)	4.9** (p < .0001)

Tukey's t-test standardized range (least square difference).
*p ⩽ .05; **p ⩽ .0001, controlling for ethnicity (Hispanic/Latino), education, and income.

Table 3. Comparison of adjusted mean knowledge scores between multimedia formats.

	Character-driven story	No character-driven story	Total
Audio	Animated videos	Slideshows with voice-over	Audio* 64.2
No audio	Comics	Text	No audio* 59.0
Total	Character-driven story 61.9	No character-driven story 61.3	

Tukey's t-test standardized range (least square difference).
*p < .0001, controlling for ethnicity (Hispanic/Latino), education, and income.

Difference in knowledge across multimedia format of informational aids

Knowledge scores were significantly higher for the two informational aids with an audio component (animated videos and slideshows with voice-over) than in the two without (comics and text): 64.2% versus 60.0% (p < .0001). There was no significant difference between the two informational aids with a character-driven story component (animated videos and comics) and the two without (slideshows with voice-over and text) (Table 3).

Discussion

Multimedia format

Overall, respondents who viewed either the slideshows with voice-over or the animated videos performed best on the knowledge questions. Each of these aids contained both audio and visual components: the slideshows combined a descriptive voice-over with minimal images and text in a bulleted summary format, while the animated videos used voice-over to tell the story of a series of moving cartoons. Our results accord with the cognitive theory of multimedia learning, which states that people learn best when provided with limited but cohesive information simultaneously through aural and visual channels[29–31] and has been supported in the empirical literature.[32,33] The slideshows with voice-over may also have benefited from being relatively short and simple, allowing for low cognitive load and easy information processing,[30,34] and from containing some, but not too much, text.[35] Moreover, these results align with the informal feedback we received throughout our cognitive interview process from interviewees who stated that they preferred getting information through multiple channels. However, while we found a statistically significant difference between aids with and without an audio component, our results do not address the value of investing in multimedia aids to gain a relatively small increase in understanding, which is a trade-off that may differ depending on the specific study and the content of the multimedia aid. Nonetheless, to the extent that increased understanding is indicative of a more robust informed consent process, the ability of our multimedia aids to improve prospective participants' understanding suggests that there is room to improve informed consent.

Of our four informational aids, respondents randomized to the text-only approach performed worst on the knowledge questions; this is an important finding given that the text was identical to the narration in the slideshows with voice-over. Notably, this arm most closely approximates the traditional approach to informed consent for research, which suggests there is room for improving the consent process using one or more of our multimedia approaches. In practice, of course, traditional written informed consent is intended to be accompanied by a discussion, and in fact discussions have been shown to be one of the most effective ways of improving participant understanding.[18,19,36] Our study did not include discussion in any arm, but presumably a discussion could supplement, rather than be replaced by, any of the informational aids in our study.[37] Indeed, our results suggest that moving toward simple multimedia approaches to

informed consent can help participants understand complex concepts, presented in a consistent and standardized manner, and facilitate more informed discussions with members of the research team. Moreover, this can be done at relatively low cost; our slideshows with voice-over were filmed entirely in-house with simple recording software. However, this does not take into account the effort and resources that we invested to develop effective language and visual metaphors when initially developing the animated videos, which we later used to create the slideshows with voice-over.

Difficult concepts

Although some questions seemed to be effectively taught by at least some of our informational aids, others performed poorly on all arms. Indeed, even in the highest-scoring arm, respondents answered on average only two-thirds of the questions correctly, which aligns with similarly low knowledge scores found in reviews of the literature on informed consent for research participation.[18,19] This highlights the question of how much understanding is necessary for consent to be truly "informed." While the Common Rule identifies required elements that must be disclosed during the informed consent process (45 CFR § 46.116), there is no standard for how well a participant must understand that information prior to consenting. Some have argued that disclosure alone, without comprehension, is insufficient for a truly "informed" consent,[38,39] but alternative models do not specify what or how much participants must understand.

Our findings do not answer this question but do identify certain pitfalls to understanding that arose in the context of our study. First, we created our original animated videos for use in a separate study[16,23] and therefore not all topics received equal attention, likely resulting in some topics being more effectively taught than others.

Second, some of our knowledge questions may have resulted in lower scores because they contradicted respondents' basic assumptions about research. Prior qualitative studies have identified widespread misunderstanding about research on medical practices, particularly when participants compare it to the well-known archetype of a placebo-controlled clinical trial of new treatments.[16,17] Our study suggests that at least some aspects of research on medical practices are difficult for people to understand without explicit and direct teaching. This is an important point for researchers who are interested in developing informed consent materials about topics that are unfamiliar to prospective participants, and it highlights the need for a clear approach to teaching key learning goals. Strategies could draw on those described in the educational psychology literature such as signaling important information, using visuals to highlight difficult concepts, and actively involving participants.[30,34] Furthermore, participant understanding can be evaluated and the efficacy of multimedia aids strengthened with a robust needs assessment and user testing process.[40]

Character-driven story component

There was no significant difference between our two informational aids that were based on a character-driven story (animated videos and comics) and those that were not (slideshows with voice-over and text). For the linear transmission of information from "teacher" to "learner," more didactic pedagogical techniques seem to perform better. However, this does not preclude the possibility that the narrative story approach that characterizes comics and animations may be effective in a different setting. Narrative story–based informational aids have been shown to be effective for targeted communications to specific subpopulations—for example, immigrants and refugees,[41] low-literacy communities,[42] and the mentally ill.[43,44] Comics and animation may also be useful for clinical purposes that are outside the scope of our study, such as encouraging changes in health behaviors,[45–48] reducing health disparities using culturally targeted informational aids,[49] or teaching information over time.[46] Because the comic medium requires a collaboration with readers to construct meaning, it is essentially non-hierarchical and as such may not readily lend itself to top-down approaches to delivering information.

Moreover, our animated videos were the first of our informational aids to be created and were initially developed for another study;[16,23] in order to maintain content equivalence, the language and structure of these videos was the baseline for our other informational aids. Therefore, the benefits of our investment in producing these videos are likely understated as they included not only the character-driven story component but also simplification of language and development of visuals and metaphors. Indeed, shortening consent forms and making them more comprehensible has consistently proven to improve participant understanding.[19]

Limitations

There were differential completion rates across arms. However, the intent of our study was not to achieve external validity, but rather to achieve internal validity. Our informational aids were experiential interventions that were designed and expected to include differential respondent burden. We evaluated non-response patterns and confirmed that the non-response conformed to this assumption of differential respondent burden. Therefore, we used only data from the 300 respondents per arm who completed the survey. We also evaluated

other plausible approaches and subsequent assumptions about non-response, which confirmed the robustness of our statistical results.

Furthermore, our sample of SSI panel members, which consisted of individuals with Internet access and an interest in participating in surveys, is not generalizable to the greater US population. However, our randomized design allowed us to achieve internal validity and identify intervention-specific differences between groups.

An additional limitation is that our survey presented a hypothetical scenario rather than an actual consent process and, as noted in the "Discussion" section, did not include an opportunity to discuss the study with a researcher. While the scores on our knowledge measure revealed significant differences in understanding between arms, these scores alone are insufficient to measure the adequacy and quality of informed consent. Further study is needed to understand how these informational aids perform in the context of an actual clinical trial.

Conclusion and future directions

This study shows that, of four content-equivalent approaches to providing information about research on medical practices, our text-only informational aid was least effective at educating respondents, despite being the closest approximation to the way that research consent is typically provided in practice. Pragmatic trials in which prospective participants are randomized between consent approaches in the setting of an actual trial are needed to build on our results. In the meantime, our results show that short slideshows or videos that combine voice-over with images and visual content reinforcement can be a more effective way of educating prospective study participants. The slideshow medium is relatively simple to produce, and both slideshows and videos are adaptable to a range of technologies, such as mobile phones and websites, that can improve accessibility and engagement for many prospective participants. However, even with multimedia informational aids, overcoming the knowledge deficit about research on medical practices is a challenging task and will require concerted efforts if researchers are to enable prospective participants to give truly "informed" consent.

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References

1. Beauchamp TL and Childress JF. *Principles of biomedical ethics*. 6th ed. New York: Oxford University Press, 2008.
2. World Medical Association. Declaration of Helsinki: ethical principles for medical research involving human subjects, 2008, http://www.wma.net/en/30publications/10policies/b3/17c.pdf (accessed 15 January 2016).
3. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Belmont report: ethical principles and guidelines for the protection of human subjects research, 1979, http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html (accessed 15 January 2016).
4. *Trials of war criminals before the Nuremberg military tribunals under Control Council Law No. 10*, vol. 2. Washington, DC: US Government Printing Office, 1949, pp. 181–182.
5. Tait AR and Voepel-Lewis T. Digital media: a new approach for informed consent? *JAMA* 2015; 313: 463–464.
6. Schreiner MS. Can we keep it simple? *JAMA Pediatri* 2013; 167: 603–605.
7. Cohn E and Larson E. Improving participant comprehension in the informed consent process. *J Nurs Scholarsh* 2007; 39: 273–280.
8. Sugarman J, Lavori PW, Boeger M, et al. Evaluating the quality of informed consent. *Clin Trials* 2005; 2: 34–41.
9. Agre P, Campbell FA, Goldman BD, et al. Improving informed consent: the medium is not the message. *IRB* 2003; 25; S11–S19.
10. Joffe S, Cook EF, Cleary PD, et al. Quality of informed consent in cancer clinical trials: a cross-sectional survey. *Lancet* 2001; 358: 1772–1777.
11. Sugarman J, McCrory DC and Hubal RC. Getting meaningful informed consent from older adults: a structured literature review of empirical research. *J Am Geriatr Soc* 1998; 46: 517–524.
12. Falagas ME, Korbila IP, Giannopoulou KP, et al. Informed consent: how much and what do patients understand? *Am J Surg* 2009; 198: 420–435.
13. Jenkins V and Fallowfield L. Reasons for accepting or declining to participate in randomized clinical trials for cancer therapy. *Br J Cancer* 2000; 82: 1783–1788.
14. Sutherland HJ, Lockwood GA and Till JE. Are we getting informed consent from patients with cancer? *J R Soc Med* 1990; 83: 439–443.
15. Wilfond BS and Magnus DC. The potential harms and benefits from research on medical practices. *Hastings Cent Rep* 2015; 45: 5–6.
16. Kelley M, James C, Kraft SA, et al. Patient perspectives on the learning health system: the importance of trust and shared decision making. *Am J Bioeth* 2015; 15: 4–17.

17. Weinfurt KP, Bollinger JM, Brelsford KM, et al. Patients' views concerning research on medical practices: implications for consent. *AJOB Empir Bioeth* 2016; 7: 76–91.
18. Nishimura A, Carey J, Erwin PJ, et al. Improving understanding in the research informed consent process: a systematic review of 54 interventions tested in randomized control trials. *BMC Med Ethics* 2013; 14: 28.
19. Flory J and Emanuel E. Interventions to improve research participants' understanding in informed consent for research. *JAMA* 2004; 292: 1593–1601.
20. Karunaratne AS, Korenman SG, Thomas SL, et al. Improving communication when seeking informed consent: a randomised controlled study of a computer-based method for providing information to prospective clinical trial participants. *Med J Aust* 2010; 192: 388–392.
21. Hutchison C, Cowan C, McMahon T, et al. A randomised controlled study of an audiovisual patient information intervention on informed consent and recruitment to cancer clinical trials. *Br J Cancer* 2007; 97: 705–711.
22. Hoffner B, Bauer-Wu S, Hitchcock-Bryan S, et al. Entering a clinical trial: is it right for you? A randomized study of the clinical trials video and its impact on the informed consent process. *Cancer* 2012; 118: 1877–1883.
23. Cho MK, Magnus D, Constantine M, et al. Attitudes toward risk and informed consent for research on medical practices: a cross-sectional survey. *Ann Intern Med* 2015; 162: 690–696.
24. Kraft SA, Cho MK, Constantine M, et al. A comparison of institutional review board and patient views on consent for research on medical practices. *Clin Trials* 2016. Epub ahead of print 1 June 2016. DOI: 10.1177/1740774516648907.
25. Dillman DA, Smyth JD and Christian LM. *Internet, mail, and mixed-mode surveys: the tailored design method*. Hoboken, NJ: John Wiley & Sons, 2009.
26. Nunnally JC and Bernstein IH. *Psychometric theory*. 3rd ed. New York: McGraw-Hill, Inc., 1994.
27. Collins D. Pretesting survey instruments: an overview of cognitive methods. *Qual Life Res* 2003; 12: 229–238.
28. Nadeau R and Niemi RG. Educated guesses: the process of answering factual knowledge questions in surveys. *Publ Opin Q* 1995; 59: 323–346.
29. Mayer RE. *Multimedia learning*. 2nd ed. New York: Cambridge University Press, 2009.
30. Mayer RE and Moreno R. Nine ways to reduce cognitive load in multimedia learning. *Educ Psychol* 2003; 38: 43–52.
31. Mayer RE and Moreno R. Animation as an aid to multimedia learning. *Educ Psychol Rev* 2002; 14: 87–99.
32. Houts PS, Doak CC, Doak LG, et al. The role of pictures in improving health communication: a review of research on attention, comprehension, recall, and adherence. *Patient Educ Couns* 2006; 61: 173–190.
33. Moreno R and Mayer RE. Cognitive principles of multimedia learning: the role of modality and contiguity. *J Educ Psychol* 1999; 91: 358–368.
34. Plass JL, Homer BD and Hayward EO. Design factors for educationally effective animations and simulations. *J Comput High Educ* 2009; 21: 31–61.
35. Shneerson C, Windle R and Cox K. Innovating information-delivery for potential clinical trials participants. What do patients want from multi-media resources? *Patient Educ Couns* 2013; 90: 111–117.
36. Kass NE, Taylor HA, Ali J, et al. A pilot study of simple interventions to improve informed consent in clinical research: feasibility, approach, and results. *Clin Trials* 2015; 12: 54–66.
37. Henry J, Palmer BW, Palinkas L, et al. Reformed consent: adapting to new media and research participant preferences. *IRB* 2009; 31: 1–8.
38. Faden RR and Beauchamp TL. *A history and theory of informed consent*. New York: Oxford University Press, 1986.
39. Manson NC and O'Neill O. *Rethinking informed consent in bioethics*. New York: Cambridge University Press, 2007.
40. Aronson ID, Marsch LA and Acosta MC. Using findings in multimedia learning to inform technology-based behavioral health interventions. *Transl Behav Med* 2013; 3: 234–243.
41. Wieland ML, Nelson J, Palmer T, et al. Evaluation of a tuberculosis education video among immigrants and refugees at an adult education center: a community-based participatory approach. *J Health Commun* 2013; 18: 343–353.
42. Afolabi MO, Bojang K, D'Alessandro U, et al. Multimedia informed consent tool for a low literacy African research population: development and pilot-testing. *J Clin Res Bioeth* 2014; 5: 178.
43. Harmell AL, Palmer BW and Jeste DV. Preliminary study of a web-based tool for enhancing the informed consent process in schizophrenia research. *Schizophr Res* 2012; 141: 247–250.
44. Dunn LB, Lindamer LA, Palmer BW, et al. Enhancing comprehension of consent for research in older patients with psychosis: a randomized study of a novel consent procedure. *Am J Psychiatry* 2001; 158: 1911–1913.
45. Moran MB, Murphy ST, Frank LB, et al. The ability of narrative communication to address health-related social norms. *Int Rev Soc Res* 2013; 3: 131–149.
46. Kreuter MW, Homes K, Alcaraz K, et al. Comparing narrative and informational videos to increase mammography in low-income African American women. *Patient Educ Couns* 2010; 81: S6–S14.
47. Wise M, Han JY, Shaw B, et al. Effects of using online narrative and didactic information on healthcare participation for breast cancer patients. *Patient Educ Couns* 2008; 70: 348–356.
48. Hinyard LJ and Kreuter MW. Using narrative communication as a tool for health behavior change: a conceptual, theoretical, and empirical overview. *Health Educ Behav* 2007; 34: 777–792.
49. Murphy ST, Frank LB, Chatterjee JS, et al. Comparing the relative efficacy of narrative vs nonnarrative health messages in reducing health disparities using a randomized trial. *Am J Public Health* 2015; 105: 2117–2123.

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Informed Consent in Pediatric Otolaryngology: What Risks and Benefits Do Parents Recall?

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Abstract

Objective. To evaluate parental recall of surgical risks and benefits in pediatric otolaryngology and to assess for factors that may influence recall.

Study Design. Prospective cohort study.

Setting. Academic pediatric otolaryngology clinic.

Subjects and Methods. Eighty-four parents of children <6 years of age who underwent consultation for adeno/tonsillectomy and/or tympanostomy tube insertion were prospectively enrolled. Consultation visits were video recorded and the benefits and risks of surgery documented. Two weeks following the consultation, parents were contacted for assessment of recall of information discussed during the consultation.

Results. Overall, parents recalled only one-third of the risks of surgery mentioned by the surgeons. Parents were significantly more likely to recall the benefits of surgery as opposed to the risks ($P < .001$). Nine parents (10.7%) reported that no benefits were discussed during the consultation, and 10 (11.9%) reported no mention of any risks. Inconsistencies were present in which risks and benefits were mentioned by the providers. Parents who decided to proceed with surgery (58.3%) were significantly less likely to recall the surgical risks than those who did not ($P < .001$). The specific surgeon involved, the number of caregivers present, parental education level, and prior surgical history did not influence recall.

Conclusion. Parental recall of benefits and risks associated with common pediatric otolaryngology procedures was poor. This information is important because a low rate of recall may influence parents' perspectives of the procedure and could alter their decision-making processes or expectations. Methods to improve parental recall should be further studied.

Keywords

informed consent, complications, risks, adenotonsillectomy, tympanostomy tube insertion

An important aspect of the informed consent process is to ensure that the benefits and risks of a surgical procedure are well understood by the patients and their family members. This is particularly important in pediatric otolaryngology, as many operations in this subspecialty are elective, and the benefits are not always clear or guaranteed. Even the practice guidelines for a number of pediatric otolaryngology conditions recognize the lack of unequivocal data to support the option of some operations.[1,2] For example, a Cochrane review assessing the effectiveness of tonsillectomy in chronic/recurrent acute tonsillitis stated, ''It is clear that some children get better without any surgery. . . . The impact of surgery, as demonstrated in the included studies, is modest.''[3]

In light of the unclear benefits in some circumstances, the decision to proceed with surgery should be carefully considered by parents. Moreover, although some of the procedures in pediatric otolaryngology could be considered ''minor,'' they are not without risks. Unfortunately, research to date has shown that many patients have poor understanding of their medical conditions and treatments[4-6] and that recall of the information shared during consultation visits is inadequate.[5-9] Even after undergoing a detailed informed consent process, patients and family members have demonstrated poor recall of the risks discussed during surgical consultations.[9-13] Thus, a need exists to better understand

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the informed consent process in pediatric otolaryngology and determine what factors may influence recall of the information discussed during surgical consultations.

The primary objective of this study was to evaluate parental recall of surgical risks and benefits associated with common operations in pediatric otolaryngology. The secondary objective was to assess for factors that may influence recall. In particular, assessment was performed of whether the context of the discussion (eg, other people in the room), prior surgical history, parental education level, or treatment choice (watchful waiting or surgery) would influence the rate of recall.

Materials and Methods

This study was part of a larger mixed-methods research project assessing shared decision making in pediatric otolaryngology.[6] Local Institutional Review Board (IWK Health Centre) approval was obtained.

Participants

Participants were recruited from a tertiary-level pediatric hospital in eastern Canada. Consecutive parents were prospectively enrolled if they had children <6 years of age who were being evaluated for 1 of 4 conditions that may be treated with surgery (**Table 1**). Exclusion criteria included inability to speak English and/or the lack of decision-making authority on behalf of the child. Clinic nurses informed eligible parents of the study in the waiting room before the consultation, and interested parents met with a research assistant who described the study in detail and obtained consent.

Procedure

If surgery was considered to be a treatment option, health care providers discussed the risks and benefits of the surgical procedure during the consultation. After the discussion, the surgeon obtained consent for surgery, which was then followed by a short visit with the clinic nurse who covered information pertaining to preoperative details (eg, where to go for surgery, when to stop eating/drinking) and postoperative care (eg, pain management/analgesic use). All visits were video recorded with dual wall-mounted cameras in the consultation room (one camera captured a full room view and another captured the health care providers' faces).

Two weeks following the consultation, participants completed a telephone interview with the research assistance consisting of open- and closed-ended questions regarding their recall of the information discussed during the visit. Specifically, parents were encouraged to recall all risks and benefits of the surgery discussed during the consultation. Although parents were aware that this telephone call would occur (''cold calling'' was not allowed according to the Institutional Review Board), they were not made aware of the purpose. Each interview was transcribed; transcriptions of these conversations were later checked for accuracy.

Table 1. Baseline Information of Participants.

	n	%
Age of child, mo		
≤12	8	9.5
13-24	28	33.3
25-36	20	23.8
37-48	16	19.0
49-60	12	14.3
Martial status		
Married	59	70.2
Common law	12	14.3
Single	11	13.1
Divorced/separated	2	2.4
Ethnicity		
Caucasian	75	89.3
African Canadian	4	4.8
Asian Canadian	2	2.4
First Nations/Native	1	1.2
Middle Eastern	1	1.2
Other	1	1.2
Education level		
Completed high school or less	19	22.6
Community college	26	31.0
Undergraduate university	20	23.8
Graduate or postgraduate training	19	22.6
Conditions/surgery[a]		
Chronic/recurrent tonsillitis/ adenotonsillectomy	7	8.3
Obstructive sleep apnea/ adenotonsillectomy	31	36.9
Chronic/recurrent acute otitis media/ear tubes	55	65.5
Chronic/recurrent nasal obstruction/ adenoidectomy	7	8.3
Surgical decision		
Surgery	49	58.3
Watchful waiting	35	41.7

[a]Sixteen children (19.0%) had >1 of these conditions.

Measures

Demographic questionnaire. Relevant questions included relationship to child, parent and child age, parent marital status, education level, ethnicity, household income, presence of siblings, and previous surgical history of the patient and/or sibling.

Risks and benefits coding. Video recordings of the consultation visits and transcripts of the follow-up phone calls were coded for mention of the risks and benefits of surgery. Coding sheets were created for each operation based on review of the literature (see Appendix 1 at www.otojournal.org/supplemental).

Data Analysis

Data was managed and analyzed with SPSS 17 for Windows (IBM Corp, Armonk, New York). Descriptive statistics were used to summarize demographic characteristics and the risks and benefits mentioned and recalled. Nonparametric tests (results were not normally distributed)—including Wilcoxon signed ranks, Kruskal-Wallis, and Mann-Whitney *U* tests—were used depending on how many independent groups were included in the analyses to assess differences in recall across the various identified predictors. Sample size was assessed through analysis with the independent variable consisting of the most groups (ie, the most stringent of the analyses conducted)—specifically, 3 degrees of freedom, power of 0.95, α set at 0.05, and a medium estimated effect size of 0.5 indicated that the sample required at least 69 participants.

Results

Participants

Over a 1-year period, 131 parents were enrolled in this study, of whom 42 did not complete the follow-up interview and 5 video recordings were unable to be coded due to technical problems. This resulted in a final sample of 84 participants. No significant differences were found in any of the demographic factors between those who completed the study and those who did not complete the study.

The majority of participants were mothers (81.0%) between the ages of 19 and 44 years (mean ± SD, 33.23 ± 5.07); fathers (19.0%) were between 19 and 51 years old (35.25 ± 5.91). The mean age of children was 33.56 ± 15.20 months (range, 9-60), and about half (59.5%) were boys. Most parents were married (70.2%) and Caucasian (89.3%). Seventeen (20.2%) participant children had undergone surgery, and 13 (15.5%) parents reported that other children in the family had previous surgery. Of the 84 families, 26 (31.0%) had 2 parents present at the consultation visit. A summary of the demographic details is presented in **Table 1**.

Three fellowship-trained pediatric otolaryngologists, who ranged in age from 37 to 47 years, conducted the consultation appointments. Two were men, 1 was a woman, and all were in a salaried academic practice. All 3 completed their otolaryngology–head and neck surgery residency in Canada, with fellowship training in the United States (n = 2) and Australia (n = 1). Medical trainees were present in 33 video recordings (39.3%), and 1 of 2 female nurses was involved in 49 (58%) visits.

Risks and Benefits Mentioned

The specific benefits and risks mentioned during the consultation and those recalled by the participants for adenotonsillectomy and tympanostomy tube insertion are shown in **Tables 2 and 3**. The rare benefits and risks documented in the literature (eg, death from bleeding) but not mentioned during the consultations are not included in the tables.

Across all procedures, the most common benefits of surgery mentioned were the reduced number of infections (otitis media or tonsillitis, 37%) and the reduced number of oral antibiotics required postsurgery (18%). Specific to adenotonsillectomy, better breathing (21%) and improved sleep (18%) were most commonly mentioned by the surgeons. Most common risks mentioned during the consultation were risk of general anesthesia (42%) and readmission (36%). For adeno/tonsillectomy, bleeding/hemorrhage (43%) and discomfort/pain (39%) were most commonly mentioned.

Table 2. Risks and Benefits Mentioned and Recalled Associated with Adenotonsillectomy.

	Mentioned during Consultation	Mentioned at 2-wk Follow-up Interview
Benefits of surgery		
Better breathing	18	16
Growth spurt	6	5
Improve attention issues[a]	1	1
Improved cognitive/learning[a]	1	0
Fewer colds	1	0
Reduced nasal discharge/secretion[b]	4	2
Improved eating/appetite[c]	2	6
Reduced apneas[a]	2	1
Improved sleep	15	9
Improved daytime energy[a]	1	0
Reduced number of infections[a]	31	27
Reduced number of oral antibiotics[a]	15	2
Reduced days of daycare/school/ work missed[a]	1	0
Improved speech/voice[a,c]	1	2
Improved quality of life[a]	7	7
Prevents long term comorbidities[a]	1	0
Risks of surgery		
General anesthesia	35	17
Bleeding/hemorrhage	36	26
Bad breath	14	1
Discomfort/pain	33	2
Vomiting/nausea[a]	5	0
Fever	6	0
Time off from school and activities	18	5
Regrowth of adenoids over time[b]	4	1
Dehydration	17	0
Reduce oral intake[a]	9	0
Readmission[a]	30	11
Need for blood transfusion[a]	14	0

[a]Tonsillectomy only.
[b]Adenoidectomy only.
[c]Gray shading indicates that risk or benefit was mentioned by more parents than those who were told in the consultation visit about it.

Risk and Benefits Recalled

The most commonly recalled benefits were reduced infections (32%) and better breathing (19%). The most commonly recalled risks were risk of general anesthesia (20%) and bleeding/hemorrhage (31%). Specific to tympanostomy

Table 3. Risks and Benefits Mentioned and Recalled Associated with Tympanostomy Tube Insertion.

	Mentioned during Consultation	Mentioned at 2-wk Follow-up Interview
Benefits of surgery		
Reduced number of infections	31	27
Reduced number of oral antibiotics	15	2
Reduced days of day care/ school/work missed	1	0
Improved quality of life	7	7
Temporarily improved hearing	14	7
Improved speech development (young children)	5	5
Easier to treat future acute otitis media episodes	12	8
Consequences of surgery		
General anesthesia	35	17
Readmission	30	11
Tympanic membrane perforation	27	14
Otorrhea	26	4
Water precautions	26	2
Premature tube extrusion[a]	2	5
Retained tube	3	1
Tube blockage	2	0
Myringosclerosis or tympanosclerosis[a]	0	1

[a]Gray shading indicates that consequence was mentioned by more parents than those who were told in the consultation visit about it.

tube insertion, the risk of tympanic membrane perforation (17%) was most commonly recalled. Thirty-six parents recalled as many benefits as were mentioned during the visit, and 21 parents recalled as many risks as were mentioned during the child's consultation. Overall, parents recalled one-third the risks of surgery and half the benefits of surgery mentioned by the surgeons.

Nine (10.7%) parents reported that no benefits were discussed during the consultation; the video analysis showed that 1 of these parents had 2 benefits mentioned during consultation. Ten (11.9%) parents reported that no risks were mentioned; however, in 5 consultations, risks were mentioned. Two (2.4%) parents reported that benefits were reviewed during the appointment, but they could not recall the content of those benefits; 2 (2.4%) parents reported that risks were mentioned but could not specify those risks. During 4 visits (4.8%), surgeons used nonspecific language when discussing the risks and benefits (eg, ''Something bad may happen''), and during 1 visit, the surgeon did not explicitly state how surgery would improve the child's symptoms (eg, ''These things may all get better with the surgery'').

Overall, the participants recalled a higher proportion of benefits than risks ($Z = -4.25$, $P < .001$). When participants were divided into those who decided to proceed with surgery (58.3%) versus those who chose watchful waiting (41.7%), parents in the latter group were significantly more likely to recall the risks of surgery (median = 1, SD = 1.05) than were those who chose surgery (median = 0, SD = 0.83; $Z = -3.75$, $P < .001$). No significant differences were found in the recall of risks and benefits of surgery at the 2-week follow-up phone call, in terms of the following: consulting surgeon, type of surgery, presence of 1 or 2 caregivers during the visit, child's previous surgical experience, other children's previous surgical experience in the family, and parental education level (**Tables 4** and **5**).

Discussion

The overall recall rate for risks and benefits of surgery was low. Parents remembered about half the benefits of surgery and only one-third the risks mentioned during the consultation. As well, those parents who elected to monitor their children rather than proceed with surgery were significantly more likely to recall the risks of surgery. Selective recall or confirmation bias (tendency to prefer and recall information that will confirm a person's beliefs/hypotheses) may have played a role, as parents may selectively recall the advantages of surgical treatment because they are hopeful that it will alleviate their children's symptoms.

The risk recall rate found in this study was similar to that reported in other studies in surgical settings.[5-9,12-14] A study in pediatric surgery, for example, found that >20% of parents did not recall any risks being discussed, and <40% recalled the commonly mentioned risks, such as bleeding and infection.[13] However, no studies to date have used objective assessment of the consultation interaction and recall of the information discussed during the visit. Specifically, previous research has relied on what the physician remembered stating, sometimes along with an educational aid, as the information given during the consultation and relating it to what was recalled by patients and family members.[5,7-12,14] In our study, we used video recordings of the physician-parent interaction to determine what specific risks and benefits were discussed during the visit. Providers will have different styles of interaction and deliver different amounts of information; thus, it is important to objectively assess exactly what information was shared during the consultation.

Although there are a number of theoretical risks for any surgery, some are incredibly rare and may not be mentioned during the consultation. An unexpected finding in this study was that several rare risks and benefits were either not mentioned or mentioned rarely. Furthermore, some risks and benefits were inconsistently mentioned across providers, even within each provider. Some benefits of surgery documented in the literature but not mentioned included improved school performance[15] and alleviation of headaches[16] for children with sleep-disordered breathing. Some risks of surgery found in the literature but not mentioned by

Table 4. Benefits of Surgery Mentioned by Parents in Relation to Demographic and Consultation Factors.

	Median Scores	Interquartile Range	Mean Rank	Mann-Whitney *U* (*Z*) or Kruskal-Wallis (χ^2)
No. of caregivers at consultation				$Z = -0.89$, $P = .37$
1	1.00	0.50-1.00	38.86	
2	0.67	0.33-1.00	34.30	
Index child previous surgery				$Z = -1.43$, $P = .15$
Yes	0.50	0.00-1.00	30.87	
No	1.00	0.50-1.00	39.19	
Any child previous surgery				$Z = -0.69$, $P = .49$
Yes	1.00	0.56-1.00	31.50	
No	1.00	0.50-1.00	27.85	
Consulting surgeon				$\chi^2 = 0.58$, $P = .75$
1	1.00	0.00-1.00	34.93	
2	1.00	0.50-1.00	38.06	
3	1.00	0.50-1.00	39.58	
Education level				$\chi^2 = 2.74$, $P = .43$
High school or less	1.00	0.50-1.00	38.87	
Community college	1.00	0.50-1.00	42.31	
Undergraduate	0.83	0.31-1.00	33.33	
Graduate or higher	0.67	0.33-1.00	33.91	
Surgery type				$Z = -0.74$, $P = .54$
Adeno/tonsillectomy	1.00	0.50-1.00	38.06	
Ear tubes	1.00	0.31-1.00	33.93	

Table 5. Risks of Surgery Mentioned by Parents in Relation to Demographic and Consultation Factors.

	Median Scores	Interquartile Range	Mean Rank	Mann-Whitney *U* (*Z*) or Kruskal-Wallis (χ^2)
No. of caregivers at consultation				$Z = -1.44$, $P = .15$
1	0.33	0.20-0.67	39.96	
2	0.55	0.20-1.00	48.17	
Index child previous surgery				$Z = -1.09$, $P = .28$
Yes	0.25	0.18-0.58	36.82	
No	0.40	0.20-1.00	43.94	
Any child previous surgery				$Z = -0.87$, $P = .38$
Yes	0.33	0.16-0.75	27.69	
No	0.40	0.20-1.00	32.51	
Consulting surgeon				$\chi^2 = 0.90$, $P = .64$
1	0.33	0.18-0.67	39.86	
2	0.33	0.16-1.00	41.95	
3	0.37	0.20-1.00	46.43	
Education level				$\chi^2 = 1.45$, $P = .69$
High school or less	0.33	0.11-1.00	41.39	
Community college	0.40	0.20-0.75	43.08	
Undergraduate	0.42	0.25-1.00	47.10	
Graduate or higher	0.33	0.13-0.67	37.97	
Surgery type				$Z = -0.85$, $P = .34$
Adeno/tonsillectomy	1.00	0.18-1.00	36.16	
Ear tubes	1.00	0.11-1.00	40.93	

the surgeons included death and tongue/uvular swelling.[17] The reason for which specific risks and benefits were mentioned during consultation is unclear; however, it likely depends on the experience (eg, recent occurrence of a rare complication) and training of the surgeon. As well, some of the benefits of surgery could have been considered to be intuitive by the provider (eg, ear tubes will improve ear infections). Although the inconsistencies among surgeons can be concerning, each interaction between the surgeon and parent is unique. Thus, it is incumbent on the surgeon to provide appropriate amount of information for that specific interaction. For instance, if the surgeon gets an impression that a parent is anxious and does not want to hear the details about surgery, then perhaps only the essential information should be shared. However, if a parent is asking many questions and is being inquisitive, the surgeon may provide more details.

Surgeons must make decisions about what risks and benefits to discuss with their patients. However, mentioning all possible risks of surgical procedures is not practical or likely beneficial.[18] This concept of the ethics of ''everyday clinical'' practice—which changes with each clinical encounter and relationship with patients—is known as *microethics*.[19] Microethics is an important concept not traditionally discussed or taught in medical schools, as most ethical training involves extreme or unusual cases (eg, Jehovah's witness patient refusing blood transfusion). However, microethics deals with the constant small ethical decisions that occur every day in the clinical setting, such as questioning which risks and benefits should be discussed with the patient/family members.[19] Further studies in this area are needed to help clinicians fully recognize that microethical decisions are important and relevant to everyday practice.

A number of risks and benefits recalled by parents were not actually mentioned by the providers during the visit. In these cases, it may be that parents obtained supplementary information about the treatment options from sources outside the surgeon. In particular, they may seek advice or information from family members, other parents, their primary care providers, or the Internet.[6,20,21] All together, the implication is that parents are actively seeking more information beyond what was provided during consultation. Therefore, health care providers should consider developing educational tools with accurate information that can be provided for parents to review at home. As well, surgeons should emphasize the important and relatively common risks (eg, bleeding posttonsillectomy) so that parents are better able to retain information and handle the potential complications.

Several demographic and contextual factors were assessed in this study, and none of them (except the decision on whether to proceed with surgery or not) were significantly related to the proportion of recalled risks and benefits. This is in contrast to previous studies showing that education levels influenced surgical risk recall. Specifically, research has suggested that patients with higher levels of education are more likely to recall $\geq$50% of the risks,[22] while patients with lower levels of education tend to recall $<$50%.[12,23] However, other studies have found a negative correlation with education levels, where parents of pediatric patients with postsecondary education had poorer recall of surgical risks for their children's surgery.[11] Similar to education, a prior surgical history for any child in the family did not influence recall rate. It seems that regardless of education level and previous experience, some parents will have less-than-ideal recall and may therefore benefit from further support during the informed consent process.

This study provides preliminary information about parental recall of information shared during pediatric otolaryngology consultations. Surgeons should be aware that many parents have poor recall and that they tend to remember only a few specific risks and benefits. Moreover, parents were likely seeking additional information from other sources. Hence, surgeons should emphasize the important and common risks involved in a surgical procedure, as well as find ways to increase information retention (eg, via decision aids[24]).

Limitations of this study should be noted. The timeline of the follow-up phone call may have influenced parental recall. In this study, the follow-up occurred 2 weeks after the consultation, and recall may have been different if the time frame was different. Second, we did not assess for differences in recall based on different ethnicity, since the study sample was homogenous (ie, mostly Caucasian). Therefore, cultural diversity and its influence on recall of risks and benefits are unknown in the current population. Furthermore, it is possible that the results reported in this study may not be generalizable to other centers that have demographically different populations. Third, parents were aware that a phone call would be made by the research assistant after the consultation visit, which may have led to recall bias. However, parents were not aware that specific risks and benefits would be elicited, and thus it is unlikely that a Hawthorne effect would have occurred. Fourth, the surgeons did not have a standardized discussion on risks and benefits. That is, the providers mentioned different risks and benefits even though they worked at the same center; nonetheless, this is another novel finding that requires further studies to determine why only certain risks and benefits were mentioned by the providers. Although data were available on which specific risks and benefits were mentioned by the participating surgeons, we could not independently analyze these data since there was too much variability across and even within individual surgeons. Even though all surgeons mentioned the common risks of surgery (eg, posttonsillectomy bleed), many instances were observed where other information was mentioned in a tremendously varied manner (eg, premature tube extrusion, improved quality of life). Therefore, we could not analyze these data at the level of which specific risks and benefits were mentioned by the providers. Finally, a relatively small number of surgeons were included in this study, thus representing a restricted range of potential provider influences. A larger number of

surgeons may provide more generalizable results. Despite these limitations, the current study was the first to assess recall rates through objective assessments (video recordings) of what was actually discussed during the consultation.

Conclusion

Parents of children considering elective pediatric otolaryngology operations recalled less than half of the surgical risks and benefits mentioned during the informed consent discussion. The decision to proceed with surgery as compared with watchful waiting was associated with a poorer recall of surgical risks. Parents were likely seeking information from other sources about the surgical procedure. This information is significant because a low rate of recall may influence parents' perspectives of the procedure and could alter their decision-making processes or expectations. Future studies should assess methods to increase recall and understanding of the information shared during the informed consent process.

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Author Contributions

Kiersten Pianosi, collected and analyzed data, wrote article, revised article; **Ayala Y. Gorodzinsky**, designed study, analyzed data, revised article; **Jill MacLaren Chorney**, designed study, collected and analyzed data, revised article; **Gerard Corsten**, designed study, collected data, revised article; **Liane B. Johnson**, designed study, collected data, revised article; **Paul Hong**, designed study, collected and analyzed data, revised article.

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Supplemental Material

Additional supporting information may be found at http://otojournal.org/supplemental.

References

1. Section on Pediatric Pulmonology, Subcommittee on Obstructive Sleep Apnea Syndrome, American Academy of Pediatrics. Clinical practice guideline: diagnosis and management of childhood obstructive sleep apnea syndrome. *Pediatrics*. 2011;209:704-712.
2. Daniel M, Kamani T, El-Shunnar S, et al. National institute for clinical excellence guidelines on the surgical management of otitis media with effusion: are they being followed and have they changed practice? *Int J Pediatr Otorhinolaryngol*. 2013; 77:54-58.
3. Burton MJ, Glasziou PP, Chong LY, Venekamp RP. Tonsillectomy or adenotonsillectomy versus non-surgical treatment for chronic/recurrent acute tonsillitis. *Cochrane Database Syst Rev*. 2014;11:CD001802.
4. Engel KG, Heisler M, Smith DM, Robinson CH, Forman JH, Ubel PA. Patient comprehension of emergency department care and instructions: are patients aware of when they do not understand? *Ann Emerg Med*. 2009;53:454-461.
5. Hawley ST, Lantz PM, Janz NK, et al. Factors associated with patient involvement in surgical treatment decision making for breast cancer. *Patient Educ Couns*. 2007;65:387-395.
6. Gorodzinsky AY, Hong P, Chorney JM. Parental knowledge in pediatric otolaryngology surgical consultations: a qualitative content analysis. *Int J Pediatr Otorhinolaryngol*. 2015;79: 1135-1139.
7. Goldfarb J, Gupta V, Sampson H, Chiodo A. Resource development in otolaryngology-head and neck surgery: an analysis on patient education resource development. *J Otolaryngol Head Neck Surg*. 2014;43:27.
8. McAllister KA, Clement WA. Readability and content of postoperative tonsillectomy instructions given to patients in Scotland, a completed audit cycle. *Scot Med J*. 2012;57:4-7.
9. Tait AR, Voepel-Lewis T, Gauger V. Parental recall of anesthesia information: informing the practice of informed consent. *Anesth Analg*. 2011;112:918-923.
10. Papsin E, Haworth R, Chorney JM, Bezuhly M, Hong P. Pediatric otoplasty and informed consent: do information handouts improve parental risk recall? *Int J Pediatr Otorhinolaryngol*. 2014;78:2258-2261.
11. Nadeau DP, Rich JN, Brietzke SE. Informed consent in pediatric surgery: do parents understand the risks? *Arch Otolaryngol Head Neck Surg*. 2010;136:265-269.
12. Rosique I, Pérez-Cárceles MD, Romero-Martín M, Osuna E, Luna A. The use and usefulness of information for patients undergoing anaesthesia. *Med Law*. 2006;25:715-727.
13. Steven M, Broadis E, Carachi R, Brindley N. Sign on the dotted line: parental consent. *Ped Surg Int*. 2008;24:847-849.
14. Aremu SK, Alabi BS, Segun-Busari S. The role of informed consent in risks recall in otorhinolaryngology surgeries: verbal (nonintervention) vs written (intervention) summaries of risks. *Am J Otolaryngol*. 2011;32:485-489.
15. Kieran S, Gorman C, Kirby A, et al. Risk factors for desaturation after tonsillectomy: analysis of 4,092 consecutive pediatric cases. *Laryngoscope*. 2013;123:2554-2559.
16. Wei JL, Mayo MS, Smith HJ, Reese M, Weatherly RA. Improved behavior and sleep after adenotonsillectomy in children with sleep-disordered breathing. *Arch Otolaryngol Head Neck Surg*. 2007;133:974-979.
17. Isaacson G. Avoiding airway obstruction after pediatric adenotonsillectomy. *Int J Ped Otorhinolaryngol*. 2009;73:803-806.
18. Anderson OA, Wearne IMJ. Informed consent for elective surgery: what is best practice? *J R Soc Med*. 2007;100:97-100.
19. Truog RD, Brown SD, Browning D, et al. Microethics: the ethics of everyday clinical practice. *Hastings Cent Rep*. 2015; 45:11-17.
20. Crepeau AE, McKinney BI, Fox-Ryvicker M, Castelli J, Penna J, Wang ED. Prospective evaluation of patient comprehension of informed consent. *J Bone Joint Surg Am*. 2011;93:e114.

21. Bader SA, Braude RM. Patient informatics: creating new partnerships in medical decision making. *Acad Med*. 1998;73:408-411.
22. Adams MT, Chen B, Makowski R, Bevans S, Boseley M. Multimedia approach to preoperative adenotonsillectomy counseling. *Otolaryngol Head Neck Surg*. 2012;146:461-466.
23. Chan Y, Irish JC, Wood SJ, et al. Patient education and informed consent in head and neck surgery. *Arch Otolaryngol Head Neck Surg*. 2002;128:1269-1274.
24. Pynnonen MA, Randolph GW, Shin JJ. Evidence-based medicine in otolaryngology, part 5: Patient decision aids. *Otolaryngol Head Neck Surg*. 2015;153:357-363.

ORIGINAL ARTICLE

Consultation via telemedicine and access to operative care for patients with head and neck cancer in a Veterans Health Administration population

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ABSTRACT: *Background.* The purpose of this study was to evaluate a telemedicine model that utilizes an audiovisual teleconference as a preoperative visit.

Methods. Veterans Health Administration (VHA) patients with head and neck cancer at 2 remote locations were provided access to the Palo Alto Veterans Affairs (PAVA) Health Care System otolaryngology department via the telemedicine protocol: tissue diagnosis and imaging at the patient site; data review at PAVA; and a preoperative teleconference connecting the patient to PAVA. Operative care occurred at PAVA. Follow-up care was provided remotely via teleconference.

Results. Fifteen patients were evaluated. Eleven underwent surgery, 4 with high-grade neoplasms (carcinoma). Average time from referral to operation was 28 days (range, 17–36 days) and 72 (range, 31–108 days), respectively, for high-grade and low-grade groups. The average patient was spared 28 hours traveling time and $900/patient was saved on travel-related costs.

Conclusion. A telemedicine model enables timely access to surgical care and permits considerable savings among select VHA patients with head and neck cancer. © 2016 Wiley Periodicals, Inc. *Head Neck* **38:** 925–929, 2016

KEY WORDS: telemedicine, telehealth, head and neck, cancer, access, Veterans Health Administration, Veterans Affairs

INTRODUCTION

Head and neck cancer is a complex disease that is optimally treated with a multidisciplinary care team and a well-developed infrastructure. For patients who reside at a significant distance from a center with these capacities, determining a treatment plan and providing subsequent intervention can be associated with significant delays as well as travel-related costs and inconveniences. Even without such geographic hurdles, the average delay from referral to definitive treatment for cancers of the upper aerodigestive tract has been estimated at 14 to 21 weeks in the United States and Canada.[1]

The Veterans Health Administration (VHA) is the largest healthcare system in the United States, providing comprehensive healthcare to almost 9 million veterans annually.[2] The VHA system is not immune to treatment delays, a problem that has not only been highlighted recently in the press[3,4] but also spurred governmental action.[5]

Traditionally, VHA patients who live in remote areas and present with new diagnoses of head and neck cancer are transported to tertiary care VHA hospitals for evaluation and workup, or their care is fee-based to a local, non-Veterans Affairs tertiary care hospital. Transporting patients to tertiary care VHA hospitals can be associated with travel-related delays because patients with head and neck cancer often require multiple visits before beginning treatment to evaluate the tumor and determine a care plan. The use of non-VHA hospitals can permit rapid access to non-VA health systems,[6] but can be associated with significant costs for the VHA healthcare system.

Telemedicine has been proposed as a mechanism to facilitate treatment of head and neck cancer.[7] To date, telemedicine has been used to remotely present patients with head and neck cancer at multidisciplinary tumor boards[8–11] and provide guidance via secure text messaging as patients undergo treatment.[12,13] To our knowledge, no prior studies have evaluated the role of telemedicine in remote presurgical evaluation, workup, and counseling for patients with

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head and neck cancer. In this pilot study, we sought to explore the feasibility of utilizing a real-time audiovisual teleconference to remotely evaluate patients with head and neck cancer and formulate a treatment plan, replacing the traditional preoperative in-person visit that determines surgical treatment planning. Use of this teleconferencing technology has expanded to provide postoperative follow-up and surveillance visits as well. Specifically, we sought to evaluate if this model improves existing access to operative care and if it was associated with any time or financial savings. Secondarily, we sought to compare the wait times of patients evaluated with the telemedicine consultation to a cohort of patients evaluated with traditional in-person visits.

MATERIALS AND METHODS

This project was reviewed by both the Stanford University Institutional Review Board and the Research Administration at the Palo Alto Veterans Affairs (PAVA) Health Care System and was determined to be a quality improvement project. All patients gave informed consent to participate in a telemedicine encounter.

Patients

PAVA frequently provides tertiary head and neck oncologic care for veterans in the Northern California and the southwestern United States, including the New Mexico region. VHA patients requiring care at a tertiary otolaryngology facility (PAVA) who were diagnosed at 2 remote VHA sites (New Mexico Veterans Affairs Health Care System, Albuquerque, NM, and Central California Veterans Affairs Health Care System, Fresno, CA) were evaluated remotely via the telemedicine consultation protocol. VHA physicians practicing in Fresno, CA, and Albuquerque, NM, referred the patients. Remote patients were defined as those who reside >150 miles from Palo Alto, CA. Patients with referrals to PAVA for head and neck cancer treatment were eligible to participate in the protocol.

Protocol

Eligible patients were offered the option of a telemedicine consultation when the referral was received by PAVA. All patients were also offered a standard in-person consultation.

The telemedicine protocol included 3 components: (1) tissue diagnosis and imaging acquisition at a remote site; (2) review of clinical, pathological, and imaging data at the local, tertiary treatment site (PAVA), including discussion of the patient at the Stanford Department of Otolaryngology multidisciplinary head and neck tumor board; and (3) a preoperative, audiovisual teleconference to finalize the treatment plan and counsel the patient. This encounter was a real-time, 30-minute, teleconference that occurred via an encrypted line. The telemedicine consult was performed with the patient, nurse, and speech pathologist present at the patient's home site, providing the ability for real-time nasopharyngoscopy, and a head and neck surgeon (D.B.S.) at PAVA.

For surgical patients, medical services that were needed to provide preoperative clearance (primary care, cardiology, and pulmonology) were determined during the telemedicine visit. Referrals to the necessary service(s) were placed electronically by the head and neck surgeon at PAVA for patients to be evaluated at their home site before traveling to PAVA for operative care. After a treatment plan was finalized, operative intervention and immediate inpatient postoperative care were provided at PAVA. The patient traveled to the local tertiary site (PAVA) the day before surgery for an examination by the operative team. In all cases, reconstructive options up to and including microvascular free tissue transfer were available as necessary on the day of surgery. Routine outpatient follow-up care was provided at the remote site with additional telemedicine postoperative visits as necessary. Patients who did not require operative intervention were treated in their home area and/or referred to appropriate specialists.

Study design and outcome measurements

Clinical, pathological, and operative data were collected from the electronic medical record and retrospectively analyzed. Main outcome measures were the time from referral to initial consultation and subsequently to surgery, as well as travel time spared, travel cost saved, and carbon dioxide emissions avoided because of telemedicine visits. The time from referral to consultation reflects the time from when a referring VHA physician referred the patient to the head and neck surgery department at PAVA to the time the patient was evaluated by telemedicine by the PAVA department.

Parameters related to the patient's treatment timeline were calculated, including the time from the referral request to the time of telemedicine consultation and the time from telemedicine consultation to intervention. Travel time was based on average driving or flying time from remote locations to PAVA. Cost of travel and procedures were based on the federal government's reimbursement rate for travel[14] and calculations by the VHA finance department when determining the cost of the fee based on specific procedures. Carbon dioxide emissions were calculated from the Environmental Protection Agency's formula and were based on road travel in a car or light truck by each patient.[15]

A comparison group of Fresno, CA, patients who were evaluated in-person at PAVA for head and neck cancer was used to compare telemedicine visits to in-person visits. This comparison group, who traveled to PAVA for in-person evaluation, is distinct from the Fresno, CA, patients who were evaluated remotely via telemedicine and is subsequently referred to as the in-person Fresno group. For this comparison, no Albuquerque, NM, patients were included because of the fact that evaluation and treatment of these patients at PAVA began with the advent of a telemedicine program.

RESULTS

Fifteen patients were evaluated using this telemedicine protocol from August 2013 to March 2015. An additional 6 patients were followed with 24 telemedicine visits for postoperative care and cancer surveillance for a total of 21 patients. Thirty-nine telemedicine visits were performed in total. Among the 15 patients who underwent the full protocol, mean age of patients was 64 years (range, 28–95 years) and all patients were men. All 15 patients who were offered a telehealth consultation instead of an in-person

TABLE 1. Demographics of fifteen Veterans Health Administration patients who underwent telemedicine consultation for head and neck cancer.

Variables	No. of patients (%)
Mean age, y (range)	64 (28–95)
Sex	
Male	15 (100)
Female	0 (0)
Pathology, no (%)	
Carcinoma	5 (33)
Warthin's tumor	3 (20)
Low-grade salivary neoplasm	3 (20)
Osteoradionecrosis	1 (7)
Substernal goiter	1 (7)
Cystic lesion	1 (7)
Low-grade laryngeal chondrosarcoma	1 (7)

evaluation elected for a telemedicine consultation. Patient demographics and pathologies are listed in Table 1.

Of patients who underwent the full protocol, 11 of 15 underwent operative intervention at PAVA. Four of the patients had high-grade neoplasms (carcinoma) and 7 had low-grade pathologies (low-grade salivary neoplasm = 3; osteoradionecrosis = 1; substernal goiter = 1; cystic parotid lesion = 1; and low-grade chondrosarcoma of the larynx = 1). Table 2 lists the wait times from referral to telemedicine visit and from telemedicine visit to operation for high-grade and low-grade groups. For patients with high-grade pathologies, the average period from initial referral to surgery was <1 month (mean, 28 days; range, 17–36 days) and the average period from the telemedicine visit to surgery was <3 weeks (mean, 20 days; range, 11–30 days).

Four of 15 patients did not require operative intervention. Three of these 4 patients received formal treatment recommendations via telemedicine and avoided all travel to Palo Alto; 2 patients had nonoperative Warthin's tumor and 1 patient with p16+ squamous cell carcinoma of the tonsil was referred for chemoradiotherapy at his home institution. One patient with an unknown cystic lesion and hoarseness traveled to Palo Alto for an in-person examination and repeat fine-needle aspiration, which demonstrated a benign parotid cyst on final pathology.

The number of patients with high-grade pathology requiring surgery was small ($n = 4$), therefore, it was not possible to make a formal statistical comparison to patients who traveled to PAVA in person. Nonetheless, all patients from Fresno, CA, who had an initial evaluation in-person at PAVA for biopsy-proven head and neck cancer from January 2013 to March 2015, were retrospectively reviewed. This in-person Fresno group comprised 26 patients: 24 with high-grade neoplasms (carcinoma = 21; melanoma = 2; and metastatic thyroid cancer = 1) and 2 with low-grade pathology (atypical fibroxanthoma = 1, and osteoradionecrosis = 1). Ten patients had high-grade tumors requiring surgery. Among this operative group, the mean time from initial referral to in-person evaluation was 21 days (range, 6–61 days), the mean time from evaluation to surgery was 28 days (range, 0–55 days), and the mean time from referral to surgery was 49 days (range, 22–83 days).

For the entire cohort of 21 telemedicine patients, >$19,000 was saved between patients and the VHA and 600 hours were spared on travel to PAVA by replacing traditional in-person clinic visits with telemedicine, see Table 3. This prevented 14.5 metric tons of carbon dioxide emissions based on Environmental Protection Agency formulas.[15] The average patient was saved 28 hours traveling, >1600 miles traveled, and $900 on travel-related costs.

DISCUSSION

Telemedicine is being increasingly utilized as a healthcare delivery model for complex subspecialty care in remote patient populations.[7,16] In this study, we present the results of a pilot study highlighting the benefits of telemedicine to provide remote access that can facilitate perioperative care of patients with head and neck cancer in a VHA population. Real-time audiovisual preoperative teleconferencing was used to formulate treatment plans and provide timely access to operative intervention. Based on an English-language literature search, this is the first study to evaluate this aspect of telemedicine in this population.

The data from this pilot study demonstrate that head and neck surgical care can be provided in accordance with standard of care, within an average of 1 month, for patients with high-grade malignancies who were evaluated using our telemedicine protocol. In this study, patients with high-grade pathologies were expedited for faster telemedicine consults. Patients with low-grade pathologies had a longer average time from referral to telemedicine consult.

In addition to facilitating timely operative intervention, the telemedicine protocol enabled significant travel-related time savings and financial savings for patients. Although the number of cases in the telemedicine cohort was limited, our data suggest improved wait times to surgical care compared to prior traditional in-person visits (in-person Fresno cohort). A formal statistical analysis of wait times between

TABLE 2. Time period from referral to telemedicine consultation and from telemedicine consultation to surgery among fifteen patients with head and neck cancer.

Variables	Mean time (range), days
Referral to telemedicine visit, all patients	18 (6–53)
Referral to telemedicine visit, high-grade	8 (6–11)
Referral to telemedicine visit, low-grade	28 (7–53)
Telemedicine to OR, all patients requiring surgery	48 (11–101)
Telemedicine to OR, low-grade patients requiring surgery	50 (42–101)
Telemedicine to OR, high-grade patients requiring surgery	20 (11–30)
Referral to OR, all patients requiring surgery	54 (17–108)
Referral to OR, low-grade patients requiring surgery	72 (31–108)
Referral to OR, high-grade patients requiring surgery	28 (17–36)

Abbreviation: OR, operating room.
Calculations exclude one patient with low-grade salivary neoplasm who delayed his treatment against medical advice.

TABLE 3. Visit details and related cost, travel, and carbon dioxide emission savings for twenty-one patients who underwent telemedicine consultation or telemedicine follow-up surveillance visits.

Variables	Fresno, CA*	Albuquerque, NM	Total
No. of patients	15	6	21
Preoperative telemedicine consultations	9	6	15
Postoperative telemedicine visits	18	6	24
Automobile travel distance saved, miles	8910	25,248	34,158
Travel time spared, hours	297	288	585
Carbon dioxide emissions avoided, metric tons†	3.78	10.72	14.5

* Fresno, CA, patients who were evaluated via telemedicine, not via in-person visits.
† Based on Environmental Protection Agency formulas.

telemedicine visits and in-person visits will be the subject of future studies.

The financial costs saved by telemedicine among this cohort, $19,000 in total and $900/patient, are shared between patients and the PAVA hospital. In the VHA system, patients are reimbursed by the VHA for their transportation if they meet certain eligibility criteria. Not all patients are eligible for this reimbursement, however, and some pay for their own transportation. In addition to lessening travel costs for the patients and VHA, in circumstances in which patients pay out-of-pocket for their transportation costs, telemedicine may actually remove a barrier to medical care by decreasing the cost of travel to an appointment. These data also suggest there is be an environmental benefit to telemedicine, as multiple tons of carbon dioxide emissions from transportation were spared from this small cohort, although this savings must be balanced against the environmental production costs of producing and implementing the audiovisual telemedicine equipment.

Although no prior studies have evaluated real-time teleconferencing for treatment planning and preoperative discussion, other components of telemedicine have been utilized in otolaryngology patients. Patients with head and neck cancer have been presented remotely at multidisciplinary tumor boards[8] with high diagnostic accuracy,[10] patient satisfaction,[11] and potential cost savings.[9] Secure text messaging and surveys have enabled support for patients as they undergo treatment for head and neck cancer.[12,13,17] Oropharyngeal swallowing[18] and nasopharyngoscopy[19] have been assessed remotely via video. Prior studies have documented the feasibility of diagnosing otolaryngology patients via videoconferencing.[20] However, no studies in the English-language literature have evaluated the feasibility and utility of a preoperative teleconference to determine a treatment plan and facilitate operative intervention.

One potential boon of telemedicine in otolaryngology is to expedite workup and intervention for patients in remote locations. A study by van Harten et al[21] of patients treated for head and neck cancer showed that patients who were referred to a head and neck oncology hospital from another institution were more likely to experience treatment delays and additionally demonstrated that longer waiting times were associated with a higher hazard ratio of dying. Moreover, the average delay from referral to a specialist to treatment for patients with head and neck cancer is 3 to 5 months,[1] possibly longer when patients do not have local access to head and neck surgeons.

There are other considerable economic advantages to utilizing this telemedicine model in the VHA healthcare system. Multiple studies have demonstrated that improved oncologic outcomes are associated with treatment at high-volume cancer centers,[22–25] and telemedicine may allow more patients to realize these outcomes. For patients who require complex procedures that are not geographically available near the patient's local Veterans Administration facility, the VHA typically outsources (fee-basis) the procedure to non-VHA health systems. The telemedicine protocol permits these patients to be evaluated at a VHA hospital in a timely manner and intervention to subsequently be provided within the VHA health system, at significant cost savings for the VHA and convenience to our veterans. For example, 1 patient from Albuquerque, NM, was initially fee-based to the local university in New Mexico and refused laryngectomy. The PAVA team was the third opinion on this case and expedited his workup for surgery at PAVA instead, saving the VHA a billable charge of over $74,000 for this operation. Telemedicine allowed our senior author to gain this patient's trust to consent for a possible total laryngectomy. The patient underwent a partial supracricoid laryngectomy for his 7 cm low-grade chondrosarcoma with pectoralis flap reconstruction, and is now decannulated, eating by mouth, and free of disease at 2 years of surveillance.

This study was a pilot study and is subject to certain limitations. The data were retrospectively analyzed and are therefore subject to bias. The number of patients included was small and the patients were specific to a VHA population in the United States. The telemedicine technology has capital and support costs as well as energy (environmental) setup costs, and the financial and carbon dioxide emission savings reported in this study must be interpreted in light of this. The cost savings reported in this article do not account for the cost of equipment setup or maintenance and the carbon dioxide emissions spared do not account for the energy input of producing the telemedicine equipment.

CONCLUSION

A telemedicine treatment model that provides real-time audiovisual teleconferencing may expedite treatment planning and operative management of selected patients with head and neck cancer. This treatment approach enables timely access to subspecialty surgical care and permits considerable patient convenience and financial savings. More studies are needed to evaluate the utility of this telemedicine model in this patient population.

REFERENCES

1. Stefanuto P, Doucet JC, Robertson C. Delays in treatment of oral cancer: a review of the current literature. *Oral Surg Oral Med Oral Pathol Oral Radiol* 2014;117:424–429.
2. Veterans Health Administration. Available at: http://www.va.gov/health/. Accessed March 9, 2015.

3. Bronstein S, Black N, Griffin D. Veterans dying because of health care delays. Available at: http://www.cnn.com/2014/01/30/health/veterans-dying-health-care-delays/. Accessed May 13, 2015.
4. Bronstein S, Griffin, D. A fatal wait: veterans languish and die on a VA hospital's secret list. Available at: http://www.cnn.com/2014/04/23/health/veterans-dying-health-care-delays/. Accessed May 13, 2015.
5. Obama vows action on any VA "misconduct." Available at: http://www.bbc.com/news/world-us-canada-27508745. Accessed May 13, 2015.
6. 38 U.S. Code § 1703 – Contracts for hospital care and medical services in non-department facilities. Available at: https://www.law.cornell.edu/uscode/text/38/1703. Accessed March 9, 2015.
7. Varkey P, Liu YT, Tan NC. Multidisciplinary treatment of head and neck cancer. *Semin Plast Surg* 2010;24:331–334.
8. Savage SA, Nixon I, MacKenzie K. Teleconferencing in the management of head and neck cancer. *Clin Otolaryngol* 2007;32:130–132.
9. Stalfors J, Björholt I, Westin T. A cost analysis of participation via personal attendance versus telemedicine at a head and neck oncology multidisciplinary team meeting. *J Telemed Telecare* 2005;11:205–210.
10. Stalfors J, Edström S, Björk–Eriksson T, Mercke C, Nyman J, Westin T. Accuracy of tele-oncology compared with face-to-face consultation in head and neck cancer case conferences. *J Telemed Telecare* 2001;7:338–343.
11. Stalfors J, Holm–Sjögren L, Schwieler A, Törnqvist H, Westin T. Satisfaction with telemedicine presentation at a multidisciplinary tumour meeting among patients with head and neck cancer. *J Telemed Telecare* 2003;9:150–155.
12. Head BA, Keeney C, Studts JL, Khayat M, Bumpous J, Pfeifer M. Feasibility and acceptance of a telehealth intervention to promote symptom management during treatment for head and neck cancer. *J Support Oncol* 2011;9:e1–e11.
13. Head BA, Studts JL, Bumpous JM, et al. Development of a telehealth intervention for head and neck cancer patients. *Telemed J E Health* 2009;15:44–52.
14. Privately owned vehicle mileage reimbursement rates. Available at: http://www.gsa.gov/portal/content/100715. Accessed March 9, 2015.
15. Passenger vehicles per year. Available at: http://www.epa.gov/cleanenergy/energy-resources/refs.html. Accessed May 13, 2015.
16. Weinstein RS, Lopez AM, Joseph BA, et al. Telemedicine, telehealth, and mobile health applications that work: opportunities and barriers. *Am J Med* 2014;127:183–187.
17. van den Brink JL, Moorman PW, de Boer MF, et al. Impact on quality of life of a telemedicine system supporting head and neck cancer patients: a controlled trial during the postoperative period at home. *J Am Med Inform Assoc* 2007;14:198–205.
18. Malandraki GA, McCullough G, He X, McWeeny E, Perlman AL. Teledynamic evaluation of oropharyngeal swallowing. *J Speech Lang Hear Res* 2011;54:1497–1505.
19. Dorrian C, Ferguson J, Ah-See K, et al. Head and neck cancer assessment by flexible endoscopy and telemedicine. *J Telemed Telecare* 2009;15:118–121.
20. Sclafani AP, Heneghan C, Ginsburg J, Sabini P, Stern J, Dolitsky JN. Teleconsultation in otolaryngology: live versus store and forward consultations. *Otolaryngol Head Neck Surg* 1999;120:62–72.
21. van Harten MC, Hoebers FJ, Kross KW, van Werkhoven ED, van den Brekel MW, van Dijk BA. Determinants of treatment waiting times for head and neck cancer in the Netherlands and their relation to survival. *Oral Oncol* 2015;51:272–278.
22. Chen AY, Fedewa S, Pavluck A, Ward EM. Improved survival is associated with treatment at high-volume teaching facilities for patients with advanced stage laryngeal cancer. *Cancer* 2010;116:4744–4752.
23. Chen AY, Pavluck A, Halpern M, Ward E. Impact of treating facilities' volume on survival for early-stage laryngeal cancer. *Head Neck* 2009;31:1137–1143.
24. Lassig AA, Joseph AM, Lindgren BR, et al. The effect of treating institution on outcomes in head and neck cancer. *Otolaryngol Head Neck Surg* 2012;147:1083–1092.
25. Wuthrick EJ, Zhang Q, Machtay M, et al. Institutional clinical trial accrual volume and survival of patients with head and neck cancer. *J Clin Oncol* 2015;33:156–164.

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Evaluating handoffs in the context of a communication framework

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Background. *The implementation of mandated restrictions in resident duty hours has led to increased handoffs for patient care and thus more opportunities for errors during transitions of care. Much of the current handoff literature is empiric, with experts recommending the study of handoffs within an established framework.*

Methods. *A prospective, single-institution study was conducted evaluating the process of handoffs for the care of surgical patients in the context of a published communication framework. Evaluation tools for the source, receiver, and observer were developed to identify factors impacting the handoff process, and inter-rater correlations were assessed. Data analysis was generated with Pearson/Spearman correlations and multivariate linear regressions. Rater consistency was assessed with intraclass correlations.*

Results. *A total of 126 handoffs were observed. Evaluations were completed by 1 observer (*N = *126), 2 observers (*N = *23), 2 receivers (*N = *39), 1 receiver (*N = *82), and 1 source (*N = *78). An average (±standard deviation) service handoff included 9.2 (±4.6) patients, lasted 9.1 (±5.4) minutes, and had 4.7 (±3.4) distractions recorded by the observer. The source and receiver(s) recognized distractions in >67% of handoffs, with the most common internal and external distractions being fatigue (60% of handoffs) and extraneous staff entering/exiting the room (31%), respectively. Teams with more patients spent less time per individual patient handoff (*$r = -0.298$; P = *.001). Statistically significant intraclass correlations (*P ≤ *.05) were moderate between observers (*$r \geq 0.4$*) but not receivers (*$r < 0.4$*). Intraclass correlation values between different types of raters were inconsistent (*P > *.05). The quality of the handoff process was affected negatively by presence of active electronic devices (*$\beta = -0.565$*; P = *.005), number of teaching discussions (*$\beta = -0.417$*; P = *.048), and a sense of hierarchy between source and receiver (*$\beta = -0.309$*; P = *.002).

Conclusion. *Studying the handoff process within an established framework highlights factors that impair communication. Internal and external distractions are common during handoffs and along with the working relationship between the source and receiver impact the quality of the handoff process. This information allows further study and targeted interventions of the handoff process to improve overall effectiveness and patient safety of the handoff. (Surgery 2016;■:■-■.)*

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Handoffs refer to a transfer of patient care between health care providers. This process includes transfer of information and responsibility concerning patient care. There is no doubt that a successful and comprehensive handoff process is important for quality and continuity of patient care, but the quality of handoffs is affected by many factors, including lack of standardized handoff tools, interruptions or distractions, variation in experience of providers, information inaccuracies, and communication or social skills.[1]

The implementation of mandated restrictions of resident duty hours at academic institutions has led to increased patient care handoffs and thus more opportunities for errors during these important transitions of care. Compliance with the duty-hour restrictions can lead to an average of up to 15 handoffs per patient over a 5-day hospitalization.[2] A recent survey of internal medicine and general surgery residents at the Massachusetts General

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Hospital reported that 59% of residents could identify ≥1 patient harmed because of problematic handoffs, and 12% reported that the harm was major.[3]

Due to the complexities of health care environments and the substantial variation in clinical practice between different specialties, efforts to standardize the handoff process have been met with resistance, with creation of various handoff tools of questionable applicability and sustainability. In addition, evaluation of the handoff process lacks a unifying structure. In a recent study, Mohorek and Webb[4] suggested using the linear model of communication as a conceptual framework for handoff research. The handoff process is a linear transition of information from one person to another person or group, many of whom may not have participated in this patient's care before and may have less career experience with the medical/surgical situation. The linear communication model, when used as a framework, allows researchers to identify 3 separate areas in which errors occur: transmitter (message encoding), channel, and receiver (signal decoding).[4]

A recent editorial in the *Journal of Graduate Medical Education* recommended studying handoffs within an established framework.[5] The aim of this study was to evaluate handoffs in surgical services in the context of a communication framework to identify factors that adversely affect the handoff process. Once these factors are delineated clearly, a targeted intervention to improve handoff effectiveness could be developed.

METHODS

Study population and setting. A prospective, single-institution study was conducted to evaluate the process of handoff of surgical patients at a tertiary care teaching hospital. The conceptual framework published previously for handoffs using communication theory was used to develop evaluation tools for the source (resident giving the handoff), receiver (resident receiving the handoff), and observer.[4]

The observers in this study were involved in the development of the evaluation tools, and consensus was achieved through an iterative process. Our residency program implemented a night-float system to address patient care needs in the setting of work hour restrictions. General surgery residents at the Medical College of Wisconsin Affiliated Hospitals were observed giving and receiving patient handoffs at the evening shift change during a 6-month period. Handoffs were observed in 3 settings. The first setting was the handoff to the night-float residents, which included 3 surgical oncology services, a colorectal surgery service, a vascular surgery service, and the minimally invasive general surgery service. This handoff took place in a remote room reserved for patient handoffs.

Given the voluntary nature of this study, residents were allowed to decline participation in the study entirely or participate intermittently. Therefore, data were collected for services individually, rather than the night-float handoff collectively as one large handoff of the 6 services. We could not therefore evaluate differences in handoff quality for those occurring earlier versus later in the handoff process.

The second setting was the trauma service handoff, which took place in the physician workroom next to the nurses' station and included the 2 services of trauma surgery and acute care surgery. The third setting was the surgical intensive care unit service, which occurred in the surgical intensive care unit. Residents of different postgraduate year levels were observed during the study period. The handoff was usually provided by one resident, the "source," and was received by 2 residents, the "receivers," a senior and a junior resident.

This quality-improvement study was approved by the institutional review board (IRB). Participants in the handoff process provided written consent. As part of the informed consent process for the IRB, all participants received an e-mail announcement as well as a group announcement describing the project design, objectives, and methods. This announcement included discussing the questions in Fig 1, *A* that were used to evaluate the handoff process.

