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ESTRO Course Book

Comprehensive Quality Management in Radiotherapy

2 - 5 October, 2017
Brussels, Belgium

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Faculty

Núria Jornet Sala & Philippe Maingon

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EUROPEAN ACCREDITATION COUNCIL
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Institution of the UEMS

The faculty of the teachers for this event has disclosed any potential conflict of interest that the teachers may have.

Quality management in radiotherapy

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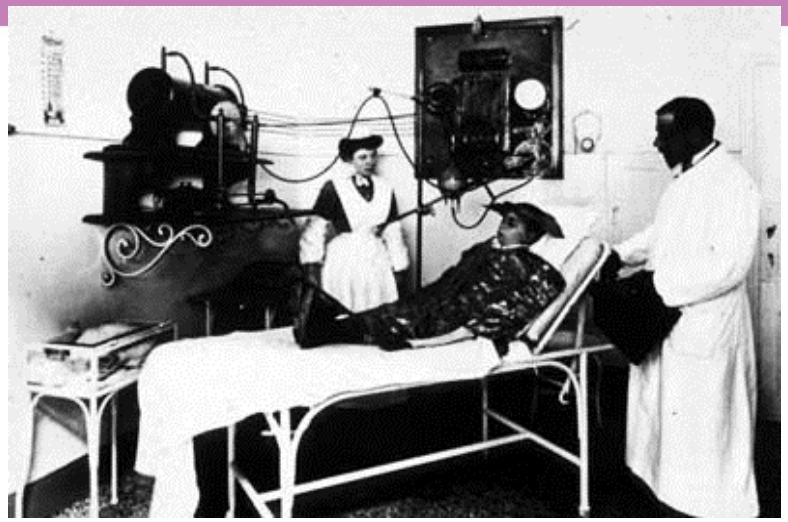
Learning objects

- To recall definitions; Quality Control, Quality Assurance, Quality management.
- To discuss the Radiation Oncologist (RO), Medical Physicist (MP), Radiation Therapist (RTT) and patient vision of quality
- To explain the impact of quality in treatment outcomes
- To introduce what is understood as quality monitoring and improvement

The aims of a radiotherapy department

- **To cure patients**
  - A long and complex process
  - Involving a lot of actors
    - Before, During, After the treatment
- **To improve the outcome of the patients**
  - How to measure it
  - How to do it
- **To teach the juniors**
  - A dedicated organization

Quality perception: What is quality in Radiation Therapy?



To have as many new techniques/technology available

Accuracy in dose determination

No waiting times

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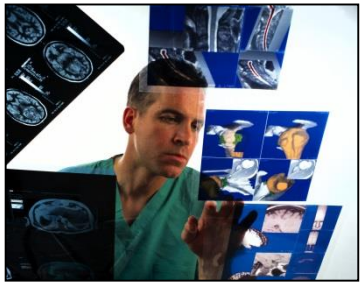
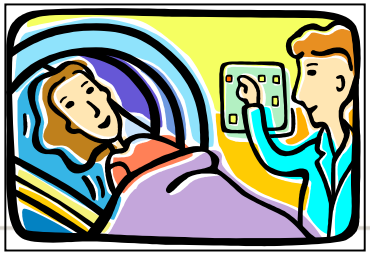
Quality perception; what is quality in Radiation therapy?

All of them would agree:





- SAFER PATIENT CARE: Reduce adverse events
- BETTER OUTCOMES IN PATIENT CARE: Comply with performance and quality standards
  - Adopt best practices that arise from evidence-based medicine
  - Monitor quality and propose quality improvement strategies

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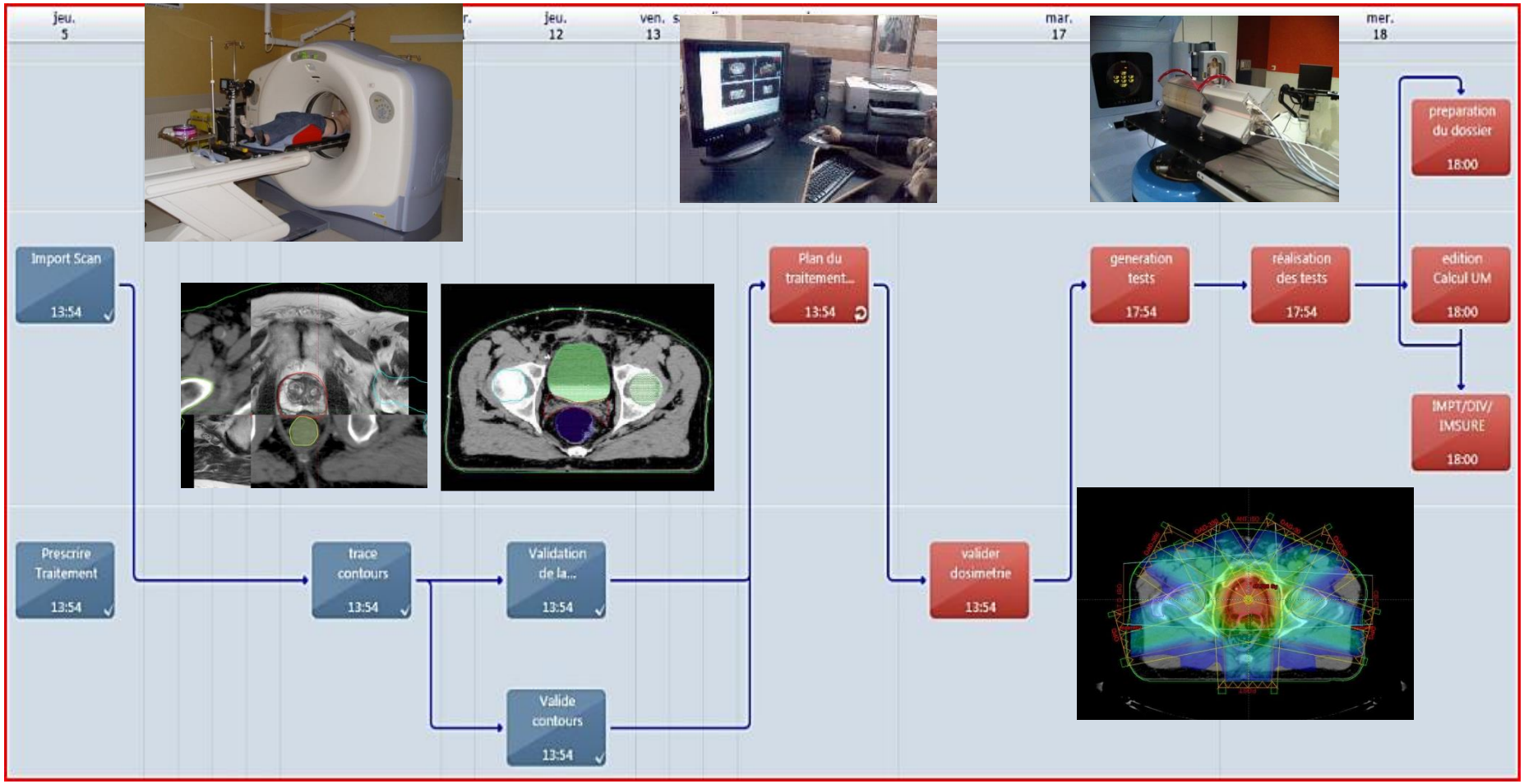
A complex and long road …



Murphy’s law

When something can go wrong, it will go wrong

Bread always lands on the side with the marmelade

How to know that at the end of the chain the patient receives the treatment as planned?

How to know that at the end of the chain the patient receives the treatment as planned?

If quality and safety standards are not fulfilled we won't be able to show that

"Radiotherapy cures cancer safely today"

"It is sobering to note that the **value of good radiotherapy**

is substantially greater than the incremental gains that have been achieved with new drugs and/or biologicals.

These results strongly reinforce the importance of **doing well** what we already know."

Peters et al. J Clin Oncol,2010

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‘Even major improvements have been shown to take up to 10 years to be applied.’

‘The treatment needs to be available.
It needs prescription at the right time.
It has to be given at the right form’.

‘The whole of these elements are covered by the process of ‘Quality Assurance’ which is the responsability of all bodies involved’.

Emmanuel van der Schueren
Radiother Oncol 1995

Poor Quality Radiotherapy will produce poor clinical outcomes

Proof: Quality in clinical trials

- All institutions should deliver prescribed radiation doses that are clinically comparable and consistent.
- Volume's definitions should be comparable and consistent (PTV and OAR).
- Plan quality (compliance with dose's goals) should be consistent.
- All institutions should comply with the protocols

Proof: Quality in clinical trials

Paediatric Oncology Group clinical trial 8725

Trial/Study question: Importance of consolidation radiation management in intermediate and risk patients with HL

Patients were **randomized for radiation therapy** to all sites of original disease defined on imaging **after completing 8 cycles** of alternating **chemo**

Results (Clinical Oncology 1999): **No difference** in survival between both arms (Chemo+RT; Chemo)

Quality in clinical trials

Paediatric Oncology Group clinical trial 8725

Retrospective analysis at QARC (Quality Assurance Review Center)

Made an evaluation making two groups of patients:

-Treatment delivered per protocol

-Treatment delivered in a non-study compliance manner

Quality in clinical trials

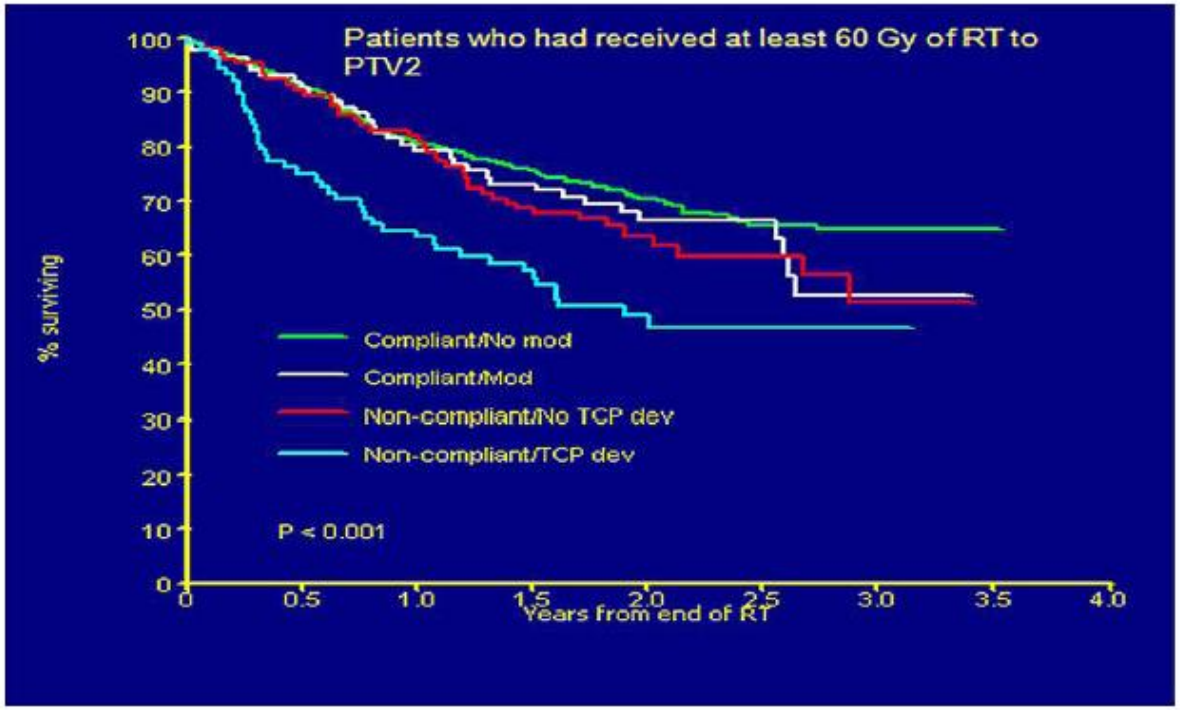
Results (5 years Relapse Free Survival (%):

Arm 1: Chemo alone	85
Arm 2: Chemo+RT	
Appropriate RT volume	96
Major or minor deviations	86

Quality in clinical trials: lessons learned

HeadSTART trial (2000-2005)

Overall survival by protocol compliance



Patient survival directly correlated to the quality of treatment plan

The primary objective of QA needs to be the limitation of study deviations to provide an uniform study population

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Quality in clinical trials: message

Extrapolating to all treatments:

Only by having high quality treatments we can have solid outcomes

To improve quality we need to standardise procedures and perform follow-up of treatment outcome