Measures. Trained observers included 1 medical student, 2 senior residents, and 1 surgery faculty member. The observers did not participate in the handoff process. Junior residents gave handoffs in person, whereas senior residents provided handoffs either in person or via telephone. We had no standardized tools for the handoff process, although all residents had received instruction on handoffs, including several handoff templates and mnemonics. Physicians discussed typically the level of acuity of patients, pertinent history, active problems, hospital course, and action plans. Evaluation forms for the source, receiver, and observer were developed based on our linear model of communication published previously.[4]

Observers utilized a standardized form to identify distractions, including number of extraneous staff entering or leaving the room, background conversations, side conversations unrelated to patient care, interruptions due to pager beeps,

A

11. Rate your perceived quality of handoff delivery. **(Check a box)**

□ 1	□ 2	□ 3	□ 4	□ 5
Poor: Major parts of the handoff were not transmitted effectively because of an unclear delivery AND an unfocused transmitter	Fair: Major parts of the handoff were not transmitted effectively because of unclear delivery OR an unfocused transmitter.	Average: Minor parts of the handoff were not transmitted effectively because of unclear delivery OR an unfocused transmitter.	Good: The majority of the handoff was transmitted; efficient and focused transmitter	Excellent: The handoff was transmitted error free; efficient and focused transmitter

12. Rate your perceived quality of handoff reception. **(Check a box)**

□ 1	□ 2	□ 3	□ 4	□ 5
Poor: Major parts of the handoff were not received; severely distracted receiver	Fair: Major parts of the handoff were not received; moderately distracted receiver.	Average: Minor parts of the handoff were not received; somewhat distracted receiver.	Good: The majority of the handoff was received; undistracted receiver.	Excellent: The handoff was fully received; undistracted receiver

13. Rate your perceived quality of the handoff environment. **(Check a box)**

□ 1	□ 2	□ 3	□ 4	□ 5
Poor: There were excessive avoidable and/or unavoidable distractions during the handoff that clearly impeded the process.	Fair: There were occasional avoidable and/or unavoidable distractions during the handoff that may have impeded the process.	Average: There were occasional avoidable and/or unavoidable distractions during the handoff that probably did not impede the process.	Good: There were occasional avoidable and/or unavoidable distractions during the handoff that did not impede the process.	Excellent: There were no distractions of any kind during the handoff.

B

4. Rank your working relationship with the senior-most physician receiving the handoff. **Check a box:**

□ 1	□ 2	□ 3	□ 4	□ 5
Poor: We often don't get along and it sometimes affects our job performance	Fair: We usually don't get along but our job performance doesn't suffer	Average: While we don't always get along, our job performance doesn't suffer	Good: We get along well but it doesn't necessarily improve job performance	Excellent: We get along well and it positively affects our job performance.

5. Rank your working relationship with the junior-most physician receiving the handoff. **Check a box:**

□ 1	□ 2	□ 3	□ 4	□ 5
Poor: We often don't get along and it sometimes affects our job performance	Fair: We usually don't get along but our job performance doesn't suffer	Average: While we don't always get along, our job performance doesn't suffer	Good: We get along well but it doesn't necessarily improve job performance	Excellent: We get along well and it positively affects our job performance.

a. If your answer to Q4 or Q5 was 3 or lower, did this poor relationship impede your ability to deliver the handoff? **Y or N**

Fig 1. (*A*) Likert scales used to evaluate the handoff delivery and reception processes, as well as the handoff environment. (*B*) Likert scales used to evaluate the source-receiver relationship.

teaching discussions, and use of electronic devices that are unrelated to the handoff process or patient care (eg, cellphones, computers, television, radio). Observers also rated the quality of the process of handoff delivery and reception, as well as the handoff environment through 3 questions, each on a Likert scale (1–5, 5 = best; Fig 1, *A*). Of note, this study evaluated the process of delivering and receiving patient handoffs, not the content or quality of the message being delivered or received.

Table I. Number of handoffs observed and number of source/receivers completing the evaluation form

Number of handoffs observed	126
Number of handoffs with 2 observers	23
Number of handoffs with source completing the evaluation form	78
Number of handoffs with 1 receiver completing the evaluation form	82
Number of handoffs with 2 receivers completing the evaluation form	39

Participants in the handoff process, both the source and the receiver, used a standardized paper form to identify distractions and rate the quality of the handoff process according to the same Likert scale (Fig 1, *A*). Evaluation forms were completed immediately following each service handoff. The source and receiver were also asked if hierarchy/chain of command served as a barrier for effective communication at any point during the handoff (Yes/No) and to evaluate the source-receiver relationship on a Likert scale (1–5, 5 = best; Fig 1, *B*). A subset of handoffs included 2 observers and/or 2 receivers to assess rater consistency.

Statistical and data analysis. Data analysis was generated with SPSS software (version 21.0; IBM Corp, Armonk, NY) with Pearson/Spearman correlations and multivariate linear regressions. Results are reported as mean (±standard deviation) for each individual service. Rater consistency was assessed with intraclass correlations (ICC 2,1).

RESULTS

During a 6-month period, 126 handoffs were observed by ≥1 trained observer; 23 handoffs included 2 observers. An evaluation form was completed by the source in 78 handoffs and by a receiver in 82 handoffs. Two receivers completed the evaluation form in 39 handoffs (Table I). The majority of handoffs observed in this study were part of the night-float system (92%). Seven percent of handoffs were completed over the phone, with the evaluation forms completed immediately and returned to the authors.

The night-float team received handoffs from 6 separate services. An average service handoff included 9.2 ± 4.6 patients and lasted 9.1 ± 5.4 minutes. Observers identified an average of 4.7 ± 3.4 distractions per service handoff. Extraneous staff entering and leaving the room was the most common type of distraction, occurring 1.5 ± 1.9 times per service handoff. Furthermore, 34% of handoffs included background conversations by extraneous staff, and 58% of handoffs were noted to have activated electronic devices unrelated to the handoff or patient care (Table II).

Table II. Observer results per 1 service handoff

	Mean (SD)
Duration of handoff (min)	9.1 (5.4)
Number of patients in handoff	9.2 (4.6)
Number of distractions counted, *N* (SD)	4.7 (3.4)
Number of extraneous staff entering/exiting the room	1.5 (1.9)
Number of side conversations by handoff staff	0.7 (1.1)
Number of pager beeps/phone calls interrupting handoff	0.8 (1.1)
Number of handoff interruptions by extraneous staff talking to handoff staff	0.6 (0.8)
Number of teaching discussions	0.2 (0.5)
Background conversations by extraneous staff (% yes)	34
Were unrelated electronic devices on during the handoff? (% yes)	58

SD, Standard deviation.

The observers noted that some form of distraction occurred in nearly every handoff; ≥3 distractions occurred in up to 70% of handoffs; ≥6 distractions occurred in up to 35% of handoffs. The number of patients per service was found to inversely correlate with the amount of time spent handing off each patient (Rs = −0.298, $P = .001$; Fig 2). In addition, the observer rating of the handoff delivery directly correlated with amount of time spent per patient ($P = .048$).

Evaluation forms completed by the source and receiver(s) reported a distraction in up to 78% of handoffs. Internal distractions, or "noise," occurred in up to 71% of handoffs, whereas external distractions were noted in up to 44% (Table III). Furthermore, the source and/or receiver acknowledged ≥1 type of distraction occurring in 78% of handoffs and 3 distinct types of distractions in up to 37% of handoffs.

Fifty-four handoffs were delivered by a postgraduate year (PGY)-1 resident, and the remainder were delivered by a PGY-2 or higher resident. There was no difference in duration of handoffs (8.2 minutes for PGY-1 residents and 9.7 minutes for more senior residents, $P = .24$). Similarly, there was no difference in the number of distractions, including side conversations by handoff providers ($P = .27$), interruptions by extraneous providers talking to handoff staff ($P = .25$), pager/phone interruptions ($P = .42$), or number of teaching discussions ($P = .74$). In contrast, the quality of handoff delivery was rated to be better by the

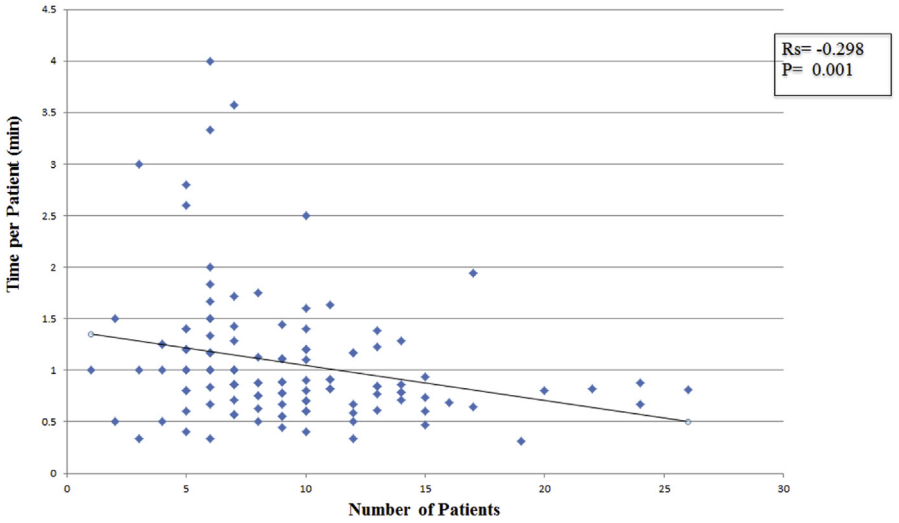

Fig 2. Time per patient handoff as a function of the number of patients being handed off. (Color version of this figure is available online.)

Table III. Distraction categories noticed by source and receivers

	Source	*Receiver 1*	*Receiver 2*
Any distraction	71	78	67
Internal noise (% yes)	56	71	62
Hunger (% yes)	26	22	23
Void (% yes)	6	4	0
Thirst (% yes)	17	17	15
Pain (% yes)	1	5	0
Fatigue (% yes)	37	60	28
Other (% yes)	1	1.2	0
Personal distractions (% yes)	12	12.2	18
External noise (% yes)	39	44	41
Extraneous staff entering/exiting the room (% yes)	28	31	15
Background conversation by extraneous staff (% yes)	5	17	3
Side conversations by handoff staff (% yes)	6	2	3
Teaching discussion during handoff (% yes)	4	4	0
Unrelated electronics on during handoff (% yes)	10	9	28

observer when a PGY-2 or higher-level resident delivered the handoff, compared with PGY-1 residents (mean of 4.3 vs 3.6, $P < .001$). The receiver scores did not show a difference based on the source PGY resident level ($P = .56$).

Table IV. Observer 1 and observer 2 comparison using ICC ($N = 23$)

	ICC	P *value*
Handoff duration (min)	0.983	<.001
Number of patients per handoff	0.986	<.001
Number of extraneous staff entering/exiting room	0.912	<.001
Background conversation by extraneous personnel (Y/N)	0.667	<.001
Number of side conversations by handoff providers	0.394	.032
Number of handoff interruptions due to pager beeps/phone	0.765	<.001
Number of handoff interruptions due to extraneous staff talking to handoff staff	0.659	<.001
Number of unrelated teaching discussions interrupting handoff	0.209	NS
Were any electronic devices on during handoff?	0.167	NS
Rate handoff delivery (1–5)	0.556	.001
Rate handoff reception (1–5)	0.062	NS
Rate handoff environment (1–5)	0.447	.016

NS, Not significant (P value >.05).

ICC was used to compare different participants of the study. Observers 1 and 2 were found to have a strong ICC when counting distractions and evaluating the handoff delivery process and handoff environment ($P < .05$). In contrast, the 2 observers diverged when evaluating the handoff reception process ($P > .05$; Table IV). Also, the 2 receivers diverged in evaluating the type of

Table V. Receiver 1 and receiver 2 comparison using ICC ($N = 39$)

	ICC	P *value*
Any extraneous staff entering/exiting room	0.216	NS
Background conversation by extraneous staff (Y/N)	−0.050	NS
Any side conversations by handoff staff	−0.027	NS
Any unrelated electronic devices on during handoff?	−0.257	NS
Rate handoff delivery (1–5)	0.234	.017
Rate handoff reception (1–5)	−0.089	NS

NS, Not significant (P value >.05).

Table VI. Linear regression analysis of predictors of handoff delivery/reception quality

Handoff delivery process	*β coefficient*	P *value*
Negative predictors		
Number of side discussions	−0.18	.046
Number of teaching discussions	−0.42	.048
Extraneous staff entering/leaving the handoff room	−0.35	.040
Positive predictors		
Source-receiver relationship	+0.83	<.001
Handoff reception process		
Negative predictors		
Number of side discussions	−0.26	.004
Number of teaching discussions	−0.20	.044
Presence of electronic devices	−0.57	.005
Source-receiver hierarchal barrier	−0.31	.002
Positive predictors		
Source-receiver relationship	+0.75	<.001

distractions and the handoff reception process and handoff environment ($P > .05$) but agreed on the handoff delivery process ($P = .017$; Table V). Comparison of different participant types (eg, comparing an observer to a receiver or source) showed divergence in responses ($P > .05$).

Linear regression analysis determined that the handoff delivery process was affected negatively by the number of side discussions ($\beta = -0.18$, $P = .046$), the number of teaching discussions ($\beta = -0.42$, $P = .048$), and by extraneous staff entering/leaving the handoff room ($\beta = -0.35$, $P = .04$). Similarly, the handoff reception process was negatively impacted by the number of side discussions ($\beta = -0.26$, $P = .004$), the number of teaching discussions ($\beta = -0.20$, $P = .044$), the presence of active, unrelated electronic devices ($\beta = -0.57$, $P = .005$), and the sense of hierarchy among handoff participants ($\beta = -0.31$, $P = .002$). The delivery ($\beta = 0.83$, $P < .001$) and reception ($\beta = 0.75$, $P < .001$) processes were affected positively by a good relationship between the source and receiver (Table VI).

DISCUSSION

Patient handoffs have become an integral part of patient care. The importance of this communication process has become evident in light of the inception of duty-hour restrictions in 2003; in one study, handoffs increased by 40%.[2] Intuitively, handoffs in patient care present a risk of loss of vital information and, consequently, the potential for adverse patient events. A large body of literature identifies flaws in patient handoffs, with attempts to improve this process,[6] but the majority of previous efforts have designed interventions either empirically or based on feedback from focus groups.[7,8]

A systematic review of the literature by Abraham et al[1] examined various handoff tools. In this review, the majority of studies focused on effectiveness of a tool as well as user satisfaction. Furthermore, the theoretic basis of most studies has been limited to some aspect(s) of the handoff process (eg, information processing, cognition, accountability). An editorial in the *Journal of Graduate Medical Education* describes the magnitude of the handoff problem and proposes a paradigm shift in how research is done to improve handoffs.[5] Specifically, future research is recommended to start with a conceptual framework based on previous research results.

This process is exactly what we sought to accomplish with our project. Our group has developed a conceptual framework utilizing communication theory to study the handoff process, break it down to its core elements, and develop an intervention that targets these various elements.[4] Our study may be the first in the literature that evaluates the handoff process in the context of a comprehensive communication framework. In our study, we evaluated specifically the process of delivering and receiving patient handoffs, not the content of the message being delivered or received.

Our study demonstrated that distractions are very common during surgery resident handoffs; 70% of residents providing handoffs reported a distraction, while 66–75% of residents receiving handoffs reported a distraction. According to the observers, an average of 4.7 ± 3.4 distractions occurred per service handoff. Extraneous

personnel entering and leaving the room was the most common type of distraction. The frequency of distractions during the handoff was highlighted in other studies.

In a recent study of surgical handoffs at 3 University of California, San Francisco (UCSF), teaching hospitals, distractions occurred in 48% of handoffs.[9] Interestingly, the authors report that pagers and patient-related telephone calls were the most common distractions. In other studies, most observed handoffs were interrupted ≥1 for every service.[10,11] Our study also demonstrated that distractions negatively affect the quality and process of delivery and reception of the handoff. Our linear regression analysis shows that the process of handoff delivery was negatively affected by the number of side or teaching discussions and the number of personnel entering or exiting the room.

We hypothesize that distractions affect the momentum of the handoff process and divert attention from important, patient-related information. Contrary to our results, the UCSF study showed that distractions increase the duration of the handoff process but do not affect the quality of the handoff process.[9] While the authors suggested that surgery residents developed tolerance to distractions, the UCSF study did not report any solicited feedback from the residents providing or receiving handoffs regarding whether they felt distractions impacted the quality of the handoff process. The authors' results were based solely on the observers' evaluation of the handoff process.

In our study, we surveyed both the source and the receiver in addition to the observers. Identifying distractions is important for quality improvement of the handoff process, because the most common distractions should be amenable to interventions. Residency programs could encourage minimization of side and teaching conversations during the handoff process. Nursing personnel could also be encouraged to minimize pages during handoff time except for urgent, patient-related issues. Similar to the sterile cockpit rule in the aviation industry that requires pilots to refrain from nonessential activities during critical phases of flights, including takeoff and landing, hospitals can consider instituting a no-page policy during handoffs.[10,12]

In our study, the quality of handoff delivery was rated significantly better by the observer when a PGY-2 or higher level resident delivered the handoff compared with a PGY-1 resident, despite the receiver scores not showing a difference based on the source PGY level. This finding has not been reported previously. We hypothesize that the ability to provide pertinent patient information and identify potential complications or issues improves with experience. Handling distractions during handoffs may also require multitasking, a skill that improves with experience. Prior studies have shown that multitasking is a complex cognitive process that improves with practice.[13] In an observed, simulated handoff experience with need to handoff multiple patients, residents with prior training in handoff or prior handoff experience achieved better scores based on assessing their handoff delivery using a 5-item checklist.[14] This finding suggests that handoff training during medical school or beginning of residency may be beneficial.

Our study demonstrated that the quality of handoff delivery and reception is impacted positively by a good relationship between the source and receiver. Furthermore, we identified this relationship as an important predictor of the quality of the handoff process. This observation was supported by 2 findings: the presence of hierarchy negatively affected the evaluation of the handoff process, and the source-receiver relationship correlated directly with the overall handoff process score, both positively and negatively.

To our knowledge, prior handoff studies have not examined the working relationship between the handoff participants as a predictor of quality, although our study of communication theory identified the relationship between the source and receiver and hierarchy as important psychologic distractions when relaying a message.[4] Developing a hierarchy-free environment during handoffs, as well as improving the source-receiver relationship, should be further studied as a means for improving communication and ultimately patient care.

When comparing the responses of different participants, we identified 2 themes. Observers were mostly congruent with one another, while different participant types were mostly incongruent. The observers only disagreed on the evaluation of the handoff reception, likely due to the passive nature of receiving information, making it difficult for a third party observer to evaluate accurately.

In contrast, when comparing the source to the receivers or observers, the observers agreed on the overall presence of distractions, but the source/receiver/observer gave divergent responses in terms of type of distractions, evaluating the handoff delivery/reception process, and the handoff environment. The divergent responses occurred due to the source and receiver being focused on their respective tasks during the handoff, while the observers were focused on evaluating the process and accounting for distractions. Furthermore, our work suggests that the source and receiver could be sensitive to

different types of distractions and have different priorities while giving or receiving the handoff.

We acknowledge limitations of our study, which is an observational study at a single institution. We did not analyze patient outcomes to determine any correlation between quality of handoff delivery or reception and presence of distractions and adverse patient outcomes. Future studies should focus on the content and quality of the message being delivered or received, evaluate patient complications due to hand-off related issues, and lead to the design and validation of interventions that target the various components of the handoff process.

Based on our results, we plan to implement a system that minimizes the number of distractions during handoffs. This will include limiting nurse calls during handoffs, minimizing use of unrelated electronic devices, and minimizing hierarchy. Our institution has received IRB approval for the second phase of this study that will evaluate the impact of handoff quality on patient care and study the impact of implementing a "sterile-cockpit" approach to patient handoffs.

In conclusion, studying the handoff process within an established framework highlights factors that impair communication. Internal and external distractions are common during handoffs and, along with the working relationship between the source and receiver, impact the quality of the handoff process. This information allows further study and targeted interventions of the handoff process to improve overall handoff effectiveness and patient safety.

REFERENCES

1. Abraham J, Kannampallil T, Patel VL. A systematic review of the literature on the evaluation of handoff tools: implications for research and practice. J Am Med Inform Assoc 2014;21:154-62.
2. Vidyarthi AR, Arora V, Schnipper JL, Wall SD, Wachter RM. Managing discontinuity in academic medical centers: strategies for a safe and effective resident sign-out. J Hosp Med 2006;1:257-66.
3. Kitch BT, Cooper JB, Zapol WM, Marder JE, Karson A, Hutter M, et al. Handoffs causing patient harm: a survey of medical and surgical house staff. Jt Comm J Qual Patient Saf 2008;34:563-70.
4. Mohorek M, Webb TP. Establishing a conceptual framework for handoffs using communication theory. J Surg Educ 2015;72:402-9.
5. Riesenberg LA. Shift-to-shift handoff research: where do we go from here? J Grad Med Educ 2012;4:4-8.
6. Foster S, Manser T. The effects of patient handoff characteristics on subsequent care: a systematic review and areas for future research. Acad Med 2012;87:1105-24.
7. Tapia NM, Fallon SC, Brandt ML, Scott BG, Suliburk JW. Assessment and standardization of resident handoff practices: PACT project. J Surg Res 2013;184:71-7.
8. Craig SR, Smith HL, Downen AM, Yost WJ. Evaluation of patient handoff methods on an inpatient teaching service. Ochsner J 2012;12:331-7.
9. Anderson CE, Nicksa GA, Stewart L. Distractions during resident handoffs. Incidence, sources and influence on handoff quality and effectiveness. JAMA Surg 2015;150:396-401.
10. Greenstein EA, Arora VM, Staisiunas PG, Banerjee SS, Farnan JM. Characterising physician listening behaviour during hospitalist handoffs using the HEAR checklist. BMJ Qual Saf 2013;22:203-9.
11. Coiera E, Tombs V. Communication behaviours in a hospital setting: an observational study. BMJ 1998;316:673-6.
12. Anthony K, Wiencek C, Bauer C, Daly B, Anthony MK. No interruptions please: impact of a no interruption zone on medication safety in intensive care units. Crit Care Nurse 2010;30:21-9.
13. Maclin EL, Mathewson KE, Low KA, Boot WR, Kramer AF, Fabiani M, et al. Learning to multitask: effects of video game practice on electrophysiological indices of attention and resource allocation. Psychophysiology 2011;48:1173-83.
14. Gaffney S, Farnan JM, Hirsch K, McGinty M, Arora VM. The modified, multi-patient observed simulated handoff experience (M-OSHE): assessment and feedback for entering resident on handoff performance. J Gen Intern Med 2016;31:438-41.

Review

Patient Portals and Patient Engagement: A State of the Science Review

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Abstract

Background: Patient portals (ie, electronic personal health records tethered to institutional electronic health records) are recognized as a promising mechanism to support greater patient engagement, yet questions remain about how health care leaders, policy makers, and designers can encourage adoption of patient portals and what factors might contribute to sustained utilization.

Objective: The purposes of this state of the science review are to (1) present the definition, background, and how current literature addresses the encouragement and support of patient engagement through the patient portal, and (2) provide a summary of future directions for patient portal research and development to meaningfully impact patient engagement.

Methods: We reviewed literature from 2006 through 2014 in PubMed, Ovid Medline, and PsycInfo using the search terms "patient portal" OR "personal health record" OR "electronic personal health record". Final inclusion criterion dictated that studies report on the patient experience and/or ways that patients may be supported to make competent health care decisions and act on those decisions using patient portal functionality.

Results: We found 120 studies that met the inclusion criteria. Based on the research questions, explicit and implicit aims of the studies, and related measures addressed, the studies were grouped into five major topics (patient adoption, provider endorsement, health literacy, usability, and utility). We discuss the findings and conclusions of studies that address the five topical areas.

Conclusions: Current research has demonstrated that patients' interest and ability to use patient portals is strongly influenced by personal factors such age, ethnicity, education level, health literacy, health status, and role as a caregiver. Health care delivery factors, mainly provider endorsement and patient portal usability also contribute to patient's ability to engage through and with the patient portal. Future directions of research should focus on identifying specific populations and contextual considerations that would benefit most from a greater degree of patient engagement through a patient portal. Ultimately, adoption by patients and endorsement by providers will come when existing patient portal features align with patients' and providers' information needs and functionality.

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KEYWORDS

electronic personal health record; patient portal; patient engagement; meaningful use

Introduction

Patient Engagement and Patient Portals

Patient engagement has been identified as an essential dimension of the multifaceted solution to the cost/quality crisis in US health care. The patient-centric definition of patient engagement by the Agency for Healthcare Research and Quality (AHRQ) is "the involvement in their own care by individuals (and others they designate to engage on their behalf), with the goal that they make competent, well-informed decisions about their health and health care and take action to support those decisions" [1].

AHRQ also defines patient engagement from a systems perspective as "a set of behaviors by patients, family members, and health professionals and a set of organizational policies and procedures that foster both the inclusion of patients and family members as active members of the health care team and collaborative partnerships with providers and provider organizations" [1].

Currently, there is an increasing awareness of health care system's responsibility to provide easily accessible ways for patients to be engaged in their own care by creating effective partnerships that lead to the patient's ability to make competent and well-informed decisions [2]. While an electronic personal health record (ePHR) tethered to an electronic health record (EHR), also known as a patient portal, is currently recognized as a promising mechanism to support greater patient engagement, questions remain about how health care leaders, policy makers, and designers can encourage adoption by both providers and patients and what factors might contribute to sustained utilization.

Definition and Background of Patient Portals

An ePHR that directly links, or is "tethered", to an EHR is most commonly referred to as a patient portal. In general, patient information from the EHR such as the problem list, allergies, and lab test results populate the patient portal. In some instances, patients may enter data to populate the EHR. In contrast, an untethered ePHR is under the control of the patient. This means an individual manually enters all information or grants permission for the information to be transferred to the ePHR, from a specific source like a laboratory or pharmacy, and determines who will have access. Thus, the value of an untethered ePHR is determined by a person's willingness to manage and maintain their ePHR information. Because there is little that health care organizations can do to initiate patient engagement using an untethered ePHR, this literature review is focused exclusively on the patient portal, directly linked to an EHR.

Patient portals were introduced and adopted by a few large health care organizations in the late 1990s (eg, MyChart at the Palo Alto Medical Foundation and Indivo at Boston Children's Hospital) [3,4]. However, patient portals did not gain widespread use until 2006 when several initiatives coincided, including the launch of ePHRs by Microsoft and Google, the awarding of Centers for Medicare and Medicaid Services (CMS) contracts to private firms to conduct feasibility studies of ePHRs using existing claims data from Medicare programs, and Blue Cross and Blue Shield Association and America's Health Insurance Plans' announcement to develop data-sharing programs that would ultimately support ePHR development [5]. These initiatives also coincided with the broad social movement towards adoption and daily use of powerful information and communication sharing tools such as smartphones and social media, illustrating the readiness of the general population to embrace technology in a new socially interactive way.

The current principal driver of patient portal development is the meaningful use (MU) criteria of the CMS EHR incentive program [6]. Features mandated by MU that directly relate to patient portal functionality include providing (1) a clinical summary to the patient after each visit, (2) secure messaging (SM) between patient and provider, (3) ability to view, download, and transmit personal health record data, (4) patient specific education, (5) patient reminders for preventative services, and (6) medication reconciliation [7]. While these criteria clearly outline tasks and goals, they do little to reflect the value proposition to the end users (patients and providers) or the steps required to engage patients in a sustained and relevant way. Therefore, an aim of this review was to explore the current research addressing the encouragement and support of patient engagement through the patient portal.

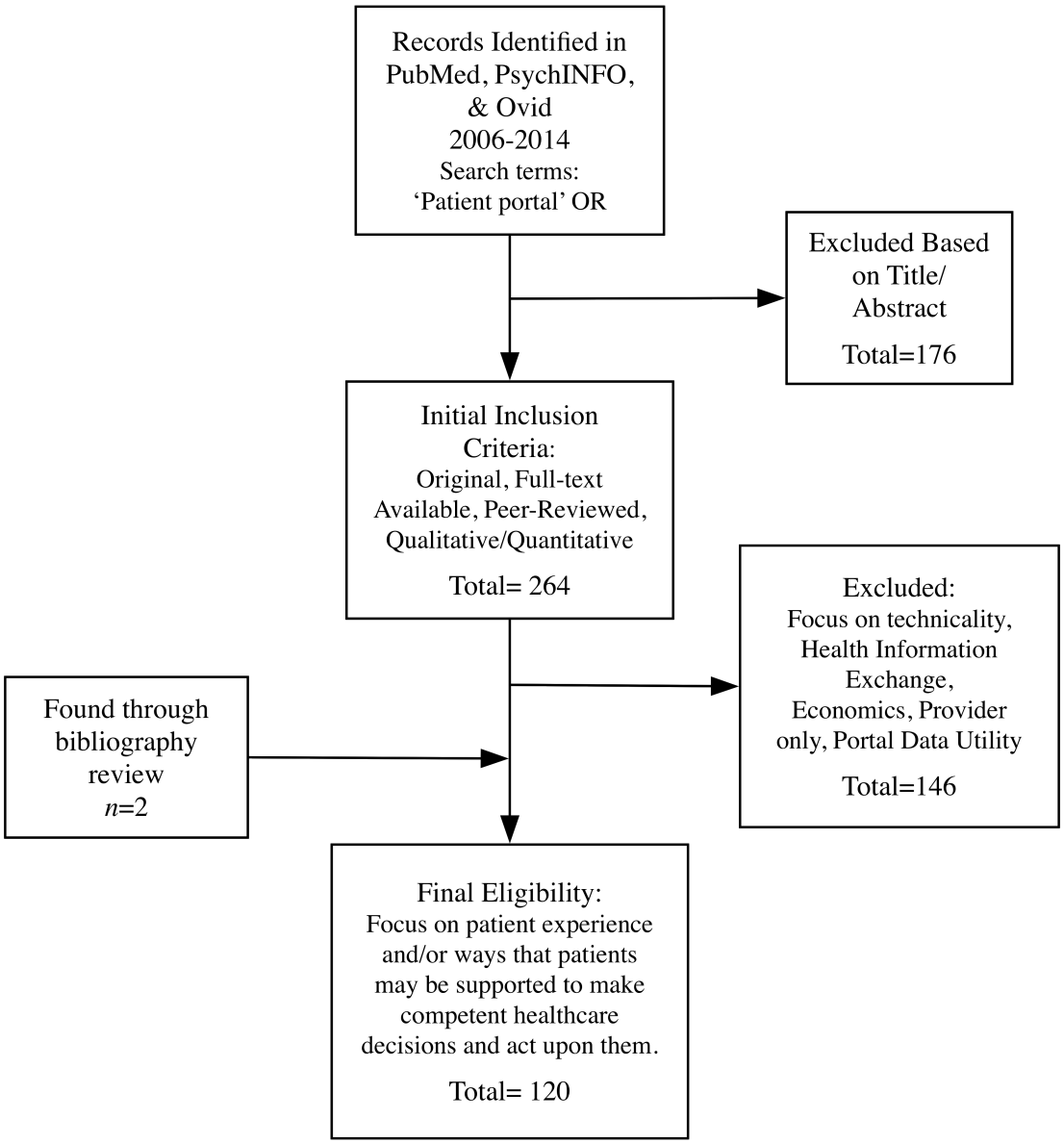
Methods

Search Strategy

Due to the advances in technology and consumer readiness in the mid-2000s, the review was limited to recent literature to better reflect current trends in design, functionality, and perceived user readiness of patient portals. We reviewed literature from 2006 through 2014 in PubMed, Ovid Medline, and PsycInfo using the search terms "patient portal" OR "personal health record" OR "electronic personal health record". Bibliographies and the literature reviews from these sources were used to identify additional studies [8,9]. Initial inclusion criteria were (1) original, peer-reviewed, qualitative, and quantitative research of tethered ePHRs or patient portals, (2) English language, and (3) available in full text. The final inclusion criterion was that the studies reported on the patient experience and/or ways that patients may be supported to make competent health care decisions and act on those decisions using patient portal functionality. Studies were not targeted to any particular patient subgroup, disease, or clinical setting.

Of the 440 articles identified by the search, 176 were excluded based on title and abstract. Further review based on the final inclusion criterion resulted in 120 articles, which were reviewed in depth (see Multimedia Appendix 1 for summaries of each). Excluded articles focused on the provider perspective only, technicalities of patient portal implementation (eg, policy issues, safety, security), implications for Health Information Exchange, economics impacts, or the utility of patient portal data for research purposes (see Figure 1).

Figure 1. Literature review flow chart.



Results

Overview

We grouped the studies into five major topics based on the research questions, explicit and implicit aims of the studies, and related measures addressed. The topics identified included patient adoption, provider endorsement, health literacy, usability, and utility (Table 1). Of the 120 articles that were reviewed, 66 (55.0%) were non-experimental descriptive, 26 (21.7%) were qualitative or mixed-methods, 14 (11.7%) were randomized controlled trials, 10 were pilot studies or case reports (8.3%), and 4 were cohort studies (3.3%) (Table 2). Only 11 articles explicitly identified a guiding theoretical framework, with the Chronic Care Model being the most common among them. The year 2011 was a turning point in the number of published articles, which coincides with the initiation of CMS EHR incentives program. The topical areas that showed the greatest increase in volume were patient adoption and utility (Table 1). See Multimedia Appendix 1 for a brief description of each article and the topical areas addressed. The following section describes each topical area and discusses relevant implications for research, development, and implementation of patient portals.

Table 1. Summary of articles on categories of patient portals for patient engagement.

Year	Provider endorsement	Health literacy	Usability	Patient adoption	Utility	Total # of articles
2006	0	0	0	1	2	3
2007	1	1	1	2	3	4
2008	0	1	1	4	6	8
2009	0	0	1	3	4	7
2010	1	2	2	7	7	11
2011	3	3	2	11	8	17
2012	1	3	3	11	10	16
2013	2	3	5	12	17	27
2014	0	3	5	11	19	27
Total	8	16	20	62	76	120

Table 2. Levels of evidence adapted from Melnyk & Fineout-Overholt, 2005.

Type of study	Level of evidence	# of studies
RCT	2	14
Cohort/Quasi-experimental	3	4
Descriptive	4	
Non-experimental (survey, correlational, etc)		66
Qualitative/Mixed method		26
Pilot study/case report	5	10

Patient Adoption

Before a patient portal can serve as a tool for individuals to become more engaged and involved in their own care, patients must first adopt it. CMS 2014 stage 2 MU regulations define adoption in terms of institutional reporting for reimbursement and require that 5% of the institutions' patient population (1) download or view electronic health information and (2) use secure electronic messages (eg, email) [6]. However, in our review, various operational definitions of adoption were used. For example, many observational studies used usage data of the initial login to the patient portal site to represent adoption; others used data from surveys about patients' intention to use the portal. Several randomized controlled trials (RCTs) used rates of patient portal intervention adherence to study protocol to define adoption, and for some of these trials, those who completed the studies were considered adopters; in others, adoption was defined as the frequency of intervention use.

Of the 62 articles [5,10-70] that focused on or described patient portal adoption as part of the report, six RCTs included detailed descriptions of intervention group participants who completed the study (and therefore were considered adopters) in comparison to those who did not. We found 12 qualitative or mixed-method studies that collected data about adoption from patients through focus groups or semistructured interviews; 21 studies focused on interest and barriers to adoption for specific populations or patient portal functions (eg, elderly, safety-net, human immunodeficiency populations, secure messaging, prescription refills).

The term "digital divide" is often used to describe major potential barriers to access of electronic tools such as a patient portal and refers to disparities among subgroups based on access to the Internet and computer literacy. However, this term does not encompass the many other factors that may contribute to adoption such as language barriers, age, race and ethnicity, social economic status, and level of patient activation [32,50,54,71]. Several studies examining adoption have shown that ethnic minorities (African American, Latino, Asian) and patients who are younger (under 35 years), healthier, and less educated were less likely to adopt patient portals [15,55,72]; however, results are mixed regarding gender differences [50,63]. People with disabilities and chronic conditions, frequent users of health care services, and caregivers of elderly parents or children tend to have the most interest in patient portals [28,50,62,73]. Other important factors of patient portal adoption include provider acceptance and promotion, and usability of the patient portal interface including ease of registration, navigation, and perceived privacy and security [18-20,74].

Provider Endorsement

Provider endorsement and continued engagement with the patient portal have been identified as important factors in a patient's decision to adopt and continue to use the patient portal functions to achieve and sustain anticipated positive outcomes [19,75]. Of the 8 articles that addressed physician endorsement [12,19,34,76-80], 5 studies were qualitative or mixed-method studies, and one RCT included a retrospective survey of physicians' use and satisfaction.

Four of the studies sought to capture attitudes of clinicians towards patient portals prior to having firsthand experience interacting with them. Prior to actual use of patient portals, clinicians expressed concerns related to patient engagement including: the potential for inducing patient anxiety regarding test results; the accuracy of patient entered data; the potential liability for tracking and acting on critical clinical information, such as blood glucose levels and blood pressure readings; implications for changes in the patient-provider relationship; and the anticipated increased workload [34,77,78,81].

Retrospective studies showed that the pre-portal concerns regarding patient anxiety about test results were not justified as demonstrated by numerous patients who found the test result feature one of the most useful [82]. In addition, while perceived increases in workload and duration of clinic visits varied among studies, clinicians believed patients were more interested in participating in their care and found that verifying the additional information in the patient portal provided during face-to-face visits was helpful, thus eliminating the accuracy concern [19]. Overall, the workflow of individual providers and the health care team as a whole, including nurses, pharmacists, support staff, and physicians, must be adapted in order to incorporate patient portal functionality, and the patient engagement it allows, into the delivery of preventative services and illness management processes [45].

Health Literacy

The definition of health literacy developed for the National Library of Medicine and used by the Healthy People 2010 initiative is "the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions" [83]. Of the 16 studies that specifically addressed health literacy [11,14,30,40,42,64,65,74,84-91], the majority included self-reported health literacy measures via survey questions or open-ended questions; only Noblin et al (42) and Taha et al [91] included validated health literacy measures. Four studies [64,85,88,91] identified conceptual knowledge, numeracy, and computer skills as particularly important literacy factors that contributed to successful patient engagement via a patient portal.

Noblin et al [42] found that 65% of participants who intended to adopt the outpatient clinic's patient portal had a higher eHealth literacy score than those who were not interested in patient portal adoption. Taha et al [91] results indicated that if health texts involved numeric concepts, users encountered problems, even if they were considered to have "adequate" health literacy. These studies underscore the importance of evaluating health literacy and health numeracy separately in order to identify specific risk factors and design flaws that could impact patient comprehension and ultimately jeopardize the accuracy of patient input and interpretation of results.

Four studies directly addressed the impact of health literacy of intended users on the successful completion of specific tasks [64,84,88,92]. Results showed that patients responded better when medical jargon and abbreviations were translated into "patient friendly" language. These results echo Haggstrom et al [85] and Monkman & Kushniruk's [88] findings of the dangers of low health and computer literacy to safe and effective use of patient portals.

Schnipper et al [92] and Sox et al [84] revealed that, despite patient involvement in early design and testing of patient portals, subsequent scenario-based usability testing uncovered navigation difficulties primarily due to the unfamiliarity with complex medical language and confusion of how and when to correct identified errors. Monkman & Kushniruk [88] suggest that including health literacy assessments in usability testing of consumer health information systems, such as patient portals, would inform the design of systems for better navigation, data input, and conceptual understanding of health information included throughout the patient portal.

Monkman & Kushniruk [88] also proposed a specific heuristic for health literacy whose purpose is to identify and categorize when clinical information within the patient portal would most likely be misunderstood by a layperson who does not possess a health care background. This study, along with several other qualitative studies showed that specific health topics (eg, medications, lab results, and allergies) required extra attention to designing with health literacy considerations in mind [45,89,93]. Proposed navigation and aiding tools that increased patients' ability to understand their personal health information more fully include integrating links to definitions of terms and detailed explanations, using movies and illustrations, substituting lay language for medical terminology and using graphs to track trending data, such as blood pressure and blood glucose levels [84,85,94].

Usability

Usability testing is the term used to describe the assessment of how easy a user interface is to operate. The word "usability" also refers to methods for improving ease of use during the design process [95]. One such method is heuristic evaluation, a method of testing a preliminary prototype by examining the interface and judging its compliance with recognized usability principles (ie, "heuristics"). Further iterative usability testing is accomplished using a series of prototypes and participatory scenario-based and "think-aloud" sessions with intended users in order to redesign the interface and workflows to better match user needs and preferences. Early usability testing, and its role in patient portal design, is important because it directly impacts whether or not a patient can easily adopt a patient portal. It also impacts the ability of the user to successfully navigate portal functions, accurately input information, and comprehend the information presented, ultimately contributing to its usefulness as a tool for patient engagement.

Of the 20 studies that addressed usability of patient portals, 6 performed some form of heuristic and usability testing with objective observation and various forms of "think aloud" sessions [25,84,85,92,94,96]. Only Schnipper et al [92] included usability testing of both the clinician and patient interfaces. The remaining 14 studies assessed users' subjective satisfaction and ease of use with questionnaires and/or interviews to evaluate overall adoption and utilization [11,38,45,47,48,64,65,73,82,88,89,91,97,98].

Schnipper et al [92] addressed the needs of both end users (ie, clinicians and patients) in the usability testing of a medication management module embedded within the patient portal. The study highlighted the need for end user-specific interfaces and functionality in order to make the user experience easier and more efficient, thus demonstrating its value and promoting sustained use. For patients, this meant striking a balance between free-text, structured, and coded data fields in order to leverage the usefulness of patient-entered data without confusing or overwhelming patients. For example, drop-down menus and scrolls bars were found to be less confusing and more efficient than dynamic text boxes that would react to the word being typed when inputting data, such as medications and allergies. In the case of clinicians, this meant integrating the clinician side of the application with their workflow so that clinicians could verify and correct patient-entered data while simultaneously facilitating the flow of that data into the EHR.

Much of the literature surrounding usability confirms that adoption and sustained use of technology are directly related to ease of navigation and the perceived usefulness of the available information [99]. While nearly all the patient portal usability studies that used subjective assessments showed positive results for ease of use and satisfaction, the in-depth objective usability studies were more effective at uncovering a variety of barriers to safe and effective use.

Utility

Utility refers to the availability of needed features. Utility and usability are equally important and together determine whether something is useful [99]; 76 studies focused in some way on patient portal utility [5,12,13,15,19,22,23,25-27,30,34,37,41,44,47,52,53,56,57,59,60,64,65,69,70,79,82,84-87,89,90,92,96,98,100-137]. The majority of descriptive, qualitative, and mixed-method studies focused on eliciting patient preferences for specific functions. Patients preferred functions that offered convenience, such as an easy way to contact and communicate with providers, order prescription refills, and access multiple family medical records. Easy-to-read, printer-friendly summaries were also viewed as helpful for sharing information with family members and providers who did not have patient portal access. The top two patient portal qualities that were deemed most utilitarian for patients were personalization and collaborative communication between patients and providers [67,138].

Personalization

While numerous descriptive and qualitative studies attest to the desire for personalized patient portal functionality, there is little research about what kind of personalization would lead to greater patient engagement. Currently, the greatest research focus is on chronic disease medication management and preventative services. Only 3 RCTs specifically tested the efficacy of patient-tailored interventions [13,30,90]. Grant et al [13] provided patient-tailored decision support and enabled the patient to author a "Diabetes Care Plan" for electronic submission to the physician prior to upcoming appointments. This intervention led to increases in pre-visit use of the patient portal and increased rates of diabetes-related medication adjustment at 12 months. Krist et al [62] provided a personally tailored list of prevention recommendations and found that at 16 months, 1 in 4 users were up-to-date on all preventive services—nearly double that of non-users. Sequist et al [30] sent personalized electronic messages that included (1) alerts for overdue health screenings and information on screening options, (2) a mechanism for patients to submit requests to schedule screening examinations, and (3) a link to a Web-based tool for patients to assess their personal risk of colorectal cancer. Findings showed that screening rates were significantly higher at 1 month for patients who received electronic messages than for those who did not, but the difference was no longer significant at 4 months.

Collaborative Communication

Collaborative communication refers to the ability for patients and providers to share timely and pertinent information, enabling patients to participate as active members of the care team beyond the hospital or clinic setting. SM and medication reconciliation are the two most common patient portal functions that offer the opportunity for such communication. Both functions also pose the greatest potential changes to provider workflow and overall impact on the patient-provider relationship.

For example, the difficulty aligning information management tools with current provider workflow and care delivery priorities was highlighted in a study of an interactive medication reconciliation module that emailed primary care physicians when a patient added or changed information [106]. Results showed that patients were willing and able to annotate their medication list, offering the most up-to-date and complete information, but email notifications were ineffective at prompting providers to update the EHR medication list outside of a clinic visit [106]. Thus, while the notion of designing patient portals to support patient involvement in their care, such as opportunities for their participation in medication reconciliation, shows promise, their effectiveness will depend on the ability to better incorporate these functions into provider workflow and delivery of care.

Other implications of electronic forms of communication via a patient portal are the potential to improve efficiency by way of substituting SM for face-to-face encounters and using SM reminders to decrease missed appointments and promote timely preventative care. However, research shows mixed results leading researchers to believe that the relationship between SM and utilization is more complex than the simple substitution of online for in-person care suggests. For example, while an earlier study at Kaiser Permanente showed a decrease in face-to-face encounters after the initiation of SM [22], a subsequent study in a different Kaiser region showed the opposite effect [115]. A study done at the Mayo Clinic, aimed at clarifying this discrepancy, focused on frequency of messages, long-term use, and importance of SM among certain subgroups [121], which showed neither an increase nor decrease in face-to-face provider visits with the use of SM.

SM is also being used as a one-way communication tool to deliver reminders for preventative care and appointments. A 2011 study at seven Duke medical clinics showed that email reminders, in combination with scheduling functionality within the patient portal, demonstrated significant declines in "no-shows" [27]. A meta-analysis and systematic review by

Guy et al [139] demonstrated a substantial increase in the likelihood of attending clinic appointments when patients received SM reminders. Perhaps the most encouraging results with SM were the large reduction in missed appointments among historically disadvantaged groups, such as Medicaid recipients, the uninsured, and black patients [27].

SM reminders via email have also been shown to be generally successful at encouraging higher rates of preventative services use. For example, a multi-practice randomized controlled trial showed improvement in the rates of certain preventive screenings and vaccinations, but preventative services as a whole were not impacted [113]. Findings suggest that SM reminders are most effective when they are tailored to the population and context, thus targeting specific goals such as herpes zoster vaccinations for older adults, or pediatric preventative care visit reminders for parents [119,129].

Discussion

Principal Findings

The current principal driver of patient portal development is CMS and Medicaid EHR incentive program meaningful use (MU) criteria [6]. While MU criteria clearly outline requirements of basic functionality and targeted adoption rates, they do not delineate the steps or features required to engage patients in a sustained and relevant way. Presently there is no clear definition of patient portal adoption beyond the minimum use requirements outlined in the MU criteria. However, in order for health care institutions to track the success of patient portals in terms of patient engagement, a multi-dimensional definition of portal adoption should include both motivating factors for initiation and use over time A definition of this kind would inform a set of universal quality and efficiency reporting measures beyond the current minimal MU criteria to include more relevant patient engagement data.

Current research has demonstrated that patients' interest and ability to use patient portals is strongly influenced by personal factors such age, ethnicity, education level, health literacy, health status, and role as a caregiver. Health care delivery factors, mainly provider endorsement and patient portal usability, also contribute to patients' ability to engage through and with the patient portal.

While health literacy has been identified as an important factor in the successful use of patient portals, few studies have used validated health literacy measures, making it difficult for future research to build on the findings. Research demonstrates that specific aspects of health literacy, mainly numeracy and familiarity with medical terminology, greatly impact the ability of patients to accurately input data and interpret the information provided in the patient portal. The direct relationship between health literacy and effective use of the patient portal supports the argument for the use of specific health literacy heuristics as part of overall usability testing.

Research also demonstrates that objective testing (as opposed to solely subjective) should also be a part of patient portal usability testing. Although objective usability testing is expensive and time consuming, studies demonstrate the need for continued work in this area in order to ensure patient portal interfaces promote patient comprehension and data entry accuracy. The promotion of content accuracy and patient comprehension impacts the overall usefulness of the information for both patients and providers.

The perceived usefulness of patient portals from the providers' perspectives cannot be underestimated. Provider endorsement is one of the most influential factors impacting patients' initial adoption, as well as its continued use as a tool for collaborative communication [20]. Yet, current research demonstrates the difficulty in aligning information management tools, such as the patient portal, with current provider workflow and care delivery priorities.

While current development and research is focused on demonstrating feasibility and efficiency of medication reconciliation and SM reminders, the research has revealed roadblocks to successful implementation rooted in the lack of provider workflow adaptations A greater understanding of the essential adjustments in provider workflow, including potential changes in the roles and responsibilities of the care team overall, is necessary in order to translate findings into practice. Few studies have focused on exploring how patient portal use should unfold within the context of the patient-provider interaction, or how it might impact the overall organization and workflow of the health care team including potential liability concerns, reimbursement, and relationships with patients.

Ultimately, successful implementation requires health care institutions to invest time and resources to systematically assess the health needs of their specific patient and caregiver populations, their individual stages of readiness to adopt a patient portal, and the types of assistance needed to do so [140]. Ideally, interactive sites would collect information on individuals' health, health behaviors and personal goals, and assess health literacy and functional ability, which would then inform the adaptation of the patient portal to accommodate the needs of the individual and/or what additional or alternative resources may be useful [2]. Such adaptations include personalized content and tailored data presentations specifically designed to enhance interpretation and comprehension of key personal health concerns and timely and pertinent action steps.

In addition, external environmental and contextual factors, such as distance between patient and clinic, and complexity and trajectory of health concerns, may impact which form of access is preferred for a specific person, provider, location, and situation. Future directions of research should focus on identifying specific populations and contextual considerations that would benefit most from a greater degree of patient engagement through a patient portal. This information could then lead to the creation of health care service policies that promote the use of a patient portal by both providers and patients within the most appropriate settings.

Conclusions

If institutions are to engage patients via the patient portal in a way that encourages them to become active members of the care team, support their competence in making health-related decisions, and help them to act on those decisions, institutional

leaders must consider the contributing factors that impact efficacy and sustained use of patient portals. According to this review, these factors include attention to the topical areas of patient adoption, provider endorsement, health literacy, usability, and utility. Ultimately, adoption by patients and endorsement by providers will come when existing patient portal features align with patients' and providers' information needs and functionality. Conceptualizing patient portals as a dynamic component of the patient-provider relationship and health care delivery system as a synergetic whole, rather than an isolated repository of information or a set of disconnected functions meant to collect patient data for provider use, may help to inform future research, improve patient portal design, and efforts to promote adoption and effectiveness.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

A brief description of each article and the topical areas it addresses.

[PDF File (Adobe PDF File), 306KB - jmir_v17i6e148_app1.pdf]

References

1. Rockville MD, Maurer M, Dardess P, Carman KL, Frazier K, Smeeding L. Guide to Patient and Family Engagement: Environmental Scan Report. 2012. URL: http://www.ahrq.gov/research/findings/final-reports/ptfamilyscan/ptfamilyscan.pdf [accessed 2015-01-17] [WebCite Cache ID 6Vel4kPos]
2. Kupchunas WR. Personal health record: new opportunity for patient education. Orthop Nurs 2007;26(3):185-91; quiz 192. [doi: 10.1097/01.NOR.0000276971.86937.c4] [Medline: 17538475]
3. Halamka JD, Mandl KD, Tang PC. Early experiences with personal health records. J Am Med Inform Assoc 2008;15(1):1-7 [FREE Full text] [doi: 10.1197/jamia.M2562] [Medline: 17947615]
4. Mandl KD, Simons WW, Crawford WCR, Abbett JM. Indivo: a personally controlled health record for health information exchange and communication. BMC Med Inform Decis Mak 2007;7:25 [FREE Full text] [doi: 10.1186/1472-6947-7-25] [Medline: 17850667]
5. Weitzman ER, Kaci L, Mandl KD. Acceptability of a personally controlled health record in a community-based setting: implications for policy and design. J Med Internet Res 2009;11(2):e14 [FREE Full text] [doi: 10.2196/jmir.1187] [Medline: 19403467]
6. Wright A, Feblowitz J, Samal L, McCoy AB, Sittig DF. The Medicare Electronic Health Record Incentive Program: provider performance on core and menu measures. Health Serv Res 2014 Feb;49(1 Pt 2):325-346 [FREE Full text] [doi: 10.1111/1475-6773.12134] [Medline: 24359554]
7. Ahern DK, Woods SS, Lightowler MC, Finley SW, Houston TK. Promise of and potential for patient-facing technologies to enable meaningful use. Am J Prev Med 2011 May;40(5 Suppl 2):S162-S172. [doi: 10.1016/j.amepre.2011.01.005] [Medline: 21521591]
8. Kim J, Jung H, Bates DW. History and Trends of "Personal Health Record" Research in PubMed. Healthc Inform Res 2011 Mar;17(1):3-17 [FREE Full text] [doi: 10.4258/hir.2011.17.1.3] [Medline: 21818452]
9. Goldzweig CL, Orshansky G, Paige NM, Towfigh AA, Haggstrom DA, Miake-Lye I, et al. Electronic patient portals: evidence on health outcomes, satisfaction, efficiency, and attitudes: a systematic review. Ann Intern Med 2013 Nov 19;159(10):677-687. [doi: 10.7326/0003-4819-159-10-201311190-00006] [Medline: 24247673]
10. Weingart SN, Rind D, Tofias Z, Sands DZ. Who uses the patient internet portal? The PatientSite experience. J Am Med Inform Assoc 2006;13(1):91-95 [FREE Full text] [doi: 10.1197/jamia.M1833] [Medline: 16221943]
11. Keselman A, Slaughter L, Smith CA, Kim H, Divita G, Browne A, et al. Towards consumer-friendly PHRs: patients' experience with reviewing their health records. AMIA Annu Symp Proc 2007:399-403 [FREE Full text] [Medline: 18693866]
12. Wald JS, Burk K, Gardner K, Feygin R, Nelson E, Epstein M, et al. Sharing electronic laboratory results in a patient portal--a feasibility pilot. Stud Health Technol Inform 2007;129(Pt 1):18-22. [Medline: 17911670]
13. Grant RW, Wald JS, Schnipper JL, Gandhi TK, Poon EG, Orav EJ, et al. Practice-linked online personal health records for type 2 diabetes mellitus: a randomized controlled trial. Arch Intern Med 2008 Sep 8;168(16):1776-1782 [FREE Full text] [doi: 10.1001/archinte.168.16.1776] [Medline: 18779465]

14. Greenhalgh T, Wood GW, Bratan T, Stramer K, Hinder S. Patients' attitudes to the summary care record and HealthSpace: qualitative study. BMJ 2008 Jun 7;336(7656):1290-1295 [FREE Full text] [doi: 10.1136/bmj.a114] [Medline: 18511764]
15. Lafky DB, Horan TA. Prospective personal health record use among different user groups: results of a multi-wave study. In: Proceedings of the 41st Annual Hawaii International Conference on System Sciences.: IEEE; 2008 Presented at: 41st Annual International Conference on System Sciences; Jan. 7-10, 2008; Hawaii. [doi: 10.1109/HICSS.2008.363]
16. Zickmund SL, Hess R, Bryce CL, McTigue K, Olshansky E, Fitzgerald K, et al. Interest in the use of computerized patient portals: role of the provider-patient relationship. J Gen Intern Med 2008 Jan;23 Suppl 1:20-26 [FREE Full text] [doi: 10.1007/s11606-007-0273-6] [Medline: 18095039]
17. Chen C, Garrido T, Chock D, Okawa G, Liang L. The Kaiser Permanente Electronic Health Record: transforming and streamlining modalities of care. Health Aff (Millwood) 2009 Apr;28(2):323-333 [FREE Full text] [doi: 10.1377/hlthaff.28.2.323] [Medline: 19275987]
18. Roblin DW, Houston TK, Allison JJ, Joski PJ, Becker ER. Disparities in use of a personal health record in a managed care organization. J Am Med Inform Assoc 2009;16(5):683-689 [FREE Full text] [doi: 10.1197/jamia.M3169] [Medline: 19567790]
19. Wald JS, Businger A, Gandhi TK, Grant RW, Poon EG, Schnipper JL, et al. Implementing practice-linked pre-visit electronic journals in primary care: patient and physician use and satisfaction. J Am Med Inform Assoc 2010;17(5):502-506 [FREE Full text] [doi: 10.1136/jamia.2009.001362] [Medline: 20819852]
20. Wald JS. Variations in patient portal adoption in four primary care practices. AMIA Annu Symp Proc 2010;2010:837-841 [FREE Full text] [Medline: 21347096]
21. Wen KY, Kreps G, Zhu F, Miller S. Consumers' perceptions about and use of the internet for personal health records and health information exchange: analysis of the 2007 Health Information National Trends Survey. J Med Internet Res 2010;12(4):e73 [FREE Full text] [doi: 10.2196/jmir.1668] [Medline: 21169163]
22. Zhou YY, Kanter MH, Wang JJ, Garrido T. Improved quality at Kaiser Permanente through e-mail between physicians and patients. Health Aff (Millwood) 2010 Jul;29(7):1370-1375 [FREE Full text] [doi: 10.1377/hlthaff.2010.0048] [Medline: 20606190]
23. Nazi KM. Veterans' voices: use of the American Customer Satisfaction Index (ACSI) Survey to identify My HealtheVet personal health record users' characteristics, needs, and preferences. J Am Med Inform Assoc 2010;17(2):203-211 [FREE Full text] [doi: 10.1136/jamia.2009.000240] [Medline: 20190065]
24. Kahn JS, Hilton JF, Van NT, Leasure S, Bryant KM, Hare CB, et al. Personal health records in a public hospital: experience at the HIV/AIDS clinic at San Francisco General Hospital. J Am Med Inform Assoc 2010;17(2):224-228 [FREE Full text] [doi: 10.1136/jamia.2009.000315] [Medline: 20190069]
25. Greenhalgh T, Hinder S, Stramer K, Bratan T, Russell J. Adoption, non-adoption, and abandonment of a personal electronic health record: case study of HealthSpace. BMJ 2010;341:c5814 [FREE Full text] [Medline: 21081595]
26. Ancker JS, Barrón Y, Rockoff ML, Hauser D, Pichardo M, Szerencsy A, et al. Use of an electronic patient portal among disadvantaged populations. J Gen Intern Med 2011 Oct;26(10):1117-1123 [FREE Full text] [doi: 10.1007/s11606-011-1749-y] [Medline: 21647748]
27. Horvath M, Levy J, L'Engle P, Carlson B, Ahmad A, Ferranti J. Impact of health portal enrollment with email reminders on adherence to clinic appointments: a pilot study. J Med Internet Res 2011;13(2):e41 [FREE Full text] [doi: 10.2196/jmir.1702] [Medline: 21616784]
28. Goel MS, Brown TL, Williams A, Cooper AJ, Hasnain-Wynia R, Baker DW. Patient reported barriers to enrolling in a patient portal. J Am Med Inform Assoc 2011 Dec;18 Suppl 1:i8-12 [FREE Full text] [doi: 10.1136/amiajnl-2011-000473] [Medline: 22071530]
29. Goel MS, Brown TL, Williams A, Hasnain-Wynia R, Thompson JA, Baker DW. Disparities in enrollment and use of an electronic patient portal. J Gen Intern Med 2011 Oct;26(10):1112-1116 [FREE Full text] [doi: 10.1007/s11606-011-1728-3] [Medline: 21538166]
30. Sequist TD, Zaslavsky AM, Colditz GA, Ayanian JZ. Electronic patient messages to promote colorectal cancer screening: a randomized controlled trial. Arch Intern Med 2011 Apr 11;171(7):636-641 [FREE Full text] [doi: 10.1001/archinternmed.2010.467] [Medline: 21149743]
31. Zulman DM, Nazi KM, Turvey CL, Wagner TH, Woods SS, An LC. Patient interest in sharing personal health record information: a web-based survey. Ann Intern Med 2011 Dec 20;155(12):805-810. [doi: 10.7326/0003-4819-155-12-201112200-00002] [Medline: 22184687]
32. Sarkar U, Karter AJ, Liu JY, Adler NE, Nguyen R, López A, et al. Social disparities in internet patient portal use in diabetes: evidence that the digital divide extends beyond access. J Am Med Inform Assoc 2011 May 1;18(3):318-321 [FREE Full text] [doi: 10.1136/jamia.2010.006015] [Medline: 21262921]
33. North F, Hanna BK, Crane SJ, Smith SA, Tulledge-Scheitel SM, Stroebel RJ. Patient portal doldrums: does an exam room promotional video during an office visit increase patient portal registrations and portal use? J Am Med Inform Assoc 2011 Dec;18 Suppl 1:i24-i27 [FREE Full text] [doi: 10.1136/amiajnl-2011-000381] [Medline: 21976028]

34. McInnes DK, Solomon JL, Bokhour BG, Asch SM, Ross D, Nazi KM, et al. Use of electronic personal health record systems to encourage HIV screening: an exploratory study of patient and provider perspectives. BMC Res Notes 2011;4:295 [FREE Full text] [doi: 10.1186/1756-0500-4-295] [Medline: 21843313]
35. Levy MA, Giuse DA, Eck C, Holder G, Lippard G, Cartwright J, et al. Integrated information systems for electronic chemotherapy medication administration. J Oncol Pract 2011 Jul;7(4):226-230 [FREE Full text] [doi: 10.1200/JOP.2011.000259] [Medline: 22043185]
36. Jung C, Padman R, Shevchik G, Paone S. Who are portal users vs. early e-Visit adopters? A preliminary analysis. AMIA Annu Symp Proc 2011;2011:1070-1079 [FREE Full text] [Medline: 22195168]
37. Nagykaldi Z, Aspy CB, Chou A, Mold JW. Impact of a Wellness Portal on the delivery of patient-centered preventive care. J Am Board Fam Med 2012 Apr;25(2):158-167 [FREE Full text] [doi: 10.3122/jabfm.2012.02.110130] [Medline: 22403196]
38. Nielsen AS, Halamka JD, Kinkel RP. Internet portal use in an academic multiple sclerosis center. J Am Med Inform Assoc 2012 Feb;19(1):128-133 [FREE Full text] [doi: 10.1136/amiajnl-2011-000177] [Medline: 21571744]
39. Tenforde M, Nowacki A, Jain A, Hickner J. The association between personal health record use and diabetes quality measures. J Gen Intern Med 2012 Apr;27(4):420-424 [FREE Full text] [doi: 10.1007/s11606-011-1889-0] [Medline: 22005937]
40. Johnson AJ, Easterling D, Nelson R, Chen MY, Frankel RM. Access to radiologic reports via a patient portal: clinical simulations to investigate patient preferences. J Am Coll Radiol 2012 Apr;9(4):256-263. [doi: 10.1016/j.jacr.2011.12.023] [Medline: 22469376]
41. Rosenbloom ST, Daniels TL, Talbot TR, McClain T, Hennes R, Stenner S, et al. Triaging patients at risk of influenza using a patient portal. J Am Med Inform Assoc 2012;19(4):549-554 [FREE Full text] [doi: 10.1136/amiajnl-2011-000382] [Medline: 22140208]
42. Noblin AM, Wan TTH, Fottler M. The impact of health literacy on a patient's decision to adopt a personal health record. Perspect Health Inf Manag 2012;9:1-13 [FREE Full text] [Medline: 23209454]
43. Wakefield DS, Kruse RL, Wakefield BJ, Koopman RJ, Keplinger LE, Canfield SM, et al. Consistency of patient preferences about a secure Internet-based patient communications portal: contemplating, enrolling, and using. Am J Med Qual 2012;27(6):494-502. [doi: 10.1177/1062860611436246] [Medline: 22517909]
44. Wagner PJ, Dias J, Howard S, Kintziger KW, Hudson MF, Seol YH, et al. Personal health records and hypertension control: a randomized trial. J Am Med Inform Assoc 2012 Aug;19(4):626-634 [FREE Full text] [doi: 10.1136/amiajnl-2011-000349] [Medline: 22234404]
45. Urowitz S, Wiljer D, Dupak K, Kuehner Z, Leonard K, Lovrics E, et al. Improving diabetes management with a patient portal: a qualitative study of diabetes self-management portal. J Med Internet Res 2012;14(6):e158 [FREE Full text] [doi: 10.2196/jmir.2265] [Medline: 23195925]
46. Tsai J, Rosenheck RA. Use of the internet and an online personal health record system by US veterans: comparison of Veterans Affairs mental health service users and other veterans nationally. J Am Med Inform Assoc 2012;19(6):1089-1094 [FREE Full text] [doi: 10.1136/amiajnl-2012-000971] [Medline: 22847305]
47. Emani S, Yamin CK, Peters E, Karson AS, Lipsitz SR, Wald JS, et al. Patient perceptions of a personal health record: a test of the diffusion of innovation model. J Med Internet Res 2012;14(6):e150 [FREE Full text] [doi: 10.2196/jmir.2278] [Medline: 23128775]
48. Ahlers-Schmidt CR, Nguyen M. Parent intention to use a patient portal as related to their children following a facilitated demonstration. Telemed J E Health 2013 Dec;19(12):979-981. [doi: 10.1089/tmj.2013.0041] [Medline: 24050608]
49. Schickedanz A, Huang D, Lopez A, Cheung E, Lyles CR, Bodenheimer T, et al. Access, interest, and attitudes toward electronic communication for health care among patients in the medical safety net. J Gen Intern Med 2013 Jul;28(7):914-920 [FREE Full text] [doi: 10.1007/s11606-012-2329-5] [Medline: 23423453]
50. Sanders MR, Winters P, Fortuna RJ, Mendoza M, Berliant M, Clark L, et al. Internet access and patient portal readiness among patients in a group of inner-city safety-net practices. J Ambul Care Manage 2013;36(3):251-259. [doi: 10.1097/JAC.0b013e31829702f9] [Medline: 23748274]
51. Ronda MCM, Dijkhorst-Oei LT, Gorter KJ, Beulens JWJ, Rutten GEHM. Differences between diabetes patients who are interested or not in the use of a patient Web portal. Diabetes Technol Ther 2013 Jul;15(7):556-563 [FREE Full text] [doi: 10.1089/dia.2013.0023] [Medline: 23777369]
52. Osborn CY, Mayberry LS, Wallston KA, Johnson KB, Elasy TA. Understanding patient portal use: implications for medication management. J Med Internet Res 2013;15(7):e133 [FREE Full text] [doi: 10.2196/jmir.2589] [Medline: 23823974]
53. Nazi KM, Hogan TP, McInnes DK, Woods SS, Graham G. Evaluating patient access to Electronic Health Records: results from a survey of veterans. Med Care 2013 Mar;51(3 Suppl 1):S52-S56. [doi: 10.1097/MLR.0b013e31827808db] [Medline: 23407012]
54. Lyles CR, Sarkar U, Ralston JD, Adler N, Schillinger D, Moffet HH, et al. Patient-provider communication and trust in relation to use of an online patient portal among diabetes patients: The Diabetes and Aging Study. J Am Med Inform Assoc 2013;20(6):1128-1131 [FREE Full text] [doi: 10.1136/amiajnl-2012-001567] [Medline: 23676243]
55. Ketterer T, West DW, Sanders VP, Hossain J, Kondo MC, Sharif I. Correlates of patient portal enrollment and activation in primary care pediatrics. Acad Pediatr 2013;13(3):264-271. [doi: 10.1016/j.acap.2013.02.002] [Medline: 23680344]

56. Kerns JW, Krist AH, Longo DR, Kuzel AJ, Woolf SH. How patients want to engage with their personal health record: a qualitative study. BMJ Open 2013;3(7):1-10 [FREE Full text] [doi: 10.1136/bmjopen-2013-002931] [Medline: 23901027]
57. Hanberger L, Ludvigsson J, Nordfeldt S. Use of a web 2.0 portal to improve education and communication in young patients with families: randomized controlled trial. J Med Internet Res 2013;15(8):e175 [FREE Full text] [doi: 10.2196/jmir.2425] [Medline: 23973555]
58. Butler JM, Carter M, Hayden C, Gibson B, Weir C, Snow L, et al. Understanding adoption of a personal health record in rural health care clinics: revealing barriers and facilitators of adoption including attributions about potential patient portal users and self-reported characteristics of early adopting users. AMIA Annu Symp Proc 2013;2013:152-161 [FREE Full text] [Medline: 24551328]
59. Gu Y, Day K. Propensity of people with long-term conditions to use personal health records. Stud Health Technol Inform 2013;188:46-51. [Medline: 23823287]
60. Gerber DE, Laccetti AL, Chen B, Yan J, Cai J, Gates S, et al. Predictors and intensity of online access to electronic medical records among patients with cancer. J Oncol Pract 2014 Sep;10(5):e307-e312 [FREE Full text] [doi: 10.1200/JOP.2013.001347] [Medline: 25006222]
61. Kondylakis H, Kazantzaki E, Koumakis L, Genitsaridi I, Marias K, Gorini A, et al. Development of interactive empowerment services in support of personalised medicine. Ecancermedicalscience 2014;8:400 [FREE Full text] [doi: 10.3332/ecancer.2014.400] [Medline: 24567757]
62. Krist AH, Woolf SH, Bello GA, Sabo RT, Longo DR, Kashiri P, et al. Engaging primary care patients to use a patient-centered personal health record. Ann Fam Med 2014;12(5):418-426 [FREE Full text] [doi: 10.1370/afm.1691] [Medline: 25354405]
63. Jung C, Padman R. Virtualized healthcare delivery: understanding users and their usage patterns of online medical consultations. Int J Med Inform 2014 Dec;83(12):901-914. [doi: 10.1016/j.ijmedinf.2014.08.004] [Medline: 25193501]
64. Haun JN, Lind JD, Shimada SL, Martin TL, Gosline RM, Antinori N, et al. Evaluating user experiences of the secure messaging tool on the Veterans Affairs' patient portal system. J Med Internet Res 2014;16(3):e75 [FREE Full text] [doi: 10.2196/jmir.2976] [Medline: 24610454]
65. van der Vaart R, Drossaert CHC, Taal E, Drossaers-Bakker KW, Vonkeman HE, van de Laar MAFJ. Impact of patient-accessible electronic medical records in rheumatology: use, satisfaction and effects on empowerment among patients. BMC Musculoskelet Disord 2014;15:102 [FREE Full text] [doi: 10.1186/1471-2474-15-102] [Medline: 24673997]
66. Ancker JS, Silver M, Kaushal R. Rapid growth in use of personal health records in New York, 2012-2013. J Gen Intern Med 2014 Jun;29(6):850-854. [doi: 10.1007/s11606-014-2792-2] [Medline: 24519102]
67. Abramson EL, Patel V, Edwards A, Kaushal R. Consumer perspectives on personal health records: a 4-community study. Am J Manag Care 2014 Apr;20(4):287-296 [FREE Full text] [Medline: 24884860]
68. Phelps RG, Taylor J, Simpson K, Samuel J, Turner AN. Patients' continuing use of an online health record: a quantitative evaluation of 14,000 patient years of access data. J Med Internet Res 2014;16(10):e241 [FREE Full text] [doi: 10.2196/jmir.3371] [Medline: 25344621]
69. Neuner J, Fedders M, Caravella M, Bradford L, Schapira M. Meaningful use and the patient portal: patient enrollment, use, and satisfaction with patient portals at a later-adopting center. Am J Med Qual 2015;30(2):105-113. [doi: 10.1177/1062860614523488] [Medline: 24563085]
70. Riippa I, Linna M, Rönkkö I. The effect of a patient portal with electronic messaging on patient activation among chronically ill patients: controlled before-and-after study. J Med Internet Res 2014;16(11):e257 [FREE Full text] [doi: 10.2196/jmir.3462] [Medline: 25413368]
71. Ancker JS, Osorio SN, Cheriff A, Cole CL, Silver M, Kaushal R. Patient activation and use of an electronic patient portal. Inform Health Soc Care 2014 Apr 30:1-13. [doi: 10.3109/17538157.2014.908200] [Medline: 24786648]
72. Lober WB, Zierler B, Herbaugh A, Shinstrom SE, Stolyar A, Kim EH, et al. Barriers to the use of a personal health record by an elderly population. AMIA Annu Symp Proc 2006:514-518 [FREE Full text] [Medline: 17238394]
73. Taha J, Czaja SJ, Sharit J, Morrow DG. Factors affecting usage of a personal health record (PHR) to manage health. Psychol Aging 2013 Dec;28(4):1124-1139. [doi: 10.1037/a0033911] [Medline: 24364414]
74. Sarkar U, Karter AJ, Liu JY, Adler NE, Nguyen R, Lopez A, et al. The literacy divide: health literacy and the use of an internet-based patient portal in an integrated health system-results from the diabetes study of northern California (DISTANCE). J Health Commun 2010;15 Suppl 2:183-196 [FREE Full text] [doi: 10.1080/10810730.2010.499988] [Medline: 20845203]
75. Logue MD, Effken JA. Modeling factors that influence personal health records adoption. Comput Inform Nurs 2012 Jul;30(7):354-362. [doi: 10.1097/NXN.0b013e3182510717] [Medline: 22525046]
76. Wynia MK, Torres GW, Lemieux J. Many physicians are willing to use patients' electronic personal health records, but doctors differ by location, gender, and practice. Health Aff (Millwood) 2011 Feb;30(2):266-273 [FREE Full text] [doi: 10.1377/hlthaff.2010.0342] [Medline: 21289348]
77. Nazi KM. The personal health record paradox: health care professionals' perspectives and the information ecology of personal health record systems in organizational and clinical settings. J Med Internet Res 2013;15(4):e70 [FREE Full text] [doi: 10.2196/jmir.2443] [Medline: 23557596]
78. Yau GL, Williams AS, Brown JB. Family physicians' perspectives on personal health records: qualitative study. Can Fam Physician 2011 May;57(5):e178-e184 [FREE Full text] [Medline: 21642732]