Peer review plays a major role in treatment quality

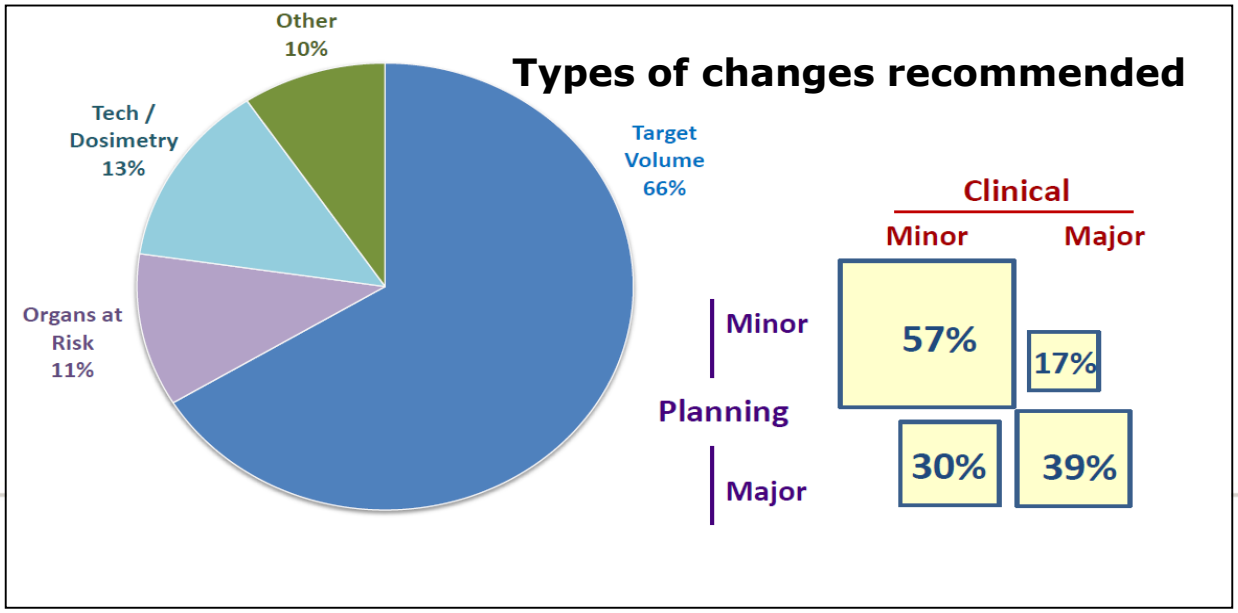
Peer Review in Radiation Oncology

- The evaluation of components of a radiation oncology treatment plan by a second radiation oncologist

  - Second check of indication, prescription, volume delineation

Results of peer review in Cananda

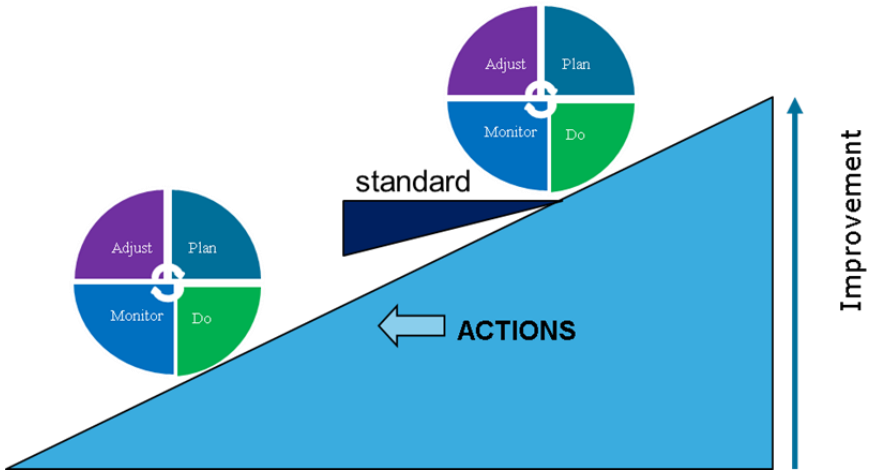
Outcome of peer review	Frequency	Percent
Change recommended	**184**	**3.3**
Minor plan change	*99*	*1.8*
Major plan change	*63*	*1.1*
Unknown	*22*	*0.4*
No change recommended	**5377**	**96.7**
	5561	**100.0**



Quality Improvement (QI)

QI consist on **systematic and continuous actions** that lead to **measurable improvement** in heath care services and the health status of targeted patient groups

Quality improvement



1. Assess quality (Quality Indicators)
2. We have to set objectives (Quality standards)
3. We have to implement actions to achieve these objectives
4. Check if they have been effective

Quality assessment; how do we know that we are performing well?

Quality standard

- A quality programme assures that the **quality standards** are fullfilled
- Need that the **quality standards** are well defined
- We need **quality indicators** that we can measure and compare with **quality standards**
- Tolerances have to be set with “clinical” criteria

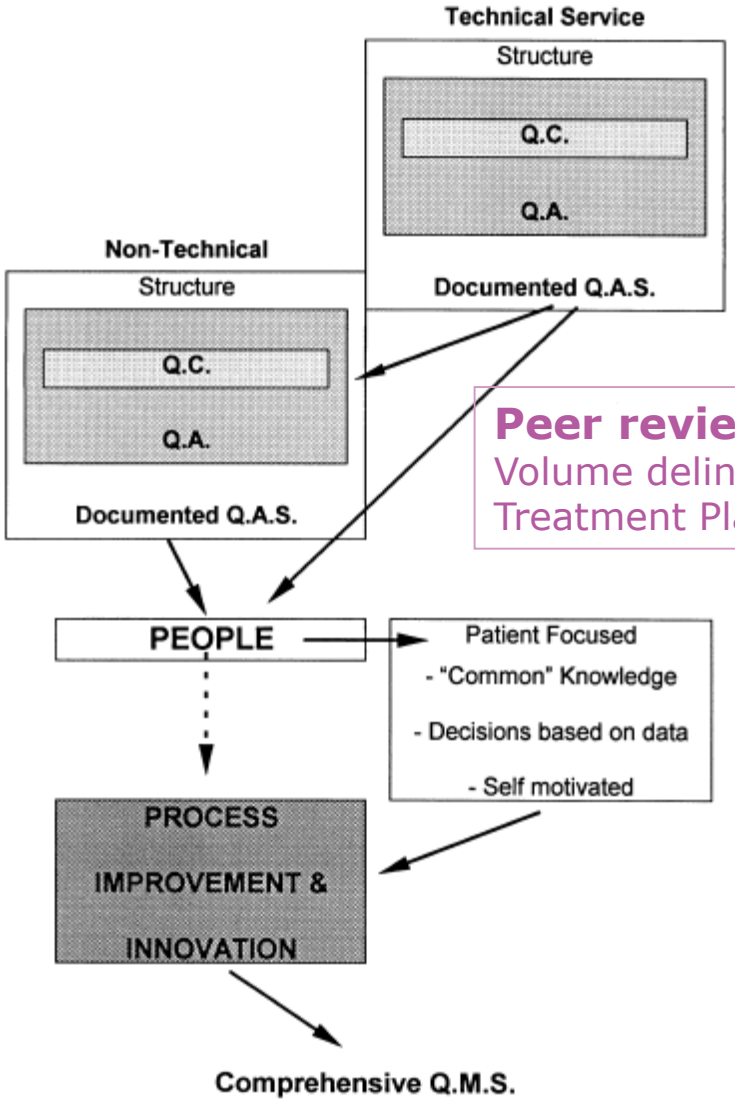
The results are as good as the quality standards

To make improvements an organisation needs to understand its structure, processess and outcomes(QI)

RESOURCES	**ACTIVITIES**	**RESULTS**
Input	**Processes**	**Outcome**
People	What is done	Health Services Delivered
Infrastructure	How it is done	Change in health behaviour
Materials	Who does it	Change in health status
Information	When it is done	Patient satisfaction
Technology		

Donabedian 1980

Some definitions: Quality management system



Treatment unit
TPS

Medical Phyicists

Peer review:
Volume delineation
Treatment Planning

Radiation Oncologist

Patient treatment:
Ipatient identification
In room imaging protocol

Radiation Technologist

Kehoe, L.-J. Rugg / Radiotherapy and Oncology 51 (1999)

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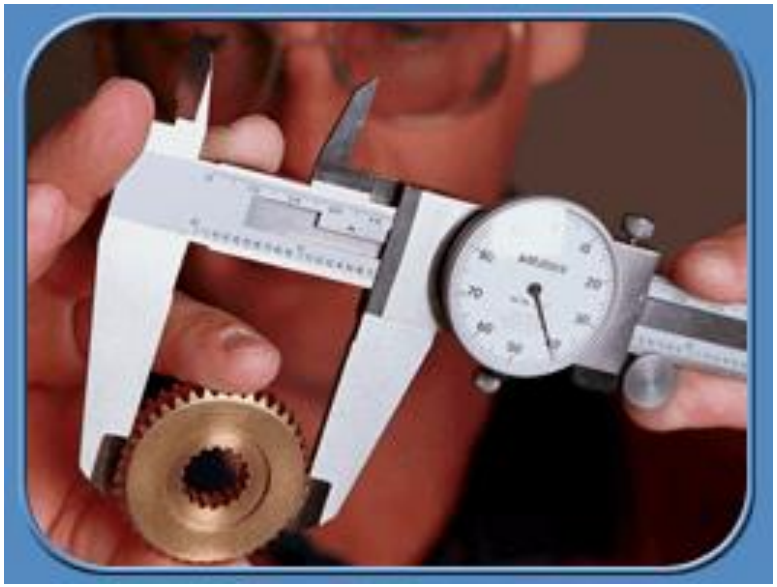
Some definitions: Quality control



TEST

Comparing the result of the measurement with the standard

Some definitions: Quality assurance

- What do we use to perform measurements?
- Who performs them?
- How?

...

QA>>QC

Quality management the role of the organisation

The organisation: safety and quality culture

Defined in the Basic Safety Standards

> The assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance

The organisation: safety and quality culture

- Encompasses organizational policies and priorities and person attitudes and habits

The organisation: safety and quality culture

Factors to consider

- Leadership
- Structure
- Staffing levels
- Communication

The organisation: safety culture

Factors to consider

- Leadership
- Structure
- Staffing levels
- Communication

The organisation: leadership

Study by Ginsburg et al. (2010)

- A strong organisational commitment to safety is necessary if learning from incidents is to take place
- This is also true for quality improvement initiatives
- It is important to clearly demonstrate this commitment

The organisation: safety and quality culture

Factors to consider

- Leadership
- Structure
- Staffing levels
- Communication

The organisation: structure

Defines how tasks are divided and resources deployed

- The set of formal tasks assigned to individuals and departments

The organisation: safety and quality culture

Factors to consider

- Leadership
- Structure
- Staffing levels
- Communication

The organisation: staffing levels

Health service is manned by human beings often under severe pressure to perform beyond their ability

- Knowledge
- Understanding
- Commitment
- Ability
- Interest
- Enthusiasm

The organisation: staffing levels

- A radiotherapy department needs to have sufficient staff in relation to the number of patients and types of treatment modalities

  International Atomic Energy Agency

- Important to consider
  - Appropriate working conditions
  - Education and training
  - Continuing Professional Development

The organisation: safety and quality culture

Factors to consider

- Leadership
- Structure
- Staffing levels
- Communication

The organisation: communication

- Communication between staff members is essential for all aspects of treatment, since many persons with various responsibilities must interact

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The organisation: communication

- There should be clear and concise written rules for communication critical to safety and quality. These rules should be posted and understood

- Documents critical to safety and quality, for example prescriptions, basic data and treatment plans, should be signed by staff who are responsible and qualified

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The organisation: safety and quality culture

- Management should provide the environment, training and provisions to maintain and exercise awareness of potential incidents of the staff

- Freedom to challenge the work of others in a spirit of goodwill often identifies potential accidents before they happen and leads to quality improvement initiatives

The organisation: risk management

Is it possible to prevent all incidents?

- Introduce factors for fault prevention
- Establish a margin of acceptable tolerance
- Monitor effectiveness

And thereby minimise the impact

The organisation: risk management

Incidents are a fact of life

- Focus on minimising/reducing the potential for harm and not relying on personal perfection

(Bagian J.)