79. van der Vaart R, Drossaert CHC, Taal E, van de Laar MAFJ. Giving rheumatology patients online home access to their electronic medical record (EMR): advantages, drawbacks and preconditions according to care providers. Rheumatol Int 2013 Sep;33(9):2405-2410 [FREE Full text] [doi: 10.1007/s00296-012-2408-2] [Medline: 22453527]
80. Urowitz S, Wiljer D, Apatu E, Eysenbach G, Delenardo C, Harth T, et al. Is Canada ready for patient accessible electronic health records? A national scan. BMC Med Inform Decis Mak 2008;8:33 [FREE Full text] [doi: 10.1186/1472-6947-8-33] [Medline: 18652695]
81. Witry MJ, Doucette WR, Daly JM, Levy BT, Chrischilles EA. Family physician perceptions of personal health records. Perspect Health Inf Manag 2010;7:1d [FREE Full text] [Medline: 20697465]
82. Pai HH, Lau F, Barnett J, Jones S. Meeting the health information needs of prostate cancer patients using personal health records. Curr Oncol 2013 Dec;20(6):e561-e569 [FREE Full text] [doi: 10.3747/co.20.1584] [Medline: 24311957]
83. Selden CR, Zorn M, Ratzan SC, Parker RM. National Library of Medicine Current Bibliographies in Medicine: Health Literacy. Washington, DC: U.S. Government Printing Office; 2000. US Department of Health and Human Services. Healthy People 2010. Introduction URL: http://chirr.nlm.nih.gov/health-literacy.php [accessed 2015-06-02] [WebCite Cache ID 6YzJ53nyH]
84. Sox CM, Gribbons WM, Loring BA, Mandl KD, Batista R, Porter SC. Patient-centered design of an information management module for a personally controlled health record. J Med Internet Res 2010;12(3):e36 [FREE Full text] [doi: 10.2196/jmir.1269] [Medline: 20805091]
85. Haggstrom DA, Saleem JJ, Russ AL, Jones J, Russell SA, Chumbler NR. Lessons learned from usability testing of the VA's personal health record. J Am Med Inform Assoc 2011 Dec;18 Suppl 1:i13-i17 [FREE Full text] [doi: 10.1136/amiajnl-2010-000082] [Medline: 21984604]
86. Krist AH, Peele E, Woolf SH, Rothemich SF, Loomis JF, Longo DR, et al. Designing a patient-centered personal health record to promote preventive care. BMC Med Inform Decis Mak 2011;11:73 [FREE Full text] [doi: 10.1186/1472-6947-11-73] [Medline: 22115059]
87. Woods SS, Schwartz E, Tuepker A, Press NA, Nazi KM, Turvey CL, et al. Patient experiences with full electronic access to health records and clinical notes through the My HealtheVet Personal Health Record Pilot: qualitative study. J Med Internet Res 2013;15(3):e65 [FREE Full text] [doi: 10.2196/jmir.2356] [Medline: 23535584]
88. Monkman H, Kushniruk A. Applying usability methods to identify health literacy issues: an example using a Personal Health Record. Stud Health Technol Inform 2013;183:179-185. [Medline: 23388278]
89. Zarcadoolas C, Vaughon WL, Czaja SJ, Levy J, Rockoff ML. Consumers' perceptions of patient-accessible electronic medical records. J Med Internet Res 2013;15(8):e168 [FREE Full text] [doi: 10.2196/jmir.2507] [Medline: 23978618]
90. Krist AH, Woolf SH, Rothemich SF, Johnson RE, Peele JE, Cunningham TD, et al. Interactive preventive health record to enhance delivery of recommended care: a randomized trial. Ann Fam Med 2012;10(4):312-319 [FREE Full text] [doi: 10.1370/afm.1383] [Medline: 22778119]
91. Taha J, Sharit J, Czaja SJ. The impact of numeracy ability and technology skills on older adults' performance of health management tasks using a patient portal. J Appl Gerontol 2014 Jun;33(4):416-436. [doi: 10.1177/0733464812447283] [Medline: 24781964]
92. Schnipper JL, Gandhi TK, Wald JS, Grant RW, Poon EG, Volk LA, et al. Design and implementation of a web-based patient portal linked to an electronic health record designed to improve medication safety: the Patient Gateway medications module. Inform Prim Care 2008;16(2):147-155. [Medline: 18713531]
93. Fuji KT, Abbott AA, Galt KA. Personal health record design: qualitative exploration of issues inhibiting optimal use. Diabetes Care 2014;37(1):e13-e14 [FREE Full text] [doi: 10.2337/dc13-1630] [Medline: 24356602]
94. Britto MT, Jimison HB, Munafo JK, Wissman J, Rogers ML, Hersh W. Usability testing finds problems for novice users of pediatric portals. J Am Med Inform Assoc 2009;16(5):660-669 [FREE Full text] [doi: 10.1197/jamia.M3154] [Medline: 19567793]
95. Kuziemsky CE, Kushniruk A. Context mediated usability testing. Stud Health Technol Inform 2014;205:905-909. [Medline: 25160319]
96. Do NV, Barnhill R, Heermann-Do KA, Salzman KL, Gimbel RW. The military health system's personal health record pilot with Microsoft HealthVault and Google Health. J Am Med Inform Assoc 2011;18(2):118-124 [FREE Full text] [doi: 10.1136/jamia.2010.004671] [Medline: 21292705]
97. Gaskin GL, Longhurst CA, Slayton R, Das AK. Sociotechnical Challenges of Developing an Interoperable Personal Health Record: Lessons Learned. Appl Clin Inform 2011;2(4):406-419 [FREE Full text] [doi: 10.4338/ACI-2011-06-RA-0035] [Medline: 22003373]
98. Ennis L, Robotham D, Denis M, Pandit N, Newton D, Rose D, et al. Collaborative development of an electronic Personal Health Record for people with severe and enduring mental health problems. BMC Psychiatry 2014;14(1):305 [FREE Full text] [doi: 10.1186/s12888-014-0305-9] [Medline: 25403285]
99. Kushniruk AW, Patel VL. Cognitive and usability engineering methods for the evaluation of clinical information systems. J Biomed Inform 2004 Feb;37(1):56-76. [doi: 10.1016/j.jbi.2004.01.003] [Medline: 15016386]

100. Tuil WS, ten Hoopen AJ, Braat DDM, de Vries RPF, Kremer JAM. Patient-centred care: using online personal medical records in IVF practice. Hum Reprod 2006 Nov;21(11):2955-2959 [FREE Full text] [doi: 10.1093/humrep/del214] [Medline: 16982658]
101. Grant RW, Wald JS, Poon EG, Schnipper JL, Gandhi TK, Volk LA, et al. Design and implementation of a web-based patient portal linked to an ambulatory care electronic health record: patient gateway for diabetes collaborative care. Diabetes Technol Ther 2006 Oct;8(5):576-586 [FREE Full text] [doi: 10.1089/dia.2006.8.576] [Medline: 17037972]
102. Hess R, Bryce CL, Paone S, Fischer G, McTigue KM, Olshansky E, et al. Exploring challenges and potentials of personal health records in diabetes self-management: implementation and initial assessment. Telemed J E Health 2007 Oct;13(5):509-517. [doi: 10.1089/tmj.2006.0089] [Medline: 17999613]
103. Kim EH, Stolyar A, Lober WB, Herbaugh AL, Shinstrom SE, Zierler BK, et al. Usage patterns of a personal health record by elderly and disabled users. AMIA Annu Symp Proc 2007:409-413 [FREE Full text] [Medline: 18693868]
104. Bergman DA, Brown NL, Wilson S. Teen use of a patient portal: a qualitative study of parent and teen attitudes. Perspect Health Inf Manag 2008;5:13 [FREE Full text] [Medline: 18923702]
105. Green BB, Cook AJ, Ralston JD, Fishman PA, Catz SL, Carlson J, et al. Effectiveness of home blood pressure monitoring, Web communication, and pharmacist care on hypertension control: a randomized controlled trial. JAMA 2008 Jun 25;299(24):2857-2867 [FREE Full text] [doi: 10.1001/jama.299.24.2857] [Medline: 18577730]
106. Staroselsky M, Volk LA, Tsurikova R, Newmark LP, Lippincott M, Litvak I, et al. An effort to improve electronic health record medication list accuracy between visits: patients' and physicians' response. Int J Med Inform 2008 Mar;77(3):153-160. [doi: 10.1016/j.ijmedinf.2007.03.001] [Medline: 17434337]
107. Wald JS, Grant RW, Schnipper JL, Gandhi TK, Poon EG, Businger AC, et al. Survey analysis of patient experience using a practice-linked PHR for type 2 diabetes mellitus. AMIA Annu Symp Proc 2009;2009:678-682 [FREE Full text] [Medline: 20351940]
108. Leveille SG, Huang A, Tsai SB, Allen M, Weingart SN, Iezzoni LI. Health coaching via an internet portal for primary care patients with chronic conditions: a randomized controlled trial. Med Care 2009 Jan;47(1):41-47. [doi: 10.1097/MLR.0b013e3181844dd0] [Medline: 19106729]
109. Kim EH, Stolyar A, Lober WB, Herbaugh AL, Shinstrom SE, Zierler BK, et al. Challenges to using an electronic personal health record by a low-income elderly population. J Med Internet Res 2009;11(4):e44 [FREE Full text] [doi: 10.2196/jmir.1256] [Medline: 19861298]
110. Wiljer D, Leonard KJ, Urowitz S, Apatu E, Massey C, Quartey NK, et al. The anxious wait: assessing the impact of patient accessible EHRs for breast cancer patients. BMC Med Inform Decis Mak 2010;10:46 [FREE Full text] [doi: 10.1186/1472-6947-10-46] [Medline: 20809950]
111. Reti SR, Feldman HJ, Ross SE, Safran C. Improving personal health records for patient-centered care. J Am Med Inform Assoc 2010;17(2):192-195 [FREE Full text] [doi: 10.1136/jamia.2009.000927] [Medline: 20190063]
112. Shaw RJ, Ferranti J. Patient-provider internet portals--patient outcomes and use. Comput Inform Nurs 2011 Dec;29(12):714-8; quiz 719. [doi: 10.1097/NCN.0b013e318224b597] [Medline: 21697705]
113. Wright A, Poon EG, Wald J, Feblowitz J, Pang JE, Schnipper JL, et al. Randomized controlled trial of health maintenance reminders provided directly to patients through an electronic PHR. J Gen Intern Med 2012 Jan;27(1):85-92 [FREE Full text] [doi: 10.1007/s11606-011-1859-6] [Medline: 21904945]
114. Schnipper JL, Gandhi TK, Wald JS, Grant RW, Poon EG, Volk LA, et al. Effects of an online personal health record on medication accuracy and safety: a cluster-randomized trial. J Am Med Inform Assoc 2012;19(5):728-734 [FREE Full text] [doi: 10.1136/amiajnl-2011-000723] [Medline: 22556186]
115. Palen TE, Ross C, Powers JD, Xu S. Association of online patient access to clinicians and medical records with use of clinical services. JAMA 2012 Nov 21;308(19):2012-2019. [doi: 10.1001/jama.2012.14126] [Medline: 23168824]
116. Schnipper JL, Gandhi TK, Wald JS, Grant RW, Poon EG, Volk LA, et al. Effects of an online personal health record on medication accuracy and safety: a cluster-randomized trial. J Am Med Inform Assoc 2012;19(5):728-734 [FREE Full text] [doi: 10.1136/amiajnl-2011-000723] [Medline: 22556186]
117. Wade-Vuturo AE, Mayberry LS, Osborn CY. Secure messaging and diabetes management: experiences and perspectives of patient portal users. J Am Med Inform Assoc 2013 May 1;20(3):519-525 [FREE Full text] [doi: 10.1136/amiajnl-2012-001253] [Medline: 23242764]
118. Sarkar U, Lyles CR, Parker MM, Allen J, Nguyen R, Moffet HH, et al. Use of the refill function through an online patient portal is associated with improved adherence to statins in an integrated health system. Med Care 2014 Mar;52(3):194-201 [FREE Full text] [doi: 10.1097/MLR.0000000000000069] [Medline: 24374412]
119. Otsuka SH, Tayal NH, Porter K, Embi PJ, Beatty SJ. Improving herpes zoster vaccination rates through use of a clinical pharmacist and a personal health record. Am J Med 2013 Sep;126(9):832.e1-832.e6 [FREE Full text] [doi: 10.1016/j.amjmed.2013.02.018] [Medline: 23830534]
120. North F, Crane SJ, Stroebel RJ, Cha SS, Edell ES, Tulledge-Scheitel SM. Patient-generated secure messages and eVisits on a patient portal: are patients at risk? J Am Med Inform Assoc 2013;20(6):1143-1149 [FREE Full text] [doi: 10.1136/amiajnl-2012-001208] [Medline: 23703826]

121. North F, Crane SJ, Chaudhry R, Ebbert JO, Ytterberg K, Tulledge-Scheitel SM, et al. Impact of patient portal secure messages and electronic visits on adult primary care office visits. Telemed J E Health 2014 Mar;20(3):192-198 [FREE Full text] [doi: 10.1089/tmj.2013.0097] [Medline: 24350803]
122. Murray MF, Giovanni MA, Klinger E, George E, Marinacci L, Getty G, et al. Comparing electronic health record portals to obtain patient-entered family health history in primary care. J Gen Intern Med 2013 Dec;28(12):1558-1564 [FREE Full text] [doi: 10.1007/s11606-013-2442-0] [Medline: 23588670]
123. Heyworth L, Paquin AM, Clark J, Kamenker V, Stewart M, Martin T, et al. Engaging patients in medication reconciliation via a patient portal following hospital discharge. J Am Med Inform Assoc 2014 Feb;21(e1):e157-e162 [FREE Full text] [doi: 10.1136/amiajnl-2013-001995] [Medline: 24036155]
124. Britto MT, Hesse EA, Kamdar OJ, Munafo JK. Parents' perceptions of a patient portal for managing their child's chronic illness. J Pediatr 2013 Jul;163(1):280-1.e1. [doi: 10.1016/j.jpeds.2013.02.041] [Medline: 23541773]
125. Aberger EW, Migliozzi D, Follick MJ, Malick T, Ahern DK. Enhancing patient engagement and blood pressure management for renal transplant recipients via home electronic monitoring and web-enabled collaborative care. Telemed J E Health 2014 Sep;20(9):850-854. [doi: 10.1089/tmj.2013.0317] [Medline: 25046403]
126. Barron J, Bedra M, Wood J, Finkelstein J. Exploring three perspectives on feasibility of a patient portal for older adults. Stud Health Technol Inform 2014;202:181-184. [Medline: 25000046]
127. Borbolla D, Del FG, Taliercio V, Otero C, Campos F, Martinez M, et al. Integrating personalized health information from MedlinePlus in a patient portal. Stud Health Technol Inform 2014;205:348-352. [Medline: 25160204]
128. Wright A, Feblowitz J, Maloney FL, Henkin S, Ramelson H, Feltman J, et al. Increasing patient engagement: patients' responses to viewing problem lists online. Appl Clin Inform 2014;5(4):930-942. [doi: 10.4338/ACI-2014-07-RA-0057] [Medline: 25589908]
129. Tom JO, Chen C, Zhou YY. Personal health record use and association with immunizations and well-child care visits recommendations. J Pediatr 2014 Jan;164(1):112-117. [doi: 10.1016/j.jpeds.2013.08.046] [Medline: 24120019]
130. Nazi KM, Turvey CL, Klein DM, Hogan TP, Woods SS. VA OpenNotes: exploring the experiences of early patient adopters with access to clinical notes. J Am Med Inform Assoc 2015 Mar;22(2):380-389. [doi: 10.1136/amiajnl-2014-003144] [Medline: 25352570]
131. Lau M, Campbell H, Tang T, Thompson DJS, Elliott T. Impact of patient use of an online patient portal on diabetes outcomes. Can J Diabetes 2014 Feb;38(1):17-21. [doi: 10.1016/j.jcjd.2013.10.005] [Medline: 24485208]
132. Hess R, Fischer GS, Sullivan SM, Dong X, Weimer M, Zeith C, et al. Patterns of response to patient-centered decision support through a personal health record. Telemed J E Health 2014 Nov;20(11):984-989. [doi: 10.1089/tmj.2013.0332] [Medline: 25243350]
133. Hall MJ, Herda MM, Handorf EA, Rybak CC, Keleher CA, Siemon M, et al. Direct-to-patient disclosure of results of mismatch repair screening for Lynch syndrome via electronic personal health record: a feasibility study. Genet Med 2014 Nov;16(11):854-861. [doi: 10.1038/gim.2014.42] [Medline: 24784156]
134. Druss BG, Ji X, Glick G, von Esenwein SA. Randomized trial of an electronic personal health record for patients with serious mental illnesses. Am J Psychiatry 2014 Mar;171(3):360-368. [doi: 10.1176/appi.ajp.2013.13070913] [Medline: 24435025]
135. Crotty BH, Tamrat Y, Mostaghimi A, Safran C, Landon BE. Patient-to-physician messaging: volume nearly tripled as more patients joined system, but per capita rate plateaued. Health Aff (Millwood) 2014 Oct;33(10):1817-1822. [doi: 10.1377/hlthaff.2013.1145] [Medline: 25288428]
136. Chrischilles EA, Hourcade JP, Doucette W, Eichmann D, Gryzlak B, Lorentzen R, et al. Personal health records: a randomized trial of effects on elder medication safety. J Am Med Inform Assoc 2014;21(4):679-686. [doi: 10.1136/amiajnl-2013-002284] [Medline: 24326536]
137. Cabitza F, Simone C, De MG. User-driven prioritization of features for a prospective InterPersonal Health Record: perceptions from the Italian context. Comput Biol Med 2015 Apr;59:202-210. [doi: 10.1016/j.compbiomed.2014.03.009] [Medline: 24768267]
138. Hargreaves JS. Will electronic personal health records benefit providers and patients in rural America? Telemed J E Health 2010 Mar;16(2):167-176. [doi: 10.1089/tmj.2009.0063] [Medline: 20082592]
139. Guy R, Hocking J, Wand H, Stott S, Ali H, Kaldor J. How effective are short message service reminders at increasing clinic attendance? A meta-analysis and systematic review. Health Serv Res 2012 Apr;47(2):614-632 [FREE Full text] [doi: 10.1111/j.1475-6773.2011.01342.x] [Medline: 22091980]
140. Simmons LA, Wolever RQ, Bechard EM, Snyderman R. Patient engagement as a risk factor in personalized health care: a systematic review of the literature on chronic disease. Genome Med 2014;6(2):16 [FREE Full text] [doi: 10.1186/gm533] [Medline: 24571651]

Abbreviations

AHRQ: Agency for Health care Research and Quality
ePHR: electronic personal health record

EHR: electronic health record
CMS: Centers for Medicare and Medicaid Services
MU: meaningful use
SM: secure messaging

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ORIGINAL RESEARCH

Smarter Hospital Communication: Secure Smartphone Text Messaging Improves Provider Satisfaction and Perception of Efficacy, Workflow

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BACKGROUND: Though current hospital paging systems are neither efficient (callbacks disrupt workflow), nor secure (pagers are not Health Insurance Portability and Accountability Act [HIPAA]-compliant), they are routinely used to communicate patient information. Smartphone-based text messaging is a potentially more convenient and efficient mobile alternative; however, commercial cellular networks are also not secure.

OBJECTIVE: To determine if augmenting one-way pagers with Medigram, a secure, HIPAA-compliant group messaging (HCGM) application for smartphones, could improve hospital team communication.

DESIGN: Eight-week prospective, cluster-randomized, controlled trial

SETTING: Stanford Hospital

INTERVENTION: Three inpatient medicine teams used the HCGM application in addition to paging, while two inpatient medicine teams used paging only for intra-team communication.

MEASUREMENTS: Baseline and post-study surveys were collected from 22 control and 41 HCGM team members.

RESULTS: When compared with paging, HCGM was rated significantly ($P < 0.05$) more effective in: (1) allowing users to communicate thoughts clearly ($P = 0.010$) and efficiently ($P = 0.009$) and (2) integrating into workflow during rounds ($P = 0.018$) and patient discharge ($P = 0.012$). Overall satisfaction with HCGM was significantly higher ($P = 0.003$). 85% of HCGM team respondents said they would recommend using an HCGM system on the wards.

CONCLUSIONS: Smartphone-based, HIPAA-compliant group messaging applications improve provider perception of in-hospital communication, while providing the information security that paging and commercial cellular networks do not. *Journal of Hospital Medicine* 2014;9:573–578.

Pagers, though reliable and familiar technology, can be suboptimal for facilitating healthcare team communication.[1,2] Most paging systems utilize single-function pagers and only allow one-way communication, requiring recipients to disrupt workflow to respond to pages. Paging transmissions can also be intercepted, and the information presented on pager displays can be viewed by anyone in possession of the pager.

Smartphones allow for instantaneous two-way and group communication through advanced technological features. Their use is widespread; over 81% of American physicians owned a smartphone in 2011.[3] Previous studies demonstrate that healthcare providers rate smartphone-based email positively, and that team smartphones can facilitate communication between nurses and physicians.[4,5] However, these studies specifically examined the utility of smartphone-based email and voice calls, and did not include text messaging. Limitations of traditional smartphone-based text messaging include Health Insurance Portability and Accountability Act (HIPAA) noncompliance and dependence on in-hospital cellular reception, which can be unreliable. HIPAA is a 1996 US federal law that established a set of privacy and security rules governing not only what is considered protected health information (PHI), but also minimum standards for the protection of such information. HIPAA compliance is defined as meeting these minimum standards for physical, network, and process security.[6,7] Though PHI is often transmitted via paging systems and commercial carrier-based text messaging, these modalities are not secure and are thus not HIPAA-compliant.

Text messaging applications that address these security and reliability issues have the potential to greatly enhance in-hospital communication. We hypothesized that a smartphone-based HIPAA-compliant group messaging application could improve in-hospital communication on the inpatient medicine service. To our

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knowledge, our study is the first to examine a HIPAA-compliant text messaging system, and also the first to compare a combination paging/HIPAA-compliant group messaging (HCGM) system with a paging-only system in assessing healthcare provider perception of communication efficiency.

METHODS

Intervention

This study utilized Medigram (Medigram, Inc., https://medigram.com), a free HCGM application for smartphones (available on iOS and Android) that allows users to send and receive encrypted, password-protected text messages via the hospital wireless fidelity (Wi-Fi) network, using commercial cellular networks as backup.

Study Design

In an eight-week prospective, cluster-randomized, controlled trial conducted at Stanford Hospital (June 25, 2012–August 17, 2012), three of five inpatient medicine teams were randomized to use Medigram in addition to the existing hospital paging system (HCGM teams); the remaining two teams were assigned to use hospital paging only (control teams). Each team included one attending physician, one resident, two interns, two medical students, and a case manager. According to prescheduled rotations, attendings rotated every two weeks, and residents, interns, and medical students rotated every four weeks. All rotations were either off-service or off-site, with the exception of two attendings who rotated between study teams but within their experimental designations. Case managers remained with the same team. Additionally, the satellite pharmacy was provided with an HCGM-equipped smartphone to communicate with experimental teams.

Participation was voluntary, with a 96% participation rate (n = 75). HCGM teams downloaded the free application onto their smartphones. Participants without smartphones were provided with one for the duration of the study. Proper application use was demonstrated by one researcher in a 10-minute standardized presentation. HCGM teams were encouraged to use the application in lieu of paging, except when patient care could be compromised.

All participants completed linked baseline and post-study surveys. Gift cards valued at $10 were provided on completion of each survey. Though participants were assigned to either HCGM or control groups based on the randomized assignment of their preset cluster (hospital team) to an HCGM or control group, analysis was performed on the individual level due to the hospital's set rotation schedule, which resulted in dynamic, frequently changing clusters. We also compared average length of stay and time of discharge for patients treated by control versus HCGM teams. Clinical outcome data were obtained from the hospital's database using Midas+ Statit Solutions (Midas+ Statit Solutions Group, Tucson, AZ). Survey and clinical outcome data were analyzed in Stata (StataCorp, College Station, TX) and R (R Foundation for Statistical Computing, Vienna, Austria).

Survey Design and Analysis

Identical, anonymous baseline surveys were administered to control and HCGM teams. These surveys assessed attitudes toward the hospital paging system using a 5-point Likert scale (1 = low, 5 = high) to evaluate perceived measures of effectiveness, workflow integration, and overall satisfaction. Wilcoxon rank sum tests were used to compare control and HCGM group responses to these questions. Free response questions asked participants to list the most effective and ineffective aspects of the paging system.

Post-study surveys included all baseline survey questions, as well as questions about personal texting behavior. Post-study HCGM surveys also included a parallel set of questions rating the HCGM application on the same measures of perceived effectiveness, workflow integration, and overall satisfaction. Wilcoxon signed rank tests were used to compare HCGM participants' baseline evaluations of paging to their post-study evaluations of the HCGM application. Baseline and post-study surveys were linked by the last four digits of respondent cell phone numbers. To compare control and HCGM group perceptions of the hospital paging system at study completion, post-study survey responses were evaluated using Wilcoxon rank sum tests. The family-wise error rate was left unadjusted due to concerns around inflated type II errors, given the high degree of correlation between survey questions.

All free response questions were analyzed using thematic analysis and grounded theory. After reviewing responses to each question, a list of overarching themes was constructed. Two researchers then independently reviewed each free-response entry to assign it to one or more of these themes (some responses included several ideas with distinct themes). Entries with concordant theme assignments (~90%) were coded as such; nonconcordant entries required an additional round of review to reach concordance. Finally, objective outcome measures including length of stay and time of discharge were analyzed by two-sample *t* test.

Information Security

The HCGM application in this study features 256-bit encryption technology and requires a six-digit password to access texts. For added security, a study-dedicated server (HP ProLiant DL 180 G6; Hewlett-Packard Co., Palo Alto, CA) with 4-TB hard drive capacity (4 Seagate Barracuda ST1000DM003 1 TB 7200 RPM internal hard drives; Seagate Technology PLC, Cupertino, CA) was installed in the Stanford School of Medicine Data Center to store encrypted

text messages. Data stored on the phones/server were accessible only to study participants, not researchers. These security measures were approved by Stanford Hospital and Stanford School of Medicine's security and privacy review process.

Hospital Paging System

Stanford Hospital and Clinics is a quaternary care academic medical center with 613 beds, 49 operating rooms, and over 25,000 inpatient admissions per year.[8] The institution uses one-way alphanumeric pagers (primary model: Daviscomm BR802 Flex Pager from USA Mobility, secondary model: Sun Telecom Titan 3 Plus from USA Mobility; USA Mobility Inc., Springfield, VA). USA Mobility operates the largest one- and two-way paging networks in the United States.[9]

RESULTS

Of 26 control and 49 HCGM group members participating in the study, linked baseline and post-study surveys were collected for 22 control and 41 HCGM participants (completion rates of 84.6% and 83.7%, respectively). To minimize recall bias, surveys not completed within a prespecified timeframe upon entering or leaving a team (two days attendings, four days others) were excluded.

Control and HCGM Group Characteristics

Control and HCGM groups were well matched demographically (Table 1). The average ages of control and HCGM group members were 30.10 and 30.95, respectively. Both groups were 59% male and 41% female.

A similar distribution of team member roles was observed in both groups, with two exceptions. First, the proportion of attending respondents in the HCGM group was lower than in the control group. This was due to the fact that several HCGM attendings entered discrepant ID codes on their surveys, thus making it impossible to link baseline and post-study responses; these data were excluded. Additionally, two HCGM attendings were on service for four, rather than the standard two weeks, meaning two additional data points from unique attendings could not be obtained. Second, the experimental group included four pharmacists, whereas the control group did not. As a sensitivity test, we analyzed the data excluding the pharmacists, and this did not change our results.

TABLE 1. Comparison of Control and HCGM Groups

	Control Group	HCGM Group
Paired surveys collected (completion rate)	22 (85%)	41 (84%)
Average age ± 95% CI	30.10 ± 1.71	30.95 ± 2.94
Gender		
Male	13 (59%)	24 (59%)
Female	9 (41%)	17 (41%)
Role		
Medical students	6 (27%)	11 (27%)
Interns (PGY 1)	7 (32%)	12 (29%)
Residents (PGY2 and 3)	3 (14%)	6 (15%)
Attending physicians	5 (23%)	5 (12%)
Case managers	1 (5%)	3 (7%)
Pharmacists	0 (0%)	4 (10%)

NOTE: **Abbreviations:** HCGM, HIPAA-compliant group messaging; CI, confidence interval; PGY, postgraduate year.

Baseline Evaluations of the Hospital Paging System

At baseline, there were no significant differences between control and HCGM participants' perceptions of paging effectiveness (see Supporting Table 1, in the online version of this article). On a 5-point rating scale (1 = low, 5 = high), 63 subjects rated their overall satisfaction with the paging system an average of 2.79 (95% confidence interval: 2.55-3.03).

In free response questions, components of the paging system most frequently cited as effective included: reliability of message transmission, alphanumeric text paging, and ease of use (30.4%, 25.0%, and 14.3% of 56 respondents, respectively) (Table 2). Ineffective aspects included: time wasted waiting for responses to pages, the unidirectional nature of pagers, and needing to find a computer to send a text page (29.3%, 24.1%, and 20.7% of 58 respondents, respectively) (Table 2).

Baseline Utilization of Text Messaging

The majority of participants were familiar with text messaging and regularly used it personally and professionally prior to the start of the study. 90.5% of participants (n = 63) reported sending an average of ≥1 personal text messages per day, with the largest proportion (39.7%) sending 1-5 texts per day (see Supporting Figure 1A in the online version of this article). 58.1% of respondents (n = 62) reported sending an average of ≥1 text messages per day related to patient care (see Supporting Figure 1B in the online version of this article), with the largest fraction (58.3%) sending 1-5 texts per day.

HCGM Adoption and Usage Patterns

Active use of HCGM was defined as using the application to send or receive an average of ≥1 text messages per day. Of HCGM participants, 67% self-reported ≥1 week of active use of the application, indicating a strong compliance rate. Among non-attendings, 70% reported sending 1 or more texts to other team members per day; this percentage increased to 86% among those whose attendings texted them at least once per day (47% of non-attendings). Respondents who text frequently in their personal lives (>5 texts/day) were more likely to use the application; 90% of these respondents sent 1 or more HCGM texts per day.

Among 12 subjects who did not report sending or receiving ≥1 HCGM text/day, the top three reasons were: other team members were not using it (67%),

TABLE 2. Effective and Ineffective Aspects of the Hospital Paging System

What do you find *effective* about the current hospital paging system?			What do you find *ineffective* about the current hospital paging system?		
Theme	No. of Respondents, (% of Total)	Response Example	Theme	No. of Respondents, (% of Total)	Response Example
Reliability of message transmission	17 (30.4%)	"Everyone is able to receive the pages I send, regardless of service"	Time wasted waiting for a response	17 (29.3%)	"Inefficient use of time waiting for reply"
Ability to text page	14 (25.0%)	"Text paging allows targeted questions"	One-way nature of communication	14 (24.1%)	"Cannot text back instantly"
Ease of use	8 (14.3%)	"Easy to use"	Needing to find a computer to send a text page	12 (20.7%)	"Have to find an available computer to send a page"
Search function	5 (8.9%)	"Search function is pretty effective in finding the people you're looking for"	Character limitation	10 (17.2%)	"Length of text allowed too short"
Ubiquity	5 (8.9%)	"Everyone is on paging system"	Search function	6 (10.3%)	"Delay in looking people up in the system"
Speed	4 (7.1%)	"Fast"	Finding a phone to return a page	5 (8.6%)	"When you receive a page you need to find a phone"
Loud alerts	4 (7.1%)	"Pager loud enough to hear all the time"	Receipt of page uncertain	3 (5.2%)	"Unknown if page received"
Staff responsiveness to pages	4 (7.1%)	"I know MD has to be onsite or covering the pager so someone eventually will call back"	Sender's pager number not always included in page	3 (5.2%)	"Not everyone puts their pager number when they page. Then it's impossible to get back to them."
Brevity of messages	3 (5.4%)	"Requires very brief messages (easier for recipient)"	Needing to remain near a phone while waiting for a page response	3 (5.2%)	"Wait by a phone for someone to call back; sometimes they do not call back"
Helpful page operators	2 (3.6%)	"Page operators very helpful"	Reliability of message transmission	3 (5.2%)	"Sometimes messages don't go through"
Other	10 (17.9%)	"It's online and allows paging from anywhere there's internet access"	Other	11 (19.0%)	"You cannot text with patient info on it"

NOTE: **Abbreviations:** MD, doctor of medicine.

no need to use it given the close proximity of other team members (67%), and "other" (33%). A Wilcoxon rank sum test was used to compare the ages of "active" versus "nonactive" users; no significant age difference was found ($P = 0.200$).

To provide an objective measure of application adoption, usage data for each HCGM participant were obtained from the application developers. Because much of the study's first week was spent onboarding and instructing participant, the first week was not included in the analysis. Of 43 individuals enrolled in the study for at least one of the seven remaining weeks, 56% sent a total of $\geq$5 texts, 44% sent $\geq$10 texts, and 28% sent $\geq$20 texts. HCGM users on three teams sent an aggregate mean of 123 texts/week. Data on number of messages received by each user were not available.

Perceived Effectiveness: Paging Versus HCGM

In post-study surveys, HCGM participants rated HCGM significantly higher ($P < 0.05$) than paging (Table 3) in terms of ability to communicate thoughts clearly ($P = 0.010$) and efficiently ($P = 0.009$). HCGM was also deemed more effective at integrating into workflow during rounds ($P = 0.018$) and patient discharge ($P = 0.012$). Overall satisfaction with HCGM was also significantly higher ($P = 0.003$).

Comparison of Pre- and Post-study Perceived Effectiveness of the Hospital Paging System

In post-study evaluations, both control and HCGM participants rated the paging system's effectiveness less favorably ($P < 0.05$) compared to baseline in terms of ability to receive messages/stay informed in real time (control $P = 0.002$, HCGM $P = 0.031$) (Table 4). Controls also reported a decrease from baseline in perceived effectiveness of paging in terms of ability to send messages ($P = 0.019$) and integrate into workflow during patient admissions ($P = 0.020$). HCGM participants found paging less effective at communicating thoughts clearly ($P = 0.004$) and efficiently ($P = 0.018$). No significant differences existed between control and HCGM groups' average

TABLE 3. Perceived Effectiveness: Paging System Versus HCGM Application, as Rated by HCGM Participants (n = 41)

Question	Baseline Average Rating of Paging System*	Post-Study Average Rating of HCGM Application	*P* Value†
Rate the effectiveness of each in allowing you to…			
Communicate your thoughts clearly	3.194	3.806	0.010
Communicate your thoughts efficiently	3.200	3.829	0.009
Send messages to other hospital staff	3.543	3.571	0.480
Receive messages/stay informed in real time	3.222	3.306	0.405
Rate the effectiveness of each in integrating into your workflow during…			
Work rounds	2.313	3.000	0.018
Patient discharge	2.448	3.276	0.012
Patient admissions	2.862	2.621	0.238
Teaching sessions	2.292	2.458	0.448
Overall satisfaction	2.811	3.459	0.003

NOTE: **Abbreviations:** HCGM, HIPAA-compliant group messaging.
*HCGM participants' baseline average ratings of the paging system in this table differ slightly from those presented in Table 3 due to the inclusion of different paired datasets (a result of different missing data values).
†*P* values are unadjusted.

TABLE 4. Comparison of Baseline and Post-Study Perceived Effectiveness of the Hospital Paging System

	Control (n = 22)			HCGM (n = 41)		
	Baseline Mean	Post-Study Mean	*P* Value*	Baseline Mean	Post-Study Mean	*P* Value*
Rate the effectiveness of each in allowing you to…						
Communicate your thoughts clearly	2.905	2.619	0.103	3.250	2.850	0.004
Communicate your thoughts efficiently	2.952	2.762	0.106	3.250	2.825	0.018
Send messages to other hospital staff	3.762	3.190	0.019	3.550	3.450	0.253
Receive messages/stay informed in real time	3.667	2.857	0.002	3.300	2.900	0.031
Rate the effectiveness of each in integrating into your workflow during…						
Work rounds	2.429	2.476	0.303	2.410	2.718	0.078
Patient discharge	2.500	2.350	0.251	2.472	2.861	0.071
Patient admissions	2.905	2.524	0.020	2.889	3.000	0.384
Teaching sessions	2.143	2.200	0.386	2.367	2.400	0.418

NOTE: Abbreviations: HCGM, HIPAA-compliant group messaging.
**P* values are unadjusted.

assessments of paging at the conclusion of the study (see Supporting Table 2, in the online version of this article).

HCGM User Experience

When asked if they would recommend using an HCGM system to facilitate communication on the internal medicine wards, 85% of HCGM participants replied "yes," 15% reported "not sure," and 0% reported "no." Based on free response entries, HCGM's most effective features (Table 5) included ease of use, group texting capacity, and speed (32.4%, 32.4%, and 23.5% of 34 respondents, respectively); its most ineffective aspects (Table 5) included lack of ubiquity, inconsistent usage by those with access to the application, and reliability of message transmission (30.3%, 24.2%, and 15.2% of 33 respondents, respectively).

DISCUSSION

We are the first to report that smartphone-based, HIPAA-compliant, group messaging applications improve provider perception of in-hospital communication, while providing the information security that paging and commercial cellular networks do not. HCGM participants rated the application more favorably than paging in terms of clarity and efficiency of communication. These findings may be attributed to the expanded functionality offered by the application, including no character limit per HCGM text, the ability to use special characters such as slashes and ampersands, group texting, and the ability to reply immediately. HCGM may result in more efficient communication by facilitating direct two-way communication via smartphones, whereas sending or returning pages requires a landline or computer.

HCGM participants rated the application higher than paging in terms of workflow integration during rounds and patient discharge, but not during patient admissions and teaching sessions. We had hypothesized that HCGM would integrate better into participants' workflows because HCGM texts could be replied to immediately. The reasons for the equivalence of HCGM and paging for workflow integration

TABLE 5. Effective and Ineffective Aspects of the HCGM Application

What do you find *effective* about the Medigram system?			What do you find *ineffective* about the Medigram system?		
Theme	No. of Respondents, (% of Total)	Response Example	Theme	No. of Respondents, (% of Total)	Response Example
Ease of use	11 (32.4%)	"Easy to use"	Lack of ubiquity	10 (30.3%)	"Not enough people using it"
Group texting feature	11 (32.4%)	"Ability to communicate with entire team—everyone seeing same message"	Inconsistent usage	8 (24.2%)	"No one used it reliably"
Speed	8 (23.5%)	"Faster than a page to send a message"	Reliability of message transmission	5 (15.2%)	"Big negative is it requires Wi-Fi"
Accessibility	5 (14.7%)	"Able to get messages across quickly and anywhere without a computer"	Missed message alerts	4 (12.1%)	"Unable to reliably know message was received if phone on silent"
Efficiency	4 (11.8%)	"Very efficient way to communicate"	Password login	3 (9.1%)	"Having to type a 6-digit password in"
Real-time communication	2 (5.9%)	"Real-time results"	User interface	2 (6.1%)	"Interface is a little convoluted"
No character limitation	2 (5.9%)	"No limit on words"	Other	10 (30.3%)	"Not sure if all of the texts were relevant"
Other	4 (11.8%)	"Great UI"			

NOTE: **Abbreviations:** UI, user interface; Wi-Fi, wireless fidelity.

during patient admissions and teaching sessions may have been due to weak Wi-Fi in certain areas of the hospital, and may warrant further investigation.

Analysis of HCGM utilization indicated that there were factors that made participants more or less likely to use the application. Individuals who reported that their attendings used HCGM regularly were more likely to use it themselves. Attending usage may legitimize use of HCGM for housestaff and medical students, who may otherwise feel that texting appears unprofessional. Participants who texted frequently in their personal lives were also more likely to utilize HCGM regularly, perhaps due to increased familiarity with/affinity for the platform.

HCGM participants who did not utilize the application regularly most often cited the fact that other team members did not use it. Among all users, the most frequently noted ineffective aspects of the application were its lack of ubiquity (HCGM was made available only to the small subset of individuals involved in the study) and inconsistent usage by those who did have access to the application. These findings suggest that HCGM effectiveness may be maximized with unrestricted access and mandated use; patchwork implementation, as in this study, detracts from perceived effectiveness.

Though objective outcome measures (average length of stay and average time of discharge) for patients of control attendings and HCGM attendings were examined, no significant differences were observed ($P = 0.089$ and 0.494, respectively). These results may be due to the small size and short duration of the study.

Limitations

Our study had several limitations. HCGM was available only to individuals in the experimental arm of the study; most members of the internal medicine department and all other departments were not reachable through the application. This lack of ubiquity was a frequently cited frustration. Among individuals to whom HCGM was made available, barriers to adoption included: close proximity to would-be message recipients, concern that smartphone usage in front of patients might appear unprofessional, and inconsistent or dropped service (weak or no Wi-Fi signal in some areas). A technical problem with the Android platform midway through the study served as a potential frustration to several participants.

Due to the aforementioned issues, some participants used the HCGM application in a very limited way. We also did not replace hospital pagers (infeasible in this hospital setting); the HCGM application was added as a supplemental system. Future studies might explore the replacement of paging systems with HCGM-type applications, as well as delve further into quantitative patient care outcomes.

It should be noted that the start of the study unintentionally coincided with the start of new interns and medical students in the hospital. Although it is possible that their relative unfamiliarity with the hospital may have made them more amenable to adopting a new technology, it is also possible that they may have been less likely to do so in the midst of such a major transitional period. Finally, this was a single-site study, and as such, its findings may not be broadly generalizable. More research on such interventions is warranted, particularly in the context of current insecure communication methods such as paging that may make hospital-wide adoption of new methods of secure communication, such as HCGM, mandatory.

CONCLUSION

Our study is the first to demonstrate that HCGM applications improve healthcare provider perception of multiple measures of in-hospital communication, including efficiency of communication, workflow integration, and overall satisfaction. Notably, 85% of HCGM team respondents said they would recommend using an HCGM system on the wards. As smartphone use is expected to continue to increase among physicians and the general population, it is increasingly important to understand how to utilize these powerful communication tools to improve healthcare in an effective and secure manner.

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References

1. Coiera E. Communication systems in healthcare. *Clin Biochem Rev*. 2006;27:89–98.
2. Espino S, Cox D, Kaplan B. Alphanumeric paging: a potential source of problems in patient care and communication. *J Surg Educ*. 2011; 68:447–451.
3. Manhattan Research. Taking the pulse: US market research report. Available at: http://manhattanresearch.com/Products-and-Services/Physician/Physician-Research-Modules. Accessed February 6, 2013.
4. O'Connor C, Friedrich JO, Scales DC, et al. The use of wireless e-mail to improve healthcare team communication. *J Am Med Inform Assoc*. 2009;16:705–713.
5. Wu RC, Morra D, Quan S, et al. The use of smartphones for clinical communication on internal medicine wards. *J Hosp Med*. 2010;5: 553–559.
6. US Department of Health and Human Services. Summary of the HIPAA privacy rule. Available at: http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/. Accessed May 11, 2013.
7. United States Department of Health and Human Services. Summary of the HIPAA security rule. Available at: http://www.hhs.gov/ocr/privacy/hipaa/understanding/srsummary.html. Accessed May 11, 2013.
8. Stanford University. Stanford facts: about Stanford. Available at: http://facts.stanford.edu/about/hospital. Accessed October 12, 2013.
9. Wikinvest. USA mobility. Available at: http://www.wikinvest.com/stock/USA_Mobility_(USMO). Accessed February 6, 2013.

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http://www.systematicreviewsjournal.com/content/3/1/56

SYSTEMATIC REVIEWS

RESEARCH Open Access

The effectiveness of computerized order entry at reducing preventable adverse drug events and medication errors in hospital settings: a systematic review and meta-analysis

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Abstract

Background: The Health Information Technology for Economic and Clinical Health (HITECH) Act subsidizes implementation by hospitals of electronic health records with computerized provider order entry (CPOE), which may reduce patient injuries caused by medication errors (preventable adverse drug events, pADEs). Effects on pADEs have not been rigorously quantified, and effects on medication errors have been variable. The objectives of this analysis were to assess the effectiveness of CPOE at reducing pADEs in hospital-related settings, and examine reasons for heterogeneous effects on medication errors.

Methods: Articles were identified using MEDLINE, Cochrane Library, Econlit, web-based databases, and bibliographies of previous systematic reviews (September 2013). Eligible studies compared CPOE with paper-order entry in acute care hospitals, and examined diverse pADEs or medication errors. Studies on children or with limited event-detection methods were excluded. Two investigators extracted data on events and factors potentially associated with effectiveness. We used random effects models to pool data.

Results: Sixteen studies addressing medication errors met pooling criteria; six also addressed pADEs. Thirteen studies used pre-post designs. Compared with paper-order entry, CPOE was associated with half as many pADEs (pooled risk ratio (RR) = 0.47, 95% CI 0.31 to 0.71) and medication errors (RR = 0.46, 95% CI 0.35 to 0.60). Regarding reasons for heterogeneous effects on medication errors, five intervention factors and two contextual factors were sufficiently reported to support subgroup analyses or meta-regression. Differences between commercial versus homegrown systems, presence and sophistication of clinical decision support, hospital-wide versus limited implementation, and US versus non-US studies were not significant, nor was timing of publication. Higher baseline rates of medication errors predicted greater reductions ($P < 0.001$). Other context and implementation variables were seldom reported.

Conclusions: In hospital-related settings, implementing CPOE is associated with a greater than 50% decline in pADEs, although the studies used weak designs. Decreases in medication errors are similar and robust to variations in important aspects of intervention design and context. This suggests that CPOE implementation, as subsidized under the HITECH Act, may benefit public health. More detailed reporting of the context and process of implementation could shed light on factors associated with greater effectiveness.

Keywords: Medical order entry systems, Drug toxicity/prevention and control, Hospitals, Adverse drug event, Medication error

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Background

The Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 incentivizes the adoption of health information technology by US hospitals. This Act, part of the American Reinvestment and Recovery Act, allocates up to $29 billion over 10 years for the implementation and 'meaningful use' of electronic health records by hospitals and healthcare providers [1]. Hospitals that satisfy meaningful use criteria can receive millions of dollars. Implementing computerized provider order entry (CPOE) with clinical decision support systems (CDSS) that check for allergies and drug-drug interactions is one of several basic (Stage 1) criteria for meaningful use by hospitals [2]. As of 2008, approximately 9% of general acute care hospitals had at least basic electronic health record (EHR) systems including CPOE for medications. By 2012, 44% had such systems, specifically, 38% of small, 47% of medium, and 62% of large hospitals [3]. Thus, despite the financial incentives, about half of small and medium hospitals and almost 40% of large hospitals had not adopted CPOE with CDSS in the most recent survey.

The primary potential benefit of adopting CPOE is reducing patient injuries caused by medication errors, called preventable adverse drug events (pADEs) [4-6]. Counterbalancing this is concern about unintended adverse consequences [7-9], including increases in medication errors and even mortality, which have been detected in some hospitals after implementation of CPOE [10,11]. To date, no systematic review has examined net effects on pADEs, the primary outcome of interest for this intervention. Previous reviews have, instead, focused almost exclusively on an intermediate outcome, medication errors. However, not all medication errors pose an equal risk of causing injury. Errors in timing, for example, are generally less risky than giving a medication to the wrong patient. Many commonly used medications, such as anti-hypertensives and antibiotics, have sufficiently long half-lives that receiving a dose an hour or two late has little clinical effect. By contrast, receiving an anti-hypertensive or antibiotic intended for someone else poses risks of low blood pressure or an allergic reaction. In one study at six hospitals, only about 20% of medication errors led to pADEs [12]. Thus, the effect of CPOE on the patient outcome of pADEs is an important clinical and policy question that has remained unanswered, until now.

In addition to focusing on medication errors rather than pADEs, previous systematic reviews have reached conflicting conclusions about the effects of CPOE on medication errors in acute care settings. Some have concluded that CPOE reduces errors, whereas others argue that net effects remain uncertain [4,5,13-42]. This controversy stems, in part, from the fact that the association between CPOE implementation and medication errors has exhibited substantial heterogeneity across primary studies [37]. Three basic types of factors could explain such variability: intervention factors, such as differences in how the intervention is designed and implemented; contextual factors, such as differences in patient populations and settings; and methodological factors, such as differences in study design and execution [43].

Uncertainty about the effects of CPOE on patient outcomes and its variable effects on medication errors may contribute to the reluctance of some hospitals and physicians to adopt CPOE, despite the financial incentives available via HITECH. Consequently, our primary objective in this study was to quantitatively assess the effectiveness of CPOE at reducing pADEs in hospital-related acute care settings. Our secondary objective was to identify factors contributing to variability in effectiveness at reducing medication errors. This analysis is timely as several studies have been published recently and, therefore, were not included in previous reviews and meta-analyses [4,13,34,37,41], enabling us to examine effects on pADEs and reasons for heterogeneity.

Methods

We adhered to recommendations in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement [44,45], including developing the protocol before undertaking the analysis.

Data sources and searches

First, we developed search strategies for eight databases: MEDLINE; Cochrane Library; Econlit; Campbell Collaboration; the Agency for Healthcare Research and Quality (AHRQ) Health Information Technology Library, Health Information Technology Bibliography, Health Information Technology Costs and Benefits Database Project, and PSNET; Information Service Center for Reviews and Dissemination at the University of York; Evidence for Policy and Practice Information and Coordinating Centre (EPPI-Centre), University of London; Oregon Health Sciences Searchable CPOE Bibliography; and Health Systems Evidence, McMaster University. A number of search terms, such as 'order entry' and 'electronic prescribing' (see Additional file 1), were chosen and strategies developed, in part based on a search strategy published by Eslami *et al*. [4].

We used this strategy to search the eight databases for systematic reviews of CPOE or CDSS that might contain potentially relevant primary studies (last updated September 23, 2013) (Figure 1). Next, we used the same strategy to search the eight databases for potentially relevant primary studies that were published after two large previous systematic reviews on CPOE (January 1, 2007 to September 23, 2013) [4,13]. In addition, we hand-searched nine websites (AHRQ HIT Library, AHRQ PSNET, National Patient Safety Foundation, Joint Commission, Leapfrog Group, Micromedex, Institute for Healthcare Improvement), the Web of Science, and bibliographies of other publications known to us.

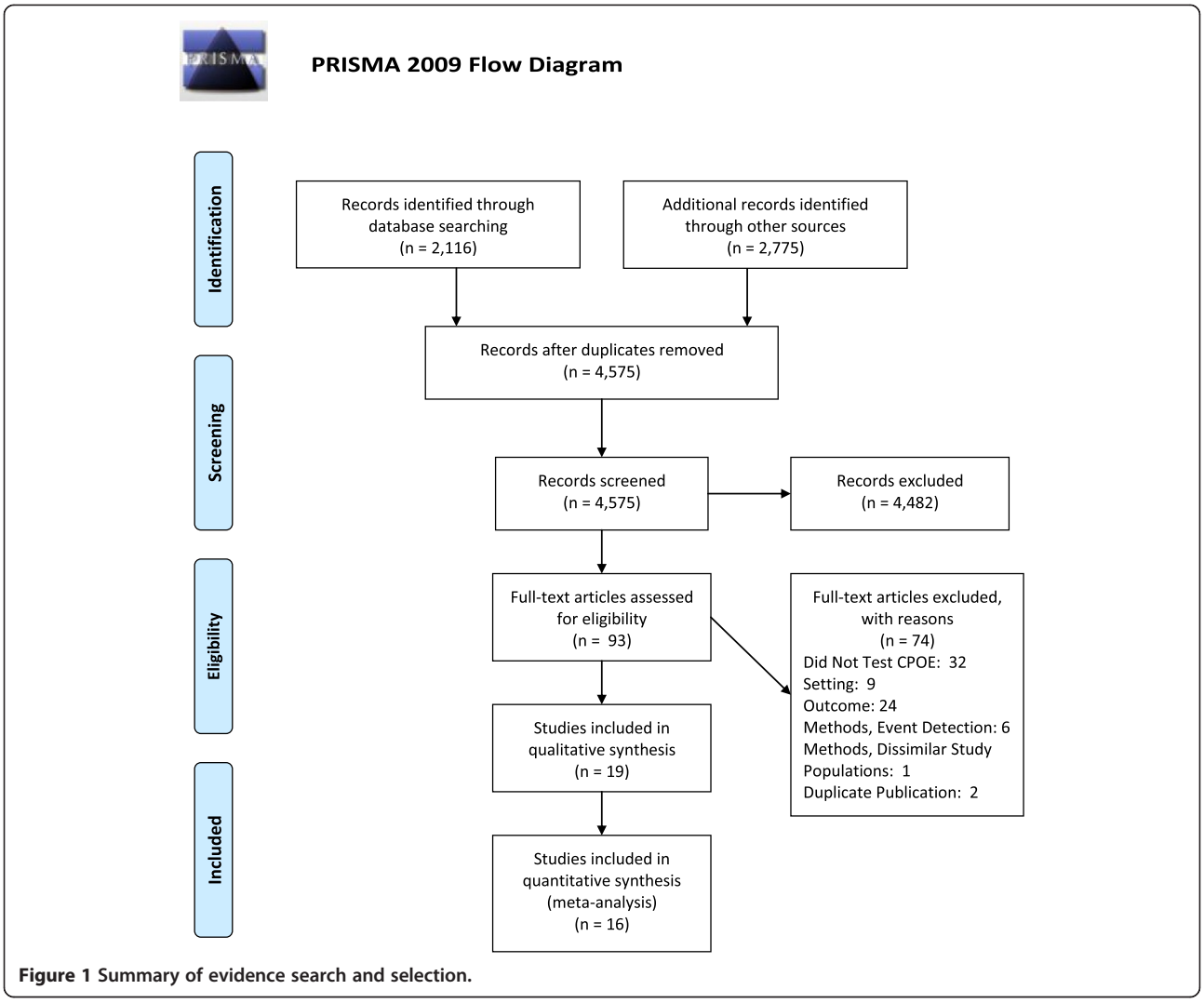

Figure 1 Summary of evidence search and selection.

Study selection

We included peer-reviewed studies, regardless of language or design, if they compared CPOE with paper-order entry and examined either of our two primary outcomes, rates of pADEs or medication errors, across a variety of clinical conditions. Eligible settings included adult medical or surgical wards, adult medical or surgical intensive care units (ICUs), emergency departments, or the entire hospital. To reduce unwarranted variability due to contextual and methodological factors, we excluded studies that were from non-hospital settings; that addressed events limited to specific conditions (for example, infections) or types of errors (for example, allergy alerts); or that compared events in highly dissimilar patient care units. As minimum criteria for study quality, we excluded studies that did not describe methods for detecting medication events, or that used incident reporting alone, which detects 0.2–-6% of events [46]. We also excluded pediatric studies because including them would increase heterogeneity: children comprise only 6% of hospitalized patients whereas ADEs disproportionately affect older adults [12,47,48].

Two investigators independently screened the article titles and then abstracts for eligibility. We obtained full-text articles when either investigator found the abstract (or title, if the abstract was unavailable) potentially eligible. Disagreements about the eligibility of full-text articles were resolved by consensus, with a third investigator participating for ties.

Data extraction and quality assessment

We defined pADEs as injuries to patients due to medication errors. Medication errors were defined as errors in the process of prescribing, transcribing, dispensing, or administration of a medication, which had the potential to or actually did cause harm. To focus on errors involving relatively higher risk, we excluded, when reported, 'errors' described as having no or

almost no potential for harm as well as incomplete or illegible orders, disallowed abbreviations, disallowed drug names, and medications given at the wrong time (see Additional file 1).

Two investigators independently extracted data from each study using a standardized form (see Additional file 1). Disagreements were resolved by consensus, with a third investigator adjudicating ties. Extracted elements included numbers of pADEs and medication errors meeting study definitions, units of exposure to risk of pADEs or medication errors (for example, number of orders, dispensed doses, admissions, or patient days). When studies reported rates or proportions rather than these elements, variance could not be estimated, so the studies could not be included in pooled effect calculations and thus we qualitatively summarized their results instead.

From the studies included in the pooled analysis of medication errors, we extracted several elements related to intervention design and implementation, context, and study methods. Elements related to intervention design included: CPOE developer (homegrown versus commercial); and presence or absence of CDSS, CDSS sophistication (basic, moderate, or advanced; see Table 1 for definitions). When information about the system developer and CDSS were missing from the published article, we contacted the original authors.

Elements related to implementation were based on an AHRQ report addressing context-sensitive patient safety practices, including CPOE. These included: factors influencing the decision to adopt, factors facilitating implementation, and aspects of implementation described in the studies, as well as timing, extent of implementation (limited number of units versus hospital-wide), and whether use was mandatory (see Additional file 1 for details) [72].

Contextual elements included setting/population (type of clinical unit within the hospital, academic status, public versus private hospital, hospital size, country, primary language in country, payer mix), and baseline proportion of hospitalizations affected by medication errors.

Methodological elements included type of study design, event detection methods, items related to study quality (adapted from relevant reporting criteria in the Standards for Quality Improvement Reporting Excellence; SQUIRE) [73], and funding source.

Data synthesis and analysis

Using the DerSimonian–Laird random effects model [74], we conducted meta-analyses for two outcomes (pADEs and medication errors) for all eligible studies combined, and for different subgroups of studies as described below. For each eligible study and outcome measure, we calculated a risk ratio (RR) as the number of events per unit of exposure in the CPOE group divided by events per unit of exposure in the paper-order entry group. Units of exposure varied across studies. If a study provided more than one unit of exposure, we selected the unit most commonly used in the included studies.

Within each meta-analysis, we tested the heterogeneity of the log-transformed RRs using Q and I^2 statistics [75]. Heterogeneity was present when the I^2 statistic was 50% or more and the P-value for the Q statistic was 0.05 or less.

We conducted two sensitivity analyses, removing one study at a time from each meta-analysis to assess the influence of each individual study, and testing whether the choice of units of exposure affected results. To assess publication bias, we examined funnel plots, Begg and Mazumdar's rank correlation test, and Egger's regression intercept test [76].

Intervention design and implementation, contextual, and methodological factors

A priori, we identified nine factors that might be associated with heterogeneity in medication errors across studies. Intervention design factors included type of CPOE developer (homegrown versus commercial), presence or absence of CDSS, and sophistication of CDSS (basic, moderate, or advanced). Intervention implementation factors included scope of implementation (hospital-wide versus limited) and timing of CPOE implementation (year CPOE was implemented or, if missing, the year the study was published). Contextual factors included country (US versus non-US) and baseline proportion of hospitalizations affected by medication errors. Methodological design factors included study design (pre-post versus other designs) and event detection methods (pharmacist order review versus more comprehensive methods). For each discrete factor, we conducted a subgroup analysis when there were at least three studies per subgroup, for example, pre/post design versus other design. For each continuous factor, we conducted a meta-regression using the factor as the sole predictor. In each meta-regression, we pooled log-transformed RRs, and presented the pooled results on the original RR scale.

Pooled meta-analyses were conducted using Comprehensive Meta-analysis, V2 (Biostat, Englewood, NJ, USA); meta-regression analyses were conducted in STATA (V13) (StataCorp LP, College Station, TX, USA).

Results

We screened 4,891 potentially eligible records, including the bibliographies of 32 systematic reviews on CPOE or CDSS [4,5,13-42], and then examined 93 full-text articles on CPOE. Of these 93 full-text articles, 74 were excluded: 32 did not test the effectiveness of CPOE, 3 addressed non-hospital settings, 6 addressed pediatric settings, 5 used incident reporting alone to detect events, 1 did not describe event detection methods, 16 addressed outcomes other

Table 1 Characteristics of included studies

Reference	Country	Number of hospitals (bed size)	Financial status	Type of hospital	Setting in hospital	Baseline error rate, %[a]	Developer of CPOE system	Use of CPOE	CDSS[b]	Study design	Event detection methods[c]
Bizovi *et al.*, 2002 [49]	USA	1 (560)	Public	Academic	ED	3.6 (visits)	Commercial (EmSTAT; CyberPlus)	Mandatory	None[d]	Pre/post	Routine pharmacist review of medication orders
Franklin *et al.*, 2009 [50-52]	UK	1 (–)	(Probably public)	Academic	General surgery ward	64.9	Commercial (ServeRx V.1:13; MDG Medical)	Mandatory	None	Pre/post	Routine pharmacist review of medication orders, medical record review, and incident reporting
Shawahna *et al.*, 2011 [53]	Pakistan	1 (1280)	Public	Academic	2 medical wards	83.8	Homegrown	Mandatory	None	Pre/post	Medical record review (R)
Shulman *et al.*, 2005 [54]	UK	1 (–)	Public	Academic	General ICU	41.1	Commercial (QS 5.6 Clinical Information System; GE Healthcare)	Not stated	None	Pre/post	Routine pharmacist review of medication orders
Leung *et al.*, 2012 [11]	USA	6 (100 to 300 each)	–	Community	Hospital-wide	42.3	Commercial (not stated)	Not stated	Present	Pre/post	Medical record and order review (B, R)
Wess *et al.*, 2007 [55]; [56]	USA	2 (665 and 555)	Private	Academic, Community	General surgery, Orthopedic/ neurosurgical units	–	Commercial (LastWord®; GE, formerly IDX)	Mandatory (n = 1) and voluntary (n = 1)	Present	Pre/post	Routine pharmacist review of medication orders, with changes signed by MD
Taylor *et al.*, 2002 [57][e]	USA	3 (1000 in total)	Private	Academic	Hospital-wide	–	Not stated	Not stated	Present	Pre/post	Quarterly review of subset of medication orders
Barron *et al.*, 2006 [58]	USA	1 (525)	Private	Academic	Hospital-wide	10.4	Homegrown	Mandatory	Basic	Pre/post	Routine pharmacist review of medication orders
Bates *et al.*, 1998 [59]	USA	1 (726)	Private	Academic	2 medical and 2 surgical wards, 2 ICUs	4.9	Homegrown	Mandatory	Basic	Pre/post	Medical record review and other means (B, R)
Van Doormal *et al.*, 2009 [60]	The Nether-lands	2 (1300 and 600)	–	Academic	2 medical wards at each hospital	99.9	Commercial (Medicator®; iSoft), Partly Homegrown (Theriak®),	Mandatory	Basic	Pre/post	Medical record and order review
Westbrook *et al.*, 2012 [61]	Australia	2 (400 and 326)	–	Academic	4 medical wards at one hospital; 1 cardiology and 1 psychiatry unit at the other hospital	99.7	Commercial (Millenium Power Orders; Cerner and MedChart; iSoft)	Exceptions allowed	Basic	Differences in differences	Routine pharmacist review of medication orders (R)
Weant *et al.*, 2007 [62][e]	USA	1 (489)	Public	Academic	Neurosurgical ICU	–	Not stated	Not stated	Moderate[d]	Pre/post	Routine pharmacist review of medication

Table 1 Characteristics of included studies *(Continued)*

											orders, incident reporting
Bates *et al.*, 1999 [63]	USA	1 (700)	Private	Academic	2 medical wards and 1 ICU	47.3	Homegrown	Mandatory	Moderate	Pre/post	Medical record and order review plus other means
Colpaert *et al.*, 2006 [64]	Belgium	1 (–)	–	Academic	3 units within a surgical ICU	98.0	Commercial (Centricity Critical Care Clinisoft; GE Healthcare Europe)	Mandatory	Moderate	Comparison of similar units	Routine pharmacist review of medication orders (B)
Mahoney *et al.*, 2007 [65]	USA	2 (247 and 719)	Private	Academic	Hospital-wide	–	Commercial (Siemens Medical Solutions CPOE; Siemens Medical Solutions Health Services Corp)	Exceptions allowed	Moderate	Pre/post	Routine pharmacist review of medication orders, with changes accepted by MD; incident reporting
Oliven *et al.*, 2005 [66]	Israel	1 (450)	Public	Academic	Pulmonary service	62.1	Homegrown	Not stated	Moderate	Compare similar units	Medical record and order review
Igboechi *et al.*, 2003 [67][e]	USA	1 (350)	Private	Community	Hospital-wide	–	Commercial (Ulticare System Database; Per Se Technologies	Mandatory	Moderate	Pre/post	Routine pharmacist review of medication orders
Aronsky *et al.*, 2007 [68,69]	USA	1 (658)	Private	Academic	ED	99.8 (visits)	Homegrown (WizOrder, later commercial-ized as Horizon Expert Orders; McKesson)	Not stated	Advanced[d]	Pre/post	Routine pharmacist review of medication orders
Mendendez *et al.*, 2012 [70]	Spain	1 (200)	–	Academic	Hospital-wide	5.0	Commercial (Selene; Siemens)	Not stated	Advanced [d]	Pre/post	Trigger tool medical record review, incident reporting, and other means

CDSS, Clinical Decision Support Systems; CPOE, computerized provider order entry; ED, emergency department; ICU, intensive care unit.
[a]Percentage of hospitalizations (or emergency department visits, where noted).
[b]None = no clinical decision support system; basic = checks for drug-allergy and drug-drug interaction; moderate = basic plus at least one additional clinical decision support function; advanced = moderate plus additional capabilities [71].
[c]T = paper described training of reviewers; B = paper described blinding of reviewers to baseline versus CPOE conditions; R = Paper described methods for assessing reviewer reliability. If none of symbols appear, these were not described.
[d]Information on CDSS obtained by contacting authors.
[e]Omitted from pooled effect calculations due to lack of data related to estimating variance.

than medication errors or pADEs (for example, workflow or cost), 5 addressed errors limited to specific conditions, 1 addressed specific types of errors, 2 (1 in French) addressed errors that were excluded because they posed a lower risks of harm, 1 (in Spanish) compared event rates in dissimilar clinical units (obstetric and oncology), and 2 were duplicate publications of articles meeting the selection criteria (Figure 1; see Additional file 1, Additional file 2).

The remaining 19 original articles met the selection criteria and addressed medication errors; 7 of these also addressed pADEs (Table 1) [11,49,50,53-55,57-68,70]. Of these 19 studies, 3 omitted the data needed to estimate variance and, therefore, were excluded from pooled effect calculations, resulting in 16 eligible studies, including 6 that addressed pADEs [57,62,67].

Of the 16 studies, half were based in the US, including two in community hospitals [11,55]. Thirteen studies used pre/post designs [11,49,50,53-55,58-60,63,65,68,70], two compared similar units within a hospital during the same time period [64,66], and one compared changes over time between intervention and control units (differences in differences design) [61]. Definitions of medication errors and the methods used to detect them varied across studies (see Additional file 1). Seven studies identified events using data from routine pharmacist review of medication orders [49,54,55,58,61,64,68]. One study provided information on reviewer training [11], three on blinding of reviewers [11,59,64], and none on reliability. The baseline percentage of hospitalizations affected by medication errors ranged from 3.6% [49] to 99.9% [60].

Nine studies assessed commercially developed CPOE systems [11,49,50,54,55,61,64,65,70], six evaluated homegrown systems [53,58,59,63,66,68], and one examined both [60]. No two studies assessed the same commercial system. CDSS was present in twelve studies [11,55,58-61, 63-66,68,70], and absent in four [49,50,53,54]; we contacted and obtained responses from authors for three of the studies (Table 1).

For all but one study [58], most of the desired information on implementation was missing (see Additional file 1). Based on the information that was reported, ten studies described the use of CPOE as mandatory at one or more sites [49,50,53,55,58-61,63,64]. CPOE was implemented hospital-wide in four studies [11,58,65,70], in the emergency department in two studies [49,68], and in a limited number of inpatient units in the rest. Four studies were conducted in complex organizations with facilities in multiple communities [55,59,63,65], another study was in a large hospital with affiliated clinics [49], and another was in community hospitals [11]. Past experience with information technology was reported in seven studies [49,50,55,58,59,63,65]. Three studies reported that organizational leadership influenced the adoption decision [55,58,65], and four stated that staff training and education facilitated implementation [53,54,58,66]. One study mentioned the role of staff time to learn CPOE, a person to lead implementation, extensive project management, an implementation timeline, teamwork, and patient safety culture related to CPOE [58]. Another study described the effects of having a responsible person, local tailoring, and teamwork [65].

The three studies omitted from the pooled analysis due to lack of variance estimates were similar to the included studies. They were conducted in the US in medium to large hospitals, including one in a community hospital. One study evaluated a commercially developed system [67]; the other two did not report the developer. Two studies included CDSS [57,67]. All three used pre/post designs, one detected events using pharmacist review of medication orders [67], and none reported reviewer training, blinding, or reliability. These studies also did not report implementation context or processes in detail [62,67], except for one, which discussed financial considerations and leadership [57].

Primary outcome: preventable adverse drug events

Of the 19 studies, 7 assessed pADEs [11,59,60,62-64,70]. For the six studies in the pooled analysis, RRs ranged from 0.17 to 0.81. Overall, CPOE was associated with about half as many pADEs as paper-order entry (pooled RR = 0.47, 95% CI 0.31 to 0.71). Studies were heterogeneous (I^2 = 69%) (Figure 2). Serial removal of each study did not substantially influence results (pooled RR range 0.40 to 0.58). There was no evidence of publication bias using a funnel plot, or Begg and Mazumdar's test (see Additional file 1). For one study excluded from the pooled analysis due to lack of data on variance, we calculated an RR of 0.11 [62].

Secondary outcome: medication errors

All 19 studies meeting selection criteria assessed medication errors [11,49,50,53-55,57-68,70]. Across the 16 studies eligible for the pooled analysis, RRs ranged from 0.16 to 2.08. The pooled estimate showed that medication errors were approximately half as common when providers used CPOE than when they used paper-order entry (pooled RR = 0.46, 95% CI 0.35 to 0.60). The studies were highly heterogeneous (I^2 = 99%) (Figure 3). Results were robust to serial removal of each individual study (pooled RR range 0.42 to 0.49), and to selection of an alternative unit of exposure in the four studies where that was possible (pooled RR = 0.45, 95% CI 0.34 to 0.59). There was no evidence of publication bias using a funnel plot, or Begg and Mazumdar's test (see Additional file 1).

Two studies included in the pooled analysis reported increases in medication errors after the introduction of CPOE, however, both also reported statistically significant decreases in preventable adverse drug events [11,70]. A third study, excluded due to lack of data on

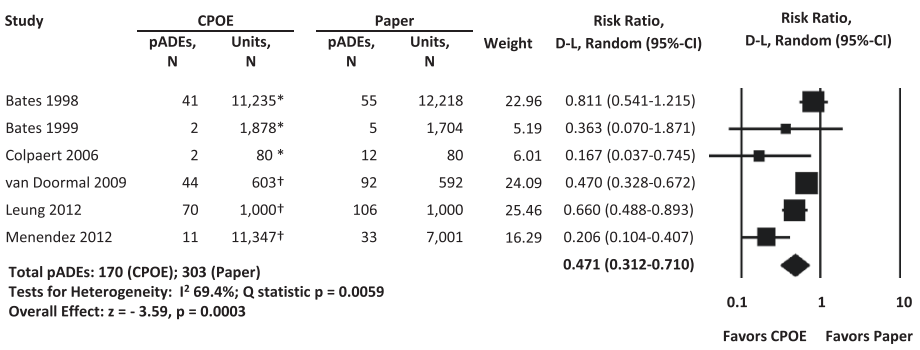

Figure 2 Meta-analysis: relative risk of preventable adverse drug events using computerized provider order entry (CPOE) versus paper-order entry in hospital acute care settings. Units of exposure: *1,000 patient days; †admissions.

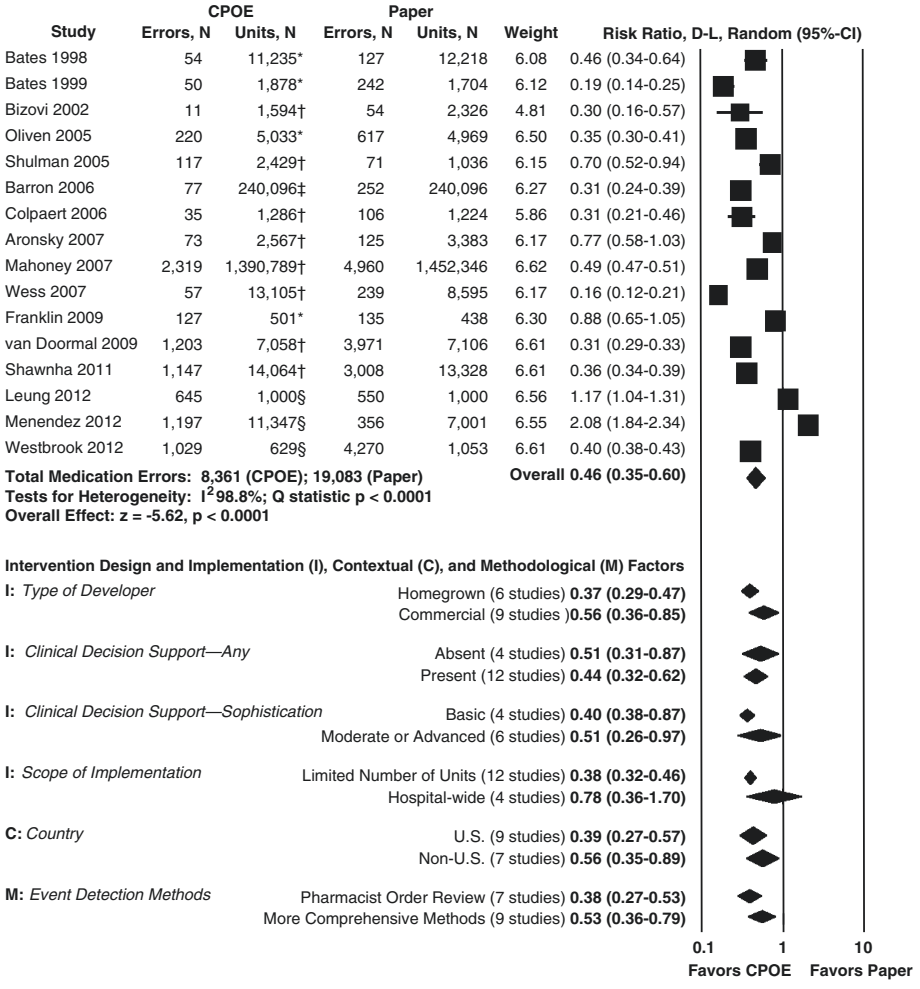

Figure 3 Meta-analysis: relative risk of medication errors using computerized provider order entry (CPOE) versus paper-order entry in hospital acute care settings. Units of exposure: *1,000 patient days; †orders; ‡dispensed doses; §admissions.

variance, also showed an increase in errors and a decrease in pADEs, but statistical testing was not performed [62].

For two studies excluded from the pooled analysis due to lack of data on variance, we calculated RRs of 0.61 [67], and 1.73, respectively [62]. In the third such study, the authors reported a 50% decline in medication errors (see Additional file 1) [57].

Intervention design and implementation, contextual, and methodological factors

Six of the *a priori* subgroup analyses met the requirement to have at least three studies per subgroup and were, therefore, conducted (two were on one variable, CDSS) (Figure 3). Two univariate meta-regression analyses were able to examine whether baseline medication error rate or year of publication (a proxy for maturity of CPOE intervention; date of implementation was frequently missing) predicted effectiveness.

Of five intervention design and implementation factors examined, none reached the conventional level of statistical significance, including type of developer (commercial 0.56 (95% CI 0.36 to 0.85) versus homegrown 0.37 (0.29 to 0.47)), type of CDSS (present 0.44 (0.32 to 0.62) versus absent 0.51 (0.31 to 0.87), and basic 0.40 (0.38 to 0.87) versus moderate or advanced 0.51 (0.26 to 0.97)), and scope of implementation (hospital-wide 0.78 (0.36 to 1.70) versus limited 0.38 (0.32 to 0.46)). Year of publication was not associated with differential effectiveness.

Two contextual factors were evaluated. Studies performed in the US showed greater effectiveness than non-US studies, but this difference was not statistically significant. As the baseline percentage of hospitalizations associated with medication errors increased from 3.6% to 99.9% (data available for 12 studies), the predicted RR of medication errors with CPOE decreased from 1.90 to 0.08 ($P < 0.001$).

Regarding methodological factors, studies that used pharmacist order review reported greater effectiveness than studies using more comprehensive event detection methods, although this difference was not statistically significant. Almost all studies used pre/post designs so this subgroup analysis was not conducted.

Discussion

The principal finding of this analysis is that CPOE is associated with a significant reduction in pADEs (hat is, the patient injuries it was designed to prevent) in adult hospital-related acute care settings. Specifically, compared with using paper orders, using CPOE was associated with about half as many pADEs. Medication errors, likewise, were also about half as common with CPOE as with paper-order entry, and the reduction was generally similar across studies with different intervention designs and different implementation, contextual, and methodological characteristics. There were no statistically significant differences in effect between commercial and homegrown systems, with or without CDSS of differing sophistication levels, and between hospital-wide or more limited implementations. The baseline rate of hospitalizations associated with medication errors was significantly associated with effectiveness, as increasing baseline rates of errors were associated with increasing effectiveness. This is expected, because, with few errors, there can be little to change.

Our pooled analysis is conclusive that CPOE is associated with a reduction in pADEs. Shamliyan *et al*. examined ADEs that might or might not have been related to medication errors, and, therefore, were not as likely to be affected by CPOE. These authors observed significant declines in only three of seven studies (including pediatric ones), and did not perform a pooled analysis [37].

With regards to the overall pooled result for medication errors, our findings are generally consistent with those of earlier, more limited systematic reviews and meta-analyses [34,37,41]. Radley and colleagues also found that medication error rates declined by about half with CPOE implementation (48%, 95% CI 41 to 55%), using a small set of early studies [34]. Van Rosse and colleagues observed greater effectiveness with CPOE than we did (RR of medication errors = 0.08, 95% CI 0.01 41 to 0.76), but examined only three diverse studies [41]. Shamliyan and colleagues found that CPOE was slightly more effective than we did (odds ratio for medication errors = 0.34, 95% CI 0.22 41 to 0.52), based on inpatient and outpatient studies from before 2006 [37]. In comparison to these previous studies, we were able to identify a greater number of relevant articles despite having more restrictive selection criteria (see Additional file 1), enabling us to explore reasons for study heterogeneity.

Also like previous reviews [37], we observed substantial variability across studies in the effectiveness of CPOE at reducing medication errors. It has long been suspected that variability in the effectiveness of a complex sociotechnical intervention such as CPOE may be related not only to intervention design but also to context and implementation factors [16,77,78]. However, across the intervention design and implementation as well as contextual variables that we assessed, we did not see any statistically significant differences in the associations between CPOE use and reductions in medication errors. Two studies of commercial CPOE systems in hospital-wide implementations reported increases in medication errors but reductions in pADEs [11,70]. One potential explanation for these seemingly contradictory results is that the CPOE systems may have created new medication errors at lower risk for causing ADEs (such as concurrent submission of duplicate orders due to order sets) but reduced medication errors at higher risk of causing ADEs (such as serious

drug-drug interactions). Alternatively, CPOE may have made errors easier to detect. The potential to create new types of low-risk medication errors calls attention to the importance of tailoring the CPOE system to the local environment because such errors place a time burden on providers.

This analysis has limitations. We relied on 32 previous systematic reviews to detect primary studies published before 2007. Because each review detected a slightly different set of publications (see Additional file 1), performing our own search of that period would have been unlikely to detect additional studies. We excluded pediatric studies instead of examining population age as a subgroup because these groups differ in their risk for experiencing medication errors and pADEs. Future investigators could evaluate the feasibility of conducting a similar meta-analysis for pediatric populations. We also excluded studies that relied upon incident reporting or did not describe event detection methods, considering these to be minimum criteria for study quality. The number of studies that examined pADEs was not large, but all studies detected declines. Most studies were conducted in academic centers, limiting generalizability to community hospitals. Finally, the included studies all used limited methods, including using pre/post designs and lacking robust data-collection methods.

Conclusion

Implementing CPOE is associated with a greater than 50% decline in pADE rates in hospital-related settings, although results vary. Medication errors decline to a similar degree. Changes in medication errors appear to be consistent across commercial and homegrown systems, with or without clinical decision support, and in individual units or hospital-wide implementations. Many context and implementation variables have, unfortunately, not been reported sufficiently to assess their association with effectiveness. Overall, these findings suggest that the CPOE requirements for meaningful use under the HITECH Act may benefit public health. Knowledge about how to make CPOE more effective would be greatly facilitated by greater reporting of context and implementation details.

Additional files

Additional file 1: Appendix.

Additional file 2: PRISMA Checklist.

Abbreviations

ADE: Adverse drug event; pADE: Preventable adverse drug event; CDSS: Clinical decision support systems; CPOE: Computerized provider order entry; ED: emergency department; EHR: Electronic health record; HITECH: Health Information Technology for Economic and Clinical Health; ICU: intensive care unit.

Competing interests

The authors have no conflicts of interest with the work.

Authors' contributions

TKN, CSS, PGS: conception and design, data collection and analysis, manuscript writing; SCM data analysis and manuscript writing; SMA conception and design; VMP, LJA, and ELD: data collection and analysis. All authors read and approved the final manuscript.

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References

1. Blumenthal D: **Wiring the health system–origins and provisions of a new federal program.** *N Engl J Med* 2011, **365**(24):2323–2329.
2. Classen DC, Bates DW: **Finding the meaning in meaningful use.** *N Engl J Med* 2011, **365**(9):855–8. doi:10.1056/NEJMsb1103659.
3. Desroches CM, Charles D, Furukawa MF, Joshi MS, Kralovec P, Mostashari F, Worzala C, Jha AK: **Adoption of electronic health records grows rapidly, but fewer than half of US hospitals had at least a basic system in 2012.** *Health Aff (Millwood)* 2013, **32**(8):1478–1485.
4. Eslami S, de Keizer NF, Abu-Hanna A: **The impact of computerized physician medication order entry in hospitalized patients–a systematic review.** *Int J Med Inform* 2008, **77**(6):365–376.
5. Weir CR, Staggers N, Phansalkar S: **The state of the evidence for computerized provider order entry: a systematic review and analysis of the quality of the literature.** *Int J Med Inform* 2009, **78**(6):365–374.
6. Bates D, Cullen D, Laird N, Petersen L, Small S, Servi D, Laffel G, Sweitzer B, Shea B, Hallisey R, Vandervliet, M, Nemeskal, R, Leape, LL: **Incidence of adverse drug events and potential adverse drug events: implications for prevention: ADE prevention study group.** *JAMA* 1995, **274**(1):29–34.
7. Campbell EM, Sittig DF, Ash JS, Guappone KP, Dykstra RH: **Types of unintended consequences related to computerized provider order entry.** *J Am Med Inform Assoc* 2006, **13**(5):547–556.
8. Koppel R, Metlay JP, Cohen A, Abaluck B, Localio AR, Kimmel SE, Strom BL: **Role of computerized physician order entry systems in facilitating medication errors.** *JAMA* 2005, **293**(10):1197–1203.
9. Magrabi F, Ong MS, Runciman W, Coiera E: **Using FDA reports to inform a classification for health information technology safety problems.** *J Am Med Inform Assoc* 2012, **19**(1):45–53.
10. Han YY, Carcillo JA, Venkataraman ST, Clark RS, Watson RS, Nguyen TC, Bayir H, Orr RA: **Unexpected increased mortality after implementation of a commercially sold computerized physician order entry system.** *Pediatrics* 2005, **116**(6):1506–1512.
11. Leung AA, Keohane C, Amato M, Simon SR, Coffey M, Kaufman N, Cadet B, Schiff G, Zimlichman E, Seger DL, Yoon C, Song P, Bates DW: **Impact of vendor computerized physician order entry in community hospitals.** *J Gen Intern Med* 2012, **7**:801–7. doi:10.1007/s11606-012-1987-7. Epub 2012 Jan 21.

12. Hug B, Witkowski D, Sox C, Keohane C, Seger D, Yoon C, Matheny M, Bates D: **Adverse drug event rates in six community hospitals and the potential impact of computerized physician order entry for prevention.** *J Gen Intern Med* 2010, **25**(1):31–38.
13. Ammenwerth E, Schnell-Inderst P, Machan C, Siebert U: **The effect of electronic prescribing on medication errors and adverse drug events: a systematic review.** *J Am Med Inform Assoc* 2008, **15**(5):585–600.
14. Bright TJ, Wong A, Dhurjati R, Bristow E, Bastian L, Coeytaux RR, Samsa G, Hasselblad V, Williams JW, Musty MD, Wing L, Kendrick AS, Sanders GD, Lobach D: **Effect of clinical decision-support systems: a systematic review.** *Ann Intern Med* 2012, **157**(1):29–43.
15. Buntin MB, Burke MF, Hoaglin MC, Blumenthal D: **The benefits of health information technology: a review of the recent literature shows predominantly positive results.** *Health Aff (Millwood)* 2011, **30**(3):464–471.
16. Chaudhry B, Wang J, Wu S, Maglione M, Mojica W, Roth E, Morton SC, Shekelle PG: **Systematic review: impact of health information technology on quality, efficiency, and costs of medical care.** *Ann Intern Med* 2006, **144**(10):742–752.
17. Colpaert K, Decruyenaere J: **Computerized physician order entry in critical care.** *Best Pract Res Clin Anaesthesiol* 2009, **23**(1):27–38.
18. Durieux P, Trinquart L, Colombet I, Nies J, Walton R, Rajeswaran A, Rege Walther M, Harvey E, Burnand B: **Computerized advice on drug dosage to improve prescribing practice.** *Cochrane Database Syst Rev* 2008, **3:** CD002894. doi:10.1002/14651858.CD002894.pub2.
19. Garg AX, Adhikari NK, McDonald H, Rosas-Arellano MP, Devereaux PJ, Beyene J, Sam J, Haynes RB: **Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: a systematic review.** *JAMA* 2005, **293**(10):1223–1238.
20. Goldzweig CL, Towfigh A, Maglione M, Shekelle PG: **Costs and benefits of health information technology: new trends from the literature.** *Health Aff* 2009, **28**(2):w282–w293.
21. Hemens BJ, Holbrook A, Tonkin M, Mackay JA, Weise-Kelly L, Navarro T, Wilczynski NL, Haynes RB: **Computerized clinical decision support systems for drug prescribing and management: a decision-maker-researcher partnership systematic review.** *Implement Sci* 2011, **6**(1):89.
22. Jamal A, McKenzie K, Clark M: **The impact of health information technology on the quality of medical and health care: a systematic review.** *HIM J* 2009, **38**(3):26–37.
23. Jones SS, Rudin RS, Perry T, Shekelle PG: **Health information technology: an updated systematic review with a focus on meaningful use.** *Ann Intern Med* In Press.
24. Kaushal R, Shojania KG, Bates DW: **Effects of computerized physician order entry and clinical decision support systems on medication safety: a systematic review.** *Arch Intern Med* 2003, **163**(12):1409–1416.
25. Kawamoto K, Lobach DF: **Clinical decision support provided within physician order entry systems: a systematic review of features effective for changing clinician behavior.** *AMIA Annu Symp Proc* 2003, 361–365.
26. Kuperman G, Bobb A, Payne T, Avery A, Gandhi T, Burns G, Classen D, Bates D: **Medication-related clinical decision support in computerized provider order entry systems: a review.** *J Am Med Inform Assoc* 2007, **14**(1):29–40.
27. Manias E, Williams A, Liew D: **Interventions to reduce medication errors in adult intensive care: a systematic review.** *Br J Clin Pharmacol* 2012, **74**(3):411–423.
28. Maslove D, Rizk N, Lowe H: **Computerized physician order entry in the critical care environment: a review of current literature.** *J Am Med Inform Assoc* 2007, **14**(1):29–40. Epub 2006 Oct 26.
29. McKibbon K, Lokker C, Handler S, Dolovich L, Holbrook A, O'Reilly D, Tamblyn R, Hemens B, Basu R, Troyan S, Roshanov P: **The effectiveness of integrated health information technologies across the phases of medication management: a systematic review of randomized controlled trials.** *J Am Med Inform Assoc* 2012, **19**(1):22–30.
30. Mollon B, Chong JJ, Holbrook A, Sung M, Thabane L, Foster G: **Features predicting the success of computerized decision support for prescribing: a systematic review of randomized controlled trials.** *BMC Med Inform Decis Mak* 2009, **9:**11. doi:10.1186/1472-6947-9-11.
31. Niès J, Colombet I, Degoulet P, Durieux P: **Determinants of success for computerized clinical decision support systems integrated in CPOE systems: a systematic review.** *AMIA Annu Symp Proc* 2006, 594–598.
32. Oren E, Shaffer E, Guglielmo B: **Impact of emerging technologies on medication errors and adverse drug events.** *Am J Health Syst Pharm* 2003, **60**(14):1447–1458.
33. Pearson S-A, Moxey A, Robertson J, Hains I, Williamson M, Reeve J, Newby D: **Do computerised clinical decision support systems for prescribing change practice? A systematic review of the literature (1990–2007).** *BMC Health Serv Res* 2009, **9**(1):154.
34. Radley DC, Wasserman MR, Olsho LE, Shoemaker SJ, Spranca MD, Bradshaw B: **Reduction in medication errors in hospitals due to adoption of computerized provider order entry systems.** *J Am Med Inform Assoc* 2013, **20**(3):470–6. doi:10.1136/amiajnl-2012-001241. Epub 2013 Feb 20.
35. Reckmann M, Westbrook J, Koh Y, Lo C, Day R: **Does computerized provider order entry reduce prescribing errors for hospital inpatients? A systematic review.** *J Am Med Inform Assoc* 2009, **16**(5):613–623.
36. Schedlbauer A, Prasad V, Mulvaney C, Phansalkar S, Stanton W, Bates DW, Avery AJ: **What evidence supports the use of computerized alerts and prompts to improve clinicians' prescribing behavior?** *J Am Med Inform Assoc* 2009, **16**(4):531–538.
37. Shamliyan TA, Duval S, Du J, Kane RL: **Just what the doctor ordered: review of the evidence of the impact of computerized physician order entry system on medication errors.** *Health Serv Res* 2008, **43**(1 Pt 1):32–53.
38. Shekelle P, Morton SC, Keeler EB: *Costs and Benefits of Health Information Technology.* Rockville (MD): Agency for Healthcare Research and Quality (US); 2006. (Evidence Reports/Technology Assessments, No. 132.) Available from: http://www.ncbi.nlm.nih.gov/books/NBK37988/.
39. Shojania KG, Jennings A, Mayhew A, Ramsay C, Eccles M, Grimshaw J: **Effect of point-of-care computer reminders on physician behaviour: a systematic review.** *Can Med Assoc J* 2010, **182**(5):E216–E225.
40. Shojania KG, Jennings A, Mayhew A, Ramsay CR, Eccles MP, Grimshaw J: **The effects of on-screen, point of care computer reminders on processes and outcomes of care.** *Cochrane Database Syst Rev* 2009, **3**, CD001096.
41. van Rosse F, Maat B, Rademaker CMA, van Vught AJ, Egberts ACG, Bollen CW: **The effect of computerized physician order entry on medication prescription errors and clinical outcome in pediatric and intensive care: a systematic review.** *Pediatrics* 2009, **123**(4):1184–1190.
42. Wolfstadt JI, Gurwitz JH, Field TS, Lee M, Kalkar S, Wu W, Rochon PA: **The effect of computerized physician order entry with clinical decision support on the rates of adverse drug events: a systematic review.** *J Gen Intern Med* 2008, **23**(4):451–458.
43. Deeks JJ, Higgins JPT, Altman DG: **Chapter 9: Analysing data and undertaking meta-analyses.** In *Cochrane Handbook for Systematic Reviews of Interventions. Version 5.0.1 [updated September 2008]. The Cochrane Collaboration, 2008.* Edited by Higgins JPT, Green S; Available from http://hiv.cochrane.org/sites/hiv.cochrane.org/files/uploads/Ch09_Analysing.pdf, last accessed June 1, 2014.
44. Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group: **Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement.** *PLoS Med* 2009, **6**(7):e1000097.
45. Shea BJ, Hamel C, Wells GA, Bouter LM, Kristjansson E, Grimshaw J, Henry DA, Boers M: **AMSTAR is a reliable and valid measurement tool to assess the methodological quality of systematic reviews.** *J Clin Epidemiol* 2009, **62**(10):1013–1020.
46. Flynn EA, Barker KN, Pepper GA, Bates DW, Mikeal RL: **Comparison of methods for detecting medication errors in 36 hospitals and skilled-nursing facilities.** *Am J Health Syst Pharm* 2002, **59**(5):436–446.
47. Centers for Disease Control and Prevention: *National Hospital Discharge Survey: Centers for disease control and prevention: national hospital discharge survey*; 2007. cited 2011 July 14]; Available from: http://www.cdc.gov/nchs/nhds/nhds_tables.htm.
48. Kaushal R, Bates DW, Landrigan C, McKenna KJ, Clapp MD, Federico F, Goldmann DA: **Medication errors and adverse drug events in pediatric inpatients.** *JAMA* 2001, **285**(16):2114–2120.
49. Assessing the Evidence for Context-Sensitive Effectiveness and Safety: *Developing Criteria.* Rockville, MD: Agency for Healthcare Research and Quality; 2010. http://www.ahrq.gov/research/findings/final-reports/contextsensitive/index.html.
50. Franklin BD, Birch S, Savage I, Wong I, Woloshynowych M, Jacklin A, Barber N: **Methodological variability in detecting prescribing errors and consequences for the evaluation of interventions.** *Pharmacoepidemiol Drug Saf* 2009, **18**(11):992–999.
51. Donyai P, O'Grady K, Jacklin A, Barber N, Franklin BD: **The effects of electronic prescribing on the quality of prescribing.** *Br J Clin Pharmacol* 2007, **65**(2):230–237.
52. Franklin BD, O'Grady K, Donya P, Jacklin A, Barber N: **The impact of a closed-loop electronic prescribing and administration system on**

prescribing errors, administration errors and staff time: a before-and-after study. *Qual Saf Health Care* 2007, **16**:279–284.
53. Shawahna R, Rahman N-U, Ahmad M, Debray M, Yliperttula M, Decleves X: **Electronic prescribing reduces prescribing error in public hospitals.** *J Clin Nurs* 2011, **20**(21–22):3233–3245.
54. Shulman R, Singer M, Goldstone J, Bellingan G: **Medication errors: a prospective cohort study of hand-written and computerised physician order entry in the intensive care unit.** *Crit Care* 2005, **9**(5):R516–R521.
55. Wess ML, Embi PJ, Besier JL, Lowry CH, Anderson PF, Besier JC, Thelen G, Hegner C: **Effect of a computerized provider order entry (CPOE) system on medication orders at a community hospital and university hospital.** *AMIA Annu Symp Proc* 2007, 796–800.
56. ITN: *Imaging technology news: health system gets the 'LastWord' with GE's centricity October 9, 2006 [cited 2013 August 14]*; Available from: http://www.itnonline.com/article/health-system-gets-%E2%80%9Clastword%E2%80%9D-ge%E2%80%99s-centricity.
57. Taylor R, Manzo J, Sinnett M: **Quantifying value for physician order-entry systems: a balance of cost and quality.** *Healthc Financ Manage* 2002, **56**(7):44–48.
58. Barron W, Reed R, Forsythe S, Hecht D, Glen J, Murphy B, Lach R, Flores S, Tu J, Concklin M: **Implementing computerized provider order entry with an existing clinical information system.** *Jt Comm J Qual Patient Saf* 2006, **32**(9):506–516.
59. Bates DW, Leape LL, Cullen DJ, Laird N, Petersen LA, Teich JM, Burdick E, Hickey M, Kleefield S, Shea B, Vander Vliet M, Seger DL: **Effect of computerized physician order entry and a team intervention on prevention of serious medication errors.** *JAMA* 1998, **280**(15):1311–1316.
60. van Doormaal JE, van den Bemt PMLA, Zaal RJ, Egberts ACG, Lenderink BW, Kosterink JGW, Haaijer-Ruskamp FM, Mol PGM: **The influence that electronic prescribing has on medication errors and preventable adverse drug events: an interrupted time-series study.** *J Am Med Inform Assoc* 2009, **16**(6):816–825.
61. Westbrook J, Reckmann M, Li L, Runciman W, Burke R, Lo C, Baysari M, Braithwaite J, Day R: **Effects of two commercial electronic prescribing systems on prescribing error rates in hospital in-patients: a before and after study.** *PLoS Med* 2012, **9**(1):e1001164.
62. Weant KA, Cook AM, Armitstead JA: **Medication-error reporting and pharmacy resident experience during implementation of computerized prescriber order entry.** *Am J Health Syst Pharm* 2007, **64**(5):526–530.
63. Bates DW, Teich JM, Lee J, Seger D, Kuperman GJ, Ma'luf N, Boyle D, Leape L: **The impact of computerized physician order entry on medication error prevention.** *JAMIA* 1999, **6**(4):313–321.
64. Colpaert K, Claus B, Somers A, Vandewoude K, Robays H, Decruyenaere J: **Impact of computerized physician order entry on medication prescription errors in the intensive care unit: a controlled cross-sectional trial.** *Crit Care* 2006, **10**(1):R21.
65. Mahoney CD, Berard-Collins CM, Coleman R, Amaral JF, Cotter CM: **Effects of an integrated clinical information system on medication safety in a multi-hospital setting.** *Am J Health Syst Pharm* 2007, **64**(18):1969–1977.
66. Oliven A, Michalake I, Zalman D, Dorman E, Yeshurun D, Odeh M: **Prevention of prescription errors by computerized, on-line surveillance of drug order entry.** *Int J Med Inform* 2005, **74**:377–386.
67. Igboechi CA, Ng CL, Yang CS, Buckner AN: **Impact of computerized prescriber order entry on medication errors at an acute tertiary care hospital.** *Hosp Pharm* 2003, **38**(3):227–231.
68. Aronsky D, Johnston PE, Jenkins G, Waitman LR, Frelix D, Jones I, Patel NR: **The effect of implementing computerized provider order entry on medication prescribing errors in an emergency department.** *AMIA Annu Symp Proc* 2007.
69. Miller RA, Waitman LR, Chen S, Rosenbloom ST: **The anatomy of decision support during inpatient care provider order entry (CPOE): empirical observations from a decade of CPOE experience at Vanderbilt.** *J Biomed Inform* 2005, **38**(6):469–485.
70. Menendez MD, Alonso J, Rancaño I, Corte JJ, Herranz V, Vázquez F: *Impact of computerized physician order entry on medication errors.* Elsevier Editorial System(tm) for Revista de Calidad Asistencial; 2012:16.
71. Wright A, Sittig DF, Ash JS, Sharma S, Pang JE, Middleton B: **Clinical decision support capabilities of commercially-available clinical information systems.** *J Am Med Inform Assoc* 2009, **16**(5):637–644.
72. Shekelle PG, Pronovost PJ, Wachter RM: *Assessing the evidence for context-sensitive effectiveness and safety of patient safety practices: developing criteria, www.ahrq.gov contract no. HHSA-290-2009-10001C.* Rockville, MD: Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services. 540 Gaither Road, Rockville; MD 208502010.
73. Ogrinc G, Mooney S, Estrada C, Foster T, Goldmann D, Hall L, Huizinga M, Liu S, Mills P, Neily J, Nelson W, Pronovos PJ, Provost L, Rubenstein L, Speroff T, Splaine M, Thomson R, Tomolo A, Watts B: **The SQUIRE (Standards for QUality improvement reporting excellence) guidelines for quality improvement reporting: explanation and elaboration.** *Qual Saf Health Care* 2008, **17**(1):i13–32.
74. DerSimonian R, Laird N: **Meta-analysis in clinical trials.** *Control Clin Trials* 1986, **7**(3):177–188.
75. Higgins JP, Thompson SG, Deeks JJ, Altman DG: **Measuring inconsistency in meta-analyses.** *BMJ* 2003, **327**(7414):557–560.
76. Sutton AJ, Duval SJ, Tweedie RL, Abrams KR, Jones DR: **Empirical assessment of effect of publication bias on meta-analyses.** *BMJ* 2000, **320**(7249):1574–1577.
77. Shekelle PG, Pronovost PJ, Wachter RM, Taylor SL, Dy SM, Foy R, Hempel S, McDonald KM, Ovretveit J, Rubenstein LV, Adams AS, Angood PB, Bates DW, Bickman L, Carayon P, Donaldson L, Duan N, Farley DO, Greenhalgh T, Haughom J, Lake ET, Lilford R, Lohr KN, Meyer GS, Miller MR, Neuhauser DV, Ryan G, Saint S, Shojania KG, Shortell SM, Stevens DP, Walshe K: **Advancing the science of patient safety.** *Ann Intern Med* 2011, **154**(10):693–696.
78. Wears RL, Berg M: **Computer technology and clinical work: still waiting for Godot.** *JAMA* 2005, **293**(10):1261–1263.

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The Laryngoscope

Involvement of Physician Extenders in Ambulatory Otolaryngology Practice

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Objectives/Hypothesis: Determine the penetration and point-of-care patterns for physician extenders in ambulatory otolaryngology practice.

Study Design: Cross-sectional analysis of national database.

Methods: The National Ambulatory Medical Care Survey was examined for 2008 and 2009, extracting all cases of ambulatory visits to an otolaryngology outpatient setting. Visit types were then segregated according to providers seen including physician, advanced practice clinicians (APCs) (nurse practitioner and/or physician assistant) and nurses. Visit types were determined (physician alone, physician with APC, or APC alone) as well as type of patient seen (new vs. established patient). The top 10 diagnoses were compiled according to provider visit type.

Results: An estimated 38.6 ± 3.7 million outpatient office otolaryngology visits were studied. An APC was seen in 6.3 ± 2.0% of visits (physician assistant, 4.6 ± 1.9% visits; nurse practitioner, 1.7 ± 0.9% of visits), and a nurse was involved in 25.1 ± 7.6% of visits. Nurse practitioners were more likely see patients independently (47.7%) than were physician assistants (23.3%). APCs were more likely to be involved with established patient visits (7.2 ± 2.3%) rather than new patient visits (4.3 ± 1.8%, $P = .08$). Disorders of the external and middle ears were the most common diagnoses seen by APCs.

Conclusions: Although APCs are expected to expand numbers in otolaryngology, contemporary data indicate that current penetration of APCs into ambulatory otolaryngology care remains relatively limited. These data provide an initial assessment for future modeling of APCs and otolaryngologic care.

Key Words: Physician extenders, ambulatory care, otolaryngology, advanced practice clinicians, nurse practitioner, physician assistant.

Level of Evidence: 2b

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INTRODUCTION

The concept of a looming physician shortage linked to an expanding and aging population in the United States has been the subject of ongoing concern and debate.[1] One option to help offset a projected physician storage, including a projected shortage in otolaryngology, is the integration of midlevel and advanced practice personnel into ambulatory and hospital-based care.[2,3] Recent commentaries have stressed the evolving role of advanced practice clinicians (APCs) and other providers in otolaryngologic practice.[3]

However, although there is a perceived need for and a seeming progression toward the integration of APCs in otolaryngologic practices, almost no data are available indicating the actual penetration of APCs and other providers into the point of care. Such data are essential as a foundation for understanding the epidemiology, economics, and patient experiences for care provided by APCs in otolaryngology. Data regarding the prevalence of care provided by APCs, interactions with physicians at the point of care, and the types of patients seen are also important components when projecting the role of APCs in future models of healthcare provision. We sought to examine current trends in APC care provided at the ambulatory otolaryngology level to help quantify these factors.

MATERIALS AND METHODS

The National Ambulatory Medical Care Survey (NAMCS) for the calendar years 2008 and 2009 formed the data source for this study. The NAMCS is a national survey conducted yearly by the Center for Healthcare Statistics, a branch of the Centers for Disease Control. It provides objective reliable information about the provision and use of ambulatory medical care services in the United States. Findings are based on a sample of visits to non-federally employed office-based physicians who are primarily engaged in direct patient care. The NAMCS uses a multistage probability design, first using primary sampling units (N = 112, adjusting for variations national geography), followed by a second-stage sampling reflecting physicians, their specialties, and random sampling time periods during the calendar year. Specially trained interviewers visit the physicians prior to their participation in the survey to provide them with survey materials and instruct them on how to complete the forms. Data are collected from the physician, rather than from the patient. Each physician is randomly assigned to a 1-week

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TABLE I.
Distribution of Medical Providers Seen for Otolaryngologic Office Visits, 2008 and 2009.

Medical Provider Seen	No.	SE	% of Visits*	SE
Physician	37,647,017	3,742,272	97.5	1.1
Physician assistant	1,770,980	702,253	4.6	1.9
Nurse practitioner	659,674	359,556	1.7	0.9
RN/LPN	9,669,216	3,500,089	25.1	7.6

No. represents number of visits.
*Provider seen is not mutually exclusive (i.e., patient may have seen both physician and nurse practitioner) thereby sum totals >100%.
SE = standard error; RN = registered nurse; LPN = licensed practical nurse.

reporting period. During this period, data for a systematic random sample of visits are recorded by the physician on an encounter form provided for that purpose. It is estimated that 84% of all ambulatory visits in the United States fall within the NAMCS sampling frame, and the survey has been previously validated in comparison to direct observation with very good accuracy with respect to the provision of health services.[4] We and others have previously used this data set to examine care provided for a number of otolaryngologic conditions including chronic rhinosinusitis, otitis media, and otologic diagnoses in the elderly.[5–8]

The study was reviewed and received an institutional review board exemption. From the combined years data set, office visits to ambulatory ear, nose, and throat (ENT) practices were extracted including diagnosis codes, patient demographic data, and provider data. Each visit contains provider data related to type of providers seen: physician, physician assistant (PA), nurse practitioner (NP), and registered nurse (RN)/licensed practical nurse (LPN). For purposes of evaluation, physician assistants and nurse practitioners were grouped together as APCs.

From the ENT office visits, the types of providers seen were tabulated. Next, for patients seen by a PA, NP, or RN, the fraction of patients seen by the auxiliary personnel alone (visit independent of physician) and auxiliary personnel with physician (collaborative visit) were determined. Furthermore, the top 10 visit diagnoses were determined and tabulated for each of the auxiliary personnel: physician, NP, and RN. Last, the relationship between auxiliary personnel and type of office visit (office new patient vs. established patient) was determined and tabulated. Because the NAMCS design uses clustering, stratification, random sampling, and weighting, appropriate statistical methods that incorporate these study design elements into statistical calculations for complex samples were used. Statistical significance was set at $P = .05$.

RESULTS

For combined calendar years 2008 and 2009, an estimated 38.6 ± 3.73 million outpatient office visits to an ENT provider/practice (raw sample, 2714 visits) were identified for analysis. The distribution of providers seen at these office visits are presented in Table I. In Table I, the providers seen are not mutually exclusive (i.e., at a given outpatient visit, the patient may have seen both a physician and an NP). In 6.3 ± 2.0% of office visits, an APC (PA or NP) was seen. A nurse (RN/LPN) was involved in 25.1 ± 7.6% of ENT office visits. Figure 1 demonstrates the joint versus independent visit rate for APCs and RNs with respect to collaborating physicians. NPs were more likely to see patients independent of a physician when compared to PAs (47.7% independent visit rate vs. 23.3%). Less than 0.5% of ambulatory otolaryngologic visits involved care provided by a RN alone (i.e., without concurrent physician-level care).

Tables II and III present the top 10 diagnoses associated with an APC- or RN-related ENT visit, as well as physician-alone visits. Disorders associated with the external and middle ear (i.e., otitis externa, cerumen impaction, acute otitis media) were the most common diseases with and APC and/or an RN component to the encounters. With respect to patient visit type, for 7.2 ± 2.3% of established patient visits, an APC was involved in the outpatient visit. In contrast, for new patient visit types, an APC was involved in the outpatient visit less frequently, 4.3 ± 1.8% of the time ($P = .080$)

DISCUSSION

There is little question that APCs are increasingly becoming part of the core healthcare providership in the United States. As the US population ages and with predicted increases in chronic conditions such as obesity, diabetes, and allergic diseases, it is further likely that care provided by physician extenders will increase across multiple medical specialties. Given that recent work suggests a increasing volume of patients who will require otolaryngologic care in the upcoming decades, coupled with a relatively aging otolaryngologic physician workforce, a significant penetration of APCs into ambulatory otolaryngologic care is likely.[2,9] As a specialty, otolaryngology–head and neck surgery will need to recruit, train, and supervise these nonphysician providers. For

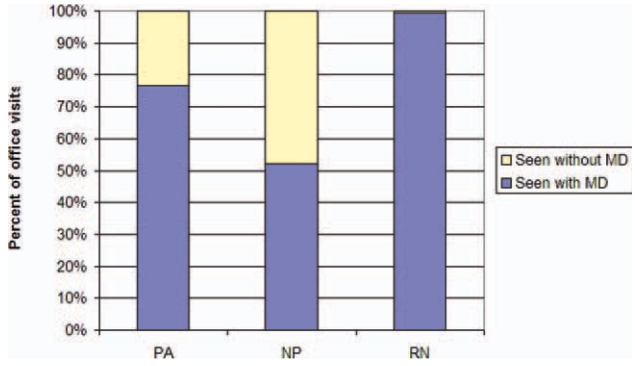

Fig. 1. Distribution of joint versus independent office visits in otolaryngology for physician assistants, nurse practitioners, and nurses. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

TABLE II.
Top 10 Diagnosis Codes Seen by Physician Assistants and Nurse Practitioners.

PA		NP	
Diagnosis	No.	Diagnosis	No.
(381) Nonsuppurative otitis media and . . .	223,440	(380) Disorders of external ear	85,981
(380) Disorders of external ear	140,130	(474) Chronic disease of tonsils and . . .	56,589
(784) Symptoms involving head and neck	110,734	(784) Symptoms involving head and neck	35,071
(706) Diseases of sebaceous glands	100,332	(530) Diseases of esophagus	32,387
(780) General symptoms	96,839	(995) Certain adverse effects, not el. . .	32,387
(472) Chronic pharyngitis and nasopha. . .	89,491	(V67) Follow-up examination	32,387
(701) Other hypertrophic and atrophic. . .	63,366	(382) Suppurative and unspecified oti. . .	26,797
(781) Symptoms involving nervous and . . .	36,366	(477) Allergic rhinitis	26,797
(785) Symptoms involving cardiovascul. . .	63,366	(462) Acute pharyngitis	18,863
(473) Chronic sinusitis	61,521	(472) Chronic pharyngitis and nasopha. . .	18,863

PA = physician assistant; NP = nurse practitioner.

example, societies are developing online training courses for education and certification for APCs in otolaryngology.[10]

The role of APCs in providing outpatient care in multiple different surgical disciplines, including otolaryngology, has been studied, particularly in countries with national health services. For example, patient satisfaction surveys have been conducted in Great Britain regarding NPs in management of snoring and aural care, among other conditions. Generally, care rendered by these APCs has been viewed as good or very good in these settings.[11,12] Similar data suggest that patients are satisfied with the care offered by surgical nurse practitioners in the Veterans Health Administration.[13] As the penetration of physician assistants in otolaryngology remains limited, there are limited data regarding patient satisfaction with visits incorporating PAs in otolaryngology. This is likely an area warranting future research.

The current data provide a national estimate of the type of care being provided by APCs and RNs in outpatient, ambulatory, otolaryngology practices. A substantial fraction (25.1%) of ambulatory patients are coming in contact with a nurse during their outpatient otolaryngology visit. Nurses may provide a broad spectrum of care, including assistance with cerumen removal, patient education, and allergy testing, among others. However, because visits provided by nurses alone are not typically subject to billing for clinical services, it is not surprising that almost all visits in which a nurse was involved also had a corresponding physician-provider component (Fig. 1). This lends to the validity of the current data.

Currently, a relative minority of otolaryngologic office visits are provided for by APCs, currently standing at only 6.3%. When APC care was involved, NPs were significantly more likely to see patients independent of a physician during the office visit relative to care provided by a PA. The greater fraction of independent NP care is to be expected given that NPs are governed by the state boards of nursing, and correspondingly, may be allowed a greater degree of autonomy than PAs.[3] In some states, NPs may be able to practice completely independently (i.e., without collaboration) of a physician for diagnosis and treatment.[2] In contrast, PA training and education are strongly geared toward physician collaboration, and

TABLE III.
Top 10 Diagnosis Codes Seen by Nurses and Physicians.

RN		MD Alone	
Diagnosis	No.	Diagnosis	No.
(381) Nonsuppurative otitis media and. . .	795,353	(380) Disorders of external ear	2,513,272
(380) Disorders of external ear	766,185	(381) Nonsuppurative otitis media and. . .	1,938,697
(382) Suppurative and unspecified oti. . .	615,322	(473) Chronic sinusitis	1,694,074
(784) Symptoms involving head and neck	493,870	(784) Symptoms involving head and neck	1,478,966
(473) Chronic sinusitis	491,677	(477) Allergic rhinitis	1,438,415
(389) Deafness	474,400	(382) Suppurative and unspecified oti. . .	1,430,729
(477) Allergic rhinitis	361,161	(389) Deafness	1,306,010
(474) Chronic disease of tonsils and . . .	349,586	(478) Other diseases of upper respira. . .	1,033,903
(388) Other disorders of ear	331,049	(388) Other disorders of ear	884,837
(478) Other diseases of upper respira. . .	316,126	(V67) Follow-up examination	844,266

RN = registered nurse; MD = medical doctor.

their practice is overseen by state medical boards. The different levels of practice for physician extenders in otolaryngology are very nicely described and summarized by Norris et al., and range from supportive to independent practice models.[3] The relatively small percentage of patient care being provided for by APCs is consistent with the fact that NPs in otolaryngology constitute only 0.2% of all active NPs, and PAs in otolaryngology constitute only 0.9% of the total PA workforce as of 2008. These percentages are better illustrated when compared to the fact that approximately 1.2% of active physicians in the United States are otolaryngologists.[14]

Interestingly, PAs, NPs, and RNs are most commonly involved in office visits that concern disorders of the ear (Tables II and III). This is likely related to the fact that ear complaints are among the most common reasons for patients' being seen in the outpatient otolaryngology setting, and ears are readily examined without the need for a procedure such as endoscopy. Furthermore, there was significant overlap in the diagnoses attributed to PA versus NP visits, which constituted both acute and chronic conditions in otolaryngology. Finally, with respect to type of patient distribution, APCs were more commonly used in established patient visits in contrast to new patient visits. This suggests that APCs in otolaryngology are being employed in the context of disease management and follow-up rather than disease diagnosis. Again, given the contemporary constraints of the healthcare system, further use of APCs in diagnostic evaluations seems likely.

CONCLUSION

Although APCs are expected to expand in numbers in otolaryngology, contemporary data indicate that current penetration of APCs into ambulatory otolaryngology care remains relatively limited. These data provide an initial assessment for future modeling of APCs in otolaryngologic care.

BIBLIOGRAPHY

1. Etzioni DA, Liu JH, Maggard MA, Ko CY. The aging population and its impact on the surgery workforce. *Ann Surg* 2003;238:170–177.
2. Reger C, Kennedy DW. Changing practice models in otolaryngology-head and neck surgery: the role for collaborative practice. *Otolaryngol Head Neck Surg* 2009;141:670–673.
3. Norris B, Harris T, Stringer S. Effective use of physician extenders in an outpatient otolaryngology setting. *Laryngoscope* 2011;121:2317–2321.
4. Gilchrist VJ, Stange KC, Flocke SA, McCord G, Bourguet CC. A comparison of the National Ambulatory Medical Care Survey (NAMCS) measurement approach with direct observation of outpatient visits. *Med Care* 2004;42:276–280.
5. Lee LN, Bhattacharyya N. Regional and specialty variations in the treatment of chronic rhinosinusitis. *Laryngoscope* 2011;121:1092–1097.
6. Bhattacharyya N, Kepnes LJ. Initial impact of the acute otitis externa clinical practice guideline on clinical care. *Otolaryngol Head Neck Surg* 2011;145:414–417.
7. Lin HW, Bhattacharyya N. Otologic diagnoses in the elderly: current utilization and predicted workload increase. *Laryngoscope* 2011;121:1504–1507.
8. Mattos JL, Woodard CR, Payne SC. Trends in common rhinologic illnesses: analysis of U.S. healthcare surveys 1995–2007. *Int Forum Allergy Rhinol* 2011;1:3–12.
9. Bhattacharyya N. The increasing workload in head and neck surgery: an epidemiologic analysis. *Laryngoscope* 2011;121:111–115.
10. Henkel G. A partner in the business: practices see mid-level providers as valuable additions. *ENT Today* May 2010. Available at: http://www.enttoday.org/details/article/690067/A_Partner_in_the_Business_Practices_see_mid-level_providers_as_valuable_addition.html2010. Accessed January 4, 2012.
11. Reddy VM, Sargent H, Prior MJ. Benign paroxysmal positional vertigo nurse-led follow-up clinic. *Eur Arch Otorhinolaryngol* 2011;268:829–832.
12. Robertson S, Maxwell C, McGarry GW, MacKenzie K. A nurse-led snoring clinic: how we do it. *Clin Otolaryngol* 2009;34:158–161.
13. Palmquist DS. *The Role, Productivity, and Patient Satisfaction of Surgical Nurse Practitioners Compared to Medical Surgeons in VHA Outpatient Surgery Clinics* [dissertation]. Cypress, CA: Trident University International, 2010.
14. Association American Medical Colleges. Center for Workforce Studies. 2008 physician specialty data. 2008; Washington, DC. Available at: https://www.aamc.org/download/47352/data/specialtydata.pdf. Accessed January 4, 2012.

The Laryngoscope

Contemporary Review

Effective Use of Physician Extenders in an Outpatient Otolaryngology Setting

Byron Norris, MD; Tristen Harris, MPAS, PA-C; Scott Stringer, MD, MS

Physician extenders may be a valuable asset to an outpatient otolaryngology practice. The adjunctive care provided by physician extenders appears to be cost effective and has the advantages of increasing patient education, promoting physician productivity, and improving management of chronic conditions. Practice types that may benefit from advanced practice providers include group or solo practices with high demand or who need improved efficiency. We discuss five different practice models for incorporation of advanced practice providers in an outpatient otolaryngology practice. These models include scribe, collaborative, limited independent, partial independent, and near complete independent practice and are based primarily on the autonomy level of the physician extender. In additon, we examine available literature discussing the cost effectiveness of physician extenders used in an outpatient setting.

Key Words: Physician extender, midlevel providers, practice management, cost–benefit.
Level of Evidence: 5.

***Laryngoscope,* 121:2317–2321, 2011**

INTRODUCTION

Physician extenders have an increasing presence in the healthcare workforce. Based on data from 2007, there are approximately 120,000 active nurse practitioners (NPs) and physician assistants (PAs) in the United States, and the use of midlevel providers is increasing in specialty and subspecialty aspects of medicine.[1] Despite the increase, the field of otolaryngology is currently underrepresented.[2] According to the 2008 American Academy of Physician Assistant's Census Report there were 251 PAs working in otolaryngology practices, representing 0.9% of the total workforce.[3] The percentage of NPs in otolaryngology is even fewer, being reported as less than 0.2% of all active NPs.[4] The increase in advanced practice providers is needed in part to offset the relative decline in practicing otolaryngologists. According to the American Association of Medical Colleges 2006 data, there are only 9,077 active otolaryngologists in the United States, with 42% of these physicians aged 55 years or older.[5]

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Physician extenders, including NPs and PAs, refer to health professionals who are trained and licensed to practice medicine under the supervision of or in collaboration with a physician. The background, education, and level of autonomy differ between NPs and PAs.[6] NPs are governed by the state boards of nursing and may have greater autonomy than PAs.[6] In addition, the requirements for education, prescribing practices, and credentialing vary between state for NPs.[2] For example, as of 2008, only 30 states required NPs to collaborate with a physician for diagnosis and treatment.[2] PA's training and education are centered around physician collaboration and are governed by state medical boards.[6] Although the training, scope of practice, and background education may differ between NPs and PAs, this manuscript groups the two subsets together to focus on similar roles in relation to an outpatient otolaryngology practice.

This manuscript is intended to highlight the changing face of healthcare with respect to the increasing presence of advanced practice providers, specifically regarding specialty practices such as otolaryngology. Pertinent literature is reviewed and five models are discussed relating to the incorporation of advanced practice providers into the outpatient otolaryngology sector. Cost analysis, impact on patient care, and future healthcare directions are reviewed. Although there are many applications of advanced practice providers for inpatient management and assisting with surgical procedures, this manuscript focuses solely on the application in the outpatient clinic setting.

TABLE I.
Utilizations Models for Physician Extenders.

	Support		Independent		
Model	Scribe	Collaborative	Limited	Partial	Near complete
Billing number used	Physician	Physician	Physician*	PE	PE
Physician in room	Yes, simultaneous	Yes, second in	No	No	No
Physician in building	Yes	Yes	Yes	Yes	No

*Incident to billing.
PE = physician extender.

DISCUSSION

We propose a framework of five practice models for the integration of advanced practice providers into an otolaryngology practice (Table I). These models are scribe, collaborative, limited independent, partial independent, and near complete independent practice. The models encompass the majority of current practice arrangements and are divided primarily based on the autonomy level of the physician extender in a support role or more independent practice. The models are further defined based on the billing number used and the location of the physician. All five models may be employed in either an academic or private practice setting, although certain aspects of each model may dictate what practice type is best. These practice management models may be instituted in isolation or as a continuum of methods to facilitate improved and more cost effective healthcare.

Although this manuscript details useful methods for integration of midlevel providers into an outpatient clinic setting, it is recommended that the practice be aware of all applicable laws governing physician extenders as these vary by state. In particular, billing practices should be reviewed and Medicare and Medicaid regulations should be followed. Practice compliance officers should verify the proper integration of advanced practice providers. The purpose of this manuscript is to supplement, not supersede, regulations governed by the state.

Scribe

The first and most basic model for advanced practice providers is the scribe format. In this model the midlevel provider shadows the physician and completes clerical tasks. The scribe model is especially useful for the orientation of new hires or the transition of advanced practice providers from other subspecialties to the field of otolaryngology. This model allows the physician extender exposure to otolaryngology protocols and physician preferences. By completing clerical tasks particularly during the transition to electronic medical records, the scribe model may promote physician efficiency and increase revenue. In primary care, documentation and patient's records are found to be "significantly better kept" when assistants such as NPs are involved with patient care.[7] In addition, the midlevel provider may provide assistance with basic in-office procedures. As the knowledge base of the midlevel provider increases they are promoted to greater degrees of responsibility and autonomy.

Collaborative Practice

The second support model is one of collaborative practice. Collaborative practice refers to advanced practice providers functioning as a team member working alongside staff physicians.[2] Utilized in this capacity, the midlevel provider gathers important information during the patient care encounter and relays this to the attending physician. The physician processes the information and functions as the manager of a medical team. Ward describes this model as "first-in-the-room provider" to emphasize the order of appearance of the healthcare personnel.[7] Although this description is technically accurate, it fails to acknowledge the collaborate effort necessary for successful implementation of this model. To function effectively, the advanced practice provider employed in this model must be able to proficiently obtain, synthesize, verify, and institute complex information from the patient care encounter.

The collaborative practice model uses the physician's billing number. Although not directly reimbursed for their services, the advanced practice provider helps to generate revenue by increasing the productivity and efficiency of the staff physician. The staff physician is able to see a greater number of patients and spend more time performing procedures. In general, a physician extender utilized under this model can promote substantial increase in patient encounters resulting in a net gain to the practice. In primary care, the literature supports increased productivity with use of PAs in a support role.[7] It is important in this scenario to appropriately document that the physician performed all work independently required to support the coding level submitted.

Limited Independent

Independent practice for midlevel providers refers to conducting patient visits and instituting treatment plans without the direct involvement or presence of a physician. However, independent practice is performed under a given set of predetermined protocols and supervised by attending physicians through a review process. According to the Congress Office of Technology Assessment, advanced practice providers can provide independent care equal to that of physicians that is "within the limits of their expertise."[8] Although the independent models do not directly affect physician productivity, physician extenders may improve practice efficiency by catering to walk-in and overflow patients. The independent models for effective use of physician extenders include limited, partial, and near complete independent practice.

The first independent model for effective use of advanced practice providers is limited independent practice. This model is based on "incident to" billing, which is a type of physician extender billing practice for select patients. Incident to billing is a Medicare provision that allows midlevel providers to perform independent care but bill at 100% reimbursement if certain criteria are met.[9,10] Stipulations for incident to billing include that the patient must be an established patient within the scope of the physician's practice. Billing utilizes the physician's billing number and the physician must be on site.[9] The ideal patients for limited independent practice and incident to billing include follow-up patients and routine postoperative patients. The low acuity and established nature of "incident to" patients promotes a gentle transition between collaborative and independent practice for physician extenders. The model of limited independent practice differs from the other independent practice models because it utilizes the physician's billing number for higher reimbursement rates. However, only select patients meet criteria for this model thereby limiting the scope of practice.

Partial Independent

In partial independent model utilization, the physician extender conducts patient encounters by himself or herself with the physician available in the office. The partial independent model promotes autonomy of the advanced practice provider while allowing the capacity for the physician to provide assistance on complex patients. This model is advantageous because it allows for increase in patient encounters without the addition of another otolaryngology physician. Ideal patients include walk-in, follow-up, routine postoperative, and low acuity new patients. Reimbursement rates for patient encounters are less than physician reimbursement due to utilization of the midlevel provider billing number. However, lower reimbursement rates are offset by the lower salary rates of physician extenders. Although the partial independent model is ideal for the busy practice, the practice must have available office space and the staffing capacity for increased patient load.

Near Complete Independent

The final model is near complete independent practice. In this setting, the advanced practice provider will practice with the supervising physician off site. The physician extender will function under a predetermined set of guidelines and practice protocols. Periodic chart reviews are often performed by the physician but the degree of required supervision is regulated by the state.[2] Although the supervising physician is out of the office, he or she is available for questions or situations that fall outside of the practice parameters. This model is advantageous, especially in solo or small group practice, because it allows utilization of office space while the physician is offsite or in the operating room. Again, reimbursement is based on the physician extender billing number but provides the best utilization of resources by preventing unused office space.

Application and Advantages of Utilization Models

Midlevel providers are useful adjuncts for practitioners who are unable to meet the clinical demand of the community they serve. Busy solo or small private practices may benefit from physician extenders employed under the independent model of practice. Advanced practice providers in this setting may improve practice efficiency and increase revenue by managing walk-in appointments, low acuity or postoperative patients, and situations where the physician is called to an emergency during clinic hours.[11] A midlevel provider in this situation may function through limited, partial, or near complete independent practice, depending on the patient, acuity of the situation, or location of the physician. It is important to consider that the same advanced practice provider has the flexibility to function within all of the model practice patterns described during the same day or over time as a practice grows and its needs change.

The addition of a midlevel provider is more economical than adding another physician partner. Reimbursement for advanced practice providers may vary based on contractual agreements with private insurance; however, is generally at 85% of the fee schedule amount for physicians.[10,12] Although reimbursement rates are moderately reduced compared to physician rates, the compensation rate of midlevel providers compared to physicians is dramatically different.[13] Dierick-van Daele et al.[13] found that "direct costs plus productivity costs were significantly lower for nurse practitioner consultations" compared with consultations of general practitioners. According to a national survey, the average base salary for advanced practice providers is $80,000 plus addition costs of 25% to 30% for benefits and overhead.[12] The annual salary for PAs in otolaryngology practices is $86,856 versus $90,019 annually for all other PAs.[3] Furthermore, adding a midlevel provider may be easier than finding an otolaryngologist available for hire particularly in rural settings and as the demand for healthcare services continues to exceed the number of specialists trained.

A final benefit for utilization of midlevel providers is one of improvement in patient care. Patient satisfaction, patient education, and management of chronic diseases are improved by creating a multidisciplinary team approach to patient care through the addition of advanced practice providers in the collaborative practice model.[2,14] Patient education may be improved in areas such as tobacco cessation or nutrition, especially for patients with head and neck cancer. In a systematic review of the recent primary care literature, patient education was found to be significantly improved when NPs participate in patient care.[7] Patient satisfaction is determined in part by time spent in the patient encounter. Rashid's integrative review found that advanced practice nurses had unhurried consultations with a tendency to reinforce messages making the patient the focus of their attention.[15] Midlevel providers may increase the amount of time spent with patients while optimizing physician efficiency.[14]

The benefit of improvement in patient care may be best utilized in an academic setting or where the

complexity of the patients requires specialty management. According to Kennedy, utilization of advanced practice providers within the collaborative practice model has the "potential to deliver an exceptionally high level of care for chronic disorders."[2] It is reported that NPs may excel in assisting in the management of chronic diseases as they are "trained specifically for health promotion and education."[16] Although the support models are the least profitable, they may still increase revenue through improving physician productivity. The need to provide efficient management of chronic disease will increase as the use of episodic bundling payments becomes more widespread posthealthcare reform implementation.

FUTURE DIRECTIONS

The integration of advanced practice providers into clinical practice continues to be in evolution. The role of a midlevel provider depends on the need of the physician and group with which they are employed.[8] In addition, the healthcare reform bill may create more demand for specialty care through a greater number of insured patients. Combined with a predicted shortage of otolaryngologist, the increase in insured individuals has the potential to overwhelm the current otolaryngology work force.[2] State law currently dictates the amount and type of physician supervision given to advanced practice providers.[12] However, with respect to the current physician shortage, the level of physician supervision may be modified to help offset escalating healthcare demands.

There has been increased usage of midlevel providers in many medical specialties and is related to shortage of physicians, expansion of practice parameters, and increase in the number of practitioners being trained.[6] For example, dermatology practices that utilize midlevel providers increased 43% from 2002 to 2007.[6] Academic practices, in particular, are most likely to employ advanced practice providers compared with other practice venues.[6] Academic and tertiary referral centers may employ more advanced practice providers due to increased resources required for training and supervision.[6] The collaborative practice model is ideal for management of complex patients treated at tertiary academic centers.[2]

There are trends for greater level of autonomy and additional postgraduate training. Residency programs are available for advanced care practitioners who desire additional training in subspecialized areas; however, no current programs are available in otolaryngology.[8,17] Although postgraduate training is not necessary for advanced practice providers to work in an otolaryngology clinic, a comfort level must be obtained before the physician extender transitions to partial or near complete independent practice.[2] We propose that a stepwise progression through these effective use models may function as a framework for informal "postgraduate training" of physician extenders in otolaryngology.

Most information related to the cost effectiveness of advanced practice providers relates to their use in primary care. A report from the American Academy of NPs found that NPs have the potential to "decrease cost per patient visit by as much as one-third" especially when practicing in an autonomous capacity.[18] A review of 206 physician providers revealed lower overall labor costs per visit when advanced practice providers were used to greater extent.[18] Research supports that quality of care and outcomes are similar between physician extenders and physicians while providing savings of 25% in specialty areas.[19] However, a recent economic analysis revealed that as NPs gain greater autonomy and prescriptive authority, their salaries will increase and cause a reflexive decrease in physician salaries.[20] This analysis likely relates to the primary care scenario where there are competing interests between NPs and physicians.

CONCLUSIONS

There are an increasing number of advanced practice providers in healthcare and in subspecialty fields such as otolaryngology. As the presence of midlevel providers increases, physicians should be aware of the practice management models available for incorporation of these practitioners in an outpatient setting. We present a framework of five utilization models to discuss the incorporation of midlevel providers into an outpatient otolaryngology clinic. These models may be of benefit to physician practices by increasing revenue and efficiency while also improving patient care and education. Improvements in patient satisfaction are also important as future changes to healthcare delivery may hinge reimbursement on level of patient satisfaction. In summary, the addition of an advanced practice provider to an otolaryngology practice may be beneficial for all involved while helping to offset an increasing healthcare provider shortage.

BIBLIOGRAPHY

1. Hooker RS. The extension of rheumatology services with physician assistants and nurse practitioners. *Best Pract Res Clin Rheumatol* 2008;22: 523–533.
2. Reger C, Kennedy D. Changing practice models in otolaryngology—head and neck surgery: the role of collaborative practice. *Otolaryngol Head Neck Surg* 2009;141:670–673.
3. American Academy of Physician Assistants. 2008 Annual Census Report. Available at: http://www.aapa.org/images/stories/Specialty_Practice/Otorhinolaryngology08C.pdf. Accessed April 15, 2010.
4. America Academy of Nurse Practitioners. 2008 Annual Report. Available at: http://www.aanp.org/NR/rdonlyres/97CD0283–59DF-4964–819B-61E58864B4F8/0/08AnnualReport.pdf. Accessed April 15, 2010.
5. Association of American Medical Colleges. 2006 Physician Specialty Data. Available at: https://services.aamc.org/publications/showfile.cfm?file=version67.pdf&prd_id=160&prv_id=190&pdf_id=67. Accessed April 22, 2010.
6. Resneck JS Jr, Kimball AB. Who else is providing care in dermatology practices? Trends in the use of nonphysician clinicians. *J Am Acad Dermatol* 2008;58:211–216.
7. Laurant M, Harmsen M, Wollersheim H, et al. The impact of nonphysician clinicians: do they improve the quality and cost-effectiveness of health care services? *Med Care Res Rev* 2009;66(6 Suppl):36S–89S.
8. Ward WT, Eberson CP, Otis SA, et al. Pediatric orthopaedic practice management: the role of midlevel providers. *J Pediatr Orthop* 2008;28:795–798.
9. Ho P, Pesicka D, Schafer A, et al. Physician assistants: trialing a new surgical health professional in Australia. *ANZ J Surg* 2010;80:430–437.
10. American Academy of Physician Assistants. Incident-to-billing. Available at: http://www.aapa.org/advocacy-and-practice-resources/reimbursement/medicare/889-incident-to-billing. Accessed August 28, 2010.
11. Center for Medicare and Medicaid services. Medicare carrier manual: part 3—claims process. Available at: http://www.cms.hhs.gov/transmittals/downloads/R1764B3.pdf. Accessed August 28, 2010.
12. American Academy of Physician Assistants. Physician Assistants In Otolaryngology. August 2006. Available at: http://www.aapa.org/images/stories/IssueBriefs/Specialty%20Practice/PAs%20in%20Otolaryngology%20-%202010.pdf. Accessed August 28, 2010.

13. Dierick-van Daele AT, Steuten LM, Metsemakers JF, et al. Economic evaluation of nurse practitioners versus GPs in treating common conditions. *Br J Gen Pract* 2010;60:e28–e35.
14. Dorn SD. Mid-level providers in gastroenterology. *Am J Gastroenterol* 2010;105:246–251.
15. Rashid C. Benefits and limitations of nurses taking on aspects of the clinical role of doctors in primary care: integrative literature review. *J Adv Nurs* 2010;66:1658–1670.
16. Ohman-Strickland PA, Orzano AJ, Hudson SV, et al. Quality of diabetes care in family medicine practices: influence of nurse-practitioners and physician's assistants. *Ann Fam Med* 2008;6:14–22.
17. Will KK, Budavari AI, Wilkens JA, et al. A hospitalist postgraduate training program for physician assistants. *J Hosp Med* 2010;5:94–98.
18. AANP. 2007. *Nurse Practitioner Cost Effectiveness*. Available from http://www.aanp.org/NR/rdonlyres/197C9C42–4BC1–42A5–911E-85FA759B0308/0/NP_Cost_Eff112907.pdf. Accessed April 15, 2010.
19. Bauer JC. Nurse practitioners as an underutilized resource for health reform: evidence-based demonstrations of cost-effectiveness. *J Am Acad Nurse Pract* 2010;22:228–231.
20. Perry JJ. The rise and impact of nurse practitioners and physician assistants on their own and cross-occupation incomes. *Contemp Econ Policy* 2009;27:491–511.

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Handoffs, safety culture, and practices: evidence from the hospital survey on patient safety culture

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Abstract

Background: The context of the study is the Agency for Healthcare Research and Quality's Hospital Survey on Patient Safety Culture (HSOPSC). The purpose of the study is to analyze how different elements of patient safety culture are associated with clinical handoffs and perceptions of patient safety.

Methods: The study was performed with hierarchical multiple linear regression on data from the 2010 Survey. We examine the statistical relationships between perceptions of handoffs and transitions practices, patient safety culture, and patient safety. We statistically controlled for the systematic effects of hospital size, type, ownership, and staffing levels on perceptions of patient safety.

Results: The main findings were that the effective handoff of information, responsibility, and accountability were necessary to positive perceptions of patient safety. Feedback and communication about errors were positively related to the transfer of patient information; teamwork within units and the frequency of events reported were positively related to the transfer of personal responsibility during shift changes; and teamwork across units was positively related to the unit transfers of accountability for patients.

Conclusions: In summary, staff views on the behavioral dimensions of handoffs influenced their perceptions of the hospital's level of patient safety. Given the known psychological links between perception, attitude, and behavior, a potential implication is that better patient safety can be achieved by a tight focus on improving handoffs through training and monitoring.

Keywords: Handoffs, Staff attitudes, Patient safety culture, Communication, Personal responsibility, Accountability

Background

Clinical handoffs, also known as sign-outs, shift reports, or handovers, occur in many places along the healthcare value chain. It involves the 'transfer of professional responsibility and accountability for some or all aspects of care for a patient, or groups of patients, to another person or professional group on a temporary or permanent basis' [1]. For example, nursing handovers occur very frequently, not only between shifts and among part-time nurses, but also because nurses serve as the communication partner and informal coordinator for all healthcare professionals to ensure the continuity of care in a 24-hour seven-days-a-week environment [2]. The transfer of professional responsibility became salient for residents due to increased work-hour restrictions in U.S. residency programs, which shortened the continuity of care and increased the number of shift changes [3]. Concern for the transfer of unit accountability heightened with the fragmentation in the healthcare to the proliferation of sub-specialties; creating more transitions and handoffs with the increase in number of providers for a single patient [4]. Consequently, handoffs are a target for quality improvements because they represent high-risk events. The Joint Commission's 2006 evaluation of accredited healthcare organizations attributed at least 35 % of sentinel events to handoff errors [5]. Recent estimates implicate handoff errors in nearly 80 % of serious events between 2004 and 2014 [6].

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Patient safety culture, which consists of shared norms, values, behavioral patterns, rituals, and traditions [7] that guide the discretionary behaviors of healthcare professionals matter in handoffs. According to the theory of planned behavior [8], staff observations of their institution's practices and coworkers' behavioral patterns in handoffs will influence their perceptions of overall level of patient safety, and their behavioral responses to such issues. Therefore, employees who perceive that their do institutions not emphasize patient safety may not pay attention to such concerns [9]. To make improvements in handoffs, healthcare policymakers must first understand how employees perceive their organizations' patient safety culture [10].

The extant literature on handoffs largely focuses on the relationship between inadequate communications and perceptions of avoidable harm [11–13]. Poor handoff communication creates an opportunity for adverse events because incomplete, inaccurate, and omitted data create ambiguities between the sending and receiving providers [14]. Yet, the literature has found little empirical evidence to suggest that effective information transfers are associated with positive perceptions of patient safety [15]. We surmise that this is because a handoff is multidimensional, involving the transfer of information, responsibility *and* accountability, implying that previous studies may have over-simplified handoff challenges [16].

This study contributes to the literature by empirically investigating what past research has largely ignored: the transfers of professional responsibility and unit accountability for patient safety between providers during handoffs [17]. In the transfer of responsibility, even with effective information exchange, whether the receiving provider feels the same sense of responsibility for the patient as the sending provider cannot be taken for granted. In the case of physicians, this sense of responsibility is defined by Horwitz and colleagues [18] as a sense among on-call physicians that they were not "just covering" for the admitting physician but rather are integral to the patient's care. A systematic review on the transfer of information during nurses' transitions of care found that senders exhibited few supportive behaviors during the shift change, resulting in a low degree of engagement by receivers as they demonstrated indifference and non-attentive behaviors [19]. Hence, we believe that during shift changes, the active role and the responsibility of healthcare providers in shaping an effective information exchange protocol go beyond the mere transmission of structured data [13, 16]. Without the effective transfer and acceptance of responsibility, there is no assurance that the handoff process has created an appropriate mental model of the patient's plan of care for the receiving provider.

Our search of the literature did not yield any research on how the transfer of unit accountability influences staff perceptions of patient safety. Between-unit transitions of care can create uncertainty over who is ultimately accountable for a patient's wellbeing. The cross-disciplinary and multi-specialty transition of care create coordination difficulties, as handoffs can be irregular and unpredictable [20, 21]. In addition, complications related to inter-professional differences in expectations, terminologies, and work practices make it challenging to build a shared mental model, necessary for effective transitions between providers [14]. Because conflicting expectations and perspectives between units increase barriers to effective handoffs, we expect that when healthcare professionals perceive a supportive environment for cooperation and joint accountability between units, they are more likely to have positive perceptions of patient safety.

We further expect handoffs of information, responsibility, and accountability to influence each other, so that improvement in one type will positively affect the other types, and degradation in one will erode the others. Specifically, handing off comprehensive and accurate patient information to a receiver is necessary for effectively handing off responsibility and accountability [22]. In a handoff, the failure of a sending unit to communicate the rationale for a decision, anticipate problems, and expectations creates uncertainties and ambiguities for the receiving unit [23]. Important information can be ignored or misinterpreted by the receiving unit when there is unclear handoff of responsibility and accountability resulting from ambiguous work procedures and a lack of supportive infrastructure [12].

We explore the factors in an organization's patient safety culture that might be associated with effective handoffs. Specifically, we posit that an organization's communication, teamwork, reporting, and management cultures will have differential influences on effective handoffs of information, responsibility, and accountability. The literature on information transfer has primarily dealt with the *mechanics* of communication (i.e., ways in which information is transmitted and received). We submit that this perspective is not complete without considering Marx's theory of *just culture* [24]. Research has shown that when providers feel supported and psychologically safe because their organizations are perceived to be fair, they are more likely to communicate completely by voicing safety concerns [25, 26]. For example, in studies on TeamSTEPPS, a teaming protocol often used in surgical teams, any member (surgeon, nurse, technician, and anesthesiologist) can speak up or call-out observations of potential error because they view each other as having equal responsibility and authority for patient safety [27]. Feedback loops between the sender and receiver are necessary for this process to work. They allow both parties to properly manage

expectations and adjust their behaviors. Hence, a strong communications culture, typified by the openness to and willingness of clinicians to speak up, ask questions, and provide feedback, would enhance effective handoff of information.

In the case of shift changes, a culture of professionalism can mitigate errors and procedural violations that arise primarily from aberrant mental processes such as forgetfulness, inattention, low motivation, carelessness, or negligence [28, 29]. Medical professionalism includes a commitment to collaborating with others while engaging in self-regulation to make the best clinical decisions [30]. Professionalism in nursing focuses on value-based cognitive and attitudinal attributes that are harnessed to deliver patient centered care [31]. Nurses often utilize handoffs as an avenue for socialization, education, and emotional support to facilitate integration and staff cohesion [19]. A teamwork culture facilitates handoff of responsibility between the sending and receiving providers by seeking assistance or voicing concerns and clarifying issues through bidirectional conversations. This process creates a *shared* mental model of the patient's clinical conditional and plan of care [32]. Professionalism also implies proactive surveillance, detection, and the voluntary reporting of adverse events [33]. Errors recurrences are reduced if medical incidences and pitfalls are proactively reported to the incoming provider during shift changes [34]. Therefore, a strong teamwork culture and a culture of reporting adverse events enhance effective handoff of personal responsibility in shift changes.