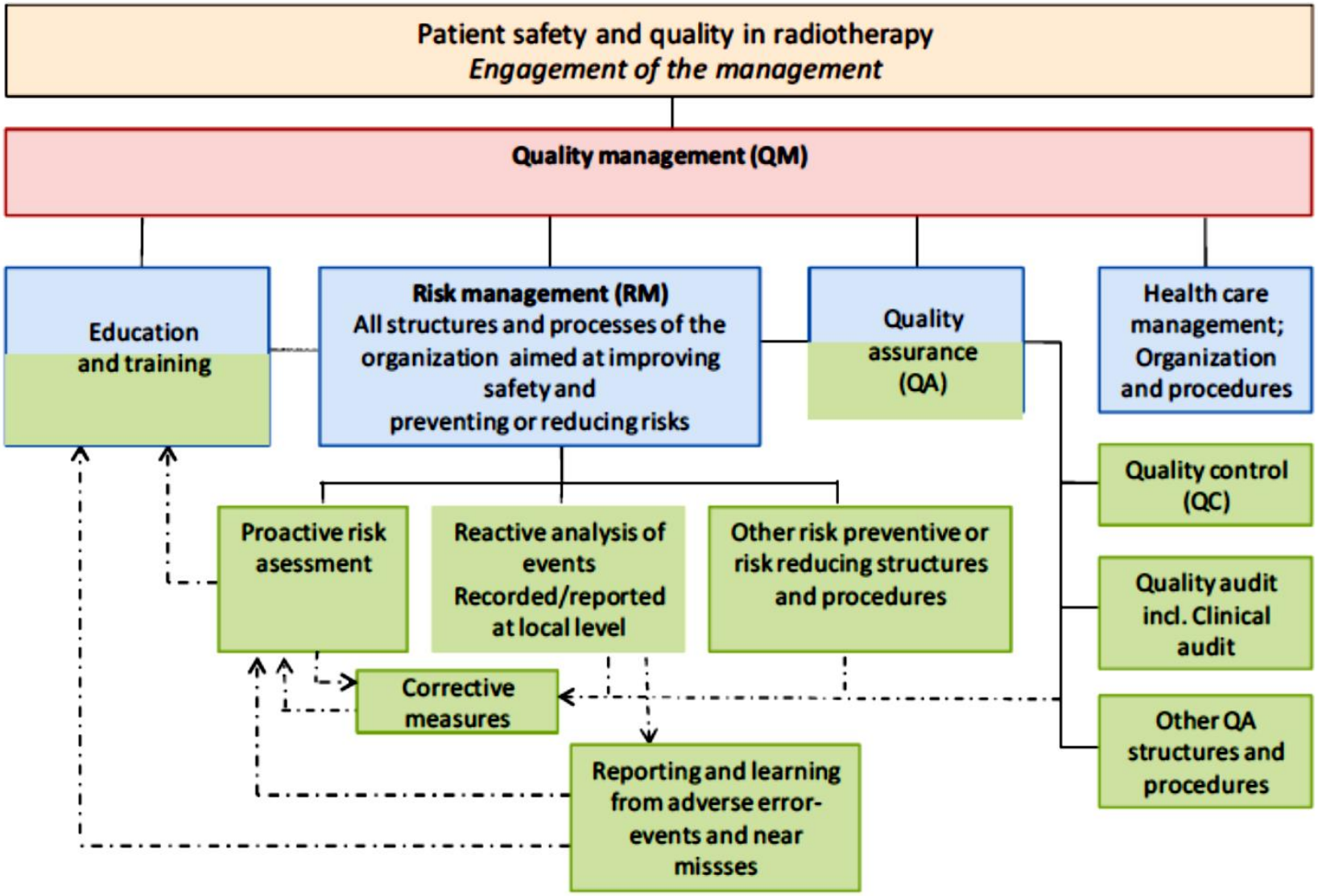
The organisation: risk management

Responsibility of an organisation

- identify unacceptable risks as a safety problem
- Create safety cases based on visible damage and safety assessment

Learn from others

Main procedural concepts



Quality management results in a better allocation of resources

Knowing the weak points in the process and the ones that have room for improvement helps

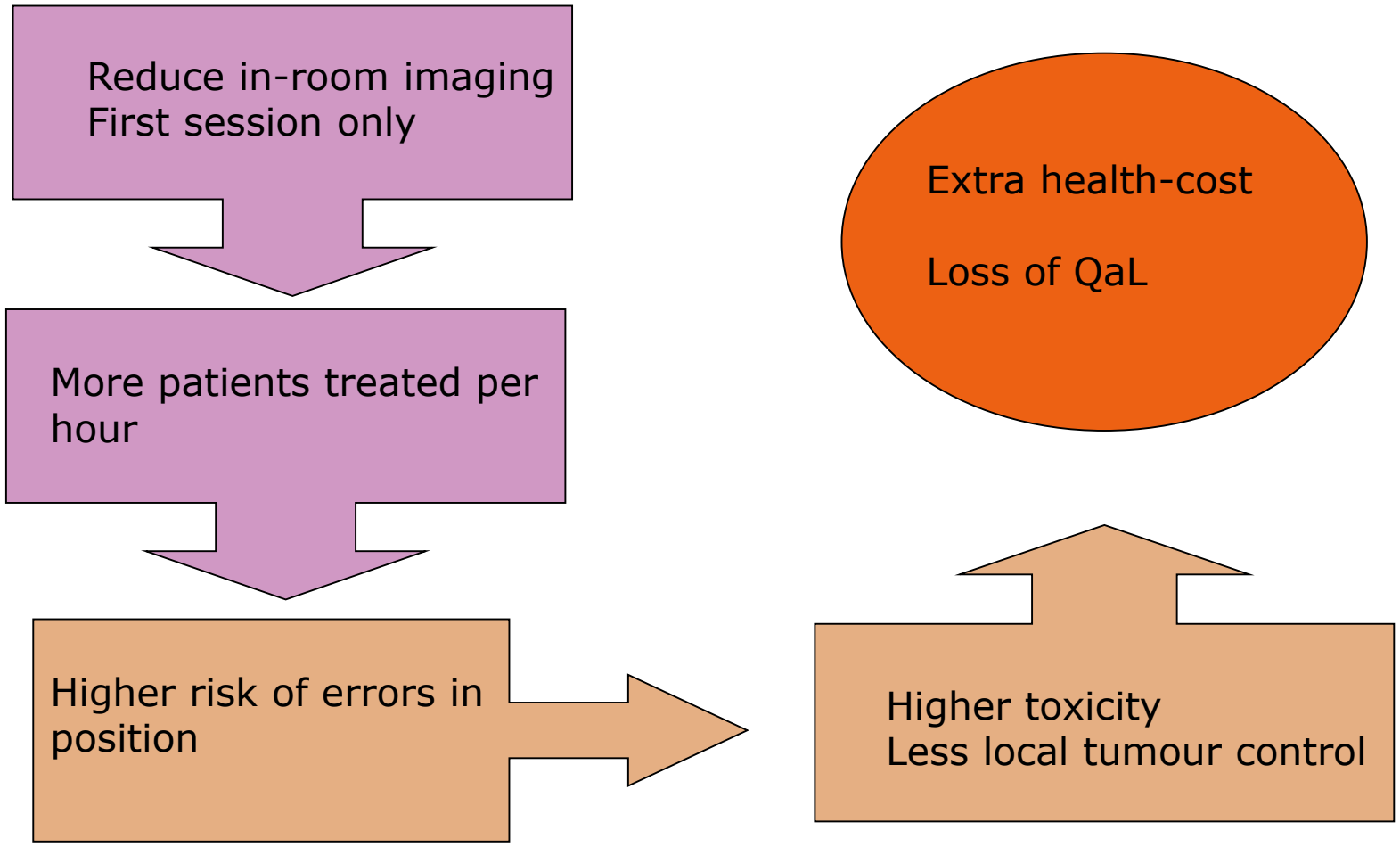
a. Quality Controls (frequency)

b. Allocation of personnel

c. Allocation of money (investment)

d. Allocation of effort.

Trying to reduce inversion in quality can result in higher costs



But whatever we do, we want to show that has an impact

- Improvement on patient satisfaction
- Improvement on patient QoL
- Improvement on Tumour control/survival
- Reduction of toxicity
- Improvement on the use of resources
- Improvement in the satisfaction of patients
- Reduction on accidents/incidents/near misses

Why is a QI program essential to a health care organisation?

- Improved patient health. Better outcomes: Better tumour control, less toxicity.
- Improved efficiency of managerial and clinical processes. Optimise tasks flow in Radiation Oncology and in Cancer Care.
- Cost reduction. Avoides costs associated with process failures, errors and poor outcomes.

Conclusion: Why is a QI program essential to a health care organisation?

- Proactive processes that recognise and solve problems before they occur ensure that system of care are reliable and predictable
- Ease technology and techniques assessment
- Reduce sampling for clinical trials, less patients will need to be included to reach significant results
- A commitment to quality shines a positive light on an organization (partnership and funding oportunities)

ESTRO and QUALITY managment

‘Even major improvements have been shown to take up to 10 years to be applied.’

‘The treatment needs to be available.
It needs prescription at the right time.
It has to be given at the right form’.

‘The whole of these elements are covered by the process of ‘Quality Assurance’ which is the responsability of all bodies involved’.