Patient transfers between units span three domains: provider, service, and location, which are accompanied by differences in social norms, terminologies, and work practices [14, 18]. Such transitions multiply the difficulties providers encounter when building a shared mental model of the patient's clinical problems and needs. Add to these are systemic workplace traps such as unclear authority structures, inconsistent management support, unclear work procedures, and the lack of supporting infrastructure, which make safe handoffs challenging [21]. Such conflicts could be addressed by improving inter-unit teamwork and coordination [25]. Moreover, the provision of expectations and policies from top management that address the assignment of accountability in the delivery of care could reduce delays and improve the coordination of care across unit boundaries. We posit that inter-unit teamwork and a top management that expects and is supportive of patient safety would facilitate effective handoff of unit accountability during patient transitions.

Methods

Data

In 2006, the United States Department of Health and Human Services' (DHHS) Agency for Healthcare Research and Quality (AHRQ) funded the development of the Hospital Survey on Patient Safety Culture (HSOPSC). This survey was administered on a voluntary basis to all hospitals in the United States. The HSOPSC assesses hospital staff opinions on 42 items that measure their institution's patient safety practices based on 5-point response scales of agreement ("strongly disagree" to "strongly agree") or frequency ("never" to "always"). The de-identified data for this study comes from the 2010 survey that was made available for public use. It can be requested from the AHRQ. It represents 885 U.S. hospitals that voluntarily participated in the survey [7]. The views of healthcare professionals were aggregated for each institution, since past studies have shown that aggregating these items from the individual- and unit-level responses to the hospital level led to more robust psychometric properties [35], which are reported in Additional file 1.

In Table 1, we report the distribution of respondents by job roles. About two thirds of respondents are from the nursing and allied health professions while another third are administrative staff. A small percentage of respondents were self-identified as physicians, although an unknown percentage of the administrative staff could also be physicians. The responses in this survey are therefore representative of the views of nurses, allied health professionals, management, and physicians.

Measures

Covariates

Four hospital characteristics pertaining to *bedsize, hospital type*, *ownership*, and *staffing* were included as baseline covariates since we expect these factors to systematically affect perceptions of patient safety. For example, large government-owned teaching hospitals may experience more incidents because they serve a more diverse population of patients that present with complex co-morbidities than smaller private specialty hospitals. The frequency distribution for each covariate is reported in Additional file 2.

Handoff transfers

Four items related to handoffs and transitions of care in the survey were used for our analyses. *Handoff of patient information* comprises two items, 'important patient care

Table 1 Percentage of respondents by job role

Job role	Percentage of respondents
Nurses (RN, PA/NP, LVN/LPN)	37.10 %
Physicians (Attending, Resident)	3.66 %
Allied Healthcare Professionals (Pharmacist, PT, RT, OT, Dietitian, Technicians, Patient Care Assistant)	24.12 %
Staff (Management, Administrative Assistant & other clerical positions)	35.10 %

information is often lost during shift changes' (reverse coded) and 'problems often occur in the exchange of information across hospital units' (reverse coded). *Handoff of personal responsibility in shift changes* is measured by the item, 'shift changes are problematic for patients in this hospital' (reverse coded). *Handoff of unit accountability* is measured by the item, 'things "fall between the cracks" when transferring patients from one unit to another' (reverse coded).

Patient safety culture

Communication culture is measured by two composites, *communication openness* and *feedback and communication about error*. Teamwork culture is measured by two composite scales, *teamwork within units* and *teamwork across units*. Reporting culture is measured by the composite, *frequency of events reported*. Supportive management action is measured by three composites, *management support for patient safety, supervisor/manager expectations and actions promoting patient safety*, and *non-punitive response to error*. The items in the HSOPSC survey that represent each of these composites are reported in Additional file 3.

Patient safety perceptions

Patient safety perceptions comprises four items that measures respondents' agreement that 'patient safety is never sacrificed to get more work done', 'our procedures and systems are good at preventing errors from happening', 'it is just by chance that more serious mistakes don't happen around here' (reverse coded), and 'we have patient safety problems in this unit' (reverse coded).

Statistical analysis

We applied hierarchical multiple linear regression analysis using SPSS v21 to analyze the data. This technique allows us to enter a fixed order of variables to control for the influence of the covariates so that we can isolate the effects of the predictors of patient safety perception. We first entered the four hospital covariates into the regression model as baseline predictors on patient safety perception. We then entered each handoff transfer variable into the regression model. Similarly, to assess the effects of patient safety culture on each handoff transfer, we first entered the four hospital covariates as baseline predictors on each handoff transfer followed by the respective patient safety culture composite.

Results

First, we check for multicollinearity among the covariates and predictors. Multicollinearity, shown by the variance inflation factor (VIF), results in an inflated variance or R^2 in the outcome variable in the regression model [36]. In our sample, the VIF was below 3.0, meaning that any significant relationships found are not inflated by correlations between the predictor variables [36]. Table 2 reports strong support for the hypothesis that effective handoffs of information, responsibility, and accountability are statistically significantly ($p < .001$) related to patient safety perceptions.

Table 3 reports the inter-relationships among handoffs of information, responsibility, and accountability. Model 1 in Table 3 reports that enhancing handoffs of responsibility and unit accountability *enhance* the handoff of patient information. Model 2 in Table 3 explores the relationship between communication culture and the handoff of information. The results in Model 2 shows that while *feedback and communication on error* had a significantly positive effect on perceptions of effective handoff of patient information, *communication openness* had no influence on perceptions of effective handoff of patient information. Thus, a strong communication culture only partially enhances the effective handoff of patient information.

Model 3 in Table 3 shows that enhancing handoffs of patient information *and* unit accountability enhance the handoff of responsibility during shift changes. Model 4 in Table 3 shows that both *teamwork within units* and *frequency of events reported* had statistically significant positive influences on perceptions of effective handoff of responsibility in shift changes. Thus, a strong teamwork culture *and* a reporting culture enhance the handoff of responsibility during shift changes.

Model 5 in Table 3 shows that enhancing handoffs of patient information *and* personal responsibility enhance the handoff of unit accountability. Model 6 in Table 3 shows that while *teamwork between units* had a positive and significant association on perceptions of the effective

Table 2 Hierarchical regression analyses on the impact of handoffs on patient safety perceptions

	Patient safety perceptions		
	Model 1	Model 2	Model 3
Control variables:			
Bedsize	-.01	.02	.03
Hospital type	-.02	-.04*	-.02
Ownership	-.03	-.05**	-.06**
Staffing	.60***	.62***	.64***
Predictor Variables:			
Handoff of patient information	.35***		
Handoff of personal responsibility		.32***	
Handoff of unit accountability			.32***
Change in R^2	.069***	.049***	.054***
Total Adj R^2	.76***	.74***	.745***

Values in the table are standardized beta coefficients for $n = 885$ hospitals
* $p < .05$, ** $p < .01$, *** $p < .001$

Table 3 Hierarchical regression analyses on handoffs

Dependent variables	Handoff of patient information		Handoff of responsibility		Handoff of unit accountability	
	Model 1	Model 2	Model 3	Model 4	Model 5	Model 6
Covariates						
Bedsize	-.13***	-.20***	-.12***	-.01	-.14***	-.02
Hospital Type	-.01	.02	.05**	-.02	-.03	-.02
Ownership	-.06***	.01	.03*	-.01	.05***	-.01
Staffing	.07***	.38***	.15***	.48***	-.01	.46***
Handoff transfer of						
Patient information			.51***		.66***	
Responsibility	.38***				.21***	
Unit accountability	.60***		.25***			
Patient safety culture						
Communication openness		.06				
Feedback & communication on errors		.34***				
Teamwork within units				.15***		
Frequency of events reported				.23***		
Teamwork across units						.74***
Management support for patient safety						.01
Supervisor/Manager expectations & actions promoting patient safety						-.10***
Nonpunitive response to error						.01
Change in R^2	.420***	.107***	.295***	.078***	.368***	.288***
Total Adj R^2	.862***	.539***	.813***	.594***	.848***	.768***

Values in the table are standardized beta coefficients for $n = 885$ hospitals
* $p < .05$, ** $p < .01$, *** $p < .001$

handoff of unit accountability, s*upportive management culture* and *non-punitive response to error* had no effect on the handoff of accountability. We also found that *supervisor/manager expectations and actions promoting patient safety* had a statistically *negative* influence on perceptions of unit accountability. The data indicates that a strong teamwork culture enhances the handoff of unit accountability but this is not in case for management support.

Discussion

Most handoffs studies have focused on communication issues. They generally recommend structured information handoffs, such as IPASS, as a solution to communication problems. Ours is the first to delineate and empirically test the relationships of three different handoffs in information, responsibility, and accountability on perceptions of patient safety. The results generally show that effective handoffs of patient information, personal responsibility during shift changes, and unit accountability for patient transfers are significantly related to patient safety perceptions. The results also show that each handoff influences the others such that the improvement (or degradation) of one also improves (or erodes) the others. The data shows that communication exchanges, individual behaviors, and organizational processes have to be addressed before shared beliefs and values on perceptions of patient safety can be formed [37].

The results indicate that each type of handoff is affected by different patient safety culture composites. Providing feedback and communication about errors enhanced perceptions of effective handoff of patient information. However, the results indicate that a strong communication culture only *partially* ensures the effective handoff of patient information. Since communication openness is highly correlated with feedback and communication about errors ($r = 0.63$, $p < 0.01$), this finding may be the simple result of measurement since the effect of one cultural composite may mask the effects of the other. Future studies should start with a comprehensive definition of communication culture to include having a minimum data set, the use of mnemonics for communicating relevant information, and a process that include electronic means to support communication.

The data shows that strong teamwork culture and reporting culture enhance *perceptions* of the effective handoff of responsibility during shift changes. Demonstrating such professionalism may require providers to

create protected time and space for the handoff during shift change, prepare rationales for plans of care and tasks to perform, and verify that the receiving provider has accurately understood the information received.

The data indicates that providers making the effort to ensure strong teamwork between units by demonstrating cooperation, collaboration, and coordination enhance the handoff of unit accountability. However, it was surprising that management support did not significantly enhance the handoff of unit accountability. Perhaps constant process improvement efforts can create fatigue, so that 'management support' is met with cynicism if resources to implement these efforts are insufficient. As well, frontline staff may not observe management support if the former do not routinely interact with the latter. Similarly, *non-punitive responses to error* are not observable if no actions were taken when errors were made. In short, management may need to exhibit the observable appropriate behaviors before unit accountability in handoffs can be enhanced.

The results indicate that we have to focus on specific cultural composites when designing and training healthcare professionals to improve specific types of handoffs. For example, in large hospitals or in complex medical systems, the high workload and the pressures of coordinating clinical care between different units with different experiences and expectations increase challenges to proper handoffs. Here, management may need to invoke the sense of professionalism for all healthcare providers by offering evidence on the causes and consequences of poor handoffs while providing incentives and recognition for performing good handoffs.

The strengths in using the HSOPSC survey data is the large number of hospital participants, which provide robust and stable coefficients in the regression model [38]. The limitations include the following. First, the data is cross-sectional from one time-period. A better estimation technique would be to utilize a panel of data going over several years, but that is not possible because the respondents are anonymous; a different dataset needs to be constructed. Second, physician representation in the data is low and therefore, one cannot generalize the responses or the implications of the results to physicians alone. Steps to incentivize physician participation will need to be taken for the data to represent all stakeholders in the hospital community. Third, no outcomes are reported from this dataset, such as the number of medical errors due to handoffs, the number of close-calls during transitions, or hospital length of stay. Therefore, future studies involving interventions related to handoffs of information, responsibility, and accountability are needed to correlate the implications for handoff practice to actual outcomes as there are none to date. Examples of such interventions may include having a minimum data set when handing over patient information, assessing the efficacy of inter-professional teamwork training on enhancing professionalism, and team-based governance reporting structures to improving unit accountability. Fourth, from a theoretical standpoint, we were limited by the way the constructs were operationalized in the survey and the reliance on self-report data [38]. An opportunity clearly exists to develop comprehensive measures of these constructs in future studies by considering more fine-grained measures of information exchange and communication processes, personal responsibility as it relates to learning and team behaviors as well as unit accountability related to systems improvement, training, and staff empowerment. Having noted all these limitations, we still believe that the study points us toward a richer and theoretically robust way of conceptualizing handoffs.

Conclusions

The contribution of this study lies in the deconstruction of handoffs into information, responsibility, and accountability and in identifying the accompanying patient safety culture composites that differentially influence each type of handoff. We provided an in-depth look at the cultural drivers of effective handoffs than the literature has thus far examined. The different and sometimes strong cultures between professional specialties can cause the fragmentation of shared values, making it difficult for such professionals to view themselves as part of an organization. If the organization does not have a formal process to help healthcare professionals perceive each other as a resource, the handoff process is carried out in 'silos'.

In order to help healthcare professionals navigate the tradeoff between efficiency and thoroughness, hospitals can build a strong culture of teamwork across units, while using other organizational development activities to bind its members to a common vision and shared mental model. The theory of planned behavior suggests that attitude is a key factor, which can be influenced by training and education [39]. Perhaps training healthcare professionals with handoffs procedures and protocols can be used to influence a healthcare organization's patient safety culture. Other techniques include mentoring and leading by example with a sharp focus on transitions of care as a central theme in a hospital's safety program [40–42]. The interactions between the different types of transitions we showed in this study suggest that spill-overs into other aspects of patient safety are likely to occur. More importantly, defining patient safety culture in a specific form (transitions of care) attenuates ambiguity so that stakeholders can more clearly identify with the goals and process of patient safety improvement programs.

Additional files

Additional file 1: Psychometric Properties of the Variables. Descriptive statistics and reliability analyses of the items in each patient safety culture composite. (DOCX 15 kb)

Additional file 2: Frequency Distribution of Covariates. The distribution frequency for each covariate (control) variable used in the hierarchical regression model. This is report to describe the sample characteristics. (DOCX 12 kb)

Additional file 3: Hospital Survey on Patient Safety Culture (HSOPC) survey items for each Patient Safety Culture Composite. A list of the items and descriptions from the HSOPC used in this study. (DOCX 13 kb)

Abbreviations
AHRQ, Agency for Healthcare Research and Quality; DHHS, Department of Health and Human Services (United States); HSOPSC, Hospital Survey on Patient Safety Culture

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Availability of data and material
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Authors' contributions
SHL designed the study, conducted the literature review, statistical analysis, and drafted the manuscript. PP designed the study, participated in the statistical analysis, and helped draft the manuscript. TD interpreted the data, and participated in the revision of the manuscript. SW acquired the data, interpreted the findings, and participated in the revision of the manuscript. PJP contributed to the conceptual development, interpreted the findings, and participated in the revision of the manuscript. All authors read and approved the final manuscript.

Competing interests
The authors declare that they have no competing interests.

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Not applicable. Research involved non-identifiable organization and respondent public domain data. See http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.101 (accessed: June 29, 3016)

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References
1. BMA. Safe handover: safe patients. Guidance on clinical handover for physicians and managers. Junior Doctors Committee, London: British Medical Association; 2004.
2. Institute of Medicine. The Future of Nursing, Leading Change, Advancing Health. http://www.nationalacademies.org/hmd/Reports/2010/The-Future-of-Nursing-Leading-Change-Advancing-Health.aspx; accessed 10 May 2016.
3. Borowitz SM, Waggoner-Fountain LA, Bass EJ, et al. Adequacy of information transferred at resident sign-out (in-hospital handover of care): a prospective survey. Qual Saf Health Care. 2008;17:6–10.
4. Manser T. Fragmentation of patient safety research: a critical reflection of current human factors approaches to patient handover. J Public Health Res. 2013;2(3):e33.
5. Joint Commission. Improving handoff communications: Meeting national patient safety goal 2E. Jt Comm Perspect Patient Saf. 2006;6(8):9–15.
6. Joint Commission: Sentinel Event Data - Root Causes by Event Type. Retrieved from: http://www.jointcommission.org/Sentinel_Event_Statistics/ (2014). Accessed: March 15, 2015.
7. Agency for Healthcare Research and Quality. Hospital patient safety culture surveys. Available at: http://www.ahrq.gov/qual/patientsafetyculture/hospsurvindex.htm. (2010). Accessed: March 15, 2015.
8. Ajzen I. The theory of planned behavior. Org Beh and Human Dec Proc. 1991;50(2):179–211.
9. Boan DM, Nadzam D, Clapp JR. The impact of variance in perception of the organization on capacity to improve in hospital work groups. Group Dyn. 2012;16(3):206–2179.
10. Nieva VF, Sorra J. Safety culture assessment: a tool for improving patient safety in healthcare organizations. Quality and Safety in Healthcare. 2003;12 Suppl 2:17–23.
11. Arora V, Johnson J, Lovinger D, et al. Communication failures in patient sign-out and suggestions for improvement: a critical incident analysis. Qual Saf Health Care. 2005;14:401–7.
12. Horwitz LI, Moin T, Krumholz H, et al. Consequences of inadequate sign-out for patient care. Arch Intern Med. 2008;168:1755–60.
13. Manser T, Foster S. Effective handover communication: an overview of research and improvement efforts. Best Pract Res Clin Anaesthesiol. 2011;25:181–91.
14. Apker J, Mallak LA, Gibson SC. Communicating in the "gray zone": perceptions about emergency physician–hospitalist handoffs and patient safety. Acad Emerg Med. 2007;14:884–94.
15. Riesenberg LA. Shift-to-shift handoff research: where do we go from here? J Grad Med Educ. 2012;4:4–8.
16. Manser T, Foster S, Gisin S, et al. Assessing the quality of patient handoffs at care transitions. Qual Saf Health Care. 2010;19:e44.
17. Lofgren RP, Gottlieb D, Williams RA, et al. Post-call transfer of resident responsibility: its effect on patient care. J Gen Intern Med. 1990;5:501–5.
18. Horwitz LI, Meredith T, Schuur JD, et al. Dropping the baton: a qualitative analysis of failures during the transition from emergency department to inpatient care. Ann Emerg Med. 2009;53:701–10.
19. Holly C, Poletick EB. A systematic review on the transfer of information during nurse transitions in care. J Clin Nurs. 2014;23(17–18):2387–95.
20. Arora VM, Manjarrez E, Dressler DD, et al. Hospitalist handoffs: a systematic review and task force recommendations. J Hosp Med. 2009;4:433–40.
21. Hilligoss B, Cohen MD. Hospital handoffs as multi-functional situated routines: implications for researchers and administrators. Adv Health Care Manag. 2011;11:91–132.
22. Patterson ES. Structuring flexibility: the potential good, bad and ugly in standardisation of handovers. Qual Saf Health Care. 2008;17:4–5.
23. Raduma-Tomàs MA, Flin R, Yule S, et al. Doctors' handovers in hospitals: a literature review. BMJ Qual Saf. 2011;20:128–33.
24. Marx D. Patient Safety and the "Just Culture": A Primer for Health Care Executives. New York: Columbia University; 2001.
25. Dekker SWA. Just culture: who gets to draw the line? Cogn Tech Work. 2009;11:177–85.
26. Edmondson AC. Psychological safety and learning behavior in work teams. Adm Sci Q. 1999;44:350–83.
27. Weaver SJ, Rosen MA, DiazGranados D, et al. Does teamwork improve performance in the operating room? A multilevel evaluation. Jt Comm J Qual Patient Saf. 2010;36(3):133–42.
28. Reason J. Human error: models and management. BMJ. 2000;320:768–70.
29. Abbott A. The system of professions: An essay on the division of expert labor. Chicago: The University of Chicago; 1988.
30. Foundation ABIM. Medical professionalism in the new millennium: a physician charter. Ann Intern Med. 2002;136:243–6.
31. Chiovitti RF. Professionhood and professionalism as an educational aid for facilitating nursing students' development and renewal of self and profession. J Nurs Educ Pract. 2015;5(11):51–64.
32. Wohlauer MV, Arora VM, Horwitz LI, et al. The patient handoff: a comprehensive curricular blueprint for resident education to improve continuity of care. Acad Med. 2012;87:411–8.
33. Foster AJ, Dervin G, Martin Jr C, et al. Improving patient safety through the systematic evaluation of patient outcomes. Can J Surg. 2012;55:418–25.

34. Mayer CM, Cronin D. Organizational accountability in a just culture. Urol Nurs. 2008;28:427–30.
35. Smits M, Christiaans-Dingelhoff I, Wagner C, et al. The psychometric properties of the 'Hospital Survey on Patient Safety Culture' in Dutch hospitals. BMC Health Svc Res. 2008;8:2306.
36. Hair JF, Anderson RE, Tatham RL, et al. Multivariate data analysis. 5th ed. Delhi: Pearson Education; 1998.
37. Reason J. Managing the risks of organizational accidents. Aldershot: Ashgate; 1997.
38. Sorra JA, Dyer N. Multilevel psychometric properties of the AHRQ hospital survey on patient safety culture. BMC Health Svc Res. 2010;10:199.
39. Lazarus GS, Foulke G, Bell RA, et al. The effects of a managed care educational program on faculty and trainee knowledge, attitudes, and behavioral intentions. Acad Med. 1998;73(10):1107–328.
40. Siemsen IMD, Madsen MD, Pedersen LF, et al. Factors that impact on the safety of patient handovers: an interview study. Scand J Public Health. 2012;40:439–48.
41. Beach CB, Cheung DS, Apker J, et al. Improving interunit transitions of care between emergency physicians and hospital medicine physicians: a conceptual approach. Acad Emerg Med. 2012;19:1188–95.
42. Emanuel L, Berwick D, Conway J, et al. What exactly is patient safety? In: Henriksen K, Battles JB, Keyes MA, et al., editors. Advances in patient safety: new directions and alternative approaches. Rockville: Agency for Healthcare Research and Quality; 2008.

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The influence of organizational factors on patient safety: Examining successful handoffs in health care

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Background: Although patient handoffs have been extensively studied, they continue to be problematic. Studies have shown poor handoffs are associated with increased costs, morbidity, and mortality. No prior research compared perceptions of management and clinical staff regarding handoffs.
Purpose: Our aims were (a) to determine whether perceptions of organizational factors that can influence patient safety are positively associated with perceptions of successful patient handoffs, (b) to identify organizational factors that have the greatest influence on perceptions of successful handoffs, and (c) to determine whether associations between perceptions of these factors and successful handoffs differ for management and clinical staff.
Methodology/Approach: A total of 515,637 respondents from 1,052 hospitals completed the Hospital Survey on Patient Safety Culture that assessed perceptions about organizational factors that influence patient safety. Using weighted least squares multiple regression, we tested seven organizational factors as predictors of successful handoffs. We fit three separate models using data collected from (a) all staff, (b) management only, and (c) clinical staff only.
Findings: We found that perceived teamwork across units was the most significant predictor of perceived successful handoffs. Perceptions of staffing and management support for safety were also significantly associated with perceived successful handoffs for both management and clinical staff. For management respondents, perceptions of organizational learning or continuous improvement had a significant positive association with perceived successful handoffs, whereas the association was negative for clinical staff. Perceived communication openness had a significant association only among clinical staff.
Practice Implications: Hospitals should prioritize teamwork across units and strive to improve communication across the organization in efforts to improve handoffs. In addition, hospitals should ensure sufficient staffing and management support for patient safety. Different perceptions between management and clinical staff with respect to the importance of organizational learning are noteworthy and merit additional study.

Key words: handoffs, hospitals, management, patient safety, quality improvement, safety culture

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Patient handoffs have received increased attention in recent years because of their important role in patient safety. Defined as the transfer of patient rights, duties, and obligations from one person or team to another, handoffs can occur both within units of a hospital or across units or organizational settings. Poor patient handoffs are associated with increased medical errors as well as treatment delays, increased malpractice risk, and repetitive testing (Greenberg et al., 2007; Kohn, Corrigan, & Donaldson, 1999). Furthermore, a study of three emergency departments found that 8.8% of doctors and 4.7% of patients were affected by an inadequate handoff, as measured by repetition of assessment and delays in disposition and care (Ye, Taylor, Knott, Dent, & MacBean, 2007).

Physician specialization and policy changes, including duty hour restrictions for residents and 24-hour physician coverage, have increased the number of patient handoffs over the past 10–15 years. This heightened number of handoffs, in turn, has contributed to greater fragmentation and discontinuity of care (Philibert & Leach, 2005). As a result, health outcomes have been adversely affected. A recent study of hospitalists found that a 10% increase in fragmentation of care was associated with an increased length of stay of 0.39 day for pneumonia and 0.30 day for heart failure (Epstein, Juarez, Epstein, Loya, & Singer, 2010).

We conducted this study to determine whether perceived organizational factors that may influence patient safety are positively associated with perceived successful patient handoffs to identify organizational factors with the greatest effect on perceived successful handoffs and to determine whether associations between perceptions about organizational factors and successful handoffs differ for management and clinical staff. The primary purpose of our study was to provide insight about how health care organizations can improve the percentage of successful handoffs, focusing on organizational factors that can influence patient safety.

New Contribution

This study adds four elements to existing literature on patient handoffs. First, it models seven oft-cited organizational factors that have been associated with handoffs to identify those most critical. Although other studies provided insights into factors associated with handoffs, they did not test the factors collectively nor identify those of greatest importance using inferential statistics. The closure of this gap is highly relevant given hospital resource constraints and the tradeoffs between patient safety and the costs involved in addressing patient safety concerns.

Second, this analysis examined the differences in perceptions of management and clinical staff. No quantitative study looked at differences in survey responses between management and clinical staff to determine whether associations between perceptions about organizational factors and patient handoffs differ between the two groups. Given that management controls resources and indirectly influences patient safety but clinical staff directly influences safety through patient interactions, it is important to consider differences in these perspectives to improve our understanding about how to improve overall patient safety.

Third, this research examines a large national sample of hospitals, and this approach is in contrast to prior studies that have used small quantitative samples or qualitative methods. Our use of a large national sample enabled us to use multiple linear regression and overcome the limitations of other studies that have examined handoffs primarily using descriptive methods. The expanded scope of our study presents an opportunity to confirm findings from previous qualitative and small quantitative studies and to generalize results to U.S. hospitals.

Fourth, this study has practical implications because it uses data available from a free survey that is in use at more than 1,000 hospitals. Hospitals using this survey do not need to survey additional staff to gather information about perceptions of safety but instead can immediately apply our findings to safety improvement efforts in their organizations.

Finally, although our study had several hypotheses, it was also exploratory because it aimed to identify the organizational factors most highly associated with perceived successful handoffs. Prior studies have not used inferential statistics to identify the variable with the greatest effect.

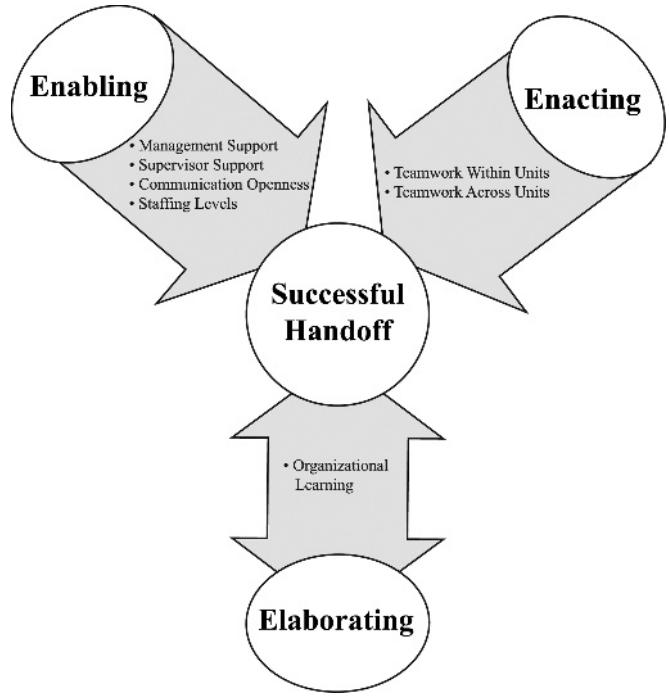
Theory/Conceptual Framework

Vogus, Sutcliffe, and Weick (2010) contend that implementing a safety culture has three phases—*enabling*, *enacting*, and *elaborating*—with each comprised of actions that influence patient safety and care outcomes. First, the *enabling phase* centers on leader actions that direct attention to patient safety and make it safe to speak up and act in ways that improve safety. In this stage, leaders create an environment for staff to safely communicate when faced with threats to patient safety. Next, the *enacting phase* involves frontline staff actions that highlight threats to safety and mobilize resources to reduce those threats. If enacting characteristics are strong, resources can be quickly mobilized and effectively used to resolve threats to safety. Finally, the *elaborating phase* consists of learning practices that enable reflection about safety outcomes to modify actions involved in the enabling and enacting phases. In the elaborating stage, frontline employees reflect on problems in order to evolve and expand safety practices. This stage also has potential to strengthen enabling and enacting actions when recommendations from the elaborating phase are communicated to management.

We adapted the model to frame our study, as shown in Figure 1, and then fit the survey data available in the Hospital Survey on Patient Safety Culture (HSOPS) data set within this conceptual model. The enabling stage contains the predictor variables of management support, supervisor

Figure 1

Conceptual model



support, communication openness, and staffing levels from the HSOPS survey. Next, the enacting stage includes teamwork within units and teamwork across units as variables from the HSOPS survey. Finally, the elaborating stage of the framework includes the organizational learning variable that is described in the independent variables section of this article.

Hypotheses

Reviews of physician and nurse literature suggest that various factors such as communication failures, hierarchy, lack of leadership focus on safety, staffing shortages, and lack of formal handoff education are barriers to successful handoffs (Riesenberg et al., 2009; Riesenberg, Leisch, & Cunningham, 2010). Given those findings and our adapted conceptual model, we framed Hypothesis 1 for our study as follows:

> *Hypothesis 1*: Higher levels of perceived organizational factors of safety are associated with perceptions of successful patient handoffs.

Although we found no study that compares management and clinical staff perspectives about the organizational factors of safety using inferential statistics, a study of 29 acute care hospitals in West Virginia that examined differences in perceptions found management had higher mean perceptions of positive patient safety than nurses in 11 of the 12 measures of safety culture studied (Hannah, Schade, Lomely, Ruddick, & Bellamy 2008). Therefore, we proposed the following as our second study hypothesis:

> *Hypothesis 2*: Associations between perceptions of organizational factors of safety and successful handoffs differ depending on whether the responses were from management or clinical staff.

Methods

Data and Sample

The data source for this study was the Agency for Healthcare Research and Quality's HSOPS comparative database. This database is a central repository for survey data from hospitals in all 50 states plus U.S. territories that have administered the HSOPS survey. The HSOPS survey has been shown to be a reliable survey instrument that can be studied at multiple levels of analysis. Psychometric analyses conducted by multiple studies confirmed that the HSOPS dimensions, each comprised of three to four survey questions, are reliable measures valid at the individual, unit, and hospital levels and can be used by researchers to assess patient safety culture (Sorra & Dyer, 2010). The survey instrument and the survey

questions that comprise each dimension can be found at www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/hospital/index.html.

Our study data set incorporated surveys completed by hospital staff from 2008 to 2011, with survey data aggregated to the hospital level. Although each individual hospital does not administer the HSOPS survey annually, hospital participants are able to submit data annually for a range of 1–4 years. We used data from prior years only when a hospital did not submit new data; in other cases, we used more recent annual data to replace older data. We chose the hospital as the unit of analysis because it allowed us to group staff that had similar experiences and give interpretations based on organizational factors influencing safety for the entire hospital. Furthermore, even though there is significant clustering of responses at the hospital level, Smits, Wagner, Spreeuwenberg, Goenewegen, and Van Der Wal (2009) confirmed that the HSOPS survey can measure group culture and not solely individual attitudes, thus enabling us to use these data to test our study hypotheses.

A total of 1,081 hospitals contributed to the data set used for this study. Of those, 29 hospitals were removed because of missing data, leaving a final study sample of 1,052 hospitals and 515,637 individual-level responses. The characteristics of the hospitals in this final sample were consistent with the overall distribution of hospitals registered with the American Hospital Association with respect to teaching status, ownership, geographic region, and bed size.

In addition, a total of 1,047 hospitals from this data set had responses for both managers (36,290 respondents) and clinical staff (237,409). We used this data set to compare perspectives between management and clinical staff across survey items. On the survey, employees provided one answer that best described their staff position in the hospital. We defined clinical staff as those that selected physician, physician assistant, nurse practitioner, registered nurse, licensed practical nurse, or medical assistant. The management group was comprised of staff that selected administration/management. For management and clinical staff comparisons, management and clinical staff responses were distinctly aggregated to the hospital level.

Measures

The HSOPS survey used a 5-point Likert scale with the response choices of *strongly disagree*, *disagree*, *neither agree nor disagree*, *agree*, or *strongly agree* for most questions. Some questions had the alternative 5-point response options of *never*, *rarely*, *sometimes*, *most of the time*, or *always*. If questions were positively worded, responses were considered positive if the person "agreed" or "strongly agreed"; if the questions were negatively worded, the responses "disagreed" or "strongly disagreed" were considered positive.

We calculated percent positive scores for the three to four related questions that comprised each variable based on averaged responses for participants from each individual hospital. These averaged scores became the values for the dependent and independent variables. Percent positive scores had a possible range of 0–100. We used the percent positive score instead of the 5-point Likert scale mean to improve interpretability of study results.

Independent Variables

The predictor variables of interest for our study included respondents' perceptions about the following organizational factors that could influence patient safety: supervisor support for safety, organizational learning, teamwork within units, communication openness, management support for patient safety, staffing levels, and teamwork across units. *Supervisor support* indicated the priority a supervisor placed on safety. *Organizational learning* reflected continuous improvement regarding patient safety, in which mistakes led to positive changes and improvements were evaluated for their effectiveness. *Teamwork within units* exhibited the support and respect that people have for one another within a unit. *Communication openness* was the comfort level of staff to question those with more authority when something did not seem right. *Management support* was the prioritization and interest hospital management placed on safety. *Staffing* conveyed whether there was enough staff to appropriately handle patient care. *Teamwork across units* examined the coordination of patient care from one unit to another. We also included control variables for each hospital. These control variables included *bed size*, *region*, *teaching hospital status*, and *government ownership status* (Table 1).

Dependent Variable

The dependent variable of interest in our study was *successful handoffs*. The survey specifically asked respondents to think about handoffs within their hospital and not handoffs to external facilities. This variable was defined based on perceptions of how well patient information was relayed on patient transfers to different units within the hospital and the effect of shift changes on patient information transfer. The complete questions, all negatively worded, used to generate the dependent variable included the following: (a) things fall between the cracks when transferring patients from one unit to another, (b) important patient care information is often lost during shift changes, (c) problems often occur in the exchange of information across hospital units, and (d) shift changes are problematic for patients in this hospital.

Procedures

We used weighted least squares multiple linear regression analysis to examine the association between perceptions about the organizational factors of interest in our study and

Table 1

Respondent demographics and summary statistics for organizational factors contributing to safety culture

	n	Mean	*SD*
Respondent demographics[a]:			
Nurse (RN, LPN, LVN)	173,296	34	
Other	100,914	20	
Technician (EKG, Lab, Radiology)	52,730	10	
Administration/management	37,296	7	
Unit assistant/clerk/secretary	31,631	6	
Physician, physician assistant, nurse practitioner	28,363	6	
Patient care assistant/hospital aide/care partner	27,026	5	
Therapist (respiratory, physical, occupational, speech)	24,021	5	
Pharmacist	9,600	2	
Dietician	5,156	1	
Missing demographic information	25,604	5	
Organizational factors contributing to safety culture[b]:			
Successful handoffs		59	7.6
Supervisor support		75	6.4
Organizational learning		72	7.1
Teamwork within units		80	5.7
Communication openness		62	6.5
Staffing levels		57	9.1
Management support		72	9.3
Teamwork across units		59	10.0

N = 1,052 hospitals; 515,637 staff.

[a]Mean reflects percentage of total respondents that belong to a specific staff group.

[b]Mean reflects the average percentage of respondents at each hospital that agreed or strongly agreed to survey questions; responses were based on 5-point Likert scale.

perceptions about successful handoffs. We calculated weights by dividing the number of hospital respondents by the number surveyed to reflect that the quality of hospital means should increase with the hospital response rate. All statistical analyses were performed using Stata: Release 11 software (StataCorp LP, College Station, TX).

Findings

We found striking results about perceptions of the effect of teamwork across units and its contribution to perceptions of successful handoffs, as well as about the importance of management support and staffing, and of differences between management and clinical staff. We also found support for our adapted conceptual model. In addition, although we found only partial support for Hypothesis 1, Hypothesis 2 was fully supported, suggesting that associations between perceptions of organizational factors and perceptions of successful handoffs differ based on respondent type. Below we describe these findings in greater detail.

Our first hypothesis, that higher levels of perceived organizational factors of safety are associated with perceptions of successful patient handoffs, was partially supported by the linear regression analysis. Among the organizational factors we studied, teamwork across units had the largest effect on perceived successful handoffs in terms of both beta coefficient and R-square ($\beta = .83$, 95% CI [0.77, 0.89], $p < .001$). Perceptions of teamwork across units explained 44% of the variability in perceived successful handoffs left unexplained by all other organizational factors, controlling for bed size, region, teaching hospital status, and government ownership status (Table 2). In contrast to perceived teamwork across units, perceived teamwork within units was negatively associated with perceived successful handoffs ($\beta = -.19$, 95% CI [−0.27, −0.10], $p < .001$). Organizational learning ($\beta = .15$, 95% CI [0.07, 0.23], $p < .001$) and staffing ($\beta = .07$, 95% CI [0.18, 0.28], $p < .001$) each had significant positive effects on perceived successful handoffs when we analyzed aggregate data of all hospital staff. The model adjusted R-square with all independent variables was .83, whereas the adjusted R-square for the model with only control variables was .31. Thus, the perceived organizational factors of safety explained a considerable amount of variation in perceived successful handoffs, beyond that explained by the control variables.

Our second hypothesis, that associations between perceived organizational factors of safety and perceived successful handoffs differ depending on respondent group, was fully supported by our analyses. As shown in Table 3, for each organizational factor studied, managers averaged higher positive perceptions of these factors than did clinical staff. Mean differences ranged from 8.7% to 18.2%. All differences were highly statistically significant ($p < .001$), based on a paired *t* test.

When comparing management and clinical staff perceptions of successful handoffs based on the possible influence of different organizational factors, we found the association with organizational learning differed between the two groups, whereas the associations with teamwork, staffing, and management support were similar (Table 4). Although analysis of all staff perceptions indicated that organizational learning was significantly associated with perceived successful handoffs, this subgroup analysis revealed that the association was not true of all staff. Holding the other organizational factors constant, organizational learning had a positive association with perceived successful patient handoffs for management respondents, whereas the association was negative for clinical staff respondents.

The association of perceived teamwork across units with successful handoffs was again the largest among all organizational factors studied and was comparable in the separate linear regressions for clinical ($\beta = .68$, 95% CI [0.63, 0.73], $p < .001$) and management staff ($\beta = .69$, 95% CI

Table 2

Weighted least squares multiple regression of successful handoffs on different organizational factors

Organizational Factor	Partial R^2	β	95% CI	
Supervisor support	<.01	.02	(−0.07, 0.11)	
Organizational learning	.01	.15	(0.07, 0.23)	***
Teamwork within units	.02	−.19	(−0.27, −0.10)	***
Communication openness	<.01	−.01	(−0.08, 0.06)	
Staffing	.07	.23	(0.18, 0.28)	***
Management support	<.01	−.04	(−0.11, 0.03)	
Teamwork across units	.44	.83	(0.77, 0.89)	***

Included all hospital staff responses; weight was a hospital's response rate; N = 1,052.

Controls included teaching hospital, government hospital, bed size, and region.

R^2 was .83 for full model; R^2 was .31 for control variables only.

*p < .05.

**p < .01.

***p < .001.

[0.63, 0.75], p < .001). Meanwhile, the association between perceived teamwork within units and perceived successful handoffs was similarly negative in the clinical (β = −.11, 95% CI [−0.18, −0.04], p < .01) and management staff (β = −.15, 95% CI [−0.27, −0.04], p < .01) models.

The staffing and management support for safety variables had a significant positive association with perceived successful handoffs in analyses of both management and clinical staff responses, thereby adding credence to their importance. Staffing had a positive association with perceived successful handoffs in the analysis of manager responses (β = .21, 95% CI [0.15, 0.28], p < .001) and of clinical staff responses (β = .18, 95% CI [0.13, 0.22], p < .001). Similarly, perceived management support for safety had a positive association with perceived successful handoffs in the analysis of manager responses (β = .10, 95% CI [0.01, 0.18], p < .05) as

Table 3

Organizational factors that may influence successful handoffs: Comparing management and clinical staff perceptions

Organizational factor	Management[a] mean	Clinical[b] mean	Difference	Significance (t Test)
Supervisor support for safety	86.3	73.2	13.1	***
Organizational learning	84.3	72.1	12.2	***
Teamwork within units	89.4	79.9	9.5	***
Communication openness	77.5	60.0	17.5	***
Staffing levels	66.0	57.3	8.7	***
Management support for safety	85.8	67.6	18.2	***
Teamwork across units	68.0	57.0	11.0	***

Values reflect the average percentage of people at each hospital that agreed or strongly agreed with the questions that related to the variable of interest; N = 1,047 hospitals.

Question responses were based on a 5-point Likert scale.

[a]Management consists of hospital staff that selected their primary staff position as administration/management.

[b]Clinical staff consists of physicians, physician assistants, nurse practitioners, registered nurses, licensed practical nurses, and medical assistants.

*p < .05.

**p < .01.

***p < .001.

Table 4

Weighted least squares multiple regression of successful handoffs on organizational factors: Comparing management and clinical staff models

	Management[a]			Clinical Staff[b]		
Organizational Factor	β	95% CI		β	95% CI	
Supervisor support	−.06	(−0.17, 0.04)		.01	(−0.06, 0.08)	
Organizational learning	.20	(0.10, 0.29)	***	−.08	(−0.15, −0.01)	*
Teamwork within units	−.15	(−0.27, −0.04)	**	−.11	(−0.18, −0.04)	**
Communication openness	.02	(−0.05, 0.10)		.13	(0.07, 0.20)	***
Staffing	.21	(0.15, 0.28)	***	.18	(0.13, 0.22)	***
Management support	.10	(0.01, 0.18)	*	.11	(0.04, 0.17)	**
Teamwork across units	.69	(0.63, 0.75)	***	.68	(0.63, 0.73)	***

Weight was hospital's overall response rate; N = 1,047 hospitals; controls included teaching hospital, government hospital, and bed size and region dummies; management and clinical staff models were run separately.

Management R^2 was .65; adjusted R^2 was .64; clinical staff R^2 was .77; adjusted R^2 was .76.

[a]Management consists of hospital staff that selected their primary staff position as administration/management.

[b]Clinical staff consists of physicians, physician assistants, nurse practitioners, registered nurses, licensed practical nurses, and medical assistants.

*p < .05.

**p < .01.

***p < .001.

well as the analysis of clinical staff responses (β = .11, 95% CI [0.04, 0.17], p < .01).

Our study also provides support for our adapted conceptual model that enabling, enacting, and elaborating actions can influence patient safety. We found that each stage of this model had at least one factor that was statistically significantly associated with perceived successful patient handoffs. First, when analyzing responses from all respondents, we found that one of the four activities we classified as *enabling*—staffing—was significantly associated with perceptions of successful handoffs. Furthermore, in subgroup analyses of management and clinical staff responses, we found significant associations between management support for safety and perceived successful handoffs. The activities we classified as *enacting* exhibited the strongest associations with perceptions of successful handoffs. We found that for all staff as well as for the management and clinical staff subgroups, perceived teamwork across units had the strongest association with perceived successful handoffs. Finally, the activity we classified as *elaborating*, organizational learning, was also significantly associated with perceptions of successful handoffs.

Discussion

Despite the efforts of hospital leaders, poor patient handoffs continue to result in adverse patient health outcomes and unnecessary costs (Greenberg et al., 2007). Considering the unfavorable impact that poor handoffs have on patient health, handoffs should be a patient safety priority for hospitals. However, strong consensus has been lacking as to which and how much organizational factors influence successful handoffs.

Results of our study provide insight into relationships between perceptions of patient handoffs and organizational factors that influence them. In general, as a hospital was perceived more favorably with regard to the organizational factors that contribute to patient safety, perceptions of its handoffs were better as well. Our analysis confirmed the results of prior small qualitative and quantitative studies involving nurses and physicians that have suggested that communication failures, hierarchy, lack of leadership focus on safety, and staffing shortages are barriers to successful handoffs (Riesenberg et al., 2009, 2010). Furthermore, because the adapted conceptual model we used to frame our study was supported by our data, we suggest that this model may have relevance for future studies that aim to examine other patient safety topics.

Impact of Teamwork and Communication Openness

We found that perceived teamwork across units had the strongest association with perceived successful handoffs and note that this relationship was consistent for both management and clinical staff. Given that only a fraction of recommended patient safety improvements can be typically adopted by a hospital because of constraints on finances and staffing (Warburton, 2005), improving our understanding

about the degree to which various organizational factors may influence successful patient handoffs is clearly important. The results of our study suggest that attention be paid to actions that prioritize improvements in teamwork across units. Those actions and the benefits of them should be well communicated to staff so that their perceptions about teamwork change. Improvement in this area will be challenging because it will involve multiple hospital units; one manager does not have the unilateral ability to make all improvements. However, Manser (2009) showed that staff perceptions of teamwork are directly related to the quality and safety of patient care; the results of our study provide additional evidence about the importance of perceptions of teamwork on handoffs, thus highlighting the need to address this issue.

Communication openness, or the comfort level staff have to question authority if something is not right, was perceived as having an impact on handoffs by the clinical staff, but not by management. This finding is important because managers are often responsible for creating initiatives designed to improve communications. Managers must be cognizant of the impact open communications have on successful handoffs in the minds of the clinical staff who actually hand off patients.

Several actions have been identified in the literature that can foster improved teamwork and communication openness. Examples include teamwork training, use of team huddles, interdisciplinary rounds, and the introduction of focus groups designed to identify teamwork issues (Farley, Sorbero, Lovejoy, & Salisbury, 2010; Kalisch, Curley, & Stefanov, 2007; O'Leary et al., 2010). Teamwork training at medical facilities is particularly important in light of the finding that only 8% of medical schools teach physicians how to properly hand off patients (Solet, Norvell, Rutan, & Frankel, 2004). Importantly, teamwork training can be conducted to improve teamwork across units and is associated with improved clinical outcomes. Blegen et al. (2010) found that multidisciplinary teamwork training significantly improved perceived teamwork across units. Similarly, one study of emergency departments found that teamwork training led to fewer clinical errors (Barrett, Gifford, Morey, Risser, & Salisbury, 2001).

Although the negative association between teamwork within units and perceived successful handoffs was unexpected, there is a plausible explanation in the overall context of teamwork. It is possible that, when holding teamwork across units constant, the strengthening of teamwork within units led staff to perceive that a handoff was more likely to be unsuccessful if made to a unit thought to have lower standards for patient safety.

Role of Staffing and Management Support

Findings from our study also suggest that staffing and management support for safety impact perceptions about successful handoffs. In practice, an adequate number of staff is essential for patient information transfer from one hospital unit to another, and the significance of staffing in our study seems to corroborate those findings. Previous studies suggested that insufficient time was a barrier to successful handoffs (Riesenberg et al., 2009, 2010), and lower staffing levels may contribute to staffs' perceptions about sufficient time. At the same time, although we suggest that increased staffing can improve handoffs, in some hospitals it may be difficult to implement such a strategy given the financial requirements of such a recommendation (May, Bazzoli, & Gerland, 2006).

Management support for safety was another factor that influenced perceived successful handoffs, and this was true among both management and clinical staff respondents. In order to increase management support, one approach may be to implement a safety board with safety subcommittees (Wong, Helsinger, & Petry, 2002). Another approach would be to include an evaluation of safety performance as part of the annual performance appraisal process for managers. Furthermore, as previously noted, managers can demonstrate support through the implementation of teamwork training programs or by convening focus groups to examine ways to improve teamwork.

Differences in Perceptions Between Management and Clinical Staff on Organizational Learning

Our comparison between management and clinical staff respondent groups highlighted some important differences in organizational learning. Such differences are relevant because, although management may control resources and indirectly influence patient safety, clinical staff directly influences patient safety through interactions with patients. It is possible that organizational learning can lead to more successful handoffs, but management may not share what is learned with clinical staff. Therefore, clinical staff may incorrectly perceive minimal benefit to the learning or improvement activities. It is also possible that learning activities are assumed by management to have a positive impact when in actuality that is not true. A third possible explanation is that continuous improvement activities lead to changes that reduce financial and operational costs from handoffs, and these impacts are observed by management. Yet, they do not positively impact the clinical status of patients, the impacts of which are observed by clinical staff. The idea that managers generally prioritize results through an operational lens whereas clinicians use a patient lens provides a fourth possible explanation for the different associations between perceptions of organizational learning and successful handoffs. Methods such as feedback, safety rounds, and video reflexive ethnography have been shown to improve organizational learning (Campbell & Thompson, 2007; Carroll, Iedema, & Kerridge, 2008), but further research should be undertaken to move beyond perceptions and determine how learning activities affect successful handoffs.

Limitations and Suggestions for Future Research

Common method bias, the degree to which correlations are altered because of a methods effect, is a potential problem in survey research and may appear when there is simultaneous measurement of predictor and outcome variables. We assessed common method bias with Harman's single factor test and a confirmatory factor analysis, consistent with approaches used by other studies in the literature (Schoenherr & Swink, 2012). These assessments indicated that common method bias was not a significant threat to the validity of our findings; specifically, the single factor model was a worse fit than the proposed model with the differentiated measurement items ($\chi^2 = 3005.697$, $df = 135$, RMSEA = 0.142, CFI = 0.494, TLI = 0.427). Consistent with Richardson, Simmering, and Sturman (2009), in our study, common method bias was partially controlled by the design of the survey instrument: reverse-coded questions, spatial separation of dependent and independent variables, question order randomization, and survey respondent anonymity. Our survey instrument included varied questions, with some positively and others negatively worded, and different response options for some of the questions.

Another possible limitation of this study is that the responses are based on perceptions. Answers may reflect what respondents think is happening, but the reality may be very different. However, a multitude of studies suggests a strong link between perceptions of safety culture and safety outcomes (Katz-Navon, Naveh, & Stern, 2005; Mardon, Khanna, Sorra, Dyer, & Famolaro, 2010), lending support to our approach. Furthermore, research in other disciplines, such as environmental reporting, has shown a relationship between perceptions and reality (Cormier, Gordon, & Magnan, 2004).

A third limitation involves the sampling method and generalizability of results. Our study was based on responses from what was essentially a convenience sample of hospitals that voluntarily submitted data and not from a randomly selected sample of all U.S. hospitals. Nonetheless, our large sample size and our finding that structural characteristics of the database hospitals were similar to characteristics of the distribution of hospitals registered with the AHA give us confidence that these results may be similar across other U.S. hospitals.

There are several paths for future studies. Because the adapted conceptual model was supported by findings from our study, this model may have relevance in future studies designed to examine other patient safety topics. In addition, future research can provide insights into the optimal way to improve teamwork across units in the context of patient safety. Future studies can also test the effect of technology and standardization in the context of teamwork across units and examine whether those factors modify the association of teamwork and handoffs. Furthermore, a future study should also be considered to clarify the role of organizational learning.

Practice Implications

Poor patient handoffs result in adverse medical and financial consequences but can be improved through targeted efforts to improve patient safety. We found that perceptions of successful patient handoffs can be influenced by perceptions of organizational factors such as teamwork, having hospital leadership demonstrate that safety is a priority, and sufficient staffing. Hospitals concerned about patient handoffs should rank improvements in teamwork across units as a top priority and consider initiatives that foster open communications, such as teamwork training. Sufficient staffing should also be provided, recognizing that resource constraints may limit some organizations' abilities to add staff. Finally, leadership should demonstrate support for safety. Methods to demonstrate support include the formation of a safety committee and an evaluation of safety performance as part of a manager's annual performance appraisal.

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References

Barrett, J., Gifford, C., Morey, J., Risser, D., & Salisbury, M. (2001). Enhancing patient safety through teamwork training. *Journal of Healthcare Risk Management, 21*(4), 57–65.

Blegen, M., Sehgal, N., Alldredge, B., Gearhart, S., Auerbach, A., & Wachter, R. (2010). Improving safety culture on adult medical units through multidisciplinary teamwork and communication interventions: The TOPS Project. *Quality and Safety in Health Care, 19*(4), 346–350.

Campbell, D., & Thompson, M. (2007). Patient safety rounds: Description of an inexpensive but important strategy to improve the safety culture. *American Journal of Medical Quality, 22*(1), 26–33.

Carroll, K., Iedema, R., & Kerridge, R. (2008). Reshaping ICU ward round practices using video-reflexive ethnography. *Qualitative Health Research, 18*(3), 380–390.

Cormier, D., Gordon, I., & Magnan, M. (2004). Corporate environmental disclosure: Contrasting management's perceptions with reality. *Journal of Business Ethics, 49*, 143–165.

Epstein, K., Juarez, E., Epstein, A., Lova, K., & Singer, A. (2010). The impact of fragmentation of hospitalist care on length of stay. *Journal of Hospital Medicine, 5*(6), 335–338.

Farley, D., Sorbero, M., Lovejoy, S., & Salisbury, M. (Eds.). (2010). *Achieving strong teamwork practices in hospital labor and delivery units*. Santa Monica, CA: RAND Center for Military Health Policy Research.

Greenberg, C., Regenbogen, S., Studdert, D., Lipsitz, S., Rogers, S., Zinner, M., & Gawande, A. (2007). Patterns of communication breakdowns resulting in injury to surgical patients. *Journal of the American College of Surgeons, 204*(4), 533–540.

Hannah, K., Schade, C., Lomely, D., Ruddick, P., & Bellamy, G. (2008). *Hospital administrative staff vs. nursing staff responses to the AHRQ Hospital Survey on Patient Safety Culture*. Rockville, MD: Agency for Healthcare Research and Quality. AHRQ Publication No. 08-0034-2. Available at http://www.ncbi.nlm.nih.gov/books/NBK43704/

Kalisch, B., Curley, M., & Stefanov, S. (2007). An intervention to enhance nursing staff teamwork and engagement. *Journal of Nursing Administration, 37*, 77–84.

Katz-Navon, T., Naveh, E., & Stern, Z. (2005). Safety climate in healthcare organizations: A multidimensional approach. *Academy of Management Journal, 48*, 1073–1087.

Kohn, K., Corrigan, J., & Donaldson, M. (Eds.). (1999). *To err is human: Building a safer health system*. Washington, DC: National Academies Press.

Mardon, R. E., Khanna, K., Sorra, J., Dyer, N., & Famolaro, T. (2010). Exploring relationships between hospital patient safety culture and adverse events. *Journal of Patient Safety, 6*, 226–232.

Manser, T. (2009). Teamwork and patient safety in dynamic domains of healthcare: A review of the literature. *Acta Anaesthesiologica Scandinavica, 53*, 143–151.

May, J., Bazzoli, G., & Gerland, A. (2006). Hospitals' responses to nurse staffing shortages. *Health Affairs, 25*(4), 316–323.

O'Leary, K., Wayne, D., Haviley, C., Slade, M., Lee, J., & Williams, M. (2010). Improving teamwork: Impact of structured interdisciplinary rounds on a medical teaching unit. *Journal of General Internal Medicine, 25*(8), 826–832.

Philibert, I., & Leach, D. (2005). Re-framing continuity of care for this century. *Quality and Safety in Health Care, 14*(6), 394–396.

Richardson, H., Simmering, M., & Sturman, M. (2009). A tale of three perspectives. Examining post hoc statistical techniques for detection and correction of common method variance. *Organizational Research Methods, 12*(4), 762–800.

Riesenberg, L., Leisch, J., & Cunningham, J. (2010). Nursing handoffs: A systematic review of the literature. *The American Journal of Nursing, 110*(4), 24–34.

Riesenberg, L., Leitzsch, J., Massucci, J., Jaeger, J., Rosenfeld, J., Patow, C., … Karpovich, K. (2009). Residents' and attending physicians' handoffs: A systematic review of the literature. *Academic Medicine, 84*(12), 1775–1787.

Schoenherr, T., & Swink, M. (2012). Revisiting the arcs of integration: Cross-validations and extensions. *Journal of Operations Management, 30*, 99–115.

Smits, M., Wagner, C., Spreeuwenberg, P., Groenewegen, P., & Van Der Wal, G. (2009). Measuring patient safety culture: An assessment of the clustering of responses at unit level and hospital level. *Quality and Safety in Health Care, 18*(4), 292–296.

Solet, D., Norvell, J., Rutan, G., & Frankel, R. (2004). Physician-to-physician communication: Methods, practice and misgivings with patient handoffs. *Journal of General Internal Medicine, 19*(S1), 108.

Sorra, J., & Dyer, N. (2010). Multilevel psychometric properties of the AHRQ Hospital Survey on Patient Safety Culture. *BMC Health Services Research, 8*(10), 199–212.

Vogus, T., Sutcliffe, K., & Weick, K. (2010). Doing no harm: Enabling, enacting, and elaborating a culture of safety in health care. *Academy of Management Perspectives, 24*(4), 60–77.

Warburton, R. (2005). Patient safety—How much is enough? *Health Policy, 71*(2), 223–232.

Wong, P., Helsinger, D., & Petry, J. (2002). Providing the right infrastructure to lead the culture change for patient safety. *The Joint Commission Journal on Quality Improvement, 28*(7), 363–372.

Ye, K., Taylor, D., Knott, J., Dent, A., & MacBean, C. (2007). Handover in the emergency department: deficiencies and adverse effects. *Emergency Medicine Australasia: EMA, 19*(5), 433–441.

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REVIEW

Do Safety Checklists Improve Teamwork and Communication in the Operating Room?

A Systematic Review

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Objectives: The aim of this systematic review was to assess the impact of surgical safety checklists on the quality of teamwork and communication in the operating room (OR).

Background: Safety checklists have been shown to impact positively on patient morbidity and mortality following surgery, but it is unclear whether this clinical improvement is related to an improvement in OR teamwork and communication.

Methods: A systematic search strategy of MEDLINE, EMBASE, PsycINFO, Google Scholar, and the Cochrane Database for Systematic Reviews was undertaken to obtain relevant articles. After de-duplication and the addition of limits, 315 articles were screened for inclusion by 2 researchers and all articles meeting a set of prespecified inclusion criteria were retained. Information regarding the type of checklist, study design, assessment tools used, outcomes, and study limitations was extracted.

Results: Twenty articles formed the basis of this systematic review. All articles described an empirical study relating to a case-specific safety checklist for surgery as the primary intervention, with some measure of change/improvement in teamwork and/or communication relating to its use. The methods for assessing teamwork and communication varied greatly, including surveys, observations, interviews, and 360° assessments. The evidence suggests that safety checklists improve the perceived quality of OR teamwork and communication and reduce observable errors relating to poor team skills. This is likely to function through establishing an open platform for communication at the start of a procedure: encouraging the sharing of critical case-related information, promoting team coordination and decision making, flagging knowledge gaps, and enhancing team cohesion. However, the evidence would also suggest that when used suboptimally or when individuals have not bought in to the process, checklists may conversely have a negative impact on the function of the team.

Conclusions: Safety checklists are beneficial for OR teamwork and communication and this may be one mechanism through which patient outcomes are improved. Future research should aim to further elucidate the relationship between *how* safety checklists are used and team skills in the OR using more consistent methodological approaches and utilizing validated measures of teamwork such that best practice guidelines can be established.

Keywords: briefing, communication, operating room, operating theatre, safety checklist, surgery, teamwork

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Safety checklists have been routinely used in aviation and other high-risk industries that require complex human interaction to prevent accidents occurring as a result of human error since as far back as the 1930s.[1] Their introduction to surgery occurred much more recently, in the last decade, and was prompted by an increased awareness of the significant number of deaths that occur each year as a result of avoidable surgical error—which are estimated to be around half a million worldwide.[2,3] Safety checklists have now been produced for use in the operating room (OR) in a number of different iterations and have been mandated according to national policy in several countries.[4] A high-profile example is the World Health Organization's (WHO's) Surgical Safety Checklist, developed as part of their 2006 "Safe Surgery Saves Lives" campaign.[2,5]

The Surgical Safety Checklist and others like it comprise a set of core safety checks to be verbally performed by the OR team at specified times during a surgical procedure (eg, preincision). These checks are designed to minimize the risk of complication and death by reinforcing and standardizing accepted safety procedures (which can be overlooked by busy teams) and by creating redundancy in the system to allow for human error to be captured.[4,6,7] A growing surgical evidence base supports that safety checklists substantially improve adherence to appropriate clinical practices (eg, antibiotic administration, DVT prophylaxis), which in turn reduce avoidable morbidity and mortality.[8–15]

As well as improving adherence to clinical practices, safety checklists are designed to improve surgical safety by influencing wider aspects of performance in the OR, that is, fostering better interprofessional teamwork and communication. Breakdowns in multidisciplinary teamwork in the OR are reported as one of the most common contributory factors towards the occurrence of wrong site surgeries and other surgical adverse events.[16–21] By promoting direct verbal communication and interaction, checklists aim to open the lines of communication between OR team members, to ensure a common understanding or "shared mental model" of the patient, procedure, and risks, and to empower individuals to voice safety concerns who may not otherwise feel able to do so, thus increasing the probability of surgical error being captured or mitigated before it is too late. Furthermore, safety checklists act to familiarize team members with one another (and some of them, like the WHO Checklist, stipulate that team members introduce themselves before a case). Research has shown that sharing the names and roles of individuals in the OR is one of the most effective methods for promoting an individual's sense of participation and responsibility in the case, again increasing the probability that individuals will speak up if they anticipate or detect a problem. This is especially relevant given that team membership is often not consistent from 1 day to the next.[1,4,22,23]

The aim of this review was to systematically evaluate the available literature relating to the impact of surgical safety checklists on teamwork and communication in the OR. The objective was to establish whether there is robust evidence to suggest that the use of safety checklists improves these team skills.

METHODS

Databases searched included Embase (1980 to February 2012 week 7), MEDLINE (1946 to February 2012), and PsycINFO (1967 to February 2012). Additional searches were also carried out on Google Scholar and the Cochrane Database of Systematic Reviews. The last search was conducted on July 24, 2012. The following search terms were used:

- *Category A (Population)*: Surgery* OR surgical* OR operating theatre* OR operating room* OR obstetric* OR gyn(a)e*
- *Category B (Intervention)*: Checklist* OR check-list* OR briefing* OR world health organi*
- *Category C (Outcome)*: Teamwork* OR non-technical* OR nontechnical* OR notec* OR communication*

After combining all 3 search categories, the following additional limits were imposed: English language articles, articles between 1980 and present, and those involving human subjects only. Titles and abstracts of all articles retrieved from the initial search were reviewed by 2 of the authors (Russ: psychologist; Rout: surgeon) to select those that were relevant to the aims of the review. All selected articles were subjected to full-text review by the same 2 authors, and those that satisfied the inclusion criteria were retained (Fig. 1).

To triangulate the search strategy, all reference lists of retained articles were checked for additional papers that may have been missed by the initial search. The studies varied widely in terms of study design and methodology which prevented data pooling and meta-analysis. Therefore, a qualitative synthesis and critical evaluation of the evidence was carried out.

RESULTS

Selected Articles

A flow diagram of the search strategy is presented in Figure 2. The initial search generated a total of 639 citations, of which 324 articles were excluded after the additional search limits were applied. Forty-four articles were selected for full-text review after evaluating all titles and abstracts. Of these, 27 articles were excluded because they did not meet the inclusion criteria. Three additional relevant articles were identified from a reference search of the selected articles, resulting in a total of 20 articles for inclusion in the current review.

1. Original empirical studies only: review articles, commentaries, editorials, conference abstracts, and articles presenting data previously reported elsewhere were excluded.
2. Surgical checklists only: checklists developed for use in other settings (e.g. intensive care units, medical wards) were excluded.
3. Safety checklists applied to individual cases only: articles reporting checklists unrelated to safety or team 'briefings' without patient-specific checklists were excluded.
4. Included studies should describe the impact of the checklist on measures of teamwork and/or communication in the OR i.e. some measure of change/improvement in these skills has been undertaken.
5. The checklist was the primary intervention and not part of a safety bundle such as a team training program.

FIGURE 1. Inclusion criteria.

Study Characteristics

Table 1 presents an overview of the characteristics of the 20 articles reviewed (ie, type of checklist used, communication/teamwork measure(s), study methodology, study site, surgical specialty). Studies spanned across 12 different countries in total, including both developed and developing countries-–1 article[38] presented a global study spanning 8 different countries. Nine of the studies focused on a single surgical specialty, all others assessed the impact of the checklist across multiple specialties. The following surgical specialties were listed: general, cardiothoracic, vascular orthopedic, trauma, ear-nose-throat (ENT), and obstetrics. One study was conducted in a simulated OR[28]; all others report data collected in relation to the use of the checklist in real OR procedures. Fourteen of the studies undertook a pre-/postintervention design, allowing for teamwork/communication postchecklist to be compared to baseline performance without a checklist.[24,26–29,31,33,34,38–43] One randomized controlled trial (RCT) was included.[37] The remaining studies assessed the impact of the checklist on performance retrospectively.[25,30,32,35,36]

Type of Checklist

Seven of the 20 articles reported on the use of the WHO's Surgical Safety Checklist or a specialty-specific modification of it.[35,38–43] The WHO Surgical Safety Checklist is designed such that safety checks are carried out at 3 operative phases: "Sign-in" (before anesthesia induction), "Time-out" (before incision), and "Sign-out" (following the procedure before team members leave the OR). Checks at "Sign-in" are completed between the anesthetic staff (at a minimum) and the patient and include confirmation of ID, consent, procedure, allergies, expected blood loss, and checking of the anesthetic equipment. The entire OR team is present for "Time-out" for team introductions and a final check of patient ID/procedure, surgical issues (expected blood loss, special equipment, potential risks), anesthetic issues (patient history, ASA grade, and monitoring equipment check), nursing issues (sterility of instruments, equipment problems), antibiotics, DVT prophylaxis, essential imaging, patient warming, hair removal, and glycemic control. Finally, at "Sign-out" the entire team confirms the name of the procedure, specimens, final counts, equipment problems, and concerns for recovery.

The remaining 13 articles[24–34,36,37] reported on safety checklists that had been either undertaken in accordance with national recommendations (eg, that of the Joint Commission on Accreditation of Healthcare Organizations, which produced guidelines for a "time-out" prior to incision for all surgical procedures, named the "Universal Protocol"),[23,26,27,31] or developed locally in response to a perceived need for improvement in surgical safety. Locally developed tools were either designed from scratch or based around an existing tool already developed to aid communication/teamwork in the OR by the authors or their collaborators. The precise development process varied but all checklists were developed by multidisciplinary groups and based on prior research, literature reviews, and/or expert opinion, and had engagement from OR members in prototype content, refinement, and piloting. They all contained very similar items to that of the WHO checklist. Nine of these 13 articles described checklists that consisted of preoperative ("Time-out" equivalent) safety checks only[24–27,29–37,40,42] 2 consisted of pre- and postoperative checks,[32,36] and 2 consisted of pre-, intra-, and postoperative checks.[28,37] Like the WHO checklist, 4 of these articles presented checklists that separated items according to the OR subteam responsible for carrying out the checks (ie, surgical team, anesthetic team, nursing team)[24,33,34,37] and team introductions formed part of the safety checks in 6 of the articles.[24,26,27,31,36,37] Furthermore, in all 13 instances, the entire OR

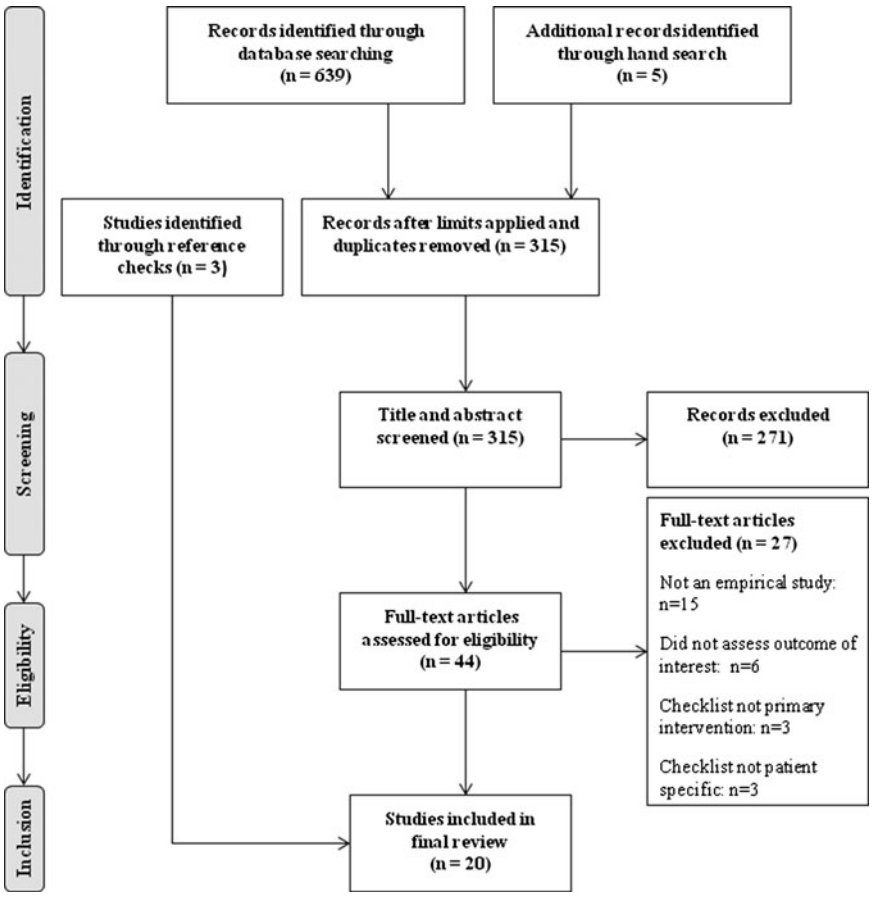

FIGURE 2. PRISMA flow diagram: Search strategy.

team (or at least one senior member of each OR subteam) was required to be present when the checks were carried out.

A paper checklist was used to prompt discussions in all 20 of the articles selected. In one article, the checklist was also presented in poster format on the OR wall.[34]

Teamwork/Communication Measures

Teamwork and communication measures varied greatly across the reviewed articles (Table 2). Broadly, 1 (or a combination) of 3 different methodological approaches was undertaken to assess the impact of the checklist on teamwork/communication: self-report, observations, or 360° ratings. Self-report was utilized in 15 of the 20 reviewed articles using questionnaires in 13 studies[24,26–2832,35,37–43] and interviews in 2 studies[25,36] to capture OR professionals' perceptions of teamwork/communication. The number of respondents ranged from 11 (Lingard et al[25]) to 1748 per study.[42] Typically, all disciplines within the OR were represented in the sample. Seven articles used observational methods to capture the quality of teamwork/communication across the OR team.[25,28–30,33,34,37] Observations were carried out by trained observers either in real-time or from videos, and the total number of observations conducted ranged from 16 (Henrickson et al[33]) to 232.[34] One article used 360° ratings of self and peers' teamwork.[31] Finally, 3 studies mixed self-report and observational approaches to assess checklist impact.[25,28,37] Of note, whereas the observational and 360° measures largely had validation evidence, self-report measures were variable in this respect, with only 4 of the 13 retrieved assessment instruments having some supportive psychometric evidence.

Impact of Checklist on Teamwork and Communication

Table 3 presents a detailed summary of data relating to the impact of safety checklists on teamwork and communication in the OR and the study limitations for all articles reviewed. The impact of the checklist on teamwork/communication has been summarized below according to the methodological approach undertaken.

Self-reported Teamwork/Communication

Of the 13 articles that utilized surveys, 10 reported a positive impact of the checklist on teamwork, including strengthened "team feeling" in the OR,[35] improved communication (relating to both preoperative and postoperative checks), for example, increased discussion of critical events,[24,32,40–42] better familiarity and knowledge of team members' names,[39–41,43] improved decision making,[26] better interprofessional coordination and assignment of tasks,[43] and fewer delays caused by miscommunications.[27]

The remaining 3 articles reported mixed results. One study found no pre-/postimprovement in scores on the teamwork climate of the SAQ; however, 85% of OR staff agreed that the checklist had improved OR communication when asked after checklist implementation.[38] Koutantji et al[28] found a pre-/postimprovement in 2 of their 4 survey items relating to the impact of the checklist on teamwork/communication; these 2 items referred to the impact of preoperative checks on teamwork, no difference was found on the items relating to postoperative checks. Finally, in an RCT, no difference in self-reported situational awareness was found between the control (no checklist) group and the intervention (checklist) group,

TABLE 1. Study Characteristics

Authors	Year	Type of Checklist	Outcome Assessed*	Study Methodology†	Country	Setting	Surgical Specialty
DeFontes and Surbida[24]	2004	Patient-specific preoperative briefing checklist	Teamwork climate	Survey—Pre/post (6 months before checklist implementation and 6 months after).	USA, Orange County	1 medical center at an integrated managed care consortium	Multispecialty
Lingard et al[25]	2005	Patient-specific checklist designed to prompt preoperative discussion	Team building and exchange of information	Interviews and observations (real ORs)—Post (Checklist implementation took place over 7 weeks during which observations were conducted)	Canada	1 quaternary academic center	Vascular surgery
Makary et al[26]	2007	Patient-specific preoperative briefing checklist	Team coordination and quality of decision making	Surveys—pre/post (Pre–data collection lasted 5 months, checklist was implemented for 3 months, post–data collection lasted 2 months)	USA	1 tertiary academic center	General surgery, plastic surgery, neurosurgery
Nundy et al (same group as above)[27]	2008	Patient-specific preoperative briefing checklist	Communication breakdowns resulting in delays in starting surgical procedures	Surveys—Pre/post (pre–data collection lasted 2 months, checklist was implemented for 3 months, post–data collection lasted 2 months)	USA	1 tertiary academic center	General surgery, plastic surgery, neurosurgery
Koutantji et al[28]	2008	Patient-specific safety checklist with pre, intra- and postoperative components	Quality of teamwork (decision making, communication, leadership, and overall teamwork) and perceived impact of checklist on teamwork and communication	Surveys and observations (in simulated OR)—pre/post (Simulation session lasted 4–5 h in total. One scenario was completed without the checklist at the start of the session, another was completed with the checklist at the end of the session)	UK, London	1 large university hospital	Simulations of general and vascular surgery procedures
Lingard et al[29]	2008	Patient-specific checklist designed to prompt preoperative discussion	Communication failures and perceived impact of checklist on proactive team communication	Observations (real ORs)—pre/post (Pre–data collection lasted 5 months, the checklist was then implemented over 3 months, post–data collection then commenced over 5 months. The study lasted 13 months in total.)	Canada	1 tertiary academic center	General surgery
Whyte et al (same group as above)[30]	2008	Patient-specific checklist designed to prompt preoperative discussion	Negative teamwork events specifically linked to checklist usage	Observation (real ORs)—Post (Checklist implementation took place over 7 weeks during which observations were conducted.)	Canada	1 tertiary academic center	General surgery

(*continued*)

TABLE 1. (*Continued*)

Authors	Year	Type of Checklist	Outcome Assessed*	Study Methodology†	Country	Setting	Surgical Specialty
Paige et al[31]	2008	Patient-specific preoperative briefing checklist	Quality of teamwork (eg, team orientation, accountability, communication)	360° ratings of self and peers (real ORs)—pre/post (The study lasted 7 months in total. No additional information regarding timings provided.)	USA, Alaska	1 rural community hospital	General surgery
Berenholtz[32]	2009	1-page, patient-specific, preoperative briefing and postoperative de-briefing checklist	Interdisciplinary communication and teamwork	Surveys—post (Data collection commenced 15 months after checklist implementation)	USA, Baltimore	1 tertiary academic center	Multispecialty
Henrickson et al[33]	2009	Patient-specific preoperative briefing checklist	Surgical flow disruptions related to miscommunication	Observations (real ORs)—pre/post (Postobservations were carried out 7 days after briefing implementation)	USA	1 tertiary academic center	Cardiovascular
Einav et al[34]	2010	Patient-specific preoperative briefing checklist (presented in poster format in all ORs)	Near-misses associated with problematic teamwork	Observations (real ORs)—pre/post (preobservations lasted 3 months, postobservations in gynecology took place 5 months later and lasted 3 months, observations in orthopedics took place 10 months later and lasted 3 months)	Israel, Jerusalem	1 tertiary care hospital	Gynecology and orthopedics
Nilsson et al[35]	2010	WHO Surgical Safety Checklist	"Team feeling" in the OR	Surveys—post (Data collection lasted for 3 weeks 1 yr after the checklist had been implemented)	Sweden, Ostergotland	2 Swedish hospitals	Multispecialty
Papaspyros et al[36]	2010	Patient-specific preoperative briefing and postoperative de-briefing checklist	Quality of communication	Interviews—Post (No information was provided regarding timings)	UK, Leeds	1 university hospital	Cardiac surgery
Calland et al[37]	2011	Patient-specific safety checklist with pre-, intra-, and postoperative components	Team coordination and communication.	Surveys and observations (from video recordings of real ORs)—RCT (The study lasted 15 months in total.)	USA, Virginia	1 university hospital	General surgery—laparoscopic cholecystectomy procedures only

(*continued*)

TABLE 1. (*Continued*)

Authors	Year	Type of Checklist	Outcome Assessed*	Study Methodology†	Country	Setting	Surgical Specialty
Haynes et al[38]	2011	WHO Surgical Safety Checklist	Teamwork climate	Survey—pre/post (Pre- and post–data collection lasted for 2 weeks. Checklist implementation lasted between 1 week and 1 month. The study ran for 1 yr in total.)	Jordan, India, Tanzania, Philippines, the United Kingdom, the United States, New Zealand, Canada	6 public hospitals, 1 district rural hospital, 1 charity hospital	Multispecialty excluding cardiac surgery
Helmio et al[39]	2011	WHO Surgical Safety Checklist	Communication between OR team members, discussion of critical events, and awareness of OR team members' names	Surveys—pre/post (Pre–data collection lasted for 1 month and commenced 4 months before the checklist was introduced, post–data collection lasted for 1 month as soon as the checklist was introduced)	Finland, Helsinki	1 university hospital	Otorhinolaryngology
Takala et al (same group as above)[40]	2011	WHO Surgical Safety Checklist	Quality of communication in the OR	Surveys—pre/post (Pre–data collection lasted 4–6 weeks, checklist was then implemented over 4 weeks, post–data collection then commenced and lasted 4–6 weeks)	Finland	4 university hospitals	Multispecialty
Kearns et al[41]	2011	Modified WHO Surgical Safety Checklist	Quality of OR communication and familiarity with team members	Surveys—pre/post (Pre–data collection lasted 1 month, post–data collection commenced 3 months after the checklist was implemented.)	UK	1 obstetric tertiary referral center	Obstetrics
Sewell et al[42]	2011	WHO Surgical Safety Checklist	Communication and teamwork	Surveys—pre/post (Pre–data collection lasted 4 months, checklist was then implemented over 1 month, postchecklist data collection then commenced and lasted 4 months)	UK, London	1 university hospital	Trauma and orthopedics
Bohmer et al[43]	2012	Modified WHO Surgical Safety Checklist	Interprofessional coordination, team communication, and familiarity with other staff members	Surveys—pre/post (Post–data collection took place 3 months after checklist implementation. No information regarding timing of pre–data collection provided)	Germany, Cologne	1 university hospital	Anesthesiology and trauma care

*For outcome assessed, the terminology of the original study has been used where possible (ie, wherever a consistent descriptor of the outcome variable was provided).
†Study methodology includes the timing of the introduction/implementation of the checklist—as this could have contributed to the impact on the outcome measures.
OR indicates operating room; WHO, Word Health Organization.

TABLE 2. Summary of Teamwork/Communication Measures

Assessment Instrument	Studies Utilizing the Instrument	Instrument Description	Validity/ Reliability Evidence Available?
Self-report instruments			
Safety Attitudes Questionnaire (SAQ)-Teamwork climate subscale	[24,38]	Self-report instrument for measuring attitudes and perceptions in safety-related domains in health care. Has several subscales (including a teamwork climate) and available in different formats (including one specific to the operating room environment). Teamwork climate consists of 14 items relating to the quality of teamwork in the department of interest, all rated on a 5-point Likert scale.	Yes[44]
OR Briefing Assessment Tool	[26,27]	A 17-item case-based version of the SAQ with 4 items relating to teamwork/ communication listed in the manuscripts (full questionnaire not provided). Items rated on a 5-point Likert scale. (*Team discussions are common in the ORs. Decision making used input from relevant personnel. Surgery anesthesia worked together as a well-coordinated team. Communication breakdowns that lead to delays in starting surgical procedures are common.)*	Yes[26]
Briefing Attitudes Questionnaire Short Version	[28]	A questionnaire for assessing staffs' views of briefing using a checklist. 14 items provided in the manuscript of which 4 were related to teamwork/communication (*To what extent do you think briefings can enhance teamwork in the operating theatre (OT)? To what extent do you think briefings can enhance communication of team members working in the OT? To what extent do you think debriefings can enhance teamwork in the OT? To what extent do you think debriefings can enhance communication of team members working in the OT?)* Scoring system not described.	No
Study-specific questionnaire	[32]	A questionnaire with both structured and free-text responses relating to the effect of the checklist on interdisciplinary communication and teamwork and the burden and average time taken to complete the tool. The authors provide the full questionnaire in the Appendix. 2 teamwork/communication-related items rated on a 5-point Likert scale (*Briefing is an effective strategy to improve interdisciplinary communication. Debriefing is an effective strategy to improve interdisciplinary communication.)*	No
Study-specific questionnaire	[35]	An 8-item questionnaire with answers provided either on a 4-point Likert scale or in binary format. The authors provide the full questionnaire in the Appendix. One item related to teamwork/communication (*Timeout strengthens the team feeling in the operating theatre. YES/NO*)	No
Study-specific questionnaire	[37]	A 24-item postcase questionnaire captured team members' subjective measures on a 5-point Likert scale. Full scale not provided but 3 items relating to teamwork/ communication were referred to in the manuscript: satisfaction with team efficiency, satisfaction with team communication, and situational awareness of team events.	No
Study-specific questionnaire	[38]	A 6-item questionnaire designed to measure the impact of the checklist. All items provided in the manuscript. One teamwork/communication related item (*Communication was improved through the use of the checklist*), answered on a 5-point Likert scale.	No
Study-specific questionnaire	[39,40]	A multiple-choice (yes, no, I don't know, not relevant) questionnaire relating to performance of safety checks and communication. The authors provide the full questionnaire in the Appendix. Three teamwork/communication related items were included (*Were critical events discussed between anesthesiologist and surgeon? Was communication successful between the team member? Was everybody aware of the name and role of each team member?*)	Yes[40]
Study-specific questionnaire	[41]	No details of the questionnaire provided. Two teamwork/communication related items were listed in the "Results" section (*I felt familiar with others in theatre, I felt communication in theatre had improved*).	No
Study-specific questionnaire	[42]	A 4-item questionnaire designed for evaluating the impact of the checklist. All items were provided in the manuscript and answered yes, not sure, or no. One item related to teamwork/communication (*The checklist improved team communication and teamwork*).	No
Study-specific questionnaire	[43]	A 19-item questionnaire using a 5-point Likert scale response system-full questionnaire provided in the manuscript. Questions covered safety-relevant aspects of the perioperative period, work process, and interprofessional cooperation. Multiple items related to communication/teamwork (eg, *I know all co-workers in the OR team, I believe the teamwork in the OR is excellent*).	No
Study-specific interviews	[25]	Interview participants were asked to describe the benefits and drawbacks of the checklist. Interviews were informal—no description of the interview schedule/approach was provided. Interviews were analyzed using a grounded theory approach to pick out emergent themes regarding how the checklist complemented/conflicted existing processes, how it was received by team members, and what effects the discussion had.	Yes[25]
Study-specific interviews	[36]	No description of interview schedule/approach provided. Interviewees were asked for their opinion of the checklist. Interviews were then subjected to a simple qualitative analysis that counted the adjectives used and how many related to communication.	No

(*continued*)

TABLE 2. (*Continued*)

Assessment Instrument	Studies Utilizing the Instrument	Instrument Description	Validity/ Reliability Evidence Available?
Observational instruments			
A theory-based instrument to evaluate team communication in the operating room	29	A checklist-type tool to capture the frequency and nature of communication failures in the OR, and any immediate consequences of these failures. Failures were categorized as content, occasion, purpose, or audience related, and were complemented by contextually relevant observation notes. Used by trained observers in real-time.	Yes[45]
Ethnographic field notes	25,30	Trained/experienced observers documented the content and process of team briefings. Procedurally relevant communication before and after the checklist discussion was documented. An emergent theme analysis was used to analyze the ethnographic field notes. In one study,[30] field notes were reviewed/analyzed to specifically identify "negative events" relating to the use of the checklist. Negative events were classified according to 5 themes: masking knowledge gaps, disrupting positive communication, reinforcing professional divisions, creating tension, and perpetuating problematic culture.	Yes[30]
The NOn-TECHnical Skills (NOTECHS) scale	28	Items assessing 5 teamwork dimensions (range of scores 1–6): communication and interaction (4 items); vigilance/situational awareness (3 items); team skills (4 items); leadership and management skills (5 items); decision-making crisis (5 items). Used by trained observers to rate behavior in simulated scenarios in real-time.	Yes[46]
Study-specific observations	33	One trained observer conducted real-time observations of surgical procedures in real and rated all disruptions in surgical flow according to 1 of 4 causal categories: patient-related, equipment or resource related, procedural knowledge issues, or miscommunication events. Miscommunication events included verbal commands failing to be conveyed, being conveyed incorrectly, or being incorrectly interpreted.	Yes[33]
Study-specific observation notes	34	One of 4 trained observers noted all activities, verbal exchanges, the use of equipment, and the times at which they occurred. Observation notes were retrospectively analyzed to pick out and classify nonroutine events into 1 of 7 categories. One category related to teamwork/communication (problems with teamwork).	Yes[34]
Study-specific observations	37	Evaluation of team communication and coordination from video recordings of surgical procedures by nonblinded assessors using a 3-point scale (not done, partially completed, completed successfully) for 5 different elements: role introductions, case presentations, roles and responsibilities review, contingency planning, and equipment check.	No
360° rating instruments			
360° OR Teamwork Assessment Scale	31	13 teamwork-related items (eg, leadership, mutual trust, backup behavior, situational awareness) rated on 6-point Likert scales following a procedure—individuals rate themselves first and then each of their OR colleagues.	Yes[31]

OR indicates operating room.

and perceptions of team efficiency and communication were actually poorer in the intervention group. However, observed team performance was rated higher in the intervention group (reported later).[37]

Three articles reported interdisciplinary differences regarding the impact of the checklist. Two studies found that anesthesiologists and nurses, but not surgeons, reported improved communication after checklist implementation.[39,40] Similarly, another study reported that nonmedical staff were more likely to perceive an improvement in communication than medical staff.[41] Finally, Helmio and colleagues[39] found that surgeons and anesthesiologists, but not nurses, reported increased knowledge of OR team members' names.

The 2 interview studies supported a positive impact of safety checklists on communication in the OR, with quotes relating to improved familiarity with team members, better understanding of fellow team members' concerns, feeling better valued as a team member, and being more willing to "speak up" about safety concerns.[25,36]

Observed Teamwork/Communication

Of the 7 articles that undertook an observational methodology, 5 reported a positive impact of the safety checklist on teamwork/communication. In 1 study, Lingard and colleagues[25] highlighted 6 positive functions of the checklist from their ethnographic field notes, 4 of which were related to team skills. These were promoting provision of case-related information (allowing more efficient and proactive planning by the team), encouraging articulation of concern, supporting interdisciplinary decision making, and enhancing team building/camaraderie.[25] In another study, the same group reported a significant reduction in OR communication failures after checklist implementation (dropping from an average of 3.95 to 1.31 failures per case), particularly for those failures with visible adverse consequences.[29] These results were mirrored by Henrickson and colleagues,[33] who reported significantly fewer miscommunication events after checklist implementation (dropping from 2.5 to 1.17 per case). Another article reported fewer nonroutine events (or near misses) associated with poor teamwork when the checklist was used.[34] Finally, in their RCT, Calland and colleagues[37] found that the quality of team communication and coordination was rated as higher in the intervention (checklist) versus the control (no checklist) group.

One simulation study reported mixed results. Whereas surgeons' decision making was rated significantly better by experts after checklist implementation, anesthesiologists' decision making was rated significantly worse. Furthermore, checklist implementation had no impact on the observed quality of communication, leadership, or overall teamwork.[28]

A single study highlighted negative impacts that safety checklists may pose on teamwork (while acknowledging that positive

TABLE 3. Impact of Safety Checklists on Teamwork and Communication in the Operating Room

Authors	Type of Checklist	Outcome and Tool	Design and Sample	Findings	Limitations*
DeFontes and Surbida[24]	Patient-specific preoperative briefing checklist	Outcome: Perceived teamwork climate Tool: SAQ—teamwork climate	Pre/postsurvey study 119 OR staff and 60 surgeons responded in total	% agreement that teamwork climate and communication were good substantially increased after initiation of briefings.	*Statistical significance of results not reported.*
Lingard et al[25]	Patient-specific checklist designed to prompt preoperative discussion	Outcome: Team building and exchange of information Tool: Interviews and ethnographic field notes from observations	Qualitative observational study Ethnographic field notes during 18 observations of real-time checklist usage post introduction Interviews after introduction of checklist 11 interviewees 3 surgeons, 1 surgical fellow, 3 nurses, 1 anesthesiology resident	Team building and camaraderie were identified as one of the functions of the checklist in interviews and observations. Increased team cohesion was noted as an outcome by surgeons.	Researchers both observed and participated in checklist intervention—creates potential bias *No control (lack of prechecklist assessments)*
Makary et al[26]	Patient-specific preoperative briefing checklist (OR Briefing 5)	Outcome: Perceived coordination of care and quality of decision making Tool: 3 "team"-related items on ORBAT: a case-based version of the SAQ	Pre/postsurvey study Pre = 306 respondents Post = 116 respondents Surgical attending physicians, surgical residents, anesthesia attending physicians, anesthesia residents, scrub nurses, circulating nurses, medical students, nurse assistants.	Agreement that surgery and anesthesia worked together as a well-coordinated team that team discussion were common in the OR and that decision making utilized input from relevant personnel increased significantly postimplementation of the checklist.	Unsure of generalizability of results to other centers *Only 2 questionnaire items related to impact of checklist on teamwork*
Nundy et al (same group as above)[27]	Patient-specific preoperative briefing checklist	Outcome: Perceived communication breakdowns resulting in delays in starting surgical procedures Tool: 1 "Team"-based item on ORBAT: a case-based version of the SAQ	Same as above	Agreement that communication problems had resulted in a delay to starting a surgical procedure significantly reduced after checklist implementation (from 80% to 65%).	Surgeons self-selected to participate—unsure of generalizability of results *Only 1 questionnaire item related to impact of checklist on teamwork*
Koutantji et al[28]	Patient-specific safety checklist with pre-, intra-, and postoperative components	Outcome: Observed quality of teamwork (decision making, communication, leadership, and overall teamwork) and perceived impact of checklist on teamwork and communication Tool: A modified version of the nontechnical Skills Human Factors Rating Scales (HFRS-M)—based on experts' observations. Briefing attitudes questionnaire—4 items relating to teamwork/	Pre/postmixed design in simulated OR environment Pre = 9 full OR teams conducted one simulated crisis scenario Post = same 9 full OR teams conducted different (but matched) simulated crisis scenario Surgeon, surgical assistant, scrub nurse, circulating nurse, anesthesiologist, anesthetic nurse/assistant	There was a significant improvement in scores for the 2 items on the briefing attitudes questionnaire that related to the impact of preoperative checks (briefings). No difference was found for the items relating to postoperative checks (de-briefings) Surgeons' decision making was rated significantly better by experts after checklist implementation, but anesthesiologists' decision making was significantly worse after the checklist implementation.	Small sample size Observers were not blinded to the use of the checklist *Evaluation of briefing based on its use in just 1 simulated scenario* *No validity/reliability data available for questionnaire*

(*continued*)

TABLE 3. (*Continued*)

Authors	Type of Checklist	Outcome and Tool	Design and Sample	Findings	Limitations*
		communication; 2 of which referred to preoperative checks (briefings), 2 referred to postoperative checks (de-briefings).		Checklist implementation had no impact on experts' ratings of communication, leadership, or overall teamwork	
Lingard et al[29]	Patient-specific checklist designed to prompt preoperative discussion	Outcome: Observed communication failures and perceived impact of checklist on team Tool: Real-time OR observations by experts rating communication failures using a validated tool	Pre/postobservational study Pre = 86 observations Post = 86 observations	The mean number of communication failures per procedure declined from 3.95 to 1.31 after the intervention—a statistically significant reduction The number of communication failures with at least 1 visible consequence declined from 207 pre to 75 post Increase in proactive and collaborative team communication	Cannot isolate the active component of the checklist
Whyte et al (same group as above)[30]	Patient-specific checklist designed to prompt preoperative discussion	Outcome: Observed negative teamwork events specifically linked to Checklist usage Tool: Ethnographic field notes from observations	Qualitative observational study Ethnographic field notes in 302 cases after checklist implementation	In 45 of the 302 briefings observed, the entire briefing was unconstructive. 5 types of negative team events relating to the checklist/briefings were recorded: masking knowledge gaps, disrupting positive communication, reinforcing professional divisions, creating tension, and perpetuating a problematic culture.	*This study only focuses on the negative effects of the checklist; however, it acknowledges that overall the checklist had a positive impact.* *No control (lack of prechecklist assessments)*
Paige et al[31]	Patient-specific preoperative briefing checklist	Outcome: Perceived quality of teamwork (eg, team orientation, accountability, communication) Tool: ORTAS (OR Teamwork Assessment Scale). 360° ratings of self and peers on 13 teamwork dimensions on 6-point scale.	Pre/postdesign Pre = 20 cases Post = 16 cases 17 OT team members participated in total	Peer-assessed scores of teamwork significantly increased after introduction of the checklist but self-assessed teamwork scores did not.	Completing the 360° assessment may have been educative in itself and led to improved teamwork scores. No improvement in self-assessed teamwork. Limited number of participants
Berenholtz et al[32]	A 1-page, patient-specific, preoperative briefing and postoperative de-briefing checklist	Outcome: Perceived interdisciplinary communication and teamwork	Surveys 1 yr after checklist implementation 40 respondents 10 surgeons, 10 anesthesiologists, 10 nurse anesthetists, and 10 circulating nurses	90% of respondents agreed that briefing is an effective strategy to improve interdisciplinary communication and teamwork 69% agreed that de-briefing was an effective strategy to improve interdisciplinary communication, whereas 72% agreed that de-briefings improve teamwork.	Survey was not validated. Survey sample was limited (N = 40) Results need to be generalized to other institutions. *No control (lack of prechecklist assessments)* *Only 2 questionnaire items related to impact of checklist on teamwork*

(*continued*)

TABLE 3. (*Continued*)

Authors	Type of Checklist	Outcome and Tool	Design and Sample	Findings	Limitations*
Henrickson et al[33]	Patient-specific preoperative briefing checklist	Outcome: Observed surgical flow disruptions related to miscommunication Tool: Real-time OR observations	Pre/postobservational study Pre = 10 observations Post = 6 observations	After implementation of briefings there were significantly (53%) fewer miscommunication events per case (1.17 post vs 2.5 pre)	Small sample size The observer was a medical student with limited clinical experience. Observer was not blinded to whether the teams had been briefed or not
Einav et al[34]	Patient-specific preoperative briefing checklist (presented in poster format in all ORs)	Outcome: Observed near-misses associated with problematic teamwork Tool: Real-time OR observations of nonroutine events associated with problems in teamwork	Pre/postobservational study Pre = 130 observations Post = 102 observations	A significant reduction in the mean number of nonroutine events associated with poor teamwork after implementation of the checklist.	
Nilsson et al[35]	WHO Surgical Safety Checklist	Outcome: Perceived "team feeling" in the OR Tool: 1 "Team"-related item on study-specific questionnaire	Surveys 1 yr after checklist implementation 331 respondents 147 surgeons, 30 anesthesiologists, 63 anesthetic nurses, 44 OR nurses, and 47 nurse assistants	65% agreed that the "Time-out" strengthens the team feeling in the OR	Lack of "pre" intervention questionnaire—no control *No mention of origin of questionnaire items and no validity/reliability data available* *Only 1 questionnaire item related to impact of checklist on teamwork*
Papaspyros et al[36]	Patient-specific preoperative briefing and postoperative de-briefing checklist	Outcome: Perceived quality of communication Tool: Interviews	Qualitative interview study postintroduction of briefings/checklist 15 interviewees Anesthesiologists, perfusionists, scrub nurses, and technicians	The checklist/briefings were perceived to have improved communication in the OR	Small sample size No control (lack of prechecklist assessments) Qualitative analysis of attitudes only—no significance testing *No validity/reliability data available for interview approach*
Calland et al[37]	Patient-specific safety checklist with pre-, intra-, and postoperative components	Outcome: Observed team coordination and communication. Perceived team communication and situational awareness. Tool: Observations of team coordination and communication by experts using the RATE tool from video recordings. Multiple items on study-specific questionnaire	RCT—control group and checklist/intervention group. Observations conducted retrospectively. Surveys conducted postprocedure Control group = no checklist—23 cases observed, 142 survey respondents Intervention group = checklist—24 cases observed, 139 survey respondents	Observations: Favorable team communication and coordination behaviors were rated higher in the intervention group. Surveys: Perceptions of team efficiency and communication were poorer in the intervention group. Perceptions of situational awareness did not significantly differ between groups.	Some residents and other staff may have contributed in both intervention and control cases—possible contamination of results (the attending surgeon was the only team member who was clearly assigned to either control or intervention group). The checklist was not always performed as intended *No mention of origin of questionnaire item and no psychometric data presented* *Researchers who scored video observations were not blinded to experimental group* *Only 1 questionnaire item related to impact of checklist on team communication*

(*continued*)

TABLE 3. (*Continued*)

Authors	Type of Checklist	Outcome and Tool	Design and Sample	Findings	Limitations*
Haynes et al[38]	WHO Surgical Safety Checklist	Outcome: Perceived teamwork climate Tool: Shortened version of the Safety Attitudes Questionnaire (SAQ) + study specific questionnaire—in total 2 "team"-related items	Pre/postsurvey study. (SAQ administered pre and post, study-specific questionnaire administered post only) Pre: 281 respondents Post: 257 respondents All clinical disciplines participated (surgeons, nurses, and anesthesiologists)	No significant difference between pre/postscores for SAQ item relating to teamwork in the OR ("The physicians and nurses here work together as a well-coordinated team"). Majority (84.8%) agreed checklist improved OR communication on study-specific questionnaire.	Did not track survey response rate so unsure if data representative Sites volunteered so results may not be generalizable Potential bias in survey responses because clinicians aware of project. *Only 2 questionnaire items related to impact of checklist on teamwork* *No validity/reliability data available for questionnaire*
Helmio et al[39]	WHO Surgical Safety Checklist	Outcome: Perceived communication between OR team members, discussion of critical events, and awareness of OR team members' names Tool: 3 "team"-related items on a study-specific questionnaire	Pre/postsurvey study Pre = 288 respondents Post = 412 respondents All OR staff	Surgeons and anesthesiologists were significantly more likely to report that they knew OR team members' names and that critical events had been discussed after checklist implementation. Anesthesiologists and nurses were significantly more likely to agree that there was successful communication after checklist implementation.	*Only 2 questionnaire items related to impact of checklist on teamwork*
Takala et al (same group as above)[40]	WHO Surgical Safety Checklist	Outcome: Perceived communication between OR team members, and awareness of OR team members' names Tool: 3 "team" items on a study-specific questionnaire	Pre/postsurvey study Pre = 901 respondents Post = 847 respondents Circulating nurses, anesthesiologists, and surgeons	Circulating nurses and anesthesiologists (but not surgeons) reported significantly improved communication after checklist implementation. There was a significant improvement for all subteams in perceived knowledge of team members' names and roles postchecklist. Anesthesiologists and surgeons reported a significant improvement in the number of cases in which critical events were discussed after checklist implementation. Operations in which failed communication was deemed to have occurred significantly reduced after checklist implementation Congruence between subteams (surgeons, anesthesiologists, and nurses) in terms of perceived communication failures was low	The heterogeneity of the participating specialties may be considered a weakness

(*continued*)

TABLE 3. (*Continued*)

Authors	Type of Checklist	Outcome and Tool	Design and Sample	Findings	Limitations*
Kearns et al[41]	Modified WHO Surgical Safety Checklist	Outcome: Perceived quality of OR communication and familiarity with team members Tool: 2 "team" items on a study-specific questionnaire	Pre/postsurvey study Pre = 53 respondents Post = 46 respondents Midwives, auxiliaries, obstetric trainees, anesthesiology residents, anesthetic nurses, attending anesthesiologists, attending obstetricians	Significantly more OR staff agreed that they felt familiar with others after checklist implementation 69.6% of staff agreed that the checklist had improved OR communication Nonmedical staff were significantly more likely than medical staff to believe that the checklist had improved communication	*Statistical difference between pre- and postquestionnaire answers not presented for communication item—only for familiarity item* *Only 2 questionnaire items related to impact of checklist on teamwork* *No mention of origin of questionnaire items and no validity/reliability data available*
Sewell et al[42]	WHO Surgical Safety Checklist	Outcome: Perceived team communication and teamwork Tool: 1 "team"-related item on a study-specific questionnaire	Pre/postsurvey study Pre = 100 respondents Post = same 100 respondents Surgeons, anesthesiologists, nurses, and allied health professionals	Agreement that the checklist improves communication and teamwork increased from 47% pre to 77% post.	*No mention of origin of questionnaire items and no validity/reliability data available* *Only 1 questionnaire item related to impact of checklist on teamwork* *Statistical significance of findings not presented*
Bohmer et al[43]	Modified WHO Surgical Safety Checklist	Outcome: Perceived interprofessional coordination, team communication, and familiarity with other staff members Tool: Multiple "team" items on a study-specific questionnaire	Pre/postsurvey study 71 respondents altogether Medical staff and other personnel involved in surgery	Anesthesiology department: Physicians reported significantly better familiarity with team members (team members' names/functions), interprofessional coordination, and communication regarding intraoperative complications, after introduction of the checklist. Department of Traumatology: Physicians reported significantly better assignment of tasks within the operating room after introduction of the checklist.	*No mention of origin of questionnaire items and no validity/reliability data available*

OR indicates operating room; ORBAT, OR Briefing Assessment Tool; ORTAS, OR Teamwork Assessment Scale; RCT, randomized controlled trial; SAQ, Safety Attitudes Questionnaire; WHO, World Health Organization.
*The text not in italics is reported by the author; the text in italic is our critical appraisal.

impacts were also observed). These included disrupting positive communication (eg, by the checklist itself becoming the focus and detracting from the sense of exchange between the team members, or by disrupting the natural flow of information in the OR), reinforcing professional divisions (eg, by leaving certain individuals or professional groups out of the checking process), and creating tension (eg, in coordinating unwilling team members, interrupting work routines, and exposing individuals' knowledge gaps).[30]

360° Ratings of Teamwork/Communication

Paige and colleagues[31] found that peer-assessed teamwork scores significantly increased following introduction of the checklist but self-assessed teamwork scores did not.

DISCUSSION

Checklists are increasingly becoming part of routine practice for ensuring safety in ORs, and their use has been linked to improved rates of mortality and morbidity.[15–22] A key mechanism through which safety checklists are intended to bring improvements to surgical care is by promoting better teamwork and communication in the OR. This is a point often argued by checklist developers and implementers[22,23,47] yet not scientifically reviewed to date. The current review aimed to examine the existing evidence base and to evaluate the claim that checklists do indeed foster such team skills.

The 20 articles included in the review were heterogeneous in terms of the methodology used to assess the impact of the checklist on teamwork/communication, largely because team skills were not always the primary outcome assessed. Nonetheless, there was a good degree of concordance between the results of individual studies. The following findings emerged:

- Self-perceptions of teamwork and communication improved following the implementation of safety checklists.[24–27,32,35,36,39–43]
- There was a reduction in visible consequences of poor communication and near-misses associated with communication errors after the checklist implementation.[29,33,34]
- The observed mechanisms through which checklists improved teamwork centered around establishing an open dialogue at the start of the case, promoting provision of case-related information, revealing knowledge gaps, encouraging articulation of concerns, provoking a change in the care plan, supporting interdisciplinary decision making and coordination, and enhancing team "feeling."[25,26,35,43]
- Where there were interdisciplinary differences in the impact of the checklist, the evidence tends to show that OR nursing personnel perceive maximum benefit to team working as a result of checklists, surgeons perceive least positive impact, and anesthesiologists fall in between.[39–41]

Although the evidence on the whole supports a highly functional impact of safety checklists on teamwork in the OR, not all of the findings were positive. Four studies reported mixed results, noting some beneficial impacts on the team when using certain measures, but no benefits when using others.[28,30,37,38] One study reported worse situational awareness for anesthesiologists when a checklist was used; however, this was based on using the checklist in just 1 simulated scenario and thus the generalizability of the findings is limited.[28] Another study outlined some of the paradoxically adverse effects a safety checklist can have on communication.[30] Whyte et al[30] describe how positive communication might actually be disrupted by the "staged" nature of the interaction that sometimes occurs during checking. In other instances, if teams choose to maintain their positive communications at the point in time they have always done so, rather than waiting for the "Time-out" or checking process, the checklist can become a redundant and even "boring" repetition of information. This puts it at risk of becoming nothing more than a tick-box exercise, promoting a degree of complacency in the system. Checklists might also create a false sense of security that critical information has been communicated, when in fact a lack of real engagement in the checking process means that things may not have been checked as rigorously as they would have been otherwise. In addition, if team members differ in the degree to which they have bought into the system, a checklist might antagonize team relationships/interactions and accentuate hierarchy gradients. Lingard and colleagues[29] emphasized that although they observed a positive impact of their safety checklist in reducing communication failures, they also encountered several cultural and team barriers that had challenged successful implementation of the tool. These included a reluctance of staff to alter their habitual workflow, a perceived threat to individual excellence, prioritization of other tasks, staff shortages, and educational duties. Such barriers, they advised, should be anticipated and strategically mitigated prior to implementation of checklists.[29]

Limitations and Implications for Future Research

The heterogeneity of research design, methodology, and study quality of the included articles (sample size, inclusion of methodological controls, etc) was recognized as a significant limitation of the research available in this area and it meant that a formal meta-analysis was not possible. This limitation has been recognized elsewhere in a review of safety checklists.[48] Many of the articles assessed multiple end-points in addition to teamwork/communication, for example, process measures (eg, delays, equipment issues, compliance with procedures) and/or patient outcome measures (eg, complication rates, mortality rates). At times this made it difficult to tease apart the various effects being reported and to identify the impact the checklist had on teamwork/communication skills specifically, indicating that the number of end-points assessed at one time should be limited. In particular, the lack of standardized, valid assessment of the quality of teamwork/communication stood out as a weakness. Nine of the 13 survey studies reported on the use of study-specific ad hoc developed questionnaires, 7 of which had not been validated, and many of which contained just 1 or 2 items relating to teamwork and/or communication. Similarly, the observational tools varied considerably with regard to the quality of the data available to support their validity/reliability. Valid, reliable, and consistent assessment of team performance is essential for making full-bodied reliable conclusions regarding the impact of safety checklists. This would suggest that it is necessary to take caution in interpreting the results from some of these studies and that more focused studies are required where the scope of the impact of checklists is limited to measuring clearly defined outcomes relating to teamwork and communication dimensions alone, and using validated, reliable scales. Several such tools are now available for measuring the quality of teamwork, via either self-report or observation in the OR in a scientific, reliable, and valid manner, for example, the Teamwork Climate Sub-scale of the Safety Attitudes Questionnaire[44,49] and the Observational Teamwork Assessment for Surgery instruments,[6,50,51] respectively. By adopting these validated tools and steering away from the use of ad hoc developed assessment tools, standardized terminology for describing the specific team performance elements being assessed can also emerge. In this review, we found great variation in the terminology used between the studies, which made it difficult to make cross-study comparisons and to draw out patterns in the evidence base.

In addition to the choice of assessment tool/instrument, the study design also varied greatly. Five of the 20 studies reviewed included no baseline/control assessment of teamwork/communication and thus only assessed the improvement in team skills retrospectively, which has limitations. We would recommend that to make reliable conclusions regarding the impact of checklists, future studies

should include baseline assessments of teamwork/communication, should take into account the need for an implementation phase (ie, an allowance of time for the checklist to be incorporated into practice and to iron out any initial teething problems), and then assess the same team skills postimplementation in a longitudinal fashion such that both initial and sustained impacts can be determined.

A final limitation of the available literature was a failure to adequately associate *how well* a checklist was used (ie, the quality of its implementation) with the impact it had on teamwork/communication. Although 2 of the articles reported an overall association between increased compliance with using the checklist and an improvement in teamwork[40,42] none of the articles related specific characteristics of checklist usage (eg, who led the checks, who was present, who paused, who contributed, how much/what information was exchanged, how long it took) to the quality of teamwork. This will be important to address in future research for developing an understanding of "best practice" in using checklists in surgery. Tools for systematically assessing variation in the quality of checklist usage are, therefore, necessary and should be developed as part of future research in this area.

Implications for Surgical Practice

Despite the limitations mentioned earlier, this review highlights a positive association between the use of safety checklists and the quality of teamwork in the OR. This may represent one mechanism through which safety checklists result in improvements to clinical outcomes and compliance with clinical processes.[8–15] However, the potential adverse effects of checklists and barriers surrounding their successful implementation that were also highlighted indicate that incorporating these structured tools into the busy, interdisciplinary OR environment is unlikely to be without challenge and that the strategy undertaken during their introduction may moderate the extent of the impact they bring about.[29,30,48,52] Although checklists have clear face validity as communication and safety tools, it is important to emphasize that just making them available in the OR or requiring OR personnel to start using them does not necessarily equate to better patient outcomes and better team working.[53] Indeed, poor usage of a checklist can have *dysfunctional* effects for the team. Given these findings, team training and education focused on instilling effective/optimal use of checklists, embedded into the OR work routine should be provided. In addition to training, a strategic and inclusive approach should be taken during their introduction to clinical practice. Enlisting all stakeholders' (ie, including OR professionals or potentially also the patients) input into checklist design and customization will likely be important in promoting buy-in and ensuring that the tool ascribes to the frontline and end user's logic of communication. Once a checklist has been produced, its introduction should be planned in advance and complemented by training and education where necessary (eg, checklists can be introduced as part of wider team training or surgical quality improvement programs, as has been reported by some institutions).[54,55] Some flexibility and accessibility to modification (for local circumstances or for a specialty) will also be important, and regular systematic feedback on the impact of the checklist on local surgical performance (including process and outcome measures) should be integrated in the implementation approach.[14,48]

Auditing of the use of checklists is also likely to be an area that requires careful consideration. The audits presented in the articles reviewed[32,40,42] were very much centered around binary compliance with checklist usage, that is, whether the checklist was completed or not, whether the form was signed, or whether certain items of the checklist were completed. This pattern resembles our own experience of the audit approach commonly undertaken in hospitals in the United Kingdom. While such audits give a broad impression of checklist uptake, they tell us little about the degree to which the checklist stimulates safety-related conversations between team members or acts as a platform for interdisciplinary communication. We take the view that more meaningful audits will emerge when we start using tools that are able to capture how exactly checklists are actually used within the busy OR setting on a daily basis and the implications this has for teamwork. Such data will likely tell us much more about whether and how checklists are becoming truly embedded within surgical practice and also what works well/not so well when such checklists are used (so they can be reviewed and modified as necessary). The currently prevalent "tickbox" approach to auditing checklist usage is not adequate.

On a wider scale, a focus on fostering a strong culture for safety within a hospital is also important for the implementation of checklists and other safety interventions. We hypothesize that a strong safety culture will increase the chance of checklists being used in the "true spirit" rather than simply being seen as a bureaucratic irritation. When completed poorly or when lacking engagement (particularly at a senior level), not only will checklists have the potential to disrupt team function, but this also likely sends out a negative message that it is not a priority to improve communication in an organization.[30] This is an important by-product of checklist implementation and we propose that it should be acknowledged and monitored at an early stage of the implementation strategy. Finally, when implementing checklists, it will be important to take into account the limitations of such interventions. Checklists can act as an inexpensive and potentially effective means to promote safety and communication in a team, but they certainly cannot address underlying systemic problems—like, for example, very low staffing levels that result in very unstable teams.[53,56] It will, therefore, be important to integrate the use of safety checklists into more comprehensive safety and quality improvement packages that take into account such systemic problems and contextual factors (eg, skills mix, task demands, infrastructure, technological resources, work environment, organizational reward systems) and have the support of social networks with a shared "safety vision" that is reinforced across the system. Well-implemented checklists are effective, but not a panacea that can solve all problems.[9,53]

CONCLUSIONS

This systematic review reveals that safety checklists improve both perceived and observed teamwork and communication in the OR. Given the close association between teamwork and patient safety, these results suggest that the optimization of safety checklists in surgery should be a priority for the prevention of surgical error. Surgeons should remain aware of the potential negative impacts a checklist might have on communication and team function when not used well. How a checklist is designed and implemented requires a strategic approach, with significant input and leadership from surgeons and other OR professionals.

REFERENCES

1. Gawande A. *The Checklist Manifesto: How to Get Things Right*. Metropolitan Books of Henry Holt and Co, New York, US; 2011.
2. World Alliance for Patient Safety. Safe surgery saves lives: second global patient safety challenge. http://www.who.int/patientsafety/safesurgery/knowledge_base/SSSL_Brochure_finalJun08.pdf. Accessed May 15, 2012.
3. Weiser TG, Regenbogen SE, Thompson KD, et al. An estimation of the global volume of surgery: a modelling strategy based on available data. *Lancet.* 2008;372:139–144.
4. Robbins J. Hospital checklists: transforming evidence-based care and patient safety protocols into routine practice. *Crit Care Nurs Q.* 2011;34:142–149.
5. WHO Surgical Safety Checklist. http://www.who.int/patientsafety/safesurgery/tools_resources/SSSL_Checklist_finalJun08.pdf. Accessed October 09, 2013.
6. Undre S, Sevdalis N, Vincent C. Observing and Assessing Surgical Teams: The Observational Teamwork Assessment for Surgery (OTAS). In: *Safer Surgery:*

Analysing Behaviour in the Operating Theatre. Ashgate Publishing Ltd, Farnham, Surrey, UK; 2009:Chapter 6.

7. Arora S, Sevdalis N, Nestel D, et al. The impact of stress on surgical performance: a systematic review of the literature. *Surgery.* 2010;147:318–330.
8. Haynes AB, Weiser TG, Berry WR, et al. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Eng J Med.* 2009;360:491–499.
9. Weiser TG, Haynes AB, Dziekan G, et al. Effect of a 19-item surgical safety checklist during urgent operations in a global patient population. *Ann Surg* 2010;251:976–980.
10. De Vries E, Dijkstra L, Smorenburg S, et al. The Surgical Patient Safety System (SURPASS) checklist optimizes timing of antibiotic prophylaxsis. *Patient Saf Surg.* 2010;4:6.
11. Paull DE, Mazzia LM, Wood SD, et al. Briefing guide study: preoperative briefing and postoperative debriefing checklists in the Veterans Health Administration medical team training program. *Am J Surg.* 2010;200:620–623.
12. Buzink SN, Lier L, de Hingh I, et al. Risk-sensitive events during laparoscopic cholecystectomy: the influence of the integrated operating room and preoperative checklist tool. *Surg Endosc.* 2010;24:1990–1995.
13. De Vries EN, Prins HA, Crolla RMPH, Den Outer AJ, Van Andel G, Van Helden SH, et al. Effect of a comprehensive surgical safety system on patient outcomes. *N Eng J Med*. 2010;363:1928–1937.
14. Askarian M, Kouchak F, Palenik CJ. Effect of surgical safety checklists on postoperative morbidity and mortality rates, Shiraz, Faghihy Hospital, a 1-year study. *Qual Manag Health Care.* 2011;20:293–297.
15. Lingard L, Regehr G, Cartmill C, et al. Evaluation of a preoperative team briefing: a new communication routine results in improved clinical practice. *BMJ Qual Saf.* 2011;20:475–482.
16. Neily J, Mills PD, Eldridge N, et al. Incorrect surgical procedures within and outside of the operating room. *Arch Surg.* 2009;144:1028–1034.
17. Healey AN, Nagpal K, Moorthy K, et al. Engineering the system of communication for safer surgery. *Cogn Technol Work.* 2011;13:1–10
18. Greenberg CC, Regenbogen SE, Studdert DM, et al. Patterns of communication breakdowns resulting in injury to surgical patients. *J Am Coll Surg.* 2007;204:533–540.
19. Rogers SO, Gawande AA, Kwaan M, et al. Analysis of surgical errors in closed malpractice claims at 4 liability insurers. *Surgery.* 2006;140:25–33.
20. Williams RG, Silverman R, Schwind C, et al. Surgeon information transfer and communication: factors affecting quality and efficiency of inpatient care. *Ann Surg.* 2007;245:159–169.
21. Hull L, Arora S, Aggarwal R, et al. The impact of nontechnical skills on technical performance in surgery: a systematic review. *J Am Coll Surg.* 2001;214:214–230.
22. World Health Organization. Implementation Manual WHO Surgical Safety Checklist 2009. http://whqlibdoc.who.int/publications/2009/9789241598590_eng.pdf. Accessed May 15, 2012.
23. The Joint Commission. Facts about the universal protocol. http://www.jointcommission.org/facts_about_the_universal_protocol/. Published 2013. Accessed March 13, 2013.
24. DeFontes J, Surbida S. Preoperative safety briefing project. *Perm J.* 2004;8:21–27.
25. Lingard L, Espin S, Rubin B, et al. Getting teams to talk: development and pilot implementation of a checklist to promote interprofessional communication in the OR. *Qual Saf Health Care.* 2005;14:340–346.
26. Makary MA, Mukherjee A, Sexton B, et al. Operating room briefings and wrong-site surgery. *J Am Coll Surg.* 2007;204:236–243
27. Nundy S, Mukherjee A, Sexton B, et al. Impact of preoperative briefings on operating room delays: a preliminary report. *Arch Surg.* 2008;143:1068–1072.
28. Koutantji M, McCulloch P, Undre S, et al. Is team training in briefings for surgical teams feasible in simulation? *Cogn Technol Work.* 2008;10:275–285
29. Lingard L, Regehr G, Orser B, et al. Evaluation of a preoperative checklist and team briefing among surgeons, nurses, and anesthesiologists to reduce failures in communication. *Arch Surg.* 2008;143:12–17.
30. Whyte S, Lingard L, Espin S, et al. Paradoxical effects of interprofessional briefings on OR team performance. *Cogn Technol Work.* 2008;10:287–294.
31. Paige JT, Aaron DL, Yang T, et al. Implementation of a preoperative briefing protocol improves accuracy of teamwork assessment in the operating room. *Am Surg.* 2008;74:817–823.
32. Berenholtz S, Schumacher K, Hayanga A, et al. Implementing standardized operating room briefings and debriefings at a large regional medical centre. *Jt Comm J Qual Patient Saf.* 2009;35:391–397
33. Henrickson S, Wadhera R, ElBardissi A, et al. Development and pilot evaluation of a preoperative briefing protocol for cardiovascular surgery. *J Am Coll Surg.* 2009;208:1115–1123.
34. Einav Y, Gopher D, Kara I, et al. Preoperative briefing in the operating room: shared cognition, teamwork, and patient safety. *Chest.* 2010;137:443–449.
35. Nilsson L, Lindberget O, Gupta A, et al. Implementing a pre-operative checklist to increase patient safety: a 1-year follow-up of personnel attitudes. *Acta Anaesthesiol Scand.* 2010;54:176–182.
36. Papaspyros SC, Javangula KC, Adluri RKP, et al. Briefing and debriefing in the cardiac operating room. Analysis of impact on theatre team attitude and patient safety. *Interact Cardiovasc Thorac Surg.* 2010;10:43–47.
37. Calland JF, Turrentine FE, Guerlain A, et al. The surgical safety checklist: lessons learned during implementation. *Am Surg.* 2011;77:1131–1137.
38. Haynes AB, Weiser TG, Berry WR, et al. Changes in safety attitude and relationship to decreased postoperative morbidity and mortality following implementation of a checklist-based surgical safety intervention. *BMJ Qual Saf.* 2011;20:102–107.
39. Helmio P, Blomgren K, Takala A, et al. Towards better patient safety: WHO Surgical Safety Checklist in otorhinolaryngology. *Clin Otolaryngol.* 2001;36:242–247.
40. Takala R, Pauniaho S, Kotkansalo A, et al. A pilot study of the implementation of WHO Surgical Checklist in Finland: improvements in activities and communication. *Acta Anaesthesiol Scand.* 2011;55:1206–1214.
41. Kearns RJ, Uppal V, Bonner J, et al. The introduction of a surgical safety checklist in a tertiary referral obstetric centre. *BMJ Qual Saf.* 2011;29:818–822.
42. Sewell M, Adebibe M, Jayakumar P, et al. Use of the WHO surgical safety checklist in trauma and orthopaedic patients. *Int Orthop.* 2011;35:897–901.
43. Bohmer A, Wappler F, Tinschmann T, et al. The implementation of a perioperative checklist increases patients' perioperative safety and staff satisfaction. *Acta Anaesthesiol Scand.* 2012;56:332–338.
44. Sexton JB, Helmreich RL, Neilands TB, et al. The Safety Attitudes Questionnaire: psychometric properties, benchmarking data, and emerging research. *BMC Health Serv Res.* 2006;6:44.
45. Lingard L, Regehr G, Espin S, et al. A theory-based instrument to evaluate team communication in the operating room: balancing measurement authenticity and reliability. *Qual Saf Health Care.* 2006;15:422–426.
46. Sevdalis N, Davis R, Koutantji M, et al. Reliability of a revised NOTECHS scale for use in surgical teams. *Am J Surg.* 2008;196:184–190.
47. De Vries EN, Hollmann MW, Smorenburg SM, et al. Development and validation of the SURgical PAtient Safety System (SURPASS). *Qual Saf Health Care.* 2009;18:121–126.
48. Borchard A, Schwappach D, Barbir A, et al. A systematic review of the effectiveness, compliance and critical factors for implementation of safety checklists in surgery. *Ann Surg.* 2012;256:925–933.
49. Sexton JB, Makary MA, Tersigni AR, et al. Teamwork in the operating room: frontline perspectives among hospitals and operating room personnel. *Anesthesiology.* 2006;105:877–884.
50. Russ S, Hull L, Rout S, et al. Observational teamwork assessment for surgery: feasibility of clinical and non-clinical assessor calibration with short-term training. *Ann Surg.* 2012;255:804–809.
51. Hull L, Arora S, Kassab E, et al. Observational teamwork assessment for surgery: content validation and tool refinement. *J Am Coll Surg.* 2011;212:234–243.
52. Vats A, Vincent C, Nagpal K, et al. Practical challenges of introducing WHO surgical checklist: UK pilot experience. *BMJ.* 2010;340:b5433.
53. Bosk CL, Dixon-Woods M, Goeschel CA, et al. The art of medicine—reality check for checklists. *Lancet.* 2009;374:444–445.
54. Awad S, Fegan S, Bellows C, et al. Bridging the communication gap in the operating room with medical team training. *Am J Surg.* 2005;190:770–774.
55. Paull D, Mazzia L, Wood S, et al. Briefing guide study: preoperative briefing and postoperative debriefing checklists in the Veterans Health Administration medical team training program. *Am J Surg.* 2010;200:620–623.
56. Sevdalis N, Hull L, Birnbach DJ. Improving patient safety in the operating theatre and peri-operative care: obstacles, interventions, and priorities for accelerating progress. *Br J Anaesth.* 2012;109:i3-i16.

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How Does TeamSTEPPS Affect Operating Room Efficiency?

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Abstract

Objective. To evaluate the effect of TeamSTEPPS (Team Strategies and Tools to Enhance Performance and Patient Safety) on operating room efficiency for the otolaryngology service at a tertiary care medical center.

Study Design. Retrospective database review.

Setting. Otolaryngology department at tertiary care medical center.

Subjects and Methods. To assess the impact of implementing an evidence-based patient safety initiative, TeamSTEPPS, on operating room efficiency in the otolaryngology department, the operative times, time lost to delayed starts, and turnover times during the year following the implementation of TeamSTEPPS were compared with the values from the prior year.

Results. The study compared 1322 cases and 644 turnovers in the year prior to TeamSTEPPS implementation with 1609 cases and 769 turnovers in the following year. There were no statistically significant decreases in operating room efficiency in the year after the TeamSTEPPS rollout.

Conclusion. Operating room efficiency was preserved after the rollout of a rigorous evidence-based patient safety initiative that requires active participation from all operating room team members.

Keywords

TeamSTEPPS, operating room efficiency, quality improvement

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The modern medical system seeks to optimize patient safety, quality, and experience, as there is increased focus placed on the disparate levels of cost and quality in the health care system.[1] The operating room (OR) is an area of this system under particular scrutiny because it is a high-stakes environment in terms of both risk for adverse events and high costs.[2,3] In addition, 66% of all medical mistakes occur in ORs, and 54% of these mistakes are preventable.[4] A growing body of research suggests that medical errors are primarily due to communication failures and ineffective leadership within surgical teams.[5] This has led to the development and implementation of systems aimed at improving teamwork and communication within surgical teams.[6]

TeamSTEPPS (TS; Team Strategies and Tools to Enhance Performance and Patient Safety) is one such patient safety tool that was developed by the Department of Defense and the Agency for Healthcare Research and Quality and has been implemented across the nation. The program is based on 4 core competencies: leadership, situational monitoring, communication, and mutual support. The ultimate goal is to improve communication and teamwork among healthcare teams.[7] The basis of TS in the OR is the preoperative briefing, which is analogous to a preflight checklist in the airline safety community.[3] In each OR, a morning briefing is conducted 30 minutes prior to the start of the first case. The attending surgeon, attending anesthesiologist or nurse anesthetist, circulating nurse, and OR technician are all present for the briefing, lasting 5 to 10 minutes. Team members are introduced by name, and the topics typically covered are detailed in **Figure 1**. Additionally, a quick debrief is conducted at the end of each case to ensure correct instrument counts, clarify postoperative plan for the patient, and discuss ways in which the team could

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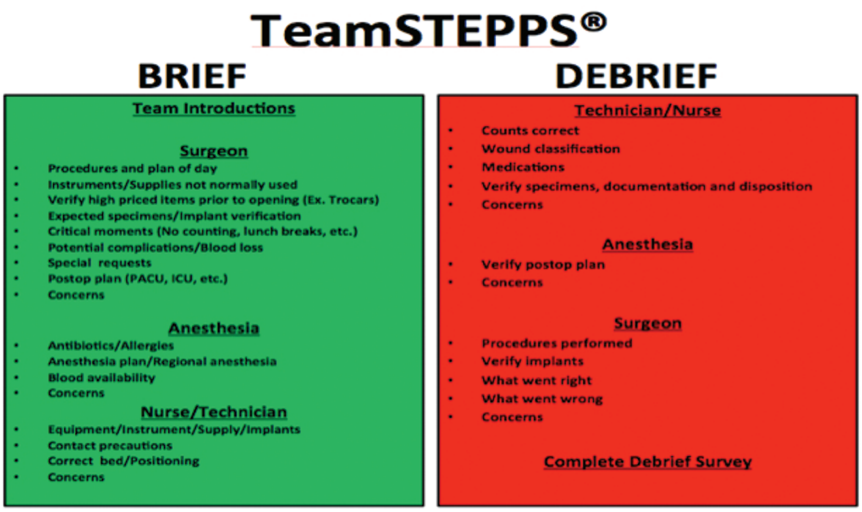

Figure 1. Graphic posted in each operating room used to guide TeamSTEPPS brief/debrief.

operate more safely and effectively in the future. All team members are encouraged to provide feedback during the morning briefing and the postoperative debriefings; this is a central aspect of TS because it helps to eliminate rigid hierarchies that can be detrimental to patient safety. Nonphysician team members often have important observations that can positively affect patient safety, but rigid hierarchies in the OR traditionally would bar them from such communication.

Multiple authors have validated TS as an effective tool that increases patient safety, team member satisfaction, and communication,[6,8] but few studies have examined its impact on the team's efficiency. Though improved efficiency is not a primary goal of TS, it is important to understand how such a program influences OR efficiency given the ever-increasing demands on health care providers. A recent study conducted by the urology department at our institution showed significant improvements in OR efficiency after the implementation of TS.[8] The goal of this study was to examine the changes in efficiency within the otolaryngology department at the same institution to evaluate whether changes attributed to TS are universal or variable between departments.

Methods

This study was exempt from Institutional Review Board review at the San Antonio Military Medical Center as a quality improvement and patient safety project. TS was implemented in ORs at our institution on November 13, 2013, after all OR personnel had been trained in the program using a series of didactic sessions. This study measured OR efficiency in the year preceding and the year following the implementation of TS. A retrospective database review of our institution's OR and anesthesia logs was conducted to measure the surgeon's operating time, total case time, turnover time, and on-time first start rates for the ear/nose/throat (ENT) department. The anesthesia log records patient movement and begins recording data when the patient is first seen in the preanesthesia holding area. Team members manually time-stamp a variety of events during a case, including the time that the patient entered the room, the time that anesthesia turned the patient over to the surgeon, incision time, operating time, and the time that the patient left the OR.

Various time intervals were calculated from the anesthesia log for all the ENT cases to measure the team's efficiency. ''Surgeon time'' is the interval from the surgeon's first incision to the time that the surgeon completed the case. ''Case time'' spans the entire time that the patient was in the OR. ''Turnover time'' is the interval of cases logged from the time that the patient leaves the room to the time that the next patient enters the room. The ''on-time first start rate'' measures how often the OR day begins at the assigned time. An ''on-time start'' is defined as the patient entering the OR at or before the scheduled start time for the case, typically 7:30 AM. The turnover time data and delayed start data are recorded daily in the institution's computerized OR log, kept by the circulating nurse. These intervals (with the exception of on-time first start data) were all measured for a year before (November 12, 2012, to November 12, 2013) and after (November 13, 2013, to November 13, 2014) TS was implemented. The first start data were measured for only the 6 months before (May 12, 2013, to November 12, 2013) and after (November 13, 2013, to May 13, 2014) TS began because of changes to the ENT service OR schedule that occurred in July 2014. To evaluate the statistical significance of these intervals before and after TS, the data were compared with a *t* test for the majority of the intervals, and a chi-square test was used for the percentage of on-time first case start data.

We began evaluating TS immediately after its implementation and did not allow for a ''washout'' interval while the health care team became acclimated to the program. We chose to start measuring efficiency changes immediately after implementation because the providers had completed extensive training before the program began, thereby obviating the need for an adjustment period. Furthermore we

Table 1. Operating Room Efficiency Data Collected from Anesthesia and Nursing Logs for the Year before and after TeamSTEPPS Implementation.

	TeamSTEPPS		
	Before	After	*P* Value
Total, n			
Cases	1322	1609	
Turnovers	644	769	
First starts in year	497	677	
First starts in 6 mo	231	336	
On-time starts in 6 mo, n (%)	107 of 231 (46.3)	171 of 336 (50.8)	.28
Average time, min			
Turnover	35.2	41.4	.54
In room to turnover-to-surgeon	11.6	12.1	.63
Turnover-to-surgeon to surgical start	17.0	17.8	.11
Surgeon	107	111.6	.32
Total case	147	152.0	.40

believe that maintaining efficiency during the initial months after a TS rollout are essential to keeping team member ''buy-in'' for the program. Allowing for a washout interval would therefore have weakened the relevance of our conclusions. However, we did measure the efficiency intervals for the first 6 months after TS implementation separately as a check to examine whether there were differences in the intervals that could be attributed to washout.

Results

The study compared 1322 cases and 644 turnovers in the year prior to TS with 1609 cases and 769 turnovers in the year following the implementation of the program. **Table 1** shows the OR efficiency data before and after the TS rollout. There was no statistically significant change in any of the efficiency metrics after the TS rollout. **Table 2** shows the OR efficiency for the first 6 months after TS rollout, and these data show no major differences from the 1-year intervals.

Table 2. Data in 6-Month "Washout" Period after TeamSTEPPS Implementation.

	After TeamSTEPPS, 6 mo
Cases, n	784
Average time, min	
In room to turnover-to-surgeon	13.7
Turnover-to-surgeon to surgical start	19.1
Surgeon	112.4
Total case	153.3

Discussion

TS has been shown to improve patient safety by fostering better communication, teamwork, and leadership among OR personnel.[3] Due to extraordinary operating costs, hospitals are financially motivated to minimize delays in the OR.[2] Such motivation could cause hesitation in adopting TS, despite the growing body of literature that supports its utility in improving patient safety. Widespread adaptation of TS would be difficult if it caused significant delays in and around the OR; thus, it is important to consider the potential for decreases in efficiency before adapting new policies or procedures. Several other authors have suggested that TS could, in fact, improve surgical case times and decrease OR delays.[8,9] One such study was conducted by the urology service at our institution, and it showed decreased mean case times within the department in the year following the implementation of TS.[8] However, the study did not include data from other surgical services. To our knowledge, there are no published examinations of how TS affects efficiency in an otolaryngology service.

OR times and turnover times are well-recognized measures of hospital efficiency. Not only do hospitals have financial motivation to minimize lost time in the OR due to high operating costs,[2] but there are potential patient benefits of decreased anesthesia time and better satisfaction due to shorter wait times.[1] The results of this study suggest that TS is not changing OR efficiency significantly in the ENT department at our institution. The lack of impact that TS has had on efficiency does not reflect negatively on the program's overall merit, because TS is a tool aimed primarily at improving patient safety. To the contrary, the fact that TS does not compromise efficiency will lead to hospitals continuing it as a patient safety measure without concern for adverse effects on the financial bottom line. Our study is not powered to measure the impact of TS on patient safety. Because sentinel events such as retained sponges and wrong site surgeries are relatively rare, more data are needed to determine if TS is having the expected positive impact on patient safety within the ENT department.

Weaknesses of this study include its retrospective nature and the fluidity of a large surgical department. The ENT service performed 287 more cases with 125 more turnovers in the year following the implementation of TS than it did the year prior. These differences may have served as confounding variables if there had been a significant change in OR efficiency in either direction. However, since efficiency was essentially the same, it is reasonable to assume that the departmental changes were not masking TS effects. Additionally, we began evaluating TS immediately after its implementation and did not allow for a ''washout'' interval while the health care team adjusted to the program. We chose to start measuring efficiency changes immediately after implementation because the providers had completed extensive training before the program began, which should have minimized the adjustment period. Nevertheless, there may have been some initial decrease in efficiency due to the process change in the OR. We did examine the efficiency data for the first 6 months after TS implementation (**Table 2**), and the intervals were very similar to those measured at 12 months, which supports the idea that there was minimal washout effect.

Conclusion

TS did not lead to significant changes in efficiency within the otolaryngology surgical service in the year after its implementation. In fact, the ENT service at a major teaching hospital was able to maintain its OR efficiency despite adopting the rigorous TS patient safety initiative. Although TS is a highly acclaimed evidence-based method improving patient safety and teamwork, more study is needed to determine if it can decrease sentinel events and other preventable medical errors.

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Author Contributions

Alexandra Shams, data collection and interpretation, drafted manuscript, final approval, accountable for accuracy; **Mostafa Ahmed**, data collection and statistical analysis, prepare and edit manuscript, final approval, accountable for accuracy; **Nicholas J. Scalzitti**, interpretation and analysis of data, preparation and editing manuscript, final approval, accountable for accuracy; **Matthew Stringer**, data collection, data analysis, review and editing manuscript, final approval, accountable for accuracy; **N. Scott Howard**, data analysis and interpretation, review and editing manuscript, final approval, accountable for accuracy; **Stephen Maturo**, study design, data analysis, review and editing manuscript, final approval, accountable for accuracy.

Disclosures

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References

1. Kesselheim AS, Ferris TG, Studdert DM. WIll physician-level measures of clinical performance be used in medical malpractice litigation? *JAMA*. 2006;295:1831-1834.
2. Bacchetta MD, Girardi LN, Southard EJ, et al. Comparison of open versus bedside percutaneous dilatational tracheostomy in the cardiothoracic surgical patient: outcomes and financial analysis. *Ann Thorac Surgery*. 2005;79:1879-1885.
3. Clancy CM. TeamSTEPPS: optimizing teamwork in the perioperative setting. *AORN J*. 2007;86:18-22.
4. Gawande AA, Thomas EJ, Zinner MJ, Brennan TA. The incidence and nature of surgical adverse events in Colorado and Utah in 1992. *Surgery*. 1999;126:66-75.
5. Steelman VM. Excellence in perioperative management: establishing a culture of safety. *AORN J*. 2014;100:1-3.
6. Forse RA, Bramble JD, McQuillan R. Team training can improve operating room performance. *Surgery*. 2011;150:771-778.
7. Clapper TC, Ng GM. Why your TeamSTEPPS™ program may not be working. *Clinical Simulation in Nursing*. 2013;9:e287-e292.
8. Weld LR, Stringer MT, Ebertowski JS, et al. TeamSTEPPS improves operating room efficiency and patient safety [published online April 17, 2015]. *Am J Med Qual*.
9. Nundy S, Mukherjee A, Sexton JB, et al. Impact of preoperative briefings on operating room delays: a preliminary report. *Arch Surg*. 2008;143:1068-1072.

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ORIGINAL ARTICLE

MAYO CLINIC

Physician Attitudes About Maintenance of Certification: A Cross-Specialty National Survey

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Abstract

Objectives: To determine physicians' perceptions of current maintenance of certification (MOC) activities and to explore how perceptions vary across specialties, practice characteristics, and physician characteristics, including burnout.

Patients and Methods: We conducted an Internet and paper survey among a national cross-specialty random sample of licensed US physicians from September 23, 2015, through April 18, 2016. The questionnaire included 13 MOC items, 2 burnout items, and demographic variables.

Results: Of 4583 potential respondents, we received 988 responses (response rate 21.6%) closely reflecting the distribution of US physician specialties. Twenty-four percent of physicians (200 of 842) agreed that MOC activities are relevant to their patients, and 15% (122 of 824) felt they are worth the time and effort. Although 27% (223 of 834) perceived adequate support for MOC activities, only 12% (101 of 832) perceived that they are well-integrated in their daily routine and 81% (673 of 835) believed they are a burden. Nine percent (76 of 834) believed that patients care about their MOC status. Forty percent or fewer agreed that various MOC activities contribute to their professional development. Attitudes varied statistically significantly ($P<.001$) across specialties, but reflected low perceived relevance and value in nearly all specialties. Thirty-eight percent of respondents met criteria for being burned out. We found no association of attitudes toward MOC with burnout, certification status, practice size, rural or urban practice location, compensation model, or time since completion of training.

Conclusion: Dissatisfaction with current MOC programs is pervasive and not localized to specific sectors or specialties. Unresolved negative perceptions will impede optimal physician engagement in MOC.

For editorial comment, see page 1325

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Certification boards emerged in the United States in the early 20th century to ensure the competence of physicians completing formal training.[1,2] To accommodate concerns that physician knowledge and skills decline over time and that medical science changes, certification has evolved from a one-time event to a program of ongoing education and assessment—maintenance of certification (MOC).[1,3] Each member board of the American Board of Medical Specialties has developed an MOC program within a 4-part framework: professional standing, lifelong learning and self-assessment, assessment of knowledge and skills, and improvement in medical practice. Maintenance of certification has a sound theoretical rationale,[4] is favorably associated with some clinical quality measures,[4,5] and many physicians support its intent,[5-8] yet substantive concerns have been raised about the effectiveness, relevance, and value of current MOC programs.[2,6,9,10] This controversy is evidenced by letters,[11] editorials,[12-14] opinion polls,[15] petitions,[16] changes in program structure,[17] and efforts to create an alternative certification board.[18]

Despite its importance in the eyes of physicians and the public, and the vocal comments of individual authors,[11-14] empirical research on physician attitudes about MOC is surprisingly limited.[5] Research in the early days of MOC, although seminal in its time, is now out-of-date.[7] The Pennsylvania Medical Society's statewide cross-specialty survey in 2014 found widespread physician dissatisfaction with MOC in practice and concept.[19] In national surveys of board-certified US physicians, pediatricians voiced disinterest in and many concerns about

MOC[20]; anesthesiologists affirmed that they value continuing certification but have concerns about MOC implementation[8]; and internal medicine physicians expressed dissatisfaction with MOC.[21] A recent focus group study among internal medicine and family medicine physicians identified concerns about the value, relevance, integration, and coherence of and support for MOC as currently operationalized,[9] but the generalizability of these findings remains uncertain. We are not aware of any national cross-specialty investigations of physician attitudes and perceptions about MOC.

A broader understanding of the current opinions of physicians about MOC and how opinions vary among different physician specialties and subgroups is lacking. For example, physicians in small practices, rural communities, and productivity-based (vs salaried) positions and those later in their careers may perceive less relevance in MOC activities or greater difficulty meeting MOC requirements. Given recent concerns about physician wellness,[22,23] it is also important to determine the relationship between burnout and MOC perceptions. Such information could help certification boards and other stakeholders refine and improve MOC to better meet the needs of physicians and patients.

To address these gaps, we conducted a cross-specialty national survey of US physicians to determine physicians' perceptions of current MOC activities and to explore how their perceptions vary across specialties, practice models, certification status, and level of burnout.

METHODS

From September 23, 2015, through April 18, 2016, we surveyed licensed US physicians via a self-administered Internet and paper questionnaire. Survey items addressed attitudes about continuing professional development and MOC; this report focuses on those related to MOC.

Sampling and Human Subjects

We obtained contact and basic demographic information (specialty, sex, and practice location) for a random sample of 4648 licensed US physicians from the LexisNexis Provider Data Management and Services database (LexisNexis Risk Solutions). Web survey completion was tracked, but all survey responses were anonymized. We informed invitees that responses would be anonymous and offered a nominal incentive (book valued <$12) for participation. This study was approved by the Mayo Clinic Institutional Review Board.

Instrument

The authors and 2 other experienced physician-educators (R.B. and D.P.), all with backgrounds working in academic medical centers, integrated care delivery systems, and medical specialty boards, created a survey questionnaire addressing various topics related to continuing professional development, including 13 Likert-scale items about MOC (quoted verbatim in Table 1; response options: 1=strongly disagree and 7=strongly agree). To keep the questionnaire length manageable, we divided it into 2 sections of approximately equal length and allowed participants to submit the survey after completing the first section ("primary items"); those willing to continue could respond to the additional "secondary" items. Eight primary items addressed concerns identified in a recent focus group study[9] (value, relevance, integration, and support), comprehensiveness in addressing professional development needs, overall burden, and 2 issues raised in recent discussions (certification board financial interests[13,14] and public [patient] attention to certification status[24]). Five secondary items concerned the value of MOC-related activities (self-assessment activities, practice improvement activities, and preparing for the examination) in supporting one's professional development, MOC's effect on patient safety, and interest in various MOC activities. We also inquired about burnout[25] and demographic characteristics. To provide a shared context and framework for participants with different backgrounds, the questionnaire instructions defined *MOC* as "a program of assessment, continuous learning, and practice improvement designed to encourage and certify ongoing development and proficiency in key professional competencies."