Emmanuel van der Schueren
Radiother Oncol 1995

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Recommendations for a Quality Assurance Programme in External Radiotherapy (ESTRO BOOKLET nº2)

Pierre Aletti, Pierre Bey (Editors), ESTRO, 1995

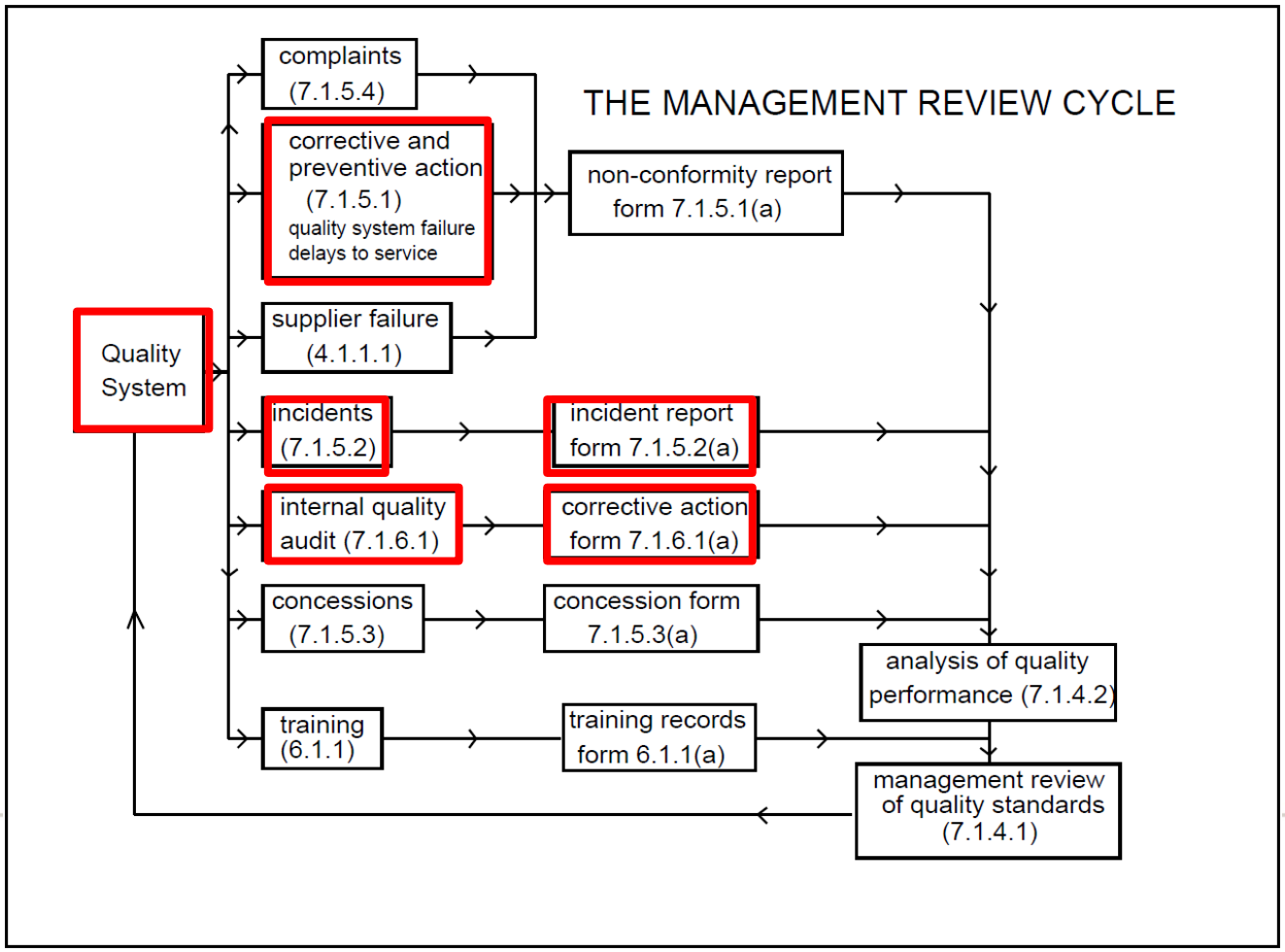
- General recommendations [task distribution, personnel, legislation, training, quality control, minimal equipment for QA)

- They look at the treatment as a process (Quality controls suggested for each step)
  - Volume definition
  - Prescription of treatment
  - Planning
  - Quality Control of daily treatments
  - Control of the dosimetric chain

Practical Guidelines for the Implementation of a Quality System in Radiotherapy

A project of the ESTRO Quality Assurance Committee sponsored by "Europe against Cancer"

Leer JWH, McKenzie AL, Scalliet P, Thwaites DI, ESTRO, 1998



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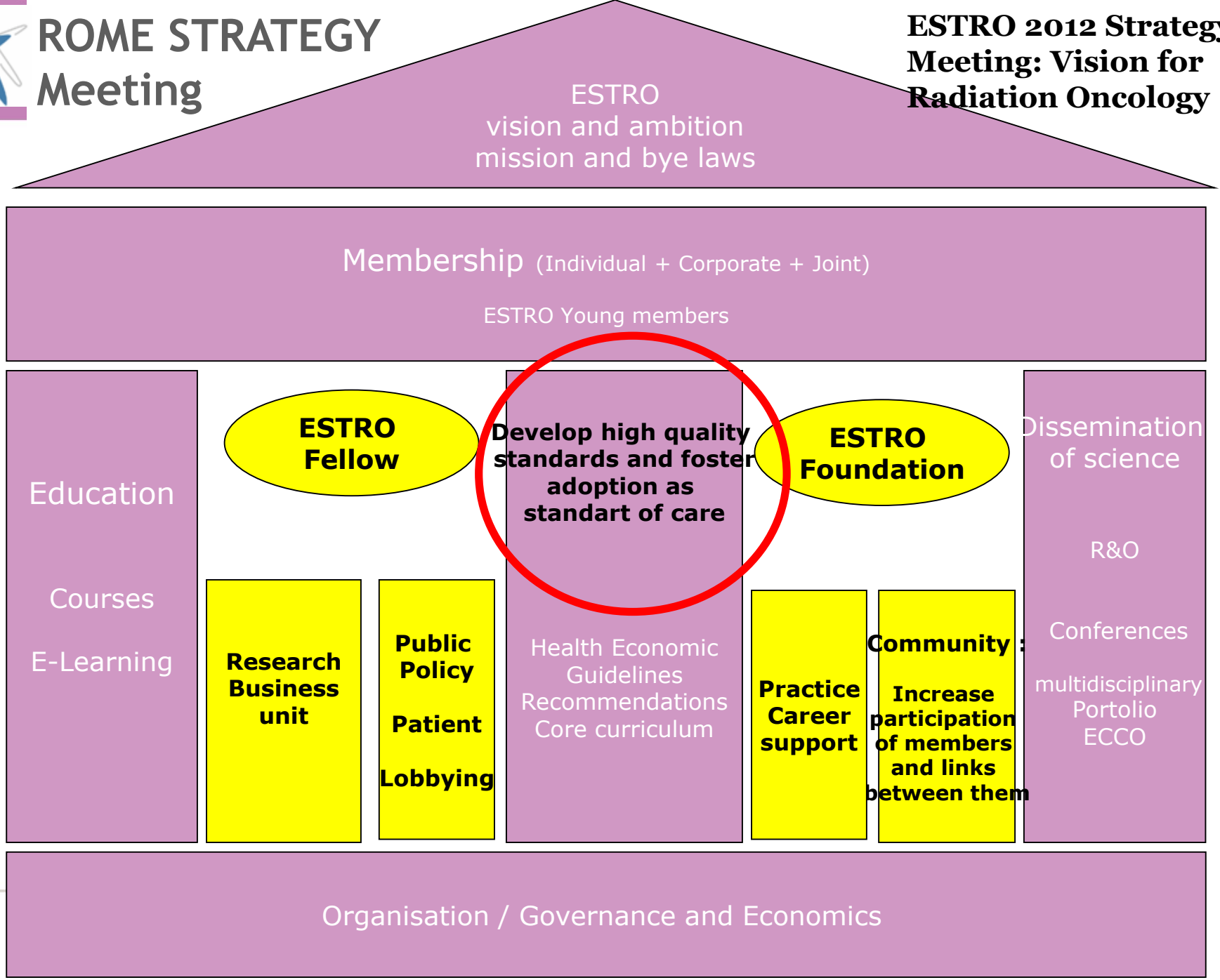
ROME STRATEGY Meeting

ESTRO 2012 Strategy Meeting: Vision for Radiation Oncology



ROME STRATEGY Meeting

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Radiotherapy and Oncology 103 (2012) 103–108

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Radiotherapy and Oncology

journal homepage: www.thegreenjournal.com

ESTRO Core Curricula

The updated ESTRO core curricula 2011 for clinicians, medical physicists and RTTs in radiotherapy/radiation oncology

Jesper G. Eriksen [a,*], Andrew W. Beavis [b], Mary A. Coffey [c], Jan Willem H. Leer [d], Stefano M. Magrini [e], Kim Benstead [f], Tobias Boelling [g], Marie Hjälm-Eriksson [h], Guy Kantor [i], Boguslaw Maciejewski [j], Maris Mezeckis [k], Angelo Oliveira [l], Pierre Thirion [m], Pavel Vitek [n], Dag Rune Olsen [o], Teresa Eudaldo [p], Wolfgang Enghardt [q], Pascal François [r], Cristina Garibaldi [s], Ben Heijmen [t], Mirjana Josipovic [u], Tibor Major [v], Stylianos Nikoletopoulos [w], Alex Rijnders [x], Michael Waligorski [y], Marta Wasilewska-Radwanska [z], Laura Mullaney [aa], Annette Boejen [ab], Aude Vaandering [ac], Guy Vandevelde [ad], Christine Verfaillie [ae], Richard Pötter [af]

The importance of quality management, governance/ risk management and a systematic approach to technology is also highlighted.

ESTRO has a long tradition in supporting high quality RT in Europe

1995 Recommendations for a Quality Assurance programme in External Beam RT

1998 Publication of practical guidelines for the implementation of a Quality System in RT

2001-2003

ESTRO
European Society for Therapeutic Radiology and Oncology

EUROPEAN COMMISSION
Directorate General Health and Consumer Protection - Europe Against Cancer Programme
ESQUIRE II Project:
Education, Science and QUality Assurance for Radiotherapy
Grant Agreements N° S12.300039 (2000CVG2-021) & SPC 2002480

- Task 1: EQUAL
- Task 2: REACT
- Task 3: EDRO
- Task 4: EQART
  EQART sub-task ROSIS
- Task 5 QUASIMODO
- Task 6: BRAPHYQS

The overall objective of the **ESQUIRE** Project was **to improve the treatment outcome**

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Spin-off from ESQUIRE project still being active

- ROSIS incident reporting system database (basis of SAFRON IAEA reporting system)
- HERO group
- BRAPHYS: Still active in drafting guidelines (some in collaboration with AAPM brachytherapy group)
- ACROP; coordination of all ESTRO proposals on guidelines, endorsement of other societies /scientific bodies guidelines
- ESTRO education Council and ESTRO school (39 active courses)

- EQUAL lab, dosimetry audits (until 2010)

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New in ESTRO

- ESTRO in 2015 created a TASK FORCE On Radiation Oncology Safety

  (chair: Mary Coffey)

- Two Courses on Quality Management:

  - Comprehensive Quality Management:

  Risk Management and Patient Safety (Course director: Pierre Scalliet)

  - Comprehensive Quality Management:

  Quality assessment and improvement (Course director: Philip Maingon, Núria Jornet)

Although advertised as multidisciplinar, most participants are physicists, RTTs and quality managers.

Need to attract more radiation oncologists.

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References

Pierre Aletti and Pierre Bey. Recommendations for a Quality Assurance Programme in External Radiotherapy. Physics for clinical radiotherapy, booklet nº2, 1995.

Kehoe, L.-J. Rugg. From technical Quality Assurance of Radiotherapy to a comprehensive quality of service management system. Radiother. Oncol. 51; 281-290, 1999.

Vincenzo Valentini,Jean Bourhis,Donal Hollywood.ESTRO 2012 Strategy Meeting: Vision for Radiation Oncology. Radiother. Oncol. 103,2012.

Thomas J. FitzGerald. What We Have Learned: The Impact of Quality From a Clinical Trials Perspective. Semin Radiat Oncol 22:18-28, 2012.