We asked 4 continuing medical education experts at nonaffiliated institutions to review the full questionnaire to identify important

TABLE 1. Main Survey Results[a]

Item	Mean ± SD, median[b]	Agree[b,c] n/N (%)
Primary survey items		
MOC activities are relevant to the patients I see[d]	2.9±1.8, 2	200/842 (23.8)
MOC is worth the time and effort required of me[d]	2.4±1.7, 2	122/824 (14.8)
I have adequate support in completing MOC activities	3.1±1.8, 3	223/834 (26.7)
MOC activities are well-integrated with my daily clinical practice	2.4±1.5, 2	101/832 (12.1)
MOC provides all I need to remain a competent physician	2.0±1.3, 2	56/827 (6.8)
MOC is a burden to me	5.6±1.7, 6	673/835 (80.6)
MOC is all about generating money for the boards	5.2±1.7, 6	574/851 (67.5)
Patients care about my MOC status	2.1±1.5, 2	76/834 (9.1)
Secondary survey items		
MOC self-assessment activities contribute to my professional development	3.2±1.8, 3	114/367 (31.1)
MOC practice improvement activities contribute to my professional development	2.8±1.7, 2	82/367 (22.3)
Studying for the board recertification exam contributes to my professional development	3.4±1.9, 3	138/359 (38.4)
MOC as a whole improves patient safety	3.0±1.7, 3	80/378 (21.2)
I would like to see a broader array of activities that qualify for MOC	5.1±1.5, 6	232/335 (69.3)

[a]MOC = maintenance of certification.
[b]Response options ranged from 1 (strongly disagree) to 7 (strongly agree). The questionnaire was divided into 2 sections, and ~55% of the respondents completed only the first section (primary items).
[c]"Agree" indicates slightly agree, agree, or strongly agree.
[d]Indicates prespecified key item.

omitted or irrelevant topics. Mayo Clinic Survey Research Center personnel with expertise in questionnaire development also reviewed items to verify structure and wording. We pilot tested the questionnaire among 17 physicians representing anesthesiology, dermatology, emergency medicine, family medicine, internal medicine, neurology, pathology, psychiatry, and surgery, soliciting feedback on item relevance and wording and revising items accordingly.

Survey Administration

We administered the Internet questionnaire using Qualtrics, a research survey administration tool (www.qualtrics.com). Each physician was contacted via e-mail with an individually tracked link, followed by e-mail reminders to nonrespondents. Those not responding to the Internet survey within 3 months were mailed a paper questionnaire. The paper questionnaire had no identifying information, so that responses could not be tracked.

Statistical Analyses

We applied standard univariate statistics to characterize the sample; we used respondent-reported demographic information when available and used information from LexisNexis to fill in missing data. We explored the possibility that nonrespondents were systematically different from respondents in 2 ways. First, we compared specialty, practice location, and sex (ie, demographic information from the LexisNexis database) between respondents and nonrespondents using chi-squared tests. Second, we compared the primary survey responses of those responding near the end of the survey (the last 15% of responses) with those responding earlier, because research suggests that the perceptions of late responders closely approximate the perceptions of those who never respond.[26] We also compared the distribution of respondents' specialties against the national distribution published in the Association of American Medical Colleges' *Physician Specialty Data Book 2014*.[27]

We were able to link Internet survey responses with the respondent's zip code. We used the US Department of Agriculture Rural-Urban Continuum Codes[28] to classify practice location as predominantly urban or rural.

We identified a priori 2 perceptions ("key items") as most salient to current MOC practice: those related to relevance and value. We hypothesized that higher burnout, generalist practice, smaller practice size, rural practice, and productivity-based compensation would be associated with less favorable opinions about MOC. We planned subanalyses by specialty, time since completion of training, certification status, and sex without specific hypotheses. We also evaluated hypothesized relationships involving MOC burden (less burden with higher relevance, integration, support, nongeneralist

TABLE 2. Demographic Characteristics of the Survey Sample[a]

Domain	Response	n (%)	
		Invited (N=4583)	Respondents (n=988)[b]
Specialty	Anesthesiology	231 (5.1)	53 (5.4)
	Diagnostic subspecialties	311 (6.8)	54 (5.5)
	Family medicine	496 (10.9)	98 (10.0)
	Internal medicine, general	586 (12.8)	108 (11.0)
	Internal medicine subspecialties	701 (15.4)	145 (14.8)
	Obstetrics-gynecology	278 (6.1)	55 (5.6)
	Pediatrics	352 (7.7)	76 (7.8)
	Pediatric subspecialties	95 (2.1)	44 (4.5)[c]
	Surgery and surgical subspecialties	694 (15.2)	148 (15.1)
	Other clinical specialties	821 (18.0)	197 (20.1)
Sex	Male	3054 (66.6)	590 (66.2)
	Female	1529 (33.4)	301 (33.8)
Region	Northeast	987 (21.6)	199 (20.6)
	Midwest	955 (20.9)	221 (22.8)
	South	1563 (34.1)	326 (33.7)
	West	1072 (23.4)	222 (22.9)
Community size[d]	Rural	359 (7.8)	43 (7.0)
	Urban	4218 (92.2)	571 (93.0)
Certification status	Lifetime	NA	260 (29.2)
	Time-limited, current		620 (69.7)
	Time-limited, not current		10 (1.1)
Burnout	Feel burned out	NA	309 (33.7)
	Feel more callous		165 (18.0)
	Either burned out or callous		349 (38.1)
Years since training	1-10	NA	181 (18.8)
	11-20		280 (29.0)
	21-30		285 (29.6)
	>30		218 (22.6)
Practice size	1 physician	NA	133 (13.6)
	2-5		226 (23.1)
	6-25		290 (29.7)
	>25		328 (33.6)
Compensation model	Salary (fixed)	NA	345 (35.3)
	Salary with incentives		305 (31.3)
	Productivity		326 (33.4)
Practice type	Self-employed	NA	243 (24.8)
	Medical group or hospital		465 (47.5)
	Academic		179 (18.3)
	Other		91 (9.3)
Race	American Indian	NA	6 (0.7)
	Asian		131 (15.2)
	Black		22 (2.6)
	Pacific Islander		2 (0.2)
	White		701 (81.3)
Ethnicity	Hispanic	NA	49 (5.9)

[a]NA = not available.
[b]Numbers may not sum to 988 because of missing data. Percentages are calculated using all available data. n=916 for burnout items.
[c]$P<.001$ compared with nonrespondents. We also compared respondents against national demographic characteristics[28] and found only small differences (see text).
[d]Community size available only for those completing the Internet survey.

specialty, and lower burnout), integration (more integration in larger practices), and support (less support with productivity-based compensation). We defined generalists as nonsubspecialist family medicine, internal medicine, and pediatric physicians.

We used general linear models to test associations between MOC opinions (outcomes, see Table 1) and respondent characteristics (predictors, as outlined above) and to compare opinions on primary survey items between those who did and who did not complete the secondary items. We calculated Spearman's ρ to evaluate correlations among MOC opinions and with burnout. We conducted analyses using the full 1- to 7-point Likert scale, but to simplify reporting we grouped responses of slightly agree, agree, or strongly agree as indicative of agreement (hereafter labeled "agree"). Because of the large sample size and multiple comparisons, we used a 2-tailed α value of .01 to define statistical significance in all analyses. We used SAS version 9.4 (SAS Institute Inc.).

RESULTS

Survey Response and Sample Characteristics

Of 4648 survey invitations sent, 646 e-mails and 223 paper questionnaires were returned as undeliverable, along with 65 returned as undeliverable via both e-mail and paper. We received 988 responses (631 via Internet and 357 via paper). Using the conservative denominator of 4583 potential respondents (excluding the 65 undeliverable via either method), our response rate was 21.6%.

Demographic characteristics of the respondents and the demographic information available for those invited to participate are reported in Table 2. About 45% of those completing the primary questionnaire items also completed the secondary items. Their responses to all primary items were similar to responses from those who did not complete the secondary items (data not shown).

The distribution of specialties among respondents was not statistically significantly different from published data for all US physicians[27] ($P>.06$), except that our sample had fewer family medicine and general internal medicine physicians (absolute difference ~4% for both; $P<.001$). Respondents and nonrespondents were comparable across all available characteristics except that we had more responses from pediatric subspecialists (see Table 2).

Nearly all respondents (99%) had current board certification (29% with lifetime certification and 70% with current time-limited certification). Three respondents (all in practice for ≥46 years) indicated they had never been board certified; they were excluded from further analysis.

Thirty-eight percent of the respondents met criteria for being burned out, defined as feeling either burned out (34%) or more callous toward others (18%) on at least a weekly basis.

Main Results

For each item, 74 to 103 respondents indicated that the statement did not apply to them, and 57 to 61 did not respond, leaving 824 to 851 quantifiable responses per item (see Table 1 for detailed response information). Twenty-four percent of physicians agreed (ie, slightly agreed, agreed, or strongly agreed) that MOC activities are relevant to their patients, and 15% felt they have value (are worth the time and effort). Although 27% perceived adequate support for MOC activities, only 12% indicated that activities are well-integrated into their daily routine and 81% believed they are a burden. Nine percent believed that patients care about their MOC status. Of those responding to the second half of the survey, about two-thirds would like to see a broader array of MOC activities, whereas 31%, 22%, and 38% agreed that self-assessment, practice improvement, and examination preparation activities (respectively) contribute to their professional development. Supplemental Table 1 (available online at http://www.mayoclinicproceedings.org) contains responses for all items using the full 1- to 7-point Likert scale.

In a planned analysis to estimate the effect of potential nonresponse bias, we compared the responses of those responding early vs late in the survey period and found no statistically significant differences for any primary survey items.

Preplanned Subgroup Analyses

Table 3 shows the association between the key items (MOC relevance and value) and

TABLE 3. Subgroup Analyses of Responses to Key Items by Respondent Characteristics

Domain	Characteristic	Relevance, agree[a] n/N (%)	Relevance, agree[a] *P* value[b]	Value, agree[a] n/N (%)	Value, agree[a] *P* value[b]
Specialty	Anesthesiology	14/39 (35.9)	<.001	13/38 (34.2)	<.001
	Diagnostic subspecialties	6/37 (16.2)		1/37 (2.7)	
	Family medicine	35/95 (36.8)		15/94 (16.0)	
	Internal medicine, general	15/92 (16.3)		15/91 (16.5)	
	Internal medicine subspecialties	23/124 (18.5)		11/123 (8.9)	
	Obstetrics-gynecology	27/48 (56.3)		19/47 (40.4)	
	Pediatrics	13/71 (18.3)		7/71 (9.9)	
	Pediatric subspecialties	10/39 (25.6)		2/37 (5.4)	
	Surgery and surgical subspecialties	31/129 (24.0)		21/126 (16.7)	
	Other clinical specialties	24/159 (15.1)		17/151 (11.3)	
Generalist	Nongeneralist	135/575 (23.5)	.99	84/559 (15.0)	.91
	Generalist[c]	63/258 (24.4)		37/256 (14.5)	
Sex	Male	121/519 (23.3)	.36	75/508 (14.8)	.62
	Female	70/274 (25.5)		39/267 (14.6)	
Region	Northeast	40/160 (25.0)	.40	19/153 (12.4)	.58
	Midwest	47/191 (24.6)		30/190 (15.8)	
	South	62/276 (22.5)		40/270 (14.8)	
	West	44/197 (22.3)		28/193 (14.5)	
Community size[d]	Rural	6/40 (15.0)	.48	7/38 (18.4)	.82
	Urban	105/482 (21.8)		70/476 (14.7)	
Certification status	Lifetime	50/185 (27.0)	.56	24/176 (13.6)	.62
	Time-limited, current	138/601 (23.0)		87/591 (14.7)	
	Time-limited, not current	3/9 (33.3)		3/10 (30.0)	
Burnout	No (neither burned out nor callous)	116/498 (23.3)	.50	73/487 (15.0)	.48
	Yes (either burned out or callous)	78/316 (24.7)		44/310 (14.2)	
Years since training	1-10	39/164 (23.8)	.32	20/166 (12.0)	.41
	11-20	58/257 (22.6)		43/255 (16.9)	
	21-30	54/245 (22.0)		32/237 (13.5)	
	>30	43/156 (27.6)		23/148 (15.5)	
Practice size	1 physician	30/108 (27.8)	.40	19/104 (18.3)	.91
	2-5	42/194 (21.6)		27/186 (14.5)	
	6-25	65/251 (25.9)		37/248 (14.9)	
	>25	61/284 (21.5)		37/281 (13.2)	
Compensation model	Salary (fixed)	70/294 (23.8)	.09	35/280 (12.5)	.15
	Salary with incentives	69/269 (25.7)		48/270 (17.8)	
	Productivity	58/271 (21.4)		38/265 (14.3)	

[a]Response options ranged from 1 (strongly disagree) to 7 (strongly agree). "Agree" in this table indicates slightly agree, agree, or strongly agree. Relevance = "MOC [maintenance of certification] activities are relevant to the patients I see." Value = "MOC is worth the time and effort required of me." Denominators vary slightly because of nonresponse to either the MOC item or the subgroup characteristic.

[b]*P* values reflect analyses of MOC attitudes using the full 1- to 7-point Likert scale.

[c]Non-subspecialist family medicine, internal medicine, and pediatric physicians were collectively regarded as generalists.

[d]Community size available only for those completing the Internet survey.

prespecified demographic characteristics. The correlation between MOC relevance and value was moderately strong (ρ=0.65; P<.001). Attitudes varied statistically significantly (P<.001) across specialties, but reflected low perceived relevance and value in nearly all specialties. Contrary to all our hypotheses, we found no significant differences for any other subgroup analyses with relevance and value. The correlations between burnout scores and relevance and value were small and statistically nonsignificant (all ρ=−0.06 to −0.04; P>.10). Supplemental Table 2 (available online at http://www.mayoclinicproceedings.org) contains responses

for relevance and value, by subgroup, using the full 1- to 7-point Likert scale.

We confirmed significant correlations between MOC burden and MOC perceptions of relevance, support, and integration ($\rho=-0.55$, $\rho=-0.42$, and $\rho=-0.49$, respectively; $P<.001$), but the magnitude of correlation was lower than that between relevance and value. The association between burden and generalist specialty did not reach statistical significance (85% [220 of 260] for generalists and 79% [446 of 566] for nongeneralists; $P=.02$). The correlation between burden and burnout was statistically significant ($P<.001$) but accounted for only 2% of the variance in scores ($\rho=0.15$ for both burnout measures).

We did not confirm expected associations between MOC support and compensation model or between MOC integration and practice size ($P\geq.19$).

Exploratory Analyses

In exploratory analyses, we found no association between the desire for various MOC activities and MOC relevance and value ($\rho=-0.01$ and $\rho=-0.05$, respectively; $P\geq.39$). We did find moderate correlations between the item about MOC generating money for the boards and MOC relevance and value ($\rho=-0.49$ and $\rho=-0.46$, respectively; $P<.001$).

DISCUSSION

In this national survey of US physicians, we found that physicians perceived that current MOC activities have little relevance or value and are neither well-supported nor well-integrated into their clinical practice. More than 80% agreed that MOC is a burden. Physicians also did not believe that patients care about their MOC status. In a smaller subsample, physicians viewed MOC activities related to self-assessment, examination preparation, or practice improvement as contributing only modestly to their professional development. Between-specialty differences were typically small. We found no association between MOC perceptions and other respondent characteristics including burnout, time-limited or lifetime certification, practice size, rural or urban practice location, productivity vs salaried compensation, or time since completion of training.

Limitations and Strengths

The response rate leaves uncertainty about how well our findings reflect the attitudes of nonresponding physicians. If those with strong MOC beliefs (favorable or unfavorable) preferentially responded, it could have biased results; however, the decision to respond could also have been prompted by beliefs about other survey topics (eg, continuing professional development). Moreover, demographic characteristics of respondents were similar to those of nonrespondents and the distribution of specialties among respondents generally mirrors that of US physicians. We also found that those responding late (ie, after several reminders) had attitudes similar to those responding early. To the extent that late responders' attitudes approximate those who never responded,[26] this provides some reassurance that our findings do not underrepresent nonrespondents.

Our survey items did not address all current issues affecting MOC, but we tried to address key issues noted in recent research and editorials.[8,9,13,14,19,20] We framed questionnaire items to focus on physicians' attitudes and perceptions rather than asking respondents to estimate or recall specific facts. We acknowledge that responses may reflect misconceptions about MOC, but maintain that physician perceptions are nonetheless vitally important. We did not ask respondents to speculate about solutions.

We note that nearly all respondents had current certification, which differs from the known distribution of currently certified US physicians (~80%[29]). Our findings may not apply directly to those not currently certified, but do apply to those with lifetime or maintained certification. We did not ask whether respondents had personally completed an MOC cycle and cannot tell how much a respondent's beliefs are based on personal experiences with MOC vs observations and other information sources. However, data on time in practice suggest that at least half of respondents had likely completed an MOC cycle. We further suggest that beliefs based on anticipated challenges are still relevant to conversations surrounding MOC.

Strengths include the nationwide cross-specialty sample that closely mirrors US

physician demographic characteristics[27]; exploration of responses by specialty, location, and other subgroups with specific hypotheses for most analyses; and ample power for these analyses. We followed a robust process of questionnaire development, including item generation by experienced educators with diverse backgrounds, review by 4 external experts, and pilot testing among physicians representing several diverse specialties. We also adhered to best practices in survey implementation and delivery, including use of a dedicated survey research center.

Integration With Previous Research

This is, to our knowledge, the first cross-specialty national survey exploring physician attitudes about MOC. Beyond the issues addressed in previous studies, our survey items focused on the integration and burden of MOC, the boards' perceived financial conflict of interest, and the desire for a broader array of MOC activities. Our findings of dissatisfaction with MOC are consonant with a recent cross-specialty survey in Pennsylvania[19] and with national surveys of pediatrics[20] and internal medicine.[21] Our results also corroborate the findings of a regional focus group study,[9] in that perceived relevance, value, support, and integration all seem to be lacking in current MOC programs.

However, some studies[8,30,31] have found more favorable attitudes both for MOC generally and for specific MOC activities. Some differences may be attributed to wording of items. For example, previous surveys indicate that physicians believe that patients value board-certified physicians,[8,20] but that patients may not care about *maintenance* of certification.[20] Of course, physician beliefs may not reflect patients' true preferences.[24] Other differences may be due to differences in specialty. For example, a survey of anesthesiologists[8] found that 35% disagreed with the statement "MOCA [MOC Anesthesiology] is not relevant to my practice" and that 59% to 82% agreed that various components of MOC were relevant to a physician's practice. In our sample, anesthesiologists (along with obstetricians/gynecologists) perceived somewhat greater MOC relevance and value than did physicians in other specialties, suggesting that specialty-specific factors may be influential. Other studies involving emergency medicine physicians also revealed favorable attitudes toward MOC examination-related tasks[31] and lifelong learning activities.[30]

Physicians' perceptions must be counterbalanced by societal demands for competent physicians and high-quality care and for public accountability in this regard.[2,32] Although limited research suggests that MOC helps to achieve these goals,[33-35] the extent and value of these benefits remain controversial.[36,37]

Implications

The uniform dissatisfaction across subgroups and survey items suggests that the problems with MOC are ubiquitous and pervasive, not localized to specific sectors, and that all elements of MOC may warrant similar efforts to improve. It is clear that to meaningfully engage physicians, MOC will need to change. What remains unclear is how to structure MOC programs that provide tangible value and adequate support to physicians, and prepare them to meet the needs of patients and society. The American Board of Medical Specialties and its member boards are simultaneously implementing and investigating innovative approaches to address these issues.[3,17,38-40] Individual physicians also need to be engaged in this process of change, providing meaningful feedback and constructive suggestions that will enable the evolution and improvement of MOC programs.

Most physicians agree with the concept of lifelong learning,[6,9,41] and research has found associations between board certification and favorable patient outcomes.[4,5,33,34] However, evidence is presently lacking about how current formal programs of *maintenance* of certification contribute to lifelong learning beyond what physicians would spontaneously do (eg, learning while caring for patients) and how MOC can be made less burdensome while achieving the same aspirational goals.[9,30,32,42] For example, evidence confirms that physicians cannot self-assess their learning needs[43,44] and that they receive inadequate feedback on their clinical performance.[45,46] To the degree that MOC supports identification and remediation of learning gaps, it serves a useful purpose.[31,47] Additional empirical evidence to support these and other benefits and to guide the

implementation of interventions that promote meaningful learning is needed.

Finally, physician perceptions must be taken seriously and at face value. Beliefs could reflect misperceptions about MOC program requirements, available supports, board finances, or benefits to self and patients, but beliefs must be acknowledged, concerns addressed, misperceptions corrected, and evidence provided. Rhetoric alone will not suffice. Before we can expect physicians to truly embrace MOC, they will need to spontaneously recognize its relevance, coherence, integration, support, and, most importantly, value to themselves and the patients they serve.

CONCLUSION

Dissatisfaction with current MOC programs is widespread. Certification boards, individual physicians, and other stakeholders will need to collaborate to continue creating and improving programs that ensure physician competence, support lifelong learning, minimize burden, and add value for physicians and patients.

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SUPPLEMENTAL ONLINE MATERIAL

Supplemental material can be found online at: http://www.mayoclinicproceedings.org. Supplemental material attached to journal articles has not been edited, and the authors take responsibility for the accuracy of all data.

Abbreviation and Acronym: **MOC** = maintenance of certification

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REFERENCES

1. Baron RJ, Johnson D. The American Board of Internal Medicine: evolving professional self-regulation. *Ann Intern Med*. 2014; 161(3):221-223.
2. Iglehart JK, Baron RB. Ensuring physicians' competence—is maintenance of certification the answer? [published correction appears in *N Engl J Med*. 2013;368(8):781]. *N Engl J Med*. 2012; 367(26):2543-2549.
3. American Board of Medical Specialties. Standards for the ABMS program for maintenance of certification (MOC): For implementation in January 2015. http://www.abms.org/media/1109/standards-for-the-abms-program-for-moc-final.pdf. Accessed March 18, 2016.
4. Hawkins RE, Lipner RS, Ham HP, Wagner R, Holmboe ES. American Board of Medical Specialties Maintenance Of Certification: theory and evidence regarding the current framework. *J Contin Educ Health Prof*. 2013;33(suppl 1):S7-S19.
5. Lipner RS, Hess BJ, Phillips RL Jr. Specialty board certification in the United States: issues and evidence. *J Contin Educ Health Prof*. 2013;33(suppl 1):S20-S35.
6. Drazen JM, Weinstein DF. Considering recertification. *N Engl J Med*. 2010;362(10):946-947.
7. Lipner RS, Bylsma WH, Arnold GK, Fortna GS, Tooker J, Cassel CK. Who is maintaining certification in internal medicine—and why? A national survey 10 years after initial certification. *Ann Intern Med*. 2006;144(1):29-36.
8. Culley DJ, Sun H, Harman AE, Warner DO. Perceived value of Board certification and the Maintenance of Certification in Anesthesiology Program (MOCA®). *J Clin Anesth*. 2013;25(1):12-19.
9. Cook DA, Holmboe ES, Sorensen KJ, Berger RA, Wilkinson JM. Getting maintenance of certification to work: a grounded theory study of physicians' perceptions. *JAMA Intern Med*. 2015; 175(1):35-42.
10. Levinson W, King TE Jr, Goldman L, Goroll AH, Kessler B. Clinical decisions: American Board of Internal Medicine maintenance of certification program. *N Engl J Med*. 2010;362(10):948-952.
11. Weiss KB, Bryant LE Jr, Morgan LB, O'Kane ME. The ABIM and recertification. *N Engl J Med*. 2010;362(25):2428-2429; author reply 2429-2430.
12. Steele R. Maintenance of certification. *Clin Pediatr (Phila)*. 2011; 50(7):584-586.
13. Strasburger VC. Ain't misbehavin': is it possible to criticize maintenance of certification (MOC)? *Clin Pediatr (Phila)*. 2011;50(7): 587-590.
14. Teirstein PS. Boarded to death—why maintenance of certification is bad for doctors and patients. *N Engl J Med*. 2015;372(2): 106-108.
15. Kritek PA, Drazen JM. Clinical decisions: American Board of Internal Medicine maintenance of certification program—polling results. *N Engl J Med*. 2010;362(15):e54.
16. Physicians for Certification Change. Petitions and pledge of non-compliance. http://nomoc.org/. Accessed March 18, 2016.
17. Baron R. ABIM announces immediate changes to MOC program. http://www.abim.org/news/abim-announces-immediate-changes-to-moc-program.aspx. Accessed February 25, 2015.

18. National Board of Physicians and Surgeons website: https://nbpas.org/. Accessed March 18, 2016.
19. Chadwick JS. Physician survey reveals widespread dissatisfaction with maintenance of certification (MOC). https://www.pamedsoc.org/PAMED_Downloads/Quick%20Consult/QCMOC.pdf. Accessed April 22, 2016.
20. Freed GL, Dunham KM, Lamarand KE; Research Advisory Committee of the American Board of Pediatrics. Permanent pediatric diplomate awareness of and perspectives on maintenance of certification. *J Pediatr*. 2009;155(6):919-923.e921.
21. American Board of Internal Medicine. All-diplomate survey: Improving the MOC assessment experience. http://transforming.abim.org/wp-content/uploads/2016/04/abim-survey-results-april-2016.pdf. Accessed August 19, 2016.
22. Dyrbye LN, West CP, Satele D, et al. Burnout among U.S. medical students, residents, and early career physicians relative to the general U.S. population. *Acad Med*. 2014;89(3):443-451.
23. Shanafelt TD, Hasan O, Dyrbye LN, et al. Changes in burnout and satisfaction with work-life balance in physicians and the general US working population between 2011 and 2014 [published correction appears in *Mayo Clin Proc*. 2016;91(2):276]. *Mayo Clin Proc*. 2015;90(12):1600-1613.
24. Freed GL, Dunham KM, Clark SJ, Davis MM; Research Advisory Committee of the American Board of Pediatrics. Perspectives and preferences among the general public regarding physician selection and board certification. *J Pediatr*. 2010;156(5):841-845;845.e841.
25. West CP, Dyrbye LN, Sloan JA, Shanafelt TD. Single item measures of emotional exhaustion and depersonalization are useful for assessing burnout in medical professionals. *J Gen Intern Med*. 2009;24(12):1318-1321.
26. Miller LE, Smith KL. Handling nonresponse issues. *JOE*. 1983;21(September/October):45-50.
27. Association of American Medical Colleges. *Physician Specialty Data Book 2014*. Washington, DC: AAMC Center for Workforce Studies; 2014.
28. United States Department of Agriculture Economic Research Service. 2013 Rural-Urban Continuum Codes. http://www.ers.usda.gov/data-products/rural-urban-continuum-codes.aspx. Accessed April 18, 2016.
29. American Board of Medical Specialties. Fact sheet: American Board of Medical Specialties. http://www.abms.org/media/100051/abms_factsheet_2016.pdf. Accessed April 14, 2016.
30. Jones JH, Smith-Coggins R, Meredith JM, Korte RC, Reisdorff EJ, Russ CM. Lifelong learning and self-assessment is relevant to emergency physicians. *J Emerg Med*. 2013;45(6):935-941.
31. Marco CA, Wahl RP, Counselman FL, et al. The American Board of Emergency Medicine ConCert™ Examination: emergency physicians' perceptions of learning and career benefits [published online ahead of print March 28, 2016]. *Acad Emerg Med*. http://dx.doi.org/10.1111/acem.12971.
32. Levinson W, Holmboe E. Maintenance of certification: 20 years later. *Am J Med*. 2011;124(2):180-185.
33. Holmboe ES, Wang Y, Meehan TP, et al. Association between maintenance of certification examination scores and quality of care for medicare beneficiaries. *Arch Intern Med*. 2008;168(13):1396-1403.
34. Gray BM, Vandergrift JL, Johnston MM, et al. Association between imposition of a Maintenance of Certification requirement and ambulatory care-sensitive hospitalizations and health care costs. *JAMA*. 2014;312(22):2348-2357.
35. O'Neill TR, Puffer JC. Maintenance of certification and its association with the clinical knowledge of family physicians. *Acad Med*. 2013;88(6):780-787.
36. Sandhu AT, Dudley RA, Kazi DS. A cost analysis of the American Board of Internal Medicine's maintenance-of-certification program. *Ann Intern Med*. 2015;163(6):401-408.
37. Hayes J, Jackson JL, McNutt GM, Hertz BJ, Ryan JJ, Pawlikowski SA. Association between physician time-unlimited vs time-limited internal medicine board certification and ambulatory patient care quality. *JAMA*. 2014;312(22):2358-2363.
38. The American Board of Anesthesiology. Why is the ABA changing MOCA? http://www.theaba.org/MOCA/About-MOCA-2-0. Accessed March 18, 2016.
39. American Board of Obstetrics + Gynecology. ABOG begins innovative pilot program to enhance maintenance of certification process. https://www.abog.org/new/ABOG_mocimp.aspx. Accessed April 20, 2016.
40. Phillips R. ABFM to simplify maintenance of certification (MOC) for family physicians and make it more meaningful: a family medicine registry. *J Am Board Fam Med*. 2015;28(3):431-433.
41. Hojat M, Veloski JJ, Gonnella JS. Measurement and correlates of physicians' lifelong learning. *Acad Med*. 2009;84(8):1066-1074.
42. Lee TH. Certifying the good physician: a work in progress. *JAMA*. 2014;312(22):2340-2342.
43. Eva KW, Regehr G. Self-assessment in the health professions: a reformulation and research agenda. *Acad Med*. 2005;80(10 suppl):S46-S54.
44. Davis DA, Mazmanian PE, Fordis M, Van Harrison R, Thorpe KE, Perrier L. Accuracy of physician self-assessment compared with observed measures of competence: a systematic review. *JAMA*. 2006;296(9):1094-1102.
45. Gallagher TH, Prouty CD, Brock DM, Liao JM, Weissman A, Holmboe ES. Internists' attitudes about assessing and maintaining clinical competence. *J Gen Intern Med*. 2014;29(4):608-614.
46. Sargeant J, Bruce D, Campbell CM. Practicing physicians' needs for assessment and feedback as part of professional development. *J Contin Educ Health Prof*. 2013;33(suppl 1):S54-S62.
47. Duffy FD, Lynn LA, Didura H, et al. Self-assessment of practice performance: development of the ABIM Practice Improvement Module (PIM). *J Contin Educ Health Prof*. 2008;28(1):38-46.

The Laryngoscope

Complications and Legal Outcomes of Tonsillectomy Malpractice Claims

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Objectives/Hypothesis: To review malpractice cases involving complications following tonsillectomy.

Study Design: Retrospective analysis at a tertiary medical center of jury verdict reports within the LexisNexis (Dayton, OH) database submitted after tonsillectomy malpractice cases.

Methods: The LexisNexis MEGA Jury Verdicts and Settlements database was reviewed from 1984 through 2010 for complications resulting from tonsillectomy. Data including year of case, surgical complication, injury, case result, and judgment awarded were collected and analyzed.

Results: One hundred seventy-eight reports met inclusion criteria and were reviewed. Postoperative bleeding was the most common complication (33.7%), followed by anoxic events (16.9%), and impaired function (15.7%). Patient death occurred in 40.4% of reports and was most frequently associated with postoperative bleeding (54.2%), followed by anoxic events (18.1%), and postoperative medication issues (16.7%). Monetary awards were available in 24.7% of reports. Anoxic event was noted to have the highest median award at $3,051,296, followed by postoperative medication at $950,000.

Conclusions: Tonsillectomy carries a large amount of risk from a malpractice standpoint. Postoperative bleeding is the complication most commonly associated with malpractice claims, but may not carry the greatest overall risk from a patient care or monetary standpoint. Hypoxic and anoxic events, although less common, appear to carry more morbidity for the patient and are associated with greater settlements and judgments in malpractice claims. Tonsillectomy continues to carry a significant mortality risk, albeit infrequent, and a high level of vigilance should be employed to help reduce these risks.

Key Words: Tonsillectomy, malpractice, litigation, settlement, complications.

Level of Evidence: 4.

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INTRODUCTION

Identification and minimization of surgical complications is of great importance to all surgeons. It leads to increased safety and improved patient outcome and care. Additionally, it is of great importance that all physicians have a better understanding of what situations lend themselves to increased exposure from a malpractice standpoint. One area in which otolaryngologists continue to be particularly vulnerable is with tonsillectomies. There are a number of circumstances that can lead to morbidity and mortality when a tonsillectomy is performed, including airway fires, hypoxic events, and bleeding, not to mention innumerable unusual events that may present themselves throughout one's career. There have been a number of studies that looked at the complications of tonsillectomies and the legal ramifications that have ensued, which have demonstrated that bleeding and burn injuries are the most commonly reported adverse events.[1] Additionally, an attempt has been made to attach a monetary value reached in settlements or judgments to some of these adverse events.[2]

This study examined the outcomes of tonsillectomy malpractice cases over the last 26 years in an effort to better illustrate what types of injuries are most commonly encountered and how they may be avoided. In addition, we attempted to see if certain injuries are more likely to lead to greater settlements or judgments against the defendant physicians.

MATERIALS AND METHODS

The MEGA Jury Verdicts and Settlements database maintained by LexisNexis (Dayton, OH) was used to search all reported jury verdicts and settlements from 1984 through 2010. Jury verdict reports are summaries of legal cases that provide information including case issues, date, injury, plaintiff, defendant, and disposition, including any judgment awarded or settlement reached. Jury verdict reports are voluntary submissions and the amount of information in each case varies significantly. Therefore, they do not represent a comprehensive and all-inclusive account of every medical malpractice claim. This study was exempt from review by an institutional review board because no human subjects were involved and no protected patient information was reviewed.

The MEGA Jury Verdicts and Settlements database was searched using "tonsillectomy" and "malpractice" as search terms. Specific information obtained from each report (if available) included year of case, alleged surgical complication,

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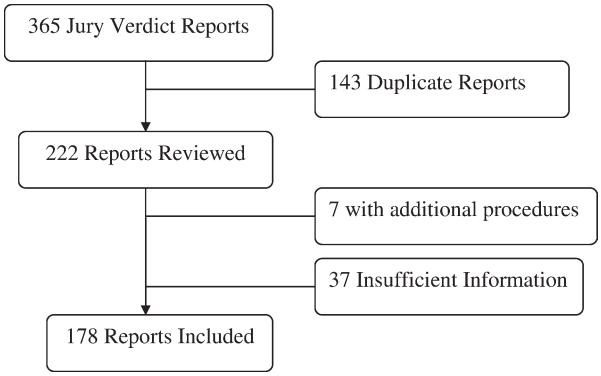

Fig. 1. Selection of jury verdict reports for analysis.

alleged injury, case result, and any monetary judgment awarded or settlement that was reached. Cases were excluded if the injury was a result of another surgical procedure, if another surgical procedure was performed in addition to tonsillectomy with or without adenoidectomy, or if it was a duplicate report. Additionally, reports were excluded if the amount of information was not enough to be useful in this study.

RESULTS

The database search returned 365 jury verdict reports with keywords "tonsillectomy" and "malpractice." Each report was reviewed for relevancy and amount of information contained within. One hundred forty-three reports were duplicates. Seven were excluded because another procedure besides adenoidectomy had been performed as well as tonsillectomy. Thirty-seven were excluded because the amount of information available in the report was not sufficient to be included in this study. This left 178 cases from 1984 through 2010 that met the inclusion criteria (Fig. 1).

Complications

Complications were grouped into several categories based on information obtained from the jury verdict reports (Table I). The most common complication was postoperative bleeding, accounting for 60 of the 178 cases (33.7%). This included claims for bleeding (extending hospital stay, need for blood products) and for airway issues that arose secondary to postoperative bleeding (aspiration of clots). Anoxic events either intraoperatively or postoperatively occurred in 30/178 cases (16.9%). Complications causing impaired function such as nerve damage, impaired swallowing, or altered taste were noted in 28/178 cases (15.7%). Other categories included 19 miscellaneous events that occurred intraoperatively (10.7%), 13 oral burns (7.3%), 12 events caused by postoperative medications (6.7%), 11 postoperative infections (6.2%), and five airway fires (2.8%).

TABLE I.
Complication Categories (N = 178).

Complication	No. (%)
Postoperative bleeding	60 (33.7)
Anoxic event	30 (16.9)
Impaired function	28 (15.7)
Intraoperative miscellaneous	19 (10.7)
Oral burn	13 (7.3)
Postoperative medication	12 (6.7)
Infection	11 (6.2)
Airway fire	5 (2.8)

TABLE II.
Mortalities From Complications (n = 72).

Complication	No. of Deaths	% of All Deaths
Postoperative bleeding	39	54.2
Anoxic event	13	18.1
Postoperative medication	12	16.7
Intraoperative event	5	6.9
Infection	3	4.2
Airway fire	0	0
Oral burn	0	0
Impaired function	0	0

Mortality

Seventy-two patients (40.4%) died and 106 cases (59.6%) resulted in patient injury. Postoperative bleeding was the most frequently noted fatal complication (39/72; 54.2%), followed by anoxic events (13/72; 18.1%), and postoperative medication issues (12/72; 16.7%) (Table II). Several categories not associated with loss of life included airway fires, functional impairment, and oral burns.

Judgments/Settlements

Data pertaining to either awarded judgments or financial settlements were available in 44 of 178 reports (24.7%). The mean monetary payment was $2,388,075 and the median payment was $625,000. Complications resulting in patient death had mean and median payments of $1,227,731 and $950,000, respectively, compared to complications resulting in injury with payments of $3,191,389 and $350,000. The complication with the greatest median payment was anoxic events at $3,051,296; followed by postoperative medication events, $950,000; postoperative bleeding, $600,000; and intraoperative miscellaneous events, $557,500 (Table III).

TABLE III.
Indemnity by Complication.

Complication	Mean Payment ($US)	Median Payment ($US)
Anoxic event	9,017,379	3,051,296
Postoperative medication	1,710,445	950,000
Postoperative bleeding	1,213,352	600,000
Intraoperative miscellaneous	574,625	557,500
Infection	350,000	350,000
Impaired function	619,678	275,000
Oral burn	289,685	180,000
Airway fire	No Data	No Data

DISCUSSION

Tonsillectomies are one of the most common procedures performed by otolaryngologists in the United States with over 700,000 performed every year.[3] Appropriate indications for tonsillectomy have been developed, and it is generally regarded as a safe procedure that is usually performed on an outpatient basis.[4] Multiple studies have shown the most frequent complications associated with tonsillectomy are postoperative bleeding, emesis, dehydration, and poor oral intake.[5–8] Complications causing death are even more remote and are reported to occur at a rate of one per 16,000 to 25,000 cases.[9,10] Even with the low rate of complications reported with tonsillectomies, it represents an area of relatively great liability exposure for the otolaryngologist.

In this analysis, we have again shown that bleeding represents a significant portion of the malpractice claims against surgeons (33.7%), which is in agreement with previously reported findings. Bleeding complications included cases with excessive blood loss requiring transfusions as well as additional medical care. Cases were also included in the bleeding category if the complication occurred during control of the postoperative bleed, such as aspiration of clot. Postoperative bleeding has been a well-established risk of tonsillectomy, with a rate of approximately 2% to 4%.[6,7,11] In a study by Windfuhr et al. evaluating sequela of serious post-tonsillectomy bleeding in children, 29/55 patients had repeat episodes of bleeding, 4/55 had neurological sequela, and 19/55 died as a result of their serious post-tonsillectomy bleeding.[12] In our series, postoperative bleeding represented the third highest median payment at $600,000. In the two cases with the highest payments, the complication was not directly related to blood loss but to airway complications as a result of the bleeding. A $5.35 million settlement was reached for "difficult intubation secondary to bleeding" resulting in anoxic brain injury, and a $3.0 million settlement was reached because of death secondary to aspiration of blood. This indicates that although postoperative bleeding remains an important source of malpractice, blood loss may not be the only complication, and an important focus should continue to be a safe and stable airway.

Hypoxic/anoxic events either intraoperatively or postoperatively were shown to be a major source of malpractice claims (16.9%). This is in agreement with a 2008 study by Morris et al., which identifies postoperative respiratory complications as a frequent cause of death or major injury in malpractice cases.[2] Hypoxia in the postanesthesia care unit (PACU) is a common event, occurring in 46% to 55% of surgical cases, but it is usually detectable and treatable without any adverse effects.[13–15] Interesting reports in our study included compression of the endotracheal tube by the mouth gag leading to hypoxia, an excessively large endotracheal tube causing airway edema and subsequent hypoxia, aspiration of a scab leading to asphyxiation postoperatively, and failure to provide oxygen during cardiopulmonary resuscitation. Some of these events are truly odd occurrences that may be unavoidable. They should, however, serve as a reminder to all otolaryngologists to have solid indications for performing surgery that are documented appropriately and to be aware and involved in all aspects of patient care when possible. Anoxic events were associated with the greatest median compensation paid to plaintiffs at almost $3.1 million per case. This coincides with the Morris study reporting the mean indemnity of postoperative respiratory complications at $3.06 million.[2] The reports with the greatest monetary payments also were noted to be associated with an anoxic event. The three greatest payments in our study included $45 million for intraoperative hypoxia, $13.9 million for hypoxia in the PACU, and $5.7 million for failure to monitor postoperatively leading to hypoxic brain injury. This information provides evidence that hypoxic events, both intraoperatively and postoperatively, are one of the most common sources of malpractice claims, the costliest to resolve, and among the most devastating to both patients and their families.

Recently, the use of narcotic pain medication in children postoperatively has come under scrutiny. There are multiple reports of anoxic brain injury or intoxication attributed to the use of codeine or codeine-containing products.[16,17] These cases involve patients with increased cytochrome P450 2D6 (CYP2D6) activity who are ultrarapid metabolizers of codeine to its active form of morphine.[18] This leads to increased accumulation of morphine and subsequent respiratory depression or arrest. Conversely, patients may also be slow metabolizers of codeine, which can lead to increased pain postoperatively. In this analysis, complications from postoperative medication were seen in 6.7% of all reports. This is consistent with a previous reports from Simonsen et al. in 2010 showing that 5.8% of malpractice claims were medication related.[1] That being said, in our study it was associated with the second greatest indemnity with a median payment of $950,000 per case. Additionally, all 12 cases associated with postoperative medication led to death of the patient. This indicates that, although these complications are somewhat rare, the ramifications can be devastating both clinically and legally. Several strategies can be implemented to help reduce the possible morbidity with postoperative pain medication. A genetic test identifying mutations in CYP2D6 is available that helps categorize patients based on metabolism of codeine.[19,20] Use of this screening test can detect patients who may be at increased risk of an adverse event, or alternatively, may not receive any pain relief from postoperative codeine use. The test is costly at the present time and not really clinically applicable. As a result, another strategy may be to increase the age limit for which codeine is used postoperatively. At our institution, codeine is not given to any child under 6 years old in an attempt to decrease the exposure to patients who are at the most risk of respiratory depression. This topic is clearly an area of controversy, and the postoperative pain control regimen should be based on the individual patient and physician.

Airway fires and oral burns are consistently reported as complications of tonsillectomy. Previous reports have shown oral burns to be a frequent cause of

malpractice claims (18.2%).[1] In our series, oral burns were the cause of 7.3% of malpractice claims and had the lowest median payment of $180,000. This may be because oral burns are a very preventable complication with relatively low morbidity when they do occur. Airway fires were also an infrequent complication (2.8%). This is due most likely to the recent increased vigilance of anesthesia, surgeon, and operating room staff in preventing surgical fires over the last several years.[21–23]

Informed consent in combination with patient and family communication are also essential to minimizing psychological morbidity in the setting of a postoperative complication. Fully detailing the potential risks, benefits, and alternatives prior to any procedure is essential to establishing a good physician-patient relationship.[24] This allows the patient to make an informed decision on whether to proceed with an elective surgery such as tonsillectomy and establishes clear expectations to postoperative outcomes. Also, documentation of informed consent in the patient's note, instead of just a signed surgical consent form, is associated with a significantly decreased indemnity risk.[25] A majority of patients who have postoperative complications do not pursue legal action.[26] Communicating with patients who experience a complication can help improve the physician-patient relationship and reduce exposure to a malpractice claim.[27] When a complication does occur, patients who experience good communication with their provider tend to perceive a no-fault event rather than assigning malicious intent or incompetence to the surgeon.[28]

CONCLUSION

Tonsillectomy continues to be a procedure that carries a relatively large amount of risk from a medicolegal and patient-care standpoint. There are multiple complications both intraoperatively and postoperatively that may expose the surgeon to a malpractice claim, and more importantly, lead to increased morbidity for the patient. Postoperative bleeding is the complication that is most commonly associated with malpractice claims but may not carry the greatest overall risk with respect to settlements or judgments. In contradistinction, anoxic and hypoxic events, although less common, are much more costly when the subject of a medical malpractice claim. Mortality from these complications continues to be a rare but a real possibility, and the otolaryngologist should be vigilant in all aspects of patient care to avoid them.

BIBLIOGRAPHY

1. Simonsen AR, Duncavage JA, Becker SS. A review of malpractice cases after tonsillectomy and adenoidectomy. *Int J Pediatric Otorhinolaryngol* 2010;74:977–979.
2. Morris LGT, Lieberman SM, Reitzen SD, et al. Characteristics and outcomes of malpractice claims after tonsillectomy. *Otolaryngol Head Neck Surgery* 2008;138:315–320.
3. Cullen KA, Hall MJ, Golosinskiy A. Ambulatory surgery in the United States, 2006, *Natl Health Stat Rep* 2009;11:1–25.
4. Baugh RF, Archer SM, Mitchell RB, et al. Clinical practice guideline: tonsillectomy in children. *Otolaryngol Head Neck Surg* 2011;144:S1–S30.
5. Gabalski EC, Mattucci KF, Setzen M, Moleski P. Ambulatory tonsillectomy and adenoidectomy. *Laryngoscope* 1996;106:77–80.
6. Handler SD, Miller L, Richmond KH, Baranak CC. Post-tonsillectomy hemorrhage: incidence, prevention and management. *Laryngoscope* 1986;96:1243–1247.
7. Tami TA, Parker GS, Taylor RE. Post-tonsillectomy bleeding: an evaluation of risk factors. *Laryngoscope* 1987;97:1307–1311.
8. Carithers JS, Gebhart DE, Williams JA. Postoperative risks of pediatric tonsilloadenoidectomy. *Laryngoscope* 1987;97:422–429.
9. Lee KJ, ed. *Essential Otolaryngology Head and Neck Surgery.* 9th ed. New York, NY: McGraw-Hill; 2008.
10. Kang J, Brodsky L, Danziger I, Volk M, Stanievich J. Coagulation profile as a predictor for post tonsillectomy and adenotonsillectomy hemorrhage. *Int J Pediatric Otorhinolaryngol* 1994;28:157–165.
11. Howells RC II, Wax MK, Ramadan HH. Value of preoperative prothrombin time/partial thromboplastin time as a predictor of postoperative hemorrhage in pediatric patients undergoing tonsillectomy. *Otolaryngol Head Neck Surg* 1997;117:628–632.
12. Windfuhr JP, Schloendorff G, Baburi D, Kremer B. Serious post-tonsillectomy hemorrhage with and without lethal outcome in children and adolescents. *Int J Pediatric Otorhinolaryngol* 2008;72:1029–1040.
13. Moller JT, Wittrup M, Johansen SH. Hypoxemia in the postanesthesia care unit: an observer study. *Anesthesiology* 1990;73:890–895.
14. Bierman MI, Stein KL, Snyder JV. Pulse oximetry in the postoperative care of cardiac surgical patients. A randomized controlled trial. *Chest* 1992;102:1367–1370.
15. Pedersen T. Does perioperative pulse oximetry improve outcome? Seeking the best available evidence to answer the clinical question. *Best Pract Res Clin Anaesthesiol* 2005;19:111–123.
16. Voronov P, Przybylo HJ, Jagannathan N. Apnea in a child after oral codeine: a genetic variant—an ultra-rapid metabolizer. *Paediatr Anaesth* 2007;17:684–687.
17. Gasche Y, Daali Y, Fathi M, et al. Codeine intoxication associated with ultrarapid CYP2D6 metabolism. *N Engl J Med* 2004;351:2827–2831.
18. Palmer SN, Giesecke NM, Body SC, Shernan SK, Fox AA, Collard CD. Pharmacogenetics of anesthetic and analgesic agents. *Anesthesiology* 2005;102:663–671.
19. Sheffield LJ, Phillimore HE. Clinical use of pharmacogenomic tests in 2009. *Clin Biochem Rev* 2009;30:55–65.
20. Madadi P, Gideon K, Cairns J, et al. Safety of codeine during breastfeeding: fatal morphine poisoning in the breastfed neonate of a mother prescribed codeine. *Can Fam Physician* 2007;53:33–35.
21. Sheinbein DS, Loeb RG. Laser surgery and fire hazards in ear, nose, and throat surgeries. *Anesthesiology Clin* 2010;28:485–496.
22. Watson DS. New recommendations for prevention of surgical fires. *AORN J* 2010;91:463–469.
23. Watson DS. Surgical fires: 100% preventable, still a problem. *AORN J* 2009;90:589–593.
24. Paterick TJ, Carson GV, Allen MC, Paterick TE. Medical informed consent: general considerations for physicians. *Mayo Clin Proc* 2008;83:313–319.
25. Bhattacharyya T, Yeon H, Harris MB. The medical-legal aspects of informed consent in orthopaedic surgery. *J Bone Joint Surg Am* 2005;87:2395–2400.
26. Bhattacharyya T. Evidence-based approaches to minimizing malpractice risk in orthopedic surgery. *Orthopedics* 2005;28:378–381.
27. Beckman HB, Markakis KM, Suchman AL, Frankel RM. The doctor-patient relationship and malpractice. Lessons from plaintiff depositions. *Arch Intern Med* 1994;154:1365–1370.
28. Duclos CW, Eichler M, Taylor L, et al. Patient perspectives of patient-provider communication after adverse events. *Int J Qual Health Care* 2005;17:479–486.

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Original Investigation

Lasers and Losers in the Eyes of the Law
Liability for Head and Neck Procedures

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IMPORTANCE Although some have noted that malpractice litigation may be "plateauing," defensive medical practices are pervasive and make up a considerable proportion of the "indirect" costs medicolegal issues contribute toward our health care system. Accordingly, these trends have spurred considerable interest in characterizing factors that play a role in alleged medical negligence, along with outcomes and awards.

OBJECTIVES To conduct a focused examination of malpractice litigation regarding laser procedures in the head and neck and to determine the reasons for initiating litigation as well as outcomes and awards.

DESIGN AND SETTING Retrospective analysis of the WestlawNext legal database, encompassing publicly available federal and state court records, to identify malpractice cases involving laser procedures in the head and neck.

MAIN OUTCOMES AND MEASURES Outcomes, awards, defendant specialty, and other allegations.

RESULTS Most cases (28 [82%]) included in this analysis involved female plaintiffs. Of 34 cases, 19 (56%) were resolved with a defendant verdict. The median indemnity was $150 000, and dermatologists, otolaryngologists, and plastic surgeons were the most commonly named defendants. The most common procedures were performed for age-related changes, acne scarring, hair removal, and vascular lesions, although there were also several rhinologic and airway cases. Of all cases, 25 (74%) involved cutaneous procedures, and common allegations noted included permanent injury (24 cases [71%]), disfigurement/scarring (23 [68%]), inadequate informed consent (17 [50%]), unnecessary/inappropriate procedure (15 [44%]), and burns (11 [32%]). Noncutaneous procedures had higher trending median payments ($600 000 vs $103 000), although this comparison did not reach statistical significance (P = .09).

CONCLUSIONS AND RELEVANCE Procedures using lasers represent a potential target for malpractice litigation should an adverse event occur. Although cutaneous/cosmetic procedures were noted among cases included in this analysis, as well as other head and neck interventions, otolaryngologists were more likely to be named as defendants in the latter category. Although cases had modest indemnities compared with prior analyses, the potential for significant amounts was present. Inclusion into the informed consent process of specific factors detailed in this analysis may potentially decrease liability. In addition, physicians and patients should undergo comprehensive discussion regarding expectations as well as contingencies should adverse events occur.

LEVEL OF EVIDENCE 4.

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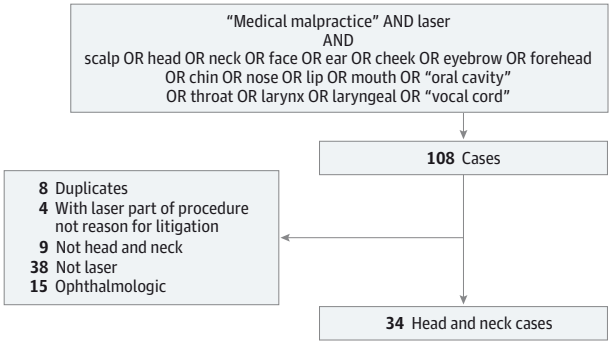
An increasingly litigious environment has characterized health care delivery in the United States during the past 3 decades.[1-5] Although some have noted malpractice litigation may be "plateauing," defensive medical practices are pervasive and make up a considerable proportion of the "indirect" costs medicolegal issues contribute toward our health care system.[6-10] Accordingly, these trends have spurred considerable interest in characterizing factors that play a role in alleged medical negligence, along with outcomes and awards. Jalian et al[11] recently examined common causes of injury in cutaneous laser surgery, noting that "hair removal" was the most commonly litigated procedure and that "lack of informed consent" was present in nearly one-third of cases. No analysis, was noted, however, regarding anatomic sites of injury. In our current analysis, we were interested in conducting a focused examination of litigation regarding cases in the head and neck, as close proximity of critical structures harbor the potential for significant functional sequelae that may adversely affect quality of life. Consequently, we hypothesized that laser-related negligence in the procedures in the head and neck, including the face, is probably associated with higher payments in cases resolved with a jury awarding damages or an out-of-court settlement.

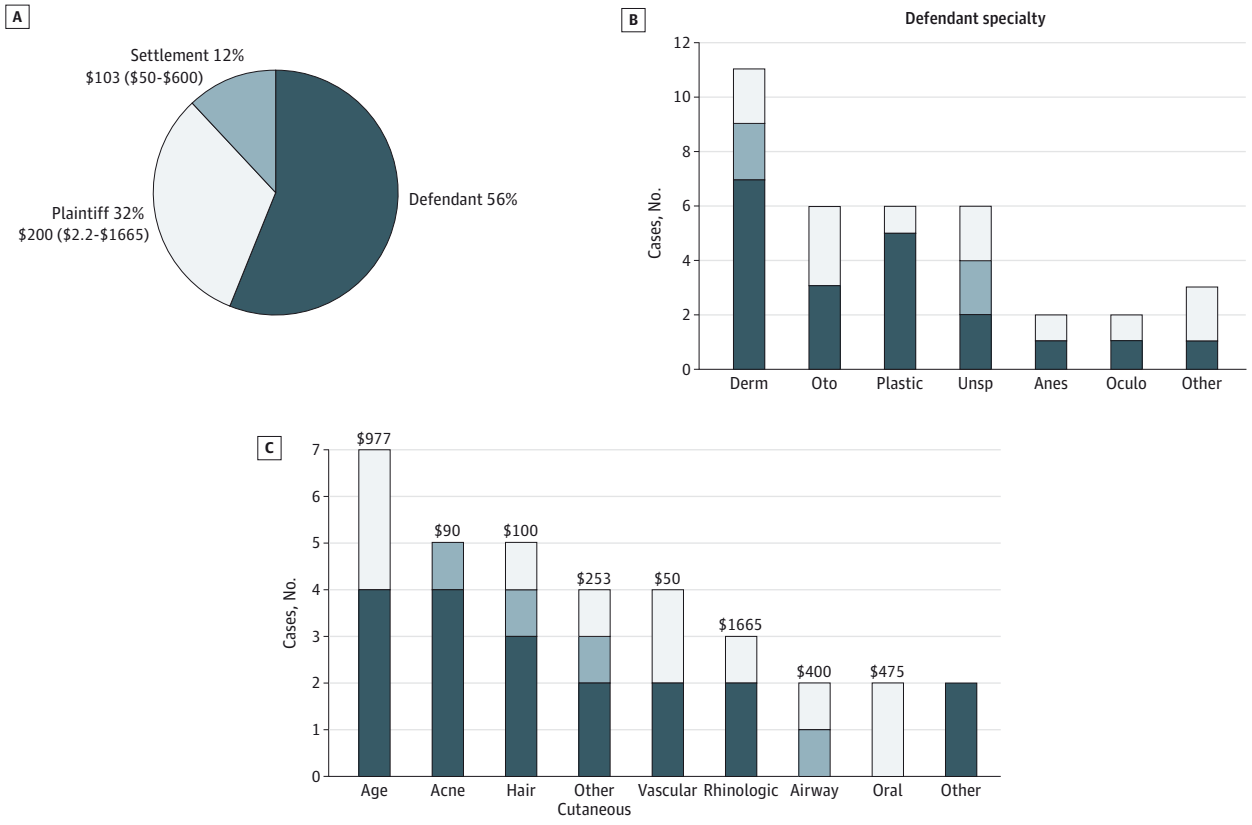
The use of lasers increasingly encompasses procedures beyond those related to cosmetic and cutaneous considerations, particularly in otolaryngology.[12-20] As such, as part of a focused examination on negligence in the head and neck, we

Figure 1. Search Terms and Results



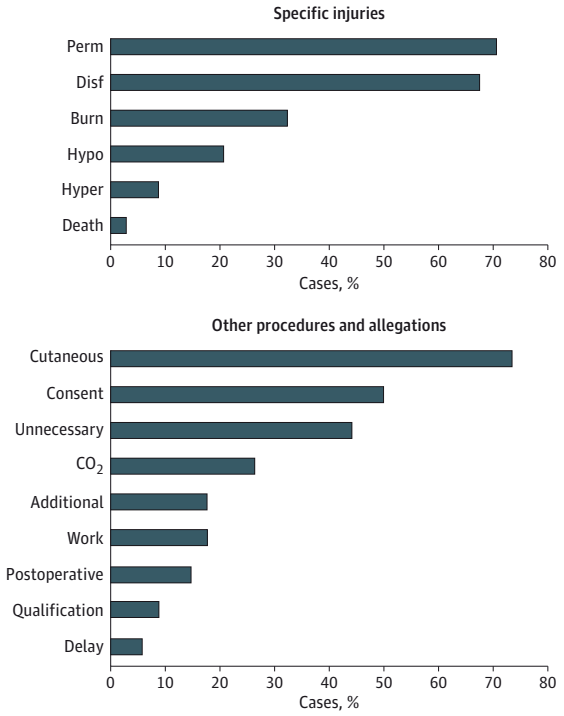
A total of 34 malpractice litigation cases concerning laser procedures in the head and neck were identified.

Figure 2. Characteristics of Cases Included in This Analysis



A, Overall outcomes and median payments, given in thousands of dollars, with ranges in parentheses. B, Specialty of physician defendants. Anes indicates anesthesiology; Derm, dermatology; Oculo, oculoplastic surgery (fellowship-trained surgeons); Oto, otolaryngology; Plastic, plastic surgery; and Unsp, unspecified. C, Indications for procedures/types of procedures included in current analysis. Acne indicates resurfacing for acne marks; age, cutaneous laser resurfacing for age-related changes; hair, hair removal; oral, oral/oropharyngeal; and vascular, removal of vascular lesions. Median payments (in thousands of dollars) for each type of procedure are noted above bars. B and C, Top portions of bars represent plaintiff decisions; middle portions, settlements; and bottom portions, defendant decisions.

Figure 3. Alleged Factors Most Frequently Raised in Litigation



Top panel depicts specific alleged injuries; bottom panel, types of procedures and allegations not regarding specific injuries. Additional indicates additional procedures required because of adverse event; CO_2, cases in which use of a carbon dioxide laser was explicitly mentioned (most others did not specify laser type); consent, alleged deficits in informed consent; cutaneous, cutaneous procedure; delay, delay in diagnosis of complication; Disf, poor cosmesis, disfigurement, or scarring; Hyper, hyperpigmentation; Hypo, hypopigmentation; Perm, permanent injury; postoperative, postoperative negligence; qualification, defendant allegedly not qualified to perform procedure; unnecessary, unnecessary or inappropriate procedure; and work, employment or income affected by injury.

were also interested in examining the occurrence of litigation regarding noncosmetic causes. Our objectives were to examine relevant cases for such factors as outcome, awards, and other allegations present in malpractice litigation, including both specific injuries as well as general considerations. For example, in addition to perceived deficits in informed consent, a previous analysis of negligence regarding cranial nerve injury found that the requirement of additional reparative procedures as well as allegations that a procedure was unnecessary or inappropriate were factors that may influence trial outcomes.[21]

Methods

We used the advanced search function of the WestlawNext database (Thomson Reuters) to identify jury verdict and settlement reports spanning from 1992 to October 2013, using the search terms illustrated in **Figure 1**. This database draws from court proceedings progressing to the point of inclusion in publicly available federal and state court records. Although some

Table 1. Common Factors and Their Effect on Case Resolution

Factor[a]	Cases Resolved With Payment, % (Median Payment, $)		*P* Value for Median Payments
	Factor Present	Factor Absent	
Noncutaneous	56 (600 000)	40 (103 000)	.09
Consent	59 (246 000)	29 (150 000)	.17
Unnecessary	33 (100 000)	53 (175 000)	.95
Burn	55 (133 000)	39 (200 000)	.61
Pigmentation	48 (150 000)	33 (158 000)	.84

[a] *Consent* refers to the presence or absence of allegations regarding perceived deficits in informed consent; *pigmentation,* allegations regarding dyspigmentation (hypopigmentation or hyperpigmentation); *unnecessary*, allegedly unnecessary or inappropriate procedure.

jurisdictions include attorney-reported cases,[22,23] nonvoluntary (ie, confidential) reports are available from most jurisdictions and are labeled with such terms as *confidential, anonymous,* or *Jane Doe/John Doe*. Along with the comprehensive detail available in most court reports, WestlawNext's ease of use (for the layperson without legal expertise) makes it a widely used resource within and beyond the legal community, and it has consequently been valuable in a multitude of medicolegal analyses.[21-48] We comprehensively examined each court record, recording plaintiff age and sex, specific issues put forward in litigation, and case outcomes. All data were collected in October 2013.

Because monetary values did not follow a symmetric distribution, jury awards and out-of-court settlements were compared as appropriate using nonparametric statistical analysis with Mann-Whitney tests. The threshold for significance was set at $P < .05$, and SPSS software (version 20; IBM) was used for statistical analysis.

Results

Most cases included in this analysis involved female plaintiffs (82%). The median plaintiff age was 46 years (range, infancy to 83 years). Of 34 cases (**Figure 2**), 19 (56%) were resolved with a defendant verdict (Figure 2A). Aggregate payments (including verdict awards and settlements) totaled $6.55 million. Median jury-awarded damages were greater than out-of-court settlements ($200 000 vs $102 750), although this difference was not statistically significant ($P = .30$). Dermatologists were the most frequently named physician defendants (11 cases [32%]), and otolaryngologists and plastic surgeons were equally represented (6 cases each [18%]) (Figure 2B). In addition, 3 cases had litigation involving nonphysician defendants. The most frequent procedures included laser treatment for age-related changes, followed by revision of acne marks and hair removal (Figure 2C). Nearly three-quarters of procedures were for cutaneous conditions, and the other most frequent allegations raised in litigation included sustaining permanent injury, disfigurement or scarring, inadequate informed consent, and undergoing unnecessary or inappropriate procedures (**Figure 3**). Procedures for noncutaneous conditions and cases with informed consent

Table 2. Cases With Alleged Intraoperative Negligence Involving Otolaryngologists

Patient Age, y/ Sex[a]	Award (S/P), $	Procedure/Underlying Condition	Postop-erative	Unnecessary	Consent	Additional	Cosmesis	Perm	Alleged Injury
M	1 665 000 (P)	Septoplasty/turbinate reduction (laser) for nasal obstruction and rosacea	No	No	Yes	No	Yes	Yes	Loss of skin/cartilage around nose; disfigurement/scarring
M	850 000 (P)	Laser UPPP and tonsil (OSA)	Yes	Yes	Yes	No	No	Yes	Nasopharyngeal stenosis; failure to address nasal septum
45/F	…[b]	Septoplasty/turbinate reduction (laser) for OSA	No	Yes	No	Yes	No	No	No improvement in symptoms; sinus symptoms developed; OSA not correct diagnosis
45/M	…[b]	Laser stapedectomy (otosclerosis)	No	Yes	Yes	No	Yes	Yes	Cranial nerve VII paralysis; diminished visual acuity and depth perception in left eye; hearing loss
64/F	…[b]	Septoplasty/turbinate reduction (laser) for deviated septum nasal symptoms	No	No	Yes	No	No	No	KTP laser; postoperative urinary retention/ ileus; did not consent to general anesthesia
83/M	200 000 (P)	Cancerous VC lesion	No	No	No	No	No	No	Airway fire; inhalation injury; death due to ARDS

Abbreviations: Additional, required additional surgery; ARDS, acute respiratory distress syndrome; consent, alleged deficits in informed consent; cosmesis, poor cosmesis (from disfigurement or scarring); KTP, potassium titanyl phosphate; OSA, obstructive sleep apnea; P, plaintiff decision; perm, permanent injury; postoperative, postoperative negligence; S/P, settlement or plaintiff decision; unnecessary, unnecessary or inappropriate procedure; UPPP, uvulopalatopharyngoplasty; VC, vocal cord.

[a] Ages were not available for some patients.

[b] Defendant decision.

allegations had higher median payments (**Table 1**), although these differences did not reach statistical significance, possibly because there were too few overall cases.

Among cases with otolaryngologists as defendants, all but 1 were exclusively for noncutaneous conditions, and 1 was a combined rhinologic procedure along with laser resurfacing for rosacea; other factors in cases with defendants confirmed to be otolaryngologists are illustrated in **Table 2**. Cases resolved with a plaintiff verdict are detailed in **Table 3**, and informed consent allegations and sustaining allegedly permanent injuries were present in a significant proportion of these cases. In addition, **Table 4** and **Table 5** list factors in cutaneous cases performed for vascular lesions or other aesthetic reasons, respectively.

Discussion

Our examination reinforces findings comprehensively detailed by Jalian et al,[11] because both analyses noted the presence of similar issues raised in malpractice litigation, including burns, scars and disfigurement, and pigmentation abnormalities. As otolaryngologists, we were interested in further focusing analysis on the use of lasers in the head and neck. The 15 cases in the current analysis resolved with an out-of-court settlement or a plaintiff verdict with a median award of $150 000, less than the median indemnity ($350 000) reported by Jalian et al.[11] This refutes our hypothesis that malpractice involving the head and neck would result in definitively higher payments owing to the close proximity of critical structures and a consequently smaller "margin for error." The reasons for this discrepancy are unclear; some of the main differences between these analyses were that the prior analysis included far more hair removal cases (63 cases) and numerous cases involving tattoo removal. Another important consideration was that we were most interested in medical malpractice and thus restricted our study to cases of medical negligence; in other words, we did not include cases dealing exclusively with product liability or deficient medical device design. Prior analyses of facial aesthetic procedures have noted that product liability claims against manufacturers occur with regularity.[11,49]

Only 3 cases involved nonphysician operators being named as codefendants, a smaller proportion than reported by Jalian et al.[11] Despite the unclear effect of nonphysician operators on our findings, there is a real potential for physicians to be named as codefendants for acts committed by nonphysician operators under their supervision, as noted in our analysis and in prior studies. In a focused examination of laser litigation associated with nonphysician operators, Jalian et al[50] estimated that nearly one-third of litigation analyzed included this scenario. This reinforces the importance of close supervision, knowledge of state laws with regard to this practice, and maximal caution in the employment of these operators.

During the past 2 decades, the use of lasers has increased in a variety of otolaryngologic procedures and conditions. Advocates of lasers in rhinologic procedures, particularly for turbinate reduction, note a decreased bleeding risk,[51] and the use of lasers has notably increased for management of laryngeal lesions.[12] Moreover, success in several otologic procedures, including revision stapedectomy, has increased when lasers are used.[20]

Physicians in multiple specialties, including otolaryngology and facial plastic and reconstructive surgery, have also increasingly used lasers for cutaneous conditions, because a multitude of conditions that previously necessitated more invasive operative intervention can now be managed with lasers.[52,53] Laser resurfacing has traditionally encompassed the use of carbon dioxide and erbium:YAG lasers, and recent developments have greatly expanded the timing available to treat unsightly scarring or other lesions, ranging from as early as an initial injury to many years later.[54]

Table 3. Cases Resolved With a Plaintiff Verdict

Patient Age, y/ Sex[a]	Award, $	Defendant	Indication	Laser	Qualification	Burn	Pigment	Postoperative	Unnecessary	Consent	Additional	Work	Perm	Comments
52/F	977 000	Derm	Aging	CO_2	Yes	Third degree	Yes	No	No	Yes	Yes	No	No	Perioral scarring
F	150 000	Unspecified	Hair	Unspecified	No	First degree	Yes	No	No	No	No	Yes	Yes	Positive erythema
F	2300	OB	Aging	Titan	No	Third degree	No	No	No	Yes	No	No	Yes	Involvement of cheeks, forehead
35/F	20 000	GS	Vascular	CO_2	No	No	No	No	Yes	Yes	No	No	Yes	"Should have" used argon laser
F	391 000	Plastic	Scar	CO_2	No	No	No	No	No	Yes	No	No	No	Lost tip of nose
71/F	1 265 000	Oculoplastic	Aging	CO_2	No	No	No	No	Yes	Yes	No	No	Yes	Skin breakdown needing HBO
F	80 000	Derm	Vascular	Unspecified	No	No	No	No	No	Yes	No	Yes	Yes	Ulcers that scarred
83/M	200 000	O/A	VC	Unspecified	No	No	No	No	No	No	No	No	No	See Table 2
M	1 665 000	Oto	Rhinologic	Unspecified	No	No	No	No	No	Yes	No	Yes	Yes	See Table 2
M	850 000	Oto	OSA	Unspecified	No	No	No	Yes	Yes	Yes	No	Yes	Yes	See Table 2
38/F	100 000	Dentist	Dental[b]	Unspecified	Yes	No	No	No	Yes	Yes	Yes	Yes	No	Loss of bone; death of 7 teeth

Abbreviations: Additional, required additional surgery; CO_2, carbon dioxide; consent, alleged deficits in informed consent; defendant, defendant specialty; Derm, dermatologist; GS, general surgeon; hair, hair removal; HBO, hyperbaric oxygen therapy; indication, indication for procedure; O/A, otolaryngologist and anesthesiologist codefendants; OB, obstetrician-gynecologist; oculoplastic, oculoplastic surgeon; OSA, obstructive sleep apnea surgery; Oto, otolaryngologist; perm, permanent injury; pigment, dyspigmentation; plastic, plastic surgeon; postoperative, postoperative negligence; qualification, defendant allegedly not qualified to perform procedure; rhinologic, rhinologic procedure; unnecessary, unnecessary or inappropriate procedure; vascular, removal of vascular anomaly; VC, vocal cord procedure; work, employment/income affected.

[a] Ages were not available for many patients.

[b] Laser gingivectomy.

Table 4. Allegations in Cases Involving Removal of Vascular Lesions

Patient Age, y/Sex[a]	Defendant	Award (S/P), $	Postoperative	Unnecessary	Consent	Additional	Perm	Comments
35/F	Not specified	20 000 (P)	No	Yes	Yes	No	Yes	CO_2 laser to remove PWS on neck/jaw; scarring; plaintiff claimed defendant should have used argon laser
8/M	Derm	…[b]	No	Yes	Yes	No	Yes	Candella laser for PWS on face, neck, and arm; hyperpigmentation; "inappropriate" candidate because patient was African American
F	Derm	80 000 (P)	No	No	Yes	No	Yes	Telangiectasias on face removed; resulting nonhealing ulcer
F	General surgeon	…[b]	Yes	No	No	No	No	Postoperative application of aloe, to which patient had known allergy; facial swelling; physician not in room during procedure; procedure for veins on cheek

Abbreviations: Additional, required additional surgery; CO_2, carbon dioxide; consent, alleged deficits in informed consent; Derm, dermatologist; P, plaintiff decision; perm, permanent injury; postoperative, postoperative negligence; PWS, port-wine stain; S/P, settlement or plaintiff decision; unnecessary, unnecessary or inappropriate procedure.

[a] Ages were not available for some patients.

[b] Defendant decision.