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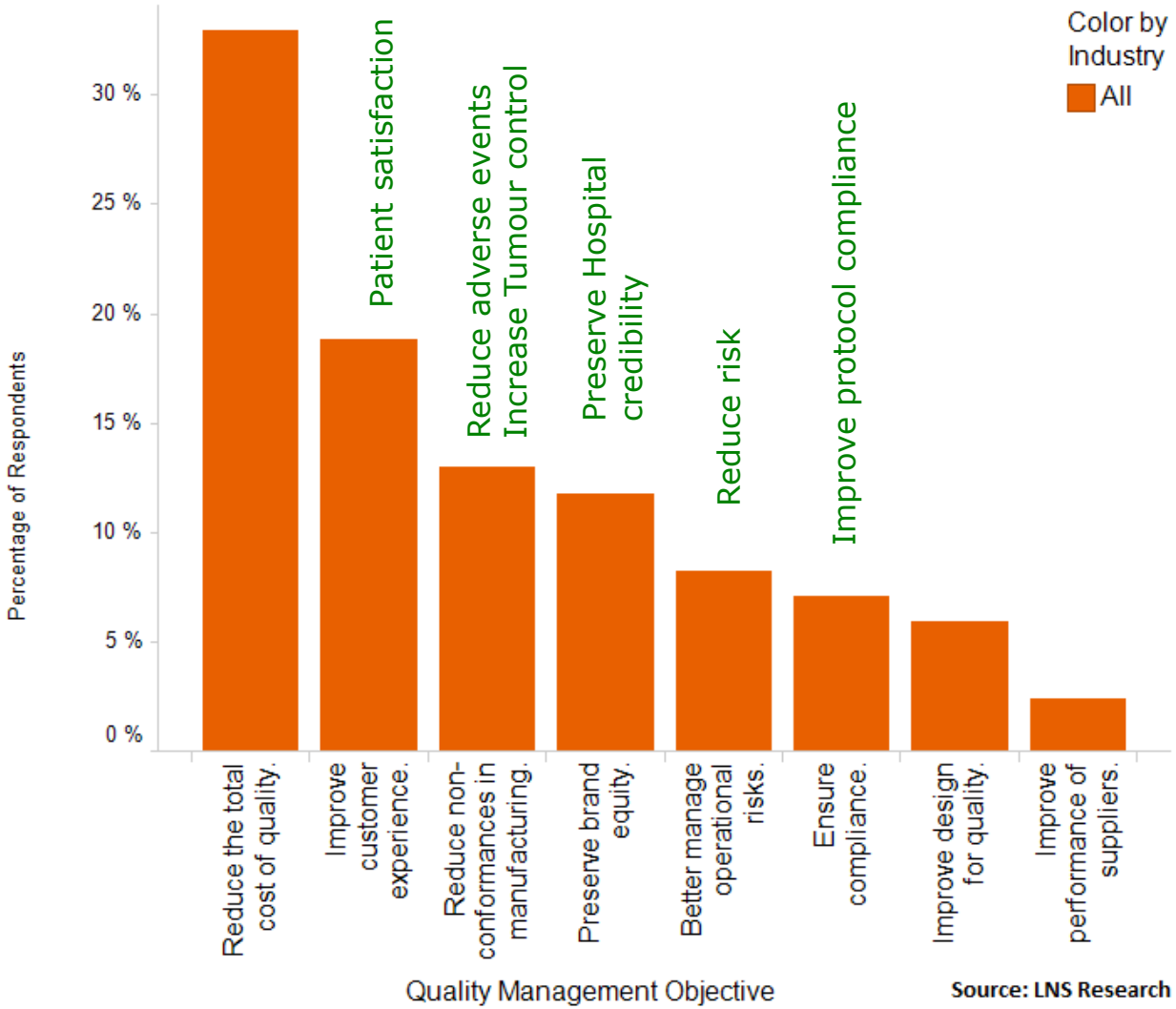
The ability to constantly improve quality is a hallmark of a successful business

Vincent Van Gogh
Couple Walking among Olive Trees in a Mountainous Landscape with Crescent Moon
May 1890

Quality management objectives in industry-health



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The need of setting up a quality system in a radiation therapy department

Dr. Nicolas POUREL

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COMPREHENSIVE QUALITY MANAGEMENT

IN RADIOTHERAPY

BRUSSELS (Belgium) – Monday, October 2nd 2017

The need of setting up a quality system in a radiation therapy department

Learning objectives

- Comprehensive Quality Management System (C-QMS): sense and framework
- Quality management in Radiation Oncology: specific aspects
- Setting up a C-QMS: benefits and pitfalls

Foreword
Quality

Quality health care is about delivering the best possible care and achieving the best possible outcomes for people every time they deal with the health care system or use its services. Essentially, it means doing the best possible job with the resources available.

(Health Canada, http://www.hc-sc.gc.ca/hcs-sss/qual/index-eng.php)

The Canadians focus on

- access/waiting time
- Patient safety

Quality within a Radiation Therapy Department

Radiotherapy is a safety critical activity

Being familiar with quality checks is NOT enough

Formal quality management is alien to healthcare professionals in RT depts.

➔ Setting up a Comprehensive Quality Management System is mandatory!

Quality is a Culture !

Socratic Paradoxes (400 B.C.)

No one errs or does wrong willingly or knowingly

Know thyself

Paradoxes of the Enlightenment (18th century A.D.)

One's freedom ends where another's begins. Rousseau

« *La liberté des uns s'arrête là où commence celle des autres* »

Liberty leading the People. Delacroix

« *La liberté guidant le peuple* »

➔Which cultural background is yours?

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Quality is a Culture !

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- Liberty leading the People. Delacroix
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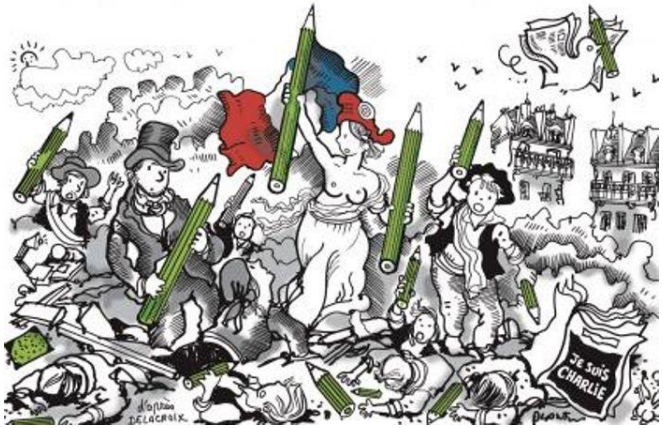
➔Which cultural background is yours?



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Quality Quality Quality

‘ Repeating Quality, Quality, Quality, while jumping like a baby goat, is a non-sense! ’ (adapted from De Gaulle C. about Europe)

Quality management may be, in the beginning, regarded as:

Useless (‘we do very well without it’)

Intrusive (‘a bureaucratic takeover’)

Abusive (‘the new dictature’)

➔ Bring enthusiasm to people you work with, but be aware that diplomatic skills are required…indeed!

Comprehensive Quality Management System (C-QMS)

Before starting anything, ask yourself:

What does quality mean to the patients/management/institution ?
What aspects of service are important to patients/management ?
What do pts. and purchasers like/dislike about the current service ?
What constitutes an appropriate quality of service ?
What professional guidance should be considered ?
(Source: 'Towards Safer Radiotherapy', U.K. Dept. Of Health)

➔ C-QMS is based on self-defined objectives

Comprehensive Quality Management System (C-QMS)

We all do quality without knowing it !

Build on existing records and documented checks

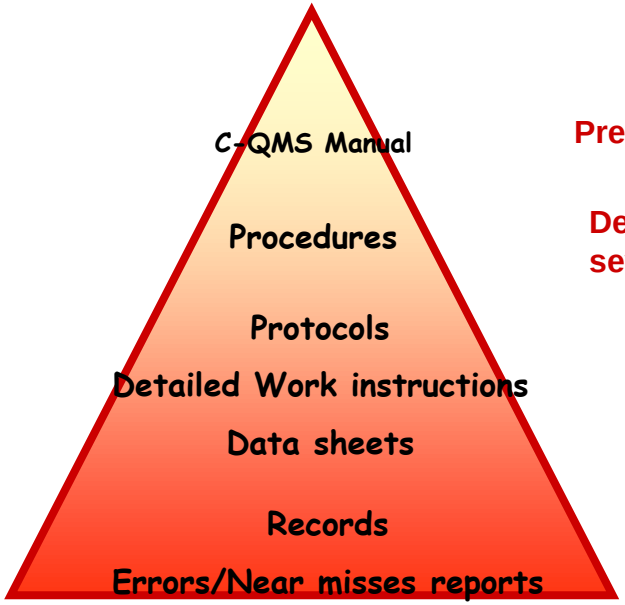
Checks on essential parts