Despite the myriad benefits accompanying these trends, there is certainly the potential for complications, including thermal injury and skin discoloration, as noted in our analysis. Allegations of inadequate informed consent were raised in 50% of cases included (17 cases) (Figure 3). Nearly 60% of these cases (10 cases) were resolved with a payment, compared with the 29% payment rate in cases without this issue, and median payments trended higher with the presence of this factor ($246 000 vs $150 000), although this trend did not reach statistical significance (P = .17) (Table 2). Alleged deficits in informed consent have been consistently found in a variety of medicolegal analyses.[21,45,55-57] This is particularly important for cosmetic procedures, in which informed consent allegations can stem from a patient's expectations not being met rather than a physician's simply not mentioning a potential risk.[44] Consequently, in a comprehensive discussion of risks, benefits, and alternatives, physicians and patients should explore specific goals of a procedure, as well as what plan to follow if expectations are not met. Although including the specific injuries detailed in this analysis (Figure 3) is certainly

Table 5. Allegations in 21 Aesthetic Cutaneous Cases Not Involving Vascular Lesions

Alleged Factor	Cases, No. (%)
Poor cosmesis	18 (86)
Burn	10 (48)
Third degree	3 (14)
Second degree	3 (14)
Informed consent	9 (43)
Unnecessary or inappropriate procedure	8 (38)
Inappropriate procedure	7 (33)
Hypopigmentation	7 (33)
Procedure for aging	7 (33)
Hair removal	5 (24)
Acne spot removal	4 (24)
Postoperative negligence	3 (14)
Underwent additional procedure	3 (14)
Defendant not qualified	2 (10)
Hyperpigmentation	2 (10)

Eight cases (38%) were resolved with payment; the median payment was $132 750.

valuable, further discussion of more general considerations (such as the potential requirement for additional surgery [Figure 3]) is also important.

The use of a carbon dioxide laser was noted in 9 cases (26%), and potassium titanyl phosphate and erbium:YAG lasers were noted in 1 case each. The other cases did not specify which types of lasers were used by the defendant. This finding illustrates a weakness inherent to the use of WestlawNext in this analysis, in that certain medical components of the case may not be detailed in numerous instances. WestlawNext is compiled to educate litigators about issues brought up in malpractice litigation,[22,23] and, consequently, many of the jury verdict and settlement reports are written to disseminate information to the layperson without medical expertise.

Another limitation of WestlawNext is that it includes only cases progressing far enough for possible inclusion into publicly available federal and state court records. Only 34 cases met inclusion criteria using our search terms. During a 22-year span, this represents 1 or 2 cases per year, a relatively low number compared with other medicolegal topics of interest. This may mean that litigation concerning head and neck laser injuries is less frequent than litigation concerning injuries elsewhere, or it may represent a higher likelihood of reaching out-of-court settlements, many of which may not progress far enough to be included in publicly available federal and state court records. Confirming which of these scenarios may be responsible for the number of cases included is beyond the scope of this resource. This limitation emphasizes the fact that WestlawNext's value lies not in estimating the prevalence of litigation specific to an injury but rather in its utility in analyzing allegations in cases to which we had access. Despite these drawbacks, WestlawNext is still one of the most detailed sources describing medicolegal proceedings and as such has been of value in many analyses.[11,21-30,32-48]

Conclusions

Procedures using lasers represent a potential target for malpractice litigation should an adverse event occur. Physicians in numerous specialties, including dermatology, plastic surgery, and otolaryngology, were named as defendants. Whereas cases in this analysis included cutaneous/cosmetic procedures as well as other head and neck interventions, otolaryngologists were more likely to be named as physician defendants in the latter category. Although cases resolved with out-of-court settlement or plaintiff verdicts had relatively modest payments (median, $150 000) compared with prior analyses, the potential for significant amounts was present; numerous plaintiff verdicts exceeded $800 000. Inclusion in the informed consent process of specific factors detailed in this analysis, such as scarring/disfigurement and pigmentation abnormalities, as well as attention to more general considerations, such as the potential need for additional surgery, may decrease liability. In addition, physicians and patients should have comprehensive discussions regarding expectations as well as contingency plans to be followed should adverse events occur.

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REFERENCES

1. Anderson GF, Hussey PS, Frogner BK, Waters HR. Health spending in the United States and the rest of the industrialized world. *Health Aff (Millwood)*. 2005;24(4):903-914.

2. Jena AB, Chandra A, Lakdawalla D, Seabury S. Outcomes of medical malpractice litigation against US physicians. *Arch Intern Med*. 2012;172(11):892-894.

3. Jena AB, Chandra A, Seabury SA. Malpractice risk among US pediatricians. *Pediatrics*. 2013;131(6):1148-1154.

4. Jena AB, Seabury S, Lakdawalla D, Chandra A. Malpractice risk according to physician specialty. *N Engl J Med*. 2011;365(7):629-636.

5. Seabury SA, Chandra A, Lakdawalla DN, Jena AB. On average, physicians spend nearly 11 percent of their 40-year careers with an open, unresolved malpractice claim. *Health Aff (Millwood)*. 2013;32(1):111-119.

6. Hertz BT, Arthurs J. Malpractice rates plateauing: the only thing to fear may be fear itself. *Med Econ*. 2011;88(22):24-25, 28-29, 32.

7. Leflar RB. Medical malpractice reform measures and their effects. *Chest*. 2013;144(1):306-318.

8. Hermer LD, Brody H. Defensive medicine, cost containment, and reform. *J Gen Intern Med*. 2010;25(5):470-473.

9. Litvin SG. An overview of medical malpractice litigation and the perceived crisis. *Clin Orthop Relat Res*. 2005;(433):8-14.

10. Nahed BV, Babu MA, Smith TR, Heary RF. Malpractice liability and defensive medicine: a national survey of neurosurgeons. *PLoS One*. 2012;7(6):e39237. doi:10.1371/journal.pone.0039237.

11. Jalian HR, Jalian CA, Avram MM. Common causes of injury and legal action in laser surgery. *JAMA Dermatol*. 2013;149(2):188-193.

12. Benninger MS. Laser surgery for nodules and other benign laryngeal lesions. *Curr Opin Otolaryngol Head Neck Surg*. 2009;17(6):440-444.

13. Zeitels SM, Burns JA. Office-based laryngeal laser surgery with the 532-nm pulsed-potassium-titanyl-phosphate laser. *Curr Opin Otolaryngol Head Neck Surg*. 2007;15(6):394-400.

14. Madani M. Laser assisted uvulopalatopharyngoplasty (LA-UPPP) for the treatment of snoring and mild to moderate obstructive sleep apnea. *Atlas Oral Maxillofac Surg Clin North Am*. 2007;15(2):129-137.

15. Littner M, Kushida CA, Hartse K, et al. Practice parameters for the use of laser-assisted uvulopalatoplasty: an update for 2000. *Sleep*. 2001;24(5):603-619.

16. Jones N. Lasers in rhinology. *J Laryngol Otol*. 2000;114(11):824-826.

17. Lippert BM, Werner JA. CO2 laser surgery of hypertrophied inferior turbinates. *Rhinology*. 1997;35(1):33-36.

18. Soh KB. Laser technology in research, diagnosis and therapy in rhinology. *Clin Otolaryngol Allied Sci*. 1996;21(2):102-105.

19. Ossoff RH, Coleman JA, Courey MS, Duncavage JA, Werkhaven JA, Reinisch L. Clinical applications of lasers in otolaryngology—head and neck surgery. *Lasers Surg Med*. 1994;15(3):217-248.

20. Stucken EZ, Brown KD, Selesnick SH. The use of KTP laser in revision stapedectomy. *Otol Neurotol*. 2012;33(8):1297-1299.

21. Svider PF, Sunaryo PL, Keeley BR, Kovalerchik O, Mauro AC, Eloy JA. Characterizing liability for cranial nerve injuries: a detailed analysis of 209 malpractice trials. *Laryngoscope*. 2013;123(5):1156-1162.

22. Nash JJ, Nash AG, Leach ME, Poetker DM. Medical malpractice and corticosteroid use. *Otolaryngol Head Neck Surg*. 2011;144(1):10-15.

23. Reilly BK, Horn GM, Sewell RK. Hearing loss resulting in malpractice litigation: what physicians need to know. *Laryngoscope*. 2012;123(1):112-117.

24. Lydiatt DD. Medical malpractice and facial nerve paralysis. *Arch Otolaryngol Head Neck Surg*. 2003;129(1):50-53.

25. Hong SS, Yheulon CG, Sniezek JC. Salivary gland surgery and medical malpractice. *Otolaryngol Head Neck Surg*. 2013;148(4):589-594.

26. Bhatt A, Safdar A, Chaudhari D, et al. Medicolegal considerations with intravenous tissue plasminogen activator in stroke: a systematic review. *Stroke Res Treat*. 2013;2013:562564. doi:10.1155/2013/562564.

27. Lekovic GP, Harrington TR. Litigation of missed cervical spine injuries in patients presenting with blunt traumatic injury. *Neurosurgery*. 2007;60(3):516-523.

28. Mitnick JS, Vazquez MF, Kronovet SZ, Roses DF. Malpractice litigation involving patients with carcinoma of the breast. *J Am Coll Surg*. 1995;181(4):315-321.

29. Frank-Stromborg M, Ganschow JR. Legal issues in the early detection and monitoring of cancer. *Semin Oncol Nurs*. 2002;18(2):128-134.

30. Morris LG, Ziff DJ, DeLacure MD. Malpractice litigation after surgical injury of the spinal accessory nerve: an evidence-based analysis. *Arch Otolaryngol Head Neck Surg*. 2008;134(1):102-107.

31. Clayton EW, Haga S, Kuszler P, Bane E, Shutske K, Burke W. Managing incidental genomic findings: legal obligations of clinicians. *Genet Med*. 2013;15(8):624-629.

32. Wegman B, Stannard JP, Bal BS. Medical liability of the physician in training. *Clin Orthop Relat Res*. 2012;470(5):1379-1385.

33. Blaivas M, Pawl R. Analysis of lawsuits filed against emergency physicians for point-of-care emergency ultrasound examination performance and interpretation over a 20-year period. *Am J Emerg Med*. 2012;30(2):338-341.

34. Khan MN, Blake DM, Vazquez A, Setzen M, Baredes S, Eloy JA. Epistaxis: the factors involved in determining medicolegal liability. *Int Forum Allergy Rhinol*. 2014;4(1):76-81.

35. Blake DM, Svider PF, Carniol ET, Mauro AC, Eloy JA, Jyung RW. Malpractice in otology. *Otolaryngol Head Neck Surg*. 2013;149(4):554-561.

36. Choudhry AJ, Anandalwar SP, Choudhry AJ, et al. Uncovering malpractice in appendectomies: a review of 234 cases. *J Gastrointest Surg*. 2013;17(10):1796-1803.

37. Eloy JA, Svider PF, D'Aguillo CM, Baredes S, Setzen M, Folbe AJ. Image-guidance in endoscopic sinus surgery: is it associated with decreased medicolegal liability? *Int Forum Allergy Rhinol*. 2013;3(12):980-985.

38. Eloy JA, Svider PF, Folbe AJ, Couldwell WT, Liu JK. Comparison of plaintiff and defendant expert witness qualification in malpractice litigation in neurological surgery. *J Neurosurg*. 2014;120(1):185-190.

39. Eloy JA, Svider PF, Patel D, Setzen M, Baredes S. Comparison of plaintiff and defendant expert witness qualification in malpractice litigation in otolaryngology. *Otolaryngol Head Neck Surg*. 2013;148(5):764-769.

40. Eloy JA, Svider PF, Patel D, Setzen M, Baredes S. In response to "comparison of plaintiff and defendant expert witness qualification in malpractice litigation in otolaryngology." *Otolaryngol Head Neck Surg*. 2013;149(4):649-650.

41. Svider PF, Blake DM, Husain Q, et al. In the eyes of the law: malpractice litigation in oculoplastic surgery. *Ophthal Plast Reconstr Surg*. 2014;30(2):119-123.

42. Svider PF, Blake DM, Sahni KP, et al. Meningitis and legal liability: an otolaryngology perspective. *Am J Otolaryngol*. 2014;35(2):198-203.

43. Svider PF, Husain Q, Kovalerchik O, et al. Determining legal responsibility in otolaryngology: a review of 44 trials since 2008. *Am J Otolaryngol*. 2013;34(6):699-705.

44. Svider PF, Keeley BR, Zumba O, Mauro AC, Setzen M, Eloy JA. From the operating room to the courtroom: a comprehensive characterization of litigation related to facial plastic surgery procedures. *Laryngoscope*. 2013;123(8):1849-1853.

45. Svider PF, Kovalerchik O, Mauro AC, Baredes S, Eloy JA. Legal liability in iatrogenic orbital injury. *Laryngoscope*. 2013;123(9):2099-2103.

46. Svider PF, Pashkova AA, Folbe AJ, et al. Obstructive sleep apnea: strategies for minimizing liability and enhancing patient safety. *Otolaryngol Head Neck Surg*. 2013;149(6):947-953.

47. Svider PF, Pashkova AA, Husain Q, et al. Determination of legal responsibility in iatrogenic tracheal and laryngeal stenosis. *Laryngoscope*. 2013;123(7):1754-1758.

48. Svider PF, Pashkova AA, Vidal GP, Mauro AC, Eloy JA, Chokshi RJ. Esophageal perforation and rupture: a comprehensive medicolegal examination of 59 jury verdicts and settlements. *J Gastrointest Surg*. 2013;17(10):1732-1738.

49. Korman JB, Jalian HR, Avram MM. Analysis of botulinum toxin products and litigation in the United States. *Dermatol Surg*. 2013;39(11):1587-1596.

50. Jalian HR, Jalian CA, Avram MM. Increased risk of litigation associated with laser surgery by nonphysician operators. *JAMA Dermatol*. 2013. doi:10.1001/jamadermatol.2013.7117.

51. Lippert BM, Werner JA. Long-term results after laser turbinectomy. *Lasers Surg Med*. 1998;22(2):126-134.

52. Fedok FG, Garritano F, Portela A. Cutaneous lasers. *Facial Plast Surg Clin North Am*. 2013;21(1):95-110.

53. Carniol PJ, Meshkov L, Grunebaum LD. Laser treatment of facial scars. *Curr Opin Otolaryngol Head Neck Surg*. 2011;19(4):283-288.

54. Oliaei S, Nelson JS, Fitzpatrick R, Wong BJ. Laser treatment of scars. *Facial Plast Surg*. 2012;28(5):518-524.

55. Patel AJ, Morrison CM. Opportunities to reduce plastic surgery claims through an analysis of complaints data. *J Plast Reconstr Aesthet Surg*. 2013;66(4):455-459.

56. Walters AL, Dacey KT, Zemlyak AY, Lincourt AE, Heniford BT. Medical malpractice and hernia repair: an analysis of case law. *J Surg Res*. 2013;180(2):196-200.

57. Lydiatt DD. Medical malpractice and head and neck cancer. *Curr Opin Otolaryngol Head Neck Surg*. 2004;12(2):71-75.

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Malpractice in Treatment of Sinonasal Disease by Otolaryngologists: A Review of the Past 10 Years

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Abstract

Objective. Sinonasal disease is a common condition treated by otolaryngologists. Malpractice in this area is the most common litigation faced by otolaryngologists. This study analyzes malpractice in the treatment of sinonasal disease.

Study Design. Case series, review of legal records.

Setting. Legal databases.

Subjects and Methods. Using 2 different computerized legal databases, the phrase *medical malpractice* was searched with terms related to sinonasal disease involving court cases in the past 10 years (2004-2013), yielding 26 cases. The cases were analyzed for pertinent data regarding plaintiffs, presenting complaint, practice setting, type of malpractice, resulting injury, result of verdict, and amount of reward or settlement.

Results. Chronic sinusitis (42%) was the most common presenting symptom. Many cases included multiple types of alleged malpractice, with the most common being negligent technique (38%) and lack of informed consent (27%). The most common alleged injuries included cerebrospinal fluid leak, meningitis, nasal obstruction, and orbital trauma. Defendants prevailed in 13 of 18 cases in which outcomes were known, with mean award of $225,000 and mean settlement of $212,500. The cases won by plaintiffs were all in a private practice setting.

Conclusion. Otolaryngologists should be aware of the causes of malpractice litigation as it relates to treatment of sinonasal disease. Lack of informed consent continues to be a common allegation, and surgeons should ensure complete informed consent is obtained and well documented. A unified and complete database of medical malpractice cases is needed to allow for further analysis of specialty-related claims.

Keywords

medical malpractice, otolaryngology, sinonasal disease, sinus surgery

Physicians are under more pressure than ever to deliver cost-effective, efficient health care without compromising patient safety. Frivolous lawsuits comprise approximately 37% of malpractice cases, accounting for about 15% of medical malpractice costs.[1,2] Recent studies have shown that rates of malpractice claims are plateauing, with most cases not resulting in payment to plaintiffs.[3,4] Regardless of the appropriateness of a lawsuit, any litigation is viewed as an attack on the character and competence of the physician involved. Given the economical, psychological, and patient safety implications, the malpractice system has a tremendous effect on physicians and patients.

The margin of error in the surgical management of sinonasal disease is small, and there are several postoperative consequences of iatrogenic injury. Endoscopic sinus surgery (ESS) in particular has well-described complications. These include blindness, diplopia, cerebrospinal fistula (with or without meningitis), intracranial brain injury, and life-threatening hemorrhage from carotid artery injury.[5] Any otolaryngologist performing sinonasal procedures should be aware of these potential adverse outcomes and take measures to avoid them.

It is pertinent for an otolaryngologist to be informed of the recent nature of malpractice suits involving the treatment of sinonasal disease. The objective of this review is to examine the most recent litigation involving the management of sinonasal disease by otolaryngologists. Information drawn from this review and analysis should help otolaryngologists to be aware

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of litigation in sinonasal disease treatment, understand the legal grounds where they are most vulnerable, promote a safer practice, and potentially improve patient care.

Methods

Two computerized legal databases (Westlaw, Thomas Reuters, New York, New York; LexisNexis, a division of Reed Elsevier, Inc, Amsterdam, the Netherlands) were searched for the term *medical malpractice* in conjunction with several terms dealing with the practice of otolaryngology and sinonasal disease for the past 10 years (2004-2013). Terms searched included *anosmia, cerebrospinal fluid leak, deviated septum, epistaxis, ethmoidectomy, fungal sinusitis, maxillary antrostomy, nasal cancer, nasal obstruction, nasal polyp, orbital injury, paranasal sinuses, rhinologist, septoplasty, sinus surgery, sinusitis, sinusotomy, sphenoidostomy, turbinate reduction*, and *vision loss*. Westlaw and LexisNexis are similar databases requiring a subscription that contain jury verdict reports from all 50 states. These reports are submitted voluntarily by attorneys and typically contain the jurisdiction, names of attorneys and expert witnesses, demographic information, verdict, award amount, and summary of the case. The Westlaw database has previously been used in multiple otolaryngology medical malpractice analyses including otology,[6] hearing loss,[7] corticosteroid use,[8] facial plastic surgery,[9] facial nerve paralysis,[10] iatrogenic tracheal stenosis,[11] iatrogenic cranial nerve injury,[12] iatrogenic cerebrospinal fluid (CSF) leak,[13] iatrogenic orbital injury,[14] and sinonasal disease.[15]

Because no protected patient information was used, no institutional review board review was sought. Data extracted from the cases included plaintiff gender, presenting complaint, practice setting, type of malpractice alleged, alleged injury, verdict, and amount of award or settlement rewarded.

Results

The search identified 26 cases involving sinonasal disease and otolaryngologists from 2004 to 2013. LexisNexis produced 2 additional cases not found in the Westlaw database. The cases involved 19 males and 7 females. Eighteen cases were in the private practice setting, and 6 involved an academic medical center. Of the 26 cases, 15 had complete results, and the verdict or outcome was known in 18 of the cases. Defendants prevailed in 72% (13/18) of these cases and the plaintiff prevailed in 16% (3/18). Of the 3 cases won by the plaintiff, 2 had published award amounts of $300,000 and $150,000. All 3 of these cases were in the private practice setting. Settlement was reached in 2 cases with a monetary award of $250,000 and $175,000. In the 8 cases in which verdicts or outcomes were not published, initial summary judgment was denied. Summary judgment is a court order ruling that no factual issues remain to be tried and therefore a complaint can be decided on certain facts without a trial.

The most common presenting complaint or reason for treatment was chronic sinusitis (42%) followed by nasal obstruction (27%; **Table 1**). The type of malpractice was divided into 7 categories. The most common allegation was negligent technique, followed by lack of informed consent. Other allegations included failure of surgery, wrongful death, surgery not indicated, failure to diagnose, and injury unrelated to surgery (**Figure 1**). Four cases alleged CSF leak, and 4 cases alleged wrongful death. Other alleged injuries included visual impairment, meningitis, nasal obstruction, headache, recirculation, anoxic brain injury, bleeding, orbital hematoma, infection, anosmia, burning mouth syndrome, foreign body in abdominal fat graft site, and need for additional surgery (**Table 2**).

Table 1. Presenting Complaint.

Presenting Complaint	No. of Cases
Chronic sinusitis	11
Nasal obstruction	7
Sleep apnea	3
Headache	2
Acute sinusitis	1
Nasal polyps	1
Allergic fungal sinusitis	1

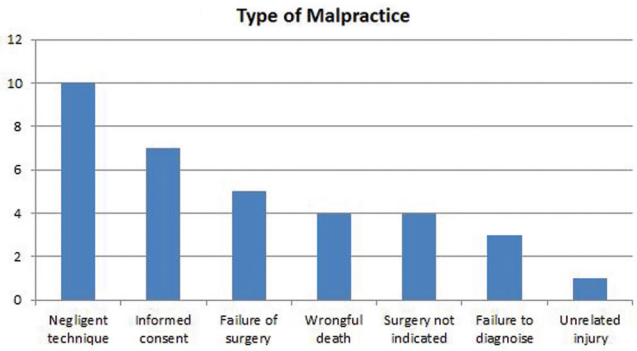

Figure 1. Type of malpractice.

The alleged injuries in the wrongful death cases included carotid artery injury, respiratory failure due to postsurgical pneumonia, and 2 cases involving failure to diagnose sinonasal cancer. The carotid artery injury case was won by the plaintiff, and the award amount was not published. The respiratory failure case and 1 of the failure-to-diagnose sinonasal cancer cases ended with a defendant verdict. The other failure-to-diagnose case had initial summary judgment denied, and the further outcome of the case was not published. The 2 other cases won by the plaintiff involved the same physician, and both cases alleged failure of surgery, recirculation, and medical fraud.

There were 7 cases that alleged lack of informed consent. Four of these cases were in private practice, and 3 were in an academic setting. Three cases were won by the defendant, and 4 cases had initial summary judgment denied and the outcome was not published. Alleged injury in cases won by

Table 2. Alleged Injury.

Alleged Injury	No. of Cases
Cerebrospinal fluid leak	4
Death	4
Meningitis	3
Visual impairment	3
Nasal obstruction	3
Headache	2
Recirculation	2
Anoxic brain injury	2
Orbital hematoma	1
Bleeding	1
Infection	1
Anosmia	1
Burning mouth syndrome	1
Foreign body in abdominal fat graft site	1
Need for further surgery	1

the defendant included 2 cases of postsurgical anoxic brain injury and a postoperative infection. In 4 cases, the outcomes were unknown. These included allegations of death, burning mouth syndrome, and 2 cases of CSF leak and meningitis.

Discussion

All physicians should at least be aware of common legal terms and the duties that both a plaintiff and a defendant have in a medical malpractice case. To prevail on a medical malpractice claim, a party is required to establish 4 elements: (1) a duty by the physician to act according to a certain standard of care, (2) a breach of the applicable standard of care, (3) injury or harm to the plaintiff, and (4) a causal connection between the breach of the applicable standard of care and the injury or harm. In addition, causation must be established by expert testimony to a reasonable degree of medical certainty.

A handful of studies have been conducted on the topic of medical malpractice and sinonasal disease using different legal or insurance databases. In Dawson et al,[16] the 2006 Physician Insurers Association of America (PIAA) data-sharing report and the 2006 PIAA Risk Management Report– Otorhinolaryngology were searched for claims referable to the nose, nasal chamber, and paranasal sinuses. This analysis showed that the most frequent malpractice claim associated with a claim against otolaryngologists between 1985 and 2005 was ''improper performance.''[17] Operative procedures involving the nose, nasal cavity, and paranasal sinuses were the most frequent conditions or diagnoses associated with improper performance. This represented 64.25% of the total indemnity paid under this classification of claims between 1985 and 2005. The top 3 most prevalent claims against otolaryngologists involved the diagnoses sinusitis, deviated nasal septum, and diseases of the upper respiratory tract, accounting for 51% of the claims. However, these claims resulted in 70.3% of the total indemnity compensation. Of all the operative claims against otolaryngologists between 1985 and 2005, 34.5% involved procedures on the nose and sinuses. This study also pointed out that about 16% of the claims against otolaryngologists for all procedures involved informed consent allegations.[16]

In Lynn-Macrae et al,[18] the electronic legal database LexisNexis was used to search all reported United States federal and state civil trials over a 14-year period in which malpractice associated with ESS was alleged. Results of this analysis of 41 cases showed that negligent technique (76%) was the majority reason for malpractice suits, followed by lack of informed consent (37%), unnecessary surgery (27%), failure to diagnose (7%), and wrongful death (5%). Chronic sinusitis (73%) was the most common indication for surgery. CSF leak (24%) was the most common injury caused by surgery, followed by diplopia (17%), brain damage (15%), atrophic rhinitis (15%), and anosmia (15%). Fifty-six percent of the cases were ruled in favor of the defendant and 41% for the plaintiff. The median plaintiff award was $410,239. The highest monetary award was for intractable pain, $1,487,000 more than the highest award for wrongful death.[18]

In Lydiatt and Sewall,[15] the Westlaw legal database was searched for all jury verdict reports involving sinonasal disease treatment by all specialties from 1988 to 2005. This search rendered 152 cases. Defendants prevailed in 62% of cases, while plaintiffs received a jury award in 23% and a settlement in 15% of cases. The median plaintiff award (jury awards and settlements) was $575,000. In this study, younger patients prevailed at a higher rate that did older patients (50% vs 35%), and men had a higher median award than did women ($1,000,000 vs $314,000). The most common claims were related to ESS, followed by sinonasal cancer and misdiagnosis. The most common complications included CSF leak (35%), orbital trauma (24%), and anosmia (19%). Lack of informed consent was claimed in 26% of the ESS cases, with plaintiffs prevailing in 36% of these cases. Patients with cancer received the highest median award, at $1.5 million.[15]

The present study of cases from 2004 to 2013 identified similar trends as previous studies when looking at both medical and surgical management of sinonasal disease by otolaryngologists. It differs from previous studies that looked at multispecialty management of sinonasal disease[15] and exclusively ESS malpractice.[18] Negligent technique (38%) continues to be the most common type of malpractice in this area, and informed consent (27%) continues to be a significant contribution to the litigation landscape in sinonasal disease. CSF leak, meningitis, nasal obstruction, and visual impairment were the most common alleged injuries after sinonasal surgery. Fifteen percent of the cases were wrongful death suits, with 2 cases involving failure to diagnose sinonasal cancer and 1 case involving perioperative pneumonia leading to respiratory failure. The mean award of $225,000 and mean settlement of $212,500 is less than that found in previous studies.

Because informed consent makes up a significant and seemingly easily preventable proportion of claims against otolaryngologists, a look into how the informed consent process can be improved is warranted. Two studies highlighted above allude to informed consent being an issue in 26% and 37% of the cases, respectively.[15,18] The current study showed a similar result, with 27% of the cases involving informed consent. Understanding the informed consent process has been reviewed in several articles since 2000.[19-23] The legal standard for informed consent is typically the ''reasonable patient'' or ''reasonable physician'' standard, outlined as follows: what would the typical physician discuss about the intervention (the reasonable physician standard), and what would the average patient need to know to make an informed decision (the reasonable patient standard)? In Wolf et al,[19] otolaryngologists were surveyed to identify what risks were discussed preoperatively. Nearly all discussed CSF leak (99.1%), bleeding (96.7%), orbital injury (96.7%), and infection (84.8%). Fewer otolaryngologists discussed changes in smell (40.2%), cerebrovascular accident (17.9%), and death (28%).[19] In a follow-up study, Wolf et al[20] studied the patient perspective as it relates to what risks patients wish to be made aware of prior to ESS. They found that 69% of patients wished to be informed of complications that occur as infrequently as 1 in 100 cases, regardless of severity.[20]

It is important for any surgeon to be aware of the expectations and level of understanding of a patient when going through the process of informed consent. For otolaryngologists specifically, it has been shown that there are wide variations in the practice of informed consent and preoperative counseling among surgeons performing ESS.[21] Existing studies have reviewed demographic details involved in the informed consent process for sinus surgery. One study found that younger patients, Caucasian patients, and more educated patients wished to know about complications at the lowest risk levels more so than black patients or uneducated patients.[22] A conclusion from a similar study discovered that patients felt that discussion of potential complications, especially CSF leak and vision changes, was important. Although these discussions triggered anxiety, this did not contribute to a significant number of case cancellations.[23]

With the advent of technological advances and changing surgical approaches, the relationship of the use or nonuse of state-of-the-art equipment and its subsequent effect on litigation must be queried. Considering the recent escalated use of image guidance in ESS, the question of the impact of this technology on ESS litigation was addressed in a recent study by Eloy et al.[24] In this study, 30 malpractice cases over the past 10 years (2004-2013) were examined. In 26 (86.7%) of the cases, image guidance was not used; however, its nonuse was not specified as an alleged cause of negligence. In the 4 (13.3%) cases that image guidance was used, this factor did not contribute to the decision to initiate litigation, nor did it affect the case outcomes. This led to the conclusion that using imaging guidance does not necessarily make one more vulnerable to malpractice litigation.[24]

In conclusion, otolaryngologists should be informed of the reasons for litigation in the treatment of sinonasal disease. Awareness of the location of the skull base and orbit during any sinonasal procedure is paramount when it comes to avoiding complications. Ensuring adequate well-informed consent and documenting to this effect is a significant factor in avoiding medical malpractice in sinonasal surgery. One limitation of this study is the relatively low number of cases (26) identified in the 2 legal databases. This number is in keeping with the previous studies. Both databases gave similar results, with LexisNexis including 2 additional cases not present in Westlaw. The voluntary nature of the case submissions, the different organization of the case summaries, incomplete information, and the need for a subscription are weaknesses of these databases. There are also elements of recall and reporting bias due to the voluntary nature of the case submissions. This most certainly leads to an underestimation of the frequency of malpractice cases in sinonasal disease. Search terms from previous studies were not explicit and so could not be replicated. A unified database dedicated to medical malpractice that is not reliant on voluntary submission and that is easily accessible to physicians is needed. Complete information on the allegations of malpractice, verdict, and award amount would be very beneficial for further analysis of specific litigation.

Author Contributions

Tyler W. Winford, design of work, data analysis, drafting, presentation, final approval, accountability for all aspects of work; **Jordan L. Wallin**, design of work, critical revision, final approval, accountability for all aspects of work; **John D. Clinger**, design of work, critical revision, final approval, accountability for all aspects of work; **Aaron M. Graham**, data analysis, interpretation of data, final approval, accountability for all aspects of work.

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References

1. Studdert DM, Mello MM, Brennan TA. Medical malpractice. *N Engl J Med*. 2004;350:283-292.
2. Studdert DM, Mello MM, Gawande AA. Claims, errors, and compensation payments in medical malpractice litigation. *N Engl J Med*. 2006;354:2024-2033.
3. Hertz BT, Arthurs J. Malpractice rates plateauing: the only thing to fear may be fear itself. *Med Econ*. 2011;88:24-25, 28-29, 32.
4. Jena AB, Seabury S, Lakdawalla D, Chandra A. Malpractice risk according to physician specialty. *N Engl J Med*. 2011;365: 629-636.
5. Stankiewicz JA. Complications of sinus surgery. In: Bailey BJ, ed. *Head and Neck Surgery: Otolaryngology*. Vol 1. Philadelphia, PA: Lippincott Williams & Wilkins; 2001:401.
6. Blake DM, Svider PF, Carniol ET, Mauro AC, Eloy JA, Jyung RW. Malpractice in otology. *Otolaryngol Head Neck Surg*. 2013;149:554-561.

7. Reilly BK, Horn GM, Sewell RK. Hearing loss resulting in malpractice litigation: what physicians need to know. *Laryngoscope*. 2013;123:112-117.
8. Nash JJ, Nash AG, Leach ME, Poetker DM. Medical malpractice and corticosteroid use. *Otolaryngol Head Neck Surg*. 2011;144:10-15.
9. Svider PF, Keeley BR, Zumba O, Maruo AC, Setzen M, Eloy JA. From the operating room to the courtroom: a comprehensive characterization of litigation related to facial plastic surgery procedures. *Laryngoscope*. 2013;123:1849-1853.
10. Lydiatt DD. Medical malpractice and facial nerve paralysis. *Arch Otolaryngol Head Neck Surg*. 2003;129:50-53.
11. Svider PF, Pashkova AA, Husain Q, et al. Determination of legal responsibility in iatrogenic tracheal and laryngeal stenosis. *Laryngoscope*. 2013;123:1754-1758.
12. Svider PF, Sunaryo PL, Keeley BR, Kovalerchik O, Mauro AC, Eloy JA. Characterizing liability for cranial nerve injuries: a detailed analysis of 209 malpractice trials. *Laryngoscope*. 2013;123:1156-1162.
13. Kovalerchik O, Mady LF, Svider PF, et al. Physician accountability in iatrogenic cerebrospinal fluid leak litigation. *Int Forum Allergy Rhinol*. 2013;3:722-725.
14. Svider PF, Kovalerchik O, Mauro AC, Barades S, Eloy JA. Legal liability in iatrogenic orbital injury. *Laryngoscope*. 2013;123:2099-2103.
15. Lydiatt DL, Sewell RK. Medical malpractice and sinonasal disease. *Otolaryngol Head Neck Surg*. 2008;139:677-681.
16. Dawson DE, Kraus EM. Medical malpractice and rhinology. *Am J Rhinol*. 2007;21:584-590.
17. Physician Insurers Association of America. *Risk Management Report–Otorhinolaryngology*. Rockville, MD: PIAA; 2006.
18. Lynn-Macrae AG, Lynn-Macrae RA, Emani J, Kern RC, Conley DB. Medicolegal analysis of injury during endoscopic sinus surgery. *Laryngoscope*. 2004;114:1492-1495.
19. Wolf JS, Malekzadeh S, Berry JA, O'Malley BW. Informed consent in functional endoscopic sinus surgery. *Laryngoscope*. 2002;112:774-778.
20. Wolf JS, Chium AG, Palmer JN, O'Malley BW, Schofield K, Taylor RT. Informed consent in sinus surgery: the patient perspective. *Laryngoscope*. 2005;115:492-494.
21. Sharp HR, Crutchfield L, Rowe-Jones JM, Mitchell DB. Major complications and consent prior to endoscopic sinus surgery. *Clin Otolaryngol*. 2001;26:33-38.
22. Taylor RT, Chiu AG, Palmer JN, Schofield K, O'Malley BW, Wolf JS. Informed consent in sinus surgery: link between demographics and patient desires. *Laryngoscope*. 2005;115:826-831.
23. Bowden MT, Church CA, Alexander GC, Vaughan WC. Informed consent in functional endoscopic sinus surgery: the patient's perspective. *Otolaryngol Head Neck Surg*. 2004;131:126-132.
24. Eloy JA, Svider PF, D'Aguillo CM, Baredes S, Setzen M, Folbe AJ. Image-guidance in endoscopic sinus surgery: is it associated with decreased medicolegal liability? *Int Forum Allergy Rhinol*. 2013;3:980-985.

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SYMPOSIUM: EVOLVING MEDICOLEGAL CONCEPTS

Medical Malpractice Reform: The Role of Alternative Dispute Resolution

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Abstract

Background Alternative dispute resolution (ADR) refers to techniques used to resolve conflicts without going to the courtroom. As healthcare and malpractice costs continue to rise, there is growing interest in tactics such as early apology, mediation, and arbitration in the medical arena.

Questions/purposes (1) Why is ADR needed? (2) Is ADR useful in health care? (3) What are the current legal and political developments favoring ADR? (4) What obstacles remain?

Methods We performed MEDLINE, PubMed, and Google Scholar searches with key words "medical malpractice", "ADR", and "alternative dispute resolution" to obtain public policy studies, law review articles, case analyses, ADR surveys, and healthcare review articles.

Results Early apology and disclosure programs report 50% to 67% success in avoiding litigation as well as substantial reductions in the amount paid per claim. Mediation boasts 75% to 90% success in avoiding litigation, cost savings of $50,000 per claim, and 90% satisfaction rates among both plaintiffs and defendants. Arbitration is viewed as less satisfying and less efficient than mediation but still more time- and cost-effective than litigation. The current legal environment is favorable to ADR with recent court decisions upholding pretreatment arbitration clauses. The main obstacle to ADR is the mandatory reporting requirement of the National Practitioner Data Bank (NPDB).

Conclusions ADR has the potential to help reform the current tort system, reducing cost and increasing both parties' satisfaction. Easing the reporting requirements for the NPDB would lead to more widespread acceptance of ADR among physicians.

Introduction

The US healthcare system needs reform [40, 45]. The current tort system is extremely expensive with estimated direct costs of $76 to $122 billion per year [6]. It is also lengthy and inefficient. Over 60% of lawsuits are summarily dismissed as having no merit, yet still cost up to $80,000 to defend [24, 45]. When cases do go to trial, they are lengthy with average trial lengths of 5 years [16, 17, 45] and have less than 10% success rates for the plaintiff [34]. Even when successful, the majority of the awards go to the attorneys, not the plaintiffs [24].

The early attempts at tort reform included caps on noneconomic damages. These have proven to be the most reliable form of tort reform in terms of cost containment [20] yet are not politically viable as a result of strong political funding by trial lawyer interests to a Democratic-controlled Senate. This has led to renewed interest in alternative dispute resolution (ADR) to altogether avoid the litigation arena as a form of tort reform [13].

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When properly implemented, ADR has an excellent track record of avoiding litigation, decreasing overall cost, and increasing satisfaction among both plaintiffs and defendants [8, 9, 13, 16, 18, 27, 36, 41]. ADR, however, has not been as quickly embraced in medical malpractice as in other fields of commercial and civil litigation [9].

We address the following questions: (1) Why is ADR needed? (2) Is ADR useful in health care? (3) What are the current legal and political developments favoring ADR? (4) What obstacles remain?

Search Strategy and Criteria

We performed MEDLINE, PubMed, and Google Scholar searches with key words "medical malpractice", "ADR", and "alternative dispute resolution" to obtain public policy studies, law review articles, case analyses, ADR surveys, and healthcare review articles. Using these searches we identified 1305 articles. We excluded 1260 articles based on language and relevance to the medical field and were left with 40 articles.

Why Is Alternative Dispute Resolution Needed?

The US healthcare system is in need of tort reform. Litigation as a primary means of dispute resolution is costly and irrational. The cost of litigation is enormous both in terms of direct costs and indirect costs. The US Department of Health and Human Services has estimated that between $76 and $126 billion is spent per year on litigation in medical malpractice [45]. In addition, there are indirect costs to the healthcare system in the form of defensive medicine, estimated at between $83 and $151 billion [22]. Worse, the costs continue to escalate. Since 1976, malpractice premiums have soared 920% [5] mostly because jury verdicts continue to rise at an alarming rate. Between 2001 and 2002, the national jury award in medical liability cases almost doubled from $3.9 million to $6.2 million [17]. Jury awards in medical malpractice are roughly 17 times greater than nonmedical fields [14].

The tort system is also irrational. More than 60% of all medical malpractice lawsuits are summarily dismissed by courts as being meritless nuisance suits [10, 45]. Closed claim studies show that only 15% of all lawsuits filed actually contain negligence [6, 24, 45]. On the other hand, only 3% of those truly injured by medical negligence actually sue [24]. In other words, the uninjured sue and the injured do not. Furthermore, the money does not even go to the plaintiffs. Only 28 cents of every dollar actually makes it to the plaintiff [31, 45]. The rest is consumed by lawyers and administrative fees. Clearly there is need for reform.

Early tort reform focused on placing caps on noneconomic damages such as pain and suffering. Although economic damages such as medical expenses and lost wages are unlimited, caps on more difficult to quantify damages such as pain and suffering have been limited by states to help avert malpractice crises. Caps limiting this portion of recovery have proven effective when implemented at the state level. Caps in California reduced the overall expenditure of medicine by 5% to 9% after passage of the 1975 MICRA laws [22]. It is estimated that this reduction in defensive medicine, if implemented on a national level, would save $83 to $151 billion per year. Caps also increase access to care. In Texas, similar caps were passed in 2003; after that, the state saw the return of more than 3000 physicians who had earlier left the state, the arrival of 22 new insurance carriers, and a 22% reduction in premiums over a 2-year period [45]. Caps also, perhaps surprisingly, help the plaintiff. A RAND Corporation study looking at awards before and after MICRA found that caps led to redistribution of awards from attorneys to plaintiffs [30]. This is likely because case lengths decreased by almost two-thirds after caps were enacted.

Despite this, attempts to pass caps on a national level have been unsuccessful. In a Democratic-controlled Senate, caps on a federal level are not politically realistic. Caps are vigorously opposed by trial lawyer interests, who strongly support the Democratic Party. According to the Center for Responsive Politics, one of the nation's strongest special interests is the American Association for Justice, whose main political agenda is fighting tort reform. Of the $31.6 million donated in the past 20 years, over 91% has gone to the Democratic Party [35]. Howard Dean, former Democratic National Convention Chair, stated the main reason tort reform was not included in the 2010 healthcare reform was to avoid running afoul of these interests [2]. In short, if tort relief is to come, it will not be politically, at least not in the near future.

Is Alternative Dispute Resolution Useful in Health Care?

Early Disclosure and Apology

The forms of ADR can be thought of as a spectrum from informal to formal. The most informal form of ADR is negotiation. This is simply a meeting between the two parties to discuss the conflict and seek to achieve some type of resolution. These exchanges may be facilitated by programs designed to facilitate apologies or even legislation attempting to mitigate emotion and anger by providing a safe haven for parties to disclose matters fully without fear that such could be misused later as proof of negligence at

trial [1, 15]. These are known as early disclosure and apology programs.

Although the desire to hear an explanation and an apology are often the main driving forces behind a lawsuit in medical malpractice, paradoxically, the threat of litigation deters the same things. Physicians and hospital systems fear that an apology will be used against them as an admission of negligence, and open dialogue about what happened may simply provide further impetus for the plaintiff's attorney at trial. Thirty-five states have passed some form of "I am sorry" legislation, which allows physicians to offer confidential and inadmissible apologies. Not all apology laws are the same. Some such as Colorado's protect both the apology as well as any admission of fault. Others such as Indiana's protect the apology but not an admission of fault. So although a statement similar to "I'm sorry this happened to you" is protected, a statement such as "I'm sorry I did this to you" is not. Other states such as Nevada, Florida, New Jersey, Pennsylvania, Oregon, Vermont, and California make the protection conditional. Apologies are only protected if the physician gives early disclosure of adverse events [42]. Furthermore, statutes may differentiate between which types of apologies, written or oral, are protected. Detailed review of each state's apology statute is beyond the scope of this article, and consultation with a health law attorney is recommended for each state's specifics.

Apology statutes, although helpful, are not always necessary. The University of Michigan Health System enacted an Open Disclosure Program in 2002, although the state has no statutes protecting physician apology. The Michigan program focuses on setting realistic expectations during the informed consent process and an early patient-centered apology and explanation process if an adverse event is encountered [3]. Despite no legislative protection, the program has seen a reduction in yearly claims from 262 to 82 [37, 42]. The University of Illinois, after implementing a similar program, saw a reduction of malpractice filings by 50%. Of 37 cases in which the hospital acknowledged preventable error and apologized, only one patient filed suit [37].

Another case study suggests early disclosure and apology reduces the amount paid during settlement. In 1987, the Veterans' Administration (VA) Hospital in Lexington, KY, instituted an apology program that not only admitted and apologized for errors but actually assisted patients in the filing of claims. This led, not surprisingly, to this particular VA being in the top 25% of all claims filed. However, it was also in the bottom 25% of total monies paid out, suggesting that early ADR substantially reduces the payment per claim [23].

Some limitations of these case studies need to be noted. Although the State of Michigan does not have an apology statute, it does have substantial caps on noneconomic damages. In the case of the Lexington VA, all federal government physicians are protected from personal liability by the Federal Tort Claims Act. Nonetheless, the basic principles that early disclosure and apology reduce both the number of claims and ultimate payouts have been validated elsewhere. In Colorado, a physician-directed medical malpractice insurance carrier named COPIC instituted an early apology program in 2000 called the 3Rs—Recognize adverse events, Respond quickly, and Resolve issues. The program included both apology and early disclosure with a focus on preserving the physician–patient relationship. The result was a 50% reduction in malpractice filings, a decrease in settlement costs of 23%, and a startlingly low average settlement award of roughly $5000 [3].

Mediation

Mediation is a negotiation that is facilitated by a neutral third-party mediator. This mediator can be an attorney or retired judge, but trained mediators usually have higher success rates. The most important characteristic of mediation is that it is nonbinding. When parties choose to attempt mediation, it is not binding and parties can break off the negotiations at any time. This is of particular benefit to the physician defendant. Jury trials, contrary to popular opinion, overwhelmingly result in a verdict for the physician, almost 90% of the time in fact [17]. The physician may want to preserve his or her right to go to trial if he or she feels they are wrongly sued [16]. A nonbinding form of ADR such as mediation preserves this right. Mediation is also relatively informal. The parties are typically not accompanied by attorneys and so the process is short and relatively inexpensive [13, 36, 39]. The informal atmosphere leads to the ability to be creative in remedies. For example, where litigation can only lead to monetary awards, mediation may lead to solutions such as implementation of future safety protocols or expressions of sympathy from the physician, which the patient may find more satisfying. In one survey of plaintiffs in medical malpractice trials, for example, money was only the third most important reason for suing after an apology and information about why the adverse event occurred [41]. Some creative solutions used have included memorials for family members who have died, opportunities to help train incoming residents by discussing their difficult experiences, and donations to charity [8, 13]. Because mediated settlements by definition are agreed on by both parties, they are associated with the greatest durability and satisfaction [27, 41].

Numerous medical centers have used mediation effectively to divert potential claims from litigation. The

University of Michigan, Johns Hopkins, Rush-Presbyterian Medical Center, the University of Pittsburgh Medical Center, and Drexel have all implemented mediation programs with the assistance of premediation agreements [13]. Unlike prearbitration agreements, these agreements do not require a waiver of either party's access to a jury trial. However, as a condition of treatment, patients agree to try mediation before pursuing litigation with any potential claims. According to Jury Verdict Research, an average of $50,000 in legal expenses alone is saved in each case, which is mediated rather than taken to trial [13, 27, 41].

Mediation boasts extremely high satisfaction rates among both plaintiffs and defendants, approximately 90% [41]. The informal process allows both parties to speak for themselves, which is understandably cathartic for both. Physicians, in particular, appreciate an opportunity to express frustration at being sued when they are not at fault and describe the toll this takes on their ability to provide care for other patients. Mediated cases are also extremely time-efficient. According to one survey of 13 ADR organizations, the average length of mediation is only 1 to 3 days with cases closing from start to finish between 85 and 165 days [41]. By comparison, it is not unusual for a litigated case to take 5 years or more to resolve [16, 30]. Attorney fees are also sharply decreased. Attorneys surveyed noted that their average preparation time for trials was 36 hours compared with only 2.5 hours for mediation [41].

Two success stories in institutionalized mediation programs are those at Drexel and the University of Pittsburgh Medical Center. Drexel's program, launched in 2004, uses two comediators, both medical malpractice attorneys trained in mediation. Of 20 cases mediated between March 2004 and August 2005, 17 were settled for an 85% success rate [8]. The remaining three cases were litigated and all resulted in verdicts for the defendant, perhaps disproving the notion that only weak cases go to mediation. Pittsburgh similarly instituted a formal mediation program in 2004. Using a single mediator model, the institution successfully settled 24 of 27 cases over a 1-year period for an 88% success rate and estimated $1,000,000 in savings in defense costs alone [8].

Mediation, however, may be less effective when ordered by the court. The State of North Carolina has a widespread practice of court-ordered mediation, and an empiric study performed by the Duke and Wake Forest law schools found the rates of success in such courts were much lower than expected at only 23.7% [33]. By comparison, noncourt-ordered mediation typically has between 75% and 90% success in avoiding litigation [18, 19, 41]. One reason for this is the different structure of court-ordered mediation. In typical mediation, there are no attorneys present unless the mediator him- or herself is an attorney. There are simply the parties and a mediator to facilitate discussion. In the North Carolina model, a mediator met with the attorneys for the parties, who acted as the primary speakers, with little participation by the parties themselves. Factors that drove settlement included the use of trained mediators instead of retired judges or attorneys and cases in which the mediator explored worst-case scenarios for both parties. Factors that did not affect the settlement rate included the amount of money demanded by the plaintiff and cases in which the mediator interjected his or her own opinion about the merits of the case. When cases did not get settled, the vast majority ended up in verdicts for the defendants (86%) [33].

Arbitration

Arbitration is a more formal and binding form of ADR. Parties are typically represented by attorneys who argue the case before an arbiter or arbitration panel. The arbiter then issues a decision. The main distinction of arbitration is that the arbiter's decision is typically binding. It is popular therefore among parties who fear the capricious nature of jury verdicts and is seen as a means of risk management [16]. One form of arbitration that is gaining popularity in the healthcare field is the pretreatment arbitration agreement. This is an agreement that patients sign as a condition of being seen by a healthcare provider stating that should a dispute arise, it will be handled through arbitration. Physicians may include such clauses in their initial contracts with new patients and so protect themselves from litigation. Several legal challenges have been raised to these clauses, but in every case, such clauses have been deemed legal and binding [43]. As such, pretreatment arbitration clauses are used by clearly on the rise, whether in agreements between physician and patient [36], physician and malpractice insurance provider [16], or patient and insurance company or HMO [13, 21]. Even entire states are starting to require arbitration [13]. Wisconsin, for example, requires aggrieved medical malpractice parties to go through ADR before litigation, and Pennsylvania provides for court-ordered ADR as a Rule of Civil Procedure whenever requested by a healthcare defendant [8].

The binding nature of arbitration can hurt both the plaintiff and defendant alike, however. The overwhelming majority of times that a physician is sued, there is no negligence involved, as the outcomes of trial litigation have confirmed repeatedly [6, 24, 45]. Physicians may therefore find it advantageous to go to jury trial to clear their names and prove there was no negligence [16]. Binding arbitration means the physicians forego this right and must take their case to an arbiter. Although arbiters award much more modest awards than juries, they are also more likely to award some type of award to the plaintiff

whether there is negligence or not [36]. The propensity of arbiters to force compromise is one criticism of arbitration [27, 33]. Other critiques are that it is too rigid and adversarial, only one step removed from an actual trial [13, 16, 36]. Costs are higher than mediation and the process is more acrimonious because lawyers are involved [8, 9, 27, 36]. Satisfaction rates among both parties are lower than mediation [36, 41] and, similar to jury trials, the only form of redress is monetary. Still, there are definite time and cost savings compared with litigation [8, 27, 36, 41], and the fact that it is binding means many potential lawsuits are diverted from the courthouse.

Arbitration also has some unique strengths. Arbiters can be selected for their unique scientific background. This makes arbitration a particularly good choice for disputes over specific issues of scientific fact. Rather than leaving the matter to a jury that is unlikely to comprehend the issue—or to a negotiation when there is a great discrepancy between the understanding of the scientific issues at play—arbitration has a unique advantage of having a skilled and knowledgeable arbiter as a decider of fact. Arbitration is also, almost by definition, extremely effective at avoiding litigation. As a binding decision, arbitration effectively only goes to trial when one of the parties appeals the decision. Even this is expedited, however. The decision of an arbiter can only be overturned for procedural error, bias, or fraud [13].

Pretrial Screenings

Pretrial screenings are informal screenings before litigation by a neutral party to assess the relative strengths of each party's case and determine whether the trial merits going to trial. It is a way to screen out cases that are not based on merit and save costs to both parties. One reason this is particularly well suited to the medical field is the high number of meritless cases in this field [24, 45]. Roughly 70% of cases are dismissed by a judge during summary judgment as meritless [10]. There are, nonetheless, costs associated with defending lawsuits, typically between $24,000 and $90,000 [17]. Pretrial screenings allow both parties to avoid these costs. Pretrial screenings are helpful for a second reason as well. One reason for the high number of meritless claims is that plaintiffs are often confused about what does and does not constitute negligence. The practice of medicine, particularly surgery, carries inherent risk. Complications such as infection, bleeding, pain, and death are inevitable no matter how well trained or conscientious the physician is. For the patient, however, complications may trigger the desire for some form of redress; when combined with emotion, the result is a lawsuit. Physicians, fearful of litigation, may try to avoid speaking with the injured patient after an adverse event or defend themselves by blaming the patient's noncompliance or biology. This engenders anger and distrust, and patients sue to seek information about why something bad happened and to hear an apology for it as much if not more than for simply money [1, 15]. Pretrial screenings help educate plaintiffs that these are not proper grounds for a successful lawsuit and help steer them to more fruitful grounds such as mediation. Roughly half of all states require pretrial screening before pursuing litigation in medical malpractice [13].

Pretrial screening, also known as early neutral evaluation, is a mandatory process in at least three states: Wisconsin, Maine, and New Mexico. In Wisconsin, a panel consisting of a lawyer, healthcare provider, and layperson screen each case before litigation. Although called Medical Mediation Panels, these in function are pretrial screening panels that act to exclude meritless claims and expedite resolution of claims with merit [46]. In Maine, a medical malpractice claim must be reviewed by a three-member prelitigation screening panel. Two members are physicians. The screening panel can be bypassed by consent of both parties. Alternatively, the panel can, again with the consent of both parties, act as a binding arbitration panel [25]. The earliest medical malpractice pretrial screening panels date back to the 1960s. In New Mexico, pretrial review panels were initially introduced as a voluntary resource in 1962. After a wave of malpractice litigation crisis, the statute was upgraded to a mandatory process in 1976. During the next 20 years, the New Mexico panels screened more than 2100 medical malpractice cases. Of these, almost 75% were successfully directed away from litigation [13].

What Are the Current Legal and Political Developments Favoring Alternative Dispute Resolution?

There is currently an advantageous legal climate for ADR. In the legal case of *Estate of Ruszala v Brookdale Living Communities*, a New Jersey arbitration clause in a nursing home preadmission agreement was at issue. The agreement clearly violated a 2003 New Jersey statute barring such agreements. Despite this, the Appellate Court found that arbitration clause was not unenforceable per se. This was because the New Jersey statute was preempted by the Federal Arbitration Act. Similar rulings have been found in the Supreme Courts of Illinois and Missouri [43]. Also, in *Moore v Woman to Woman Obstetrics & Gynecology*, a pretreatment arbitration clause was disputed. At issue was the fact that the pretreatment clause was included as part of the physician's patient intake process. The Moore court ruled that there is nothing per se unenforceable about this

arrangement [43]. Taken together, these show a disposition of courts, even courts in states generally hostile to tort reform, to embrace ADR.

Politically, also, there is impetus for ADR. Caps on damages may be an effective means of cost control, but they may not be realistic at the federal level at this time. During the recent healthcare debates at the national level, there was considerable support in favor of caps on noneconomic damages. Douglas Elmendorf, the Director of the nonpartisan Congressional Budget Office, recommended that caps on noneconomic damages be included in last year's healthcare reform, because the bill lacked any substantial cost containment provisions without it [11, 12]. President Obama's National Commission on Fiscal Responsibility and Reform, a bipartisan commission charged with deficit reduction, similarly called for caps on noneconomic damages to help control costs [38]. Despite these public policy pressures, the 2010 Patient Protection and Affordable Care Act (PPACA) notably did not pass caps or any other meaningful form of tort reform [32]. Howard Dean, former Democratic National Party Chairman, has opined that this was to avoid running afoul of trial lawyer special interests [2], which contribute 91% of their funds to the Democratic Party [35]. In fact, an earlier version of the bill actually contained a protection clause for trial lawyers, stating that healthcare reform must "not limit attorney fees or impose caps on damages" [26]. Unlike capitated damages, however, ADR is supported by the American Bar Association and is thus politically a far more feasible form of tort reform [8, 36]. From the trial attorney's perspective, litigated malpractice may be far more lucrative than a mediated claim. However, it is also higher risk. Less than 10% of cases result in a victory for the plaintiff [34]. An ADR claim, however, involves less work and has guaranteed pay. So it is a win-win-win for plaintiffs, physicians, and attorneys.

There is recognition among all parties that reform is necessary. PPACA, for example, allocates $50 million in grants and pilot studies to develop medical malpractice reforms so long as they are not caps on noneconomic damages [32]. ADR fits perfectly in this niche as a means of tort reform, which is politically feasible, has legal support from attorneys and judges, and has some early evidence showing efficacy, decreased cost, and high satisfaction.

Obstacles to Alternative Dispute Resolution

A major obstacle to more widespread use of ADR in the medical malpractice field is the National Practitioner's Data Bank (NPDB) [13, 27–29]. The NPDB is a database of all settlements and jury verdicts rendered against a physician regarding medical malpractice claims. It was intended to help prevent rogue doctors from simply relocating to a new hospital or a new state when an adverse track record was established. As such, any settlement or jury award becomes part of a physician's permanent record and affects his or her ability to obtain staff privileges at a new hospital or to obtain a license to practice in a new state. NPDB data also play a role in determination of malpractice insurance premiums. Physicians with multiple settlements in their name are deemed high risk, much like drivers with multiple moving violations or accidents, and premiums correspondingly go up.

The problem with the NPDB is that it discourages the efficient settlement of nonnegligence cases. The vast majority of malpractice cases filed do not contain negligence. Patients often sue as a result of emotional reasons or as a result of unrealized expectations. It would be inefficient for both parties to thoroughly litigate such a case. However, to arrive at a settlement, however nominal, would have detrimental repercussions for the defendant [9]. Although the physician may furnish a note explaining the circumstances, many physician defendants prefer to avoid having their names entered in the NPDB by pursuing litigation [13]. Thus, perhaps ironically, litigation may protect the physician defendant's interest better than ADR. Perhaps for this reason a growing number of malpractice insurance providers are forcing binding arbitration clauses on physicians, known as "consent to settle" clauses, so that they can force settlements on physicians even when the defendant is unwilling [16].

Another obstacle to more widespread ADR use is distrust. Although ADR has seen rapid growth in other fields, its use in health care has lagged behind [9]. This is not because ADR is unfamiliar or unknown, but because ADR has been tried and did not work. In the 1970s and 1980s, various forms of tort reform were implemented, including several that were both mandatory and very clumsy. For example, some states instituted widespread court-annexed and medical screening panels, applying them awkwardly to cases that were very close to trial. The strength of ADR is that there is a variety of options that are best implemented flexibly rather than in a mandatory, one-size-fits-all fashion. For example, arbitration is best when there is a real evidentiary point of disagreement, particularly when a complex issue of science is involved. This is because an arbiter can be selected for his or her particular scientific expertise. On the other hand, when the driving impetus of a lawsuit is a patient's need for information and apology, nonbinding and informal mediation is the best choice. The problem with early ADR tort reform initiatives is that the type of ADR forced on parties was often an internally inconsistent form of mandatory nonbinding ADR, which frustrated all parties as ineffective and time-wasting [9].

Discussion

ADR has become increasingly prominent in the medical malpractice reform discussion, in part because more proven reforms such as caps on noneconomic damages are politically not feasible, at least at this time. Early disclosure and apology programs, mediation, arbitration, and pretrial screenings are all forms of ADR that have been successfully implemented in the medical arena. Generally, the majority of claims that go through ADR are successfully resolved without litigation at considerable cost savings to the defendants and high satisfaction for the plaintiffs. However, major challenges, especially from the mandatory NPDB reporting requirements for settlements, remain. We therefore addressed the following questions: (1) Why is ADR needed? (2) Is ADR useful in health care? (3) What are the current legal and political developments favoring ADR? (4) What obstacles remain?

We recognized limitations to our review. First is the relative paucity of information. Unlike trials, which become a matter of public record, settlements such as those reached in early apology negotiations, mediations, or arbitration are privileged and confidential. This is part of the appeal of ADR, but also makes data hard to gather. Second, the quality of available data is limited. The gold standard in health policy is the data on caps on noneconomic damages, because there is a control and experimental group. Physician expenditure and patient morbidity and mortality were measured before and after enactment of caps and the results analyzed [22]. No such data exist for ADR. Rather, most of the information available about ADR is self-reported institutional data and survey data from plaintiffs, defendants, and attorneys participating in the ADR process. The potential for bias is obvious and perhaps even shows in the numbers. When self-reported, the success rate is noted to be 75% to 90% [18, 19]. On the other hand, in a study in which independent observers were dispatched to each court-ordered mediation proceeding, the success rate was much lower at 23% [33]. One explanation could simply be the difference between court-ordered ADR and voluntarily engaged ADR. Another, however, could be bias.

One obvious solution to increasing the use of ADR is to allow for some exceptions to the reporting requirements to the NPDB. An exception could be made, for example, for no fault settlements. There is inherent risk to any surgery, and complications can arise through no fault of the surgeon. Some feel that complications should be compensated regardless of fault or no fault. Allowing a no fault exception would allow for a settlement to be made but not recorded in the NPDB. This would fairly balance the competing interest in reporting and warning the public at large of incompetent and negligent physicians while preventing such cases from driving up the costs of health care and litigation. Another solution could be creation of a national apology law. Australia, British Columbia, England, and Wales [7] all provide for apology and disclosure protection in medical malpractice cases at a national level, and something similar could be considered in the United States. In 2005, a bill was introduced by then Senators Hillary Clinton and Barack Obama entitled "The National Medical Error Disclosure and Compensation Act ("MEDiC"). This legislation, which did not pass, would have mandated automatic disclosure of medical error to the patient and provide protection for any apologies that arose during negotiation of compensation. In other words, there was not only a shield protecting the physician, but also a sword prodding him or her in the back. It also was not comprehensive, protecting only apologies and not privileging the early disclosure itself. Even this has problems, however. A major issue with any federal statute is the issue of federalism. Should the federal government pass a single law or allow the states to decide for themselves? Clearly, ADR efforts at the state level have been mostly successful and reflect individual, creative efforts at resolving the so-called medical malpractice crisis. A federal law would certainly reduce the confusion currently existing about what type of apology law, if any, is in a particular state. On the other hand, the fact that there is such a variety of apology laws perhaps indicates that reasonable minds can disagree about what type of law should be in place and the matter may best be left to each individual state, consistent with the doctrine of limited federal powers over the states.

The evidence so far suggests the current medical malpractice crisis should be addressed by both caps on damages and using ADR mechanisms. Although ADR has not always been viewed favorably, and it has been applied awkwardly in the past, there is mounting evidence that it can be effective. Mediation in particular has the advantages of addressing nonmonetary patient interests, resulting in high satisfaction among both plaintiffs and defendants. Impediments to more widespread use of ADR include the NPDB, which attaches a stigma to settlement even in no fault cases as generally poor perceptions of ADR as a result of past failings. Future implementations of ADR should focus on flexibility and early interventions, and both first-generation tort reform and more consistent, comprehensive apology protection laws will almost certainly aid in its successful implementation.

In summary, there is need for ADR because the current default for resolving conflicts in medicine is the tort system, which is expensive [6, 22] and irrational [4, 20, 24, 44]. It is unrealistic to hope for political tort reform as a result of the strong influence of trial lawyer special interests [35] on the Democratic Party [2], which currently controls the Senate. Relief, then, must come from elsewhere.

A variety of ADR techniques have been successfully used in medical malpractice. Early apology and disclosure programs report 50% to 67% success in avoiding litigation as well as substantial reductions in the amount paid per claim [3, 37, 42]. Mediation boasts 75% to 90% success in avoiding litigation [8, 18, 19], cost savings of $50,000 per claim [13, 17, 41], and 90% satisfaction rates among both plaintiffs and defendants [41]. Arbitration is viewed as less satisfying and less efficient than mediation but still more time- and cost-effective than litigation [8, 9, 13, 16, 27, 36, 41].

The current political and legal environment is optimal for embracing ADR. The ABA embraces ADR [8, 36], and several recent court opinions have shown judicial favor for arbitration clauses [43]. Politicians also recognize the need for reform [38] yet are reluctant to embrace more well-studied and proven reforms such as caps on noneconomic damages [2]. Sizeable grants therefore are available to expand on the preliminary data on the efficacy of ADR in health care [32]. The main obstacle to ADR is the punitive reporting requirements of the NPDB [13, 27]. Should these be relaxed, it is likely that physicians will be more receptive to using ADR to resolve healthcare disputes.

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References

1. Arber A, Gallagher A. Breaking bad news revisited: the push for negotiated disclosure and changing practice implications. *Int J Palliat Nurs*. 2003;9:166–172.
2. Ballasy N. Howard Dean: Democrats left tort reform out of health care bill because they feared 'taking on' trial lawyers. 2009. Available at: www.CNSNews.com. Accessed August 21, 2011.
3. Boothman RC, Blackwell AC, Campbell DA Jr, Commiskey E, Anderson S. A better approach to medical malpractice claims? The University of Michigan experience. *J Health Life Sci Law*. 2009;2:125–159.
4. Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, Newhouse JP, Weiler PC, Hiatt HH; Harvard Medical Practice Study I. Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. 1991. *Qual Saf Health Care*. 2004;13:145–151; discussion 151–152.
5. Commissioners Report. Profitability by Line by State in 1976 and 2002. Kansas City, MO, USA: National Association of Insurance Commissioners; 2003.
6. "Confronting the New Health Care Crisis: Improving Health Care Quality and Lowering Costs by Fixing Our Medical Liability System." US Department of Health and Human Services (2002). Available at: http://aspe.hhs.gov/daltcp/reports/litrefm.htm. Accessed November 12, 2011.
7. *Consultation Paper: Alternative Dispute Resolution*. Dublin, UK: Law Reform Commission; 2008.
8. Creo RA, Shogan JO, Turner CT. *Malpractice Case Alternative Dispute Resolution*. Narberth, PA, USA: Physician's News Digest; 2005.
9. Dauer EA. Alternatives to litigation for health care conflicts and claims: alternative dispute resolution in medicine. *Hematol Oncol Clin North Am*. 2002;16:1415–1431.
10. DeMaria AN. Medical malpractice insurance: a multifaceted problem. *J Am Coll Cardiol*. 2003;42:1683–1684.
11. Elmendorf D. Letter to Senator Orrin Hatch, October 10, 2009. Available at: http://www.cbo.gov/ftpdocs/106xx/doc10641/10-09-Tort_Reform.pdf. Accessed August 21, 2011.
12. Elmendorf D. The Effects of Health Reform on the Federal Budget. CBO Director's Blog. 2010.
13. Fraser JJ Jr. American Academy of Pediatrics: technical report: alternative dispute resolution in medical malpractice. *Pediatrics*. 2001;107:602–607.
14. Furlong GT. *The Conflict Resolution Toolbox*. Ontario, Canada: John Wiley & Sons; 2005:38.
15. Gallagher TH, Waterman AD, Ebers AG, Fraser VJ, Levinson W. Patients' and physicians' attitudes regarding the disclosure of medical errors. *JAMA*. 2003;289:1001–1007.
16. Greer TE. Alternative dispute resolution in medical liability cases. *AAOS Now*. 2009. Available at: http://www.aaos.org/news/aaosnow/jul09/managing7.asp. Accessed November 11, 2011.
17. Hartwig R. *Medical Malpractice Insurance Jury Verdict Research*. New York, NY, USA: Insurance Information Institute; 2008:1.
18. Hyman CS, Liebman CB, Schechter CB, Sage WM. Interest-based mediation of medical malpractice lawsuits: a route to improved patient safety? *J Health Polit Policy Law*. 2010;35:797–828.
19. Hyman CS, Schechter CB. Mediating medical malpractice lawsuits against hospitals: New York City's pilot project. *Health Affairs*. 2006;25:1394–1399.
20. Kachalia A, Mello MM. New directions in medical liability reform. *N Engl J Med*. 2011;364:1564–1572.
21. Kelly C. Healthcare reimbursement: HMO arbitration clause enforced. *J Law Med Ethics*. 2003;31:731–734.
22. Kessler D, McClellan M. Do doctors practice defensive medicine? *Q J Econ*. 1996;111:353–390.
23. Kraman SS, Hamm G. Risk management: extreme honesty may be the best policy. *Ann Intern Med*. 1999;131:963–967.
24. Localio AR, Lawthers AG, Brennan TA, Laird NM, Hebert LE, Peterson LM, Newhouse JP, Weiler PC, Hiatt HH. Relation between malpractice claims and adverse events due to negligence. Results of the Harvard Medical Practice Study III. *N Engl J Med*. 1991;325:245–251.
25. Maine Rev Stats Title 24, 2851 and 2853.
26. Medicare Physician Payment Reform Act of 2009. HR 3961 (2010).
27. Metzloff TB. Alternative dispute resolution strategies in medical malpractice. *Alaska Law Review*. 1992;9:429–457.
28. National Practitioner Data Bank 2006 Annual Report, US Dept of Health and Human Services (2006). Available at: www.npdb-hipdb.hrsa.gov/resources/reports/2006NPDBAnnualReport.pdf. Accessed August 21, 2011.
29. National Practitioner Data Bank Guidebook. US Dept of Health and Human Services (1999). Available at: www.npdb-hipdb.hrsa.gov/resources/NPDBGuidebook.pdf. Accessed August 21, 2011.
30. Pace NM, Golinelli D, Zakaras L. Capping Non-Economic Awards in Medical Malpractice Trials: California Jury Verdicts Under MICRA. Santa Monica, CA, USA: RAND Corporation, Institute for Civil Justice; 2004. Available at: http://www.rand.org/pubs/monographs/2004/RAND_MG234.pdf. Accessed August 21, 2011.
31. Pate R, Hunter D. Code Blue: The Case for Serious State Medical Liability Reform. THFBN 1908; 2008.

32. Patient Protection and Affordable Care Act. HR 3590 (2010).
33. Peeples R, Harris C, Metzloff T. Following the script: an empirical analysis of court-ordered mediation of medical malpractice cases. *J Disp Resolution*. 2007;1:101–118.
34. PIAA Claim Trend Analysis (2004).
35. Politics, CfR (2011). Available at: http://www.opensecrets.org/industries/background.php?cycle=2012&ind=K01. Accessed August 21, 2011.
36. Rosengard LA, Parker M. Medical malpractice mediation: a 'healthy' resolution for patients, doctors and insurance companies. *The ADR Advisor*. 2010;Winter:1–3.
37. Sack K. Doctors say, 'I'm sorry' before see you in court. *The New York Times*. 2008.
38. Simpson A, Bowles E. Co-Chairs Proposal. NCoFR a Reform; 2010.
39. Stimpanowich TJ. ADR and the 'vanishing trial': the growth and impact of 'alternative dispute resolution.' *J Empir Legal Stud*. 2004:843–912.
40. Studdert DM, Mello MM, Gawande AA, Gandhi TK, Kachalia A, Yoon C, Puopolo AL, Brennan TA. Claims, errors, and compensation payments in medical malpractice litigation. *N Engl J Med*. 2006;354:2024–2033.
41. Szmania SJ, Johnson AM, Mulligan M. Alternative dispute resolution in medical malpractice: a survey of emerging trends and practices. *Conflict Resolution Q*. 2008;26:71–96.
42. Tabler NG. Should physicians apologize for medical errors? *The Health Lawyer*. 2007;19.
43. Webb RJ. *New Jersey Court Green Lights Provider-Patient Arbitration Agreements. Healthcare Neutral ADR Blog*. Califon, NJ, USA: Healthcare Neutral, LLC; 2010.
44. Weiler PC. *A Measure of Malpractice: Medical Injury, Malpractice Litigation, and Patient Compensation*. Cambridge, MA, USA: Harvard University Press; 1993.
45. Weinstein SL. Medical liability reform crisis 2008. *Clin Orthop Relat Res*. 2009;467:392–401.
46. Wisconsin Statute 655.42(1).

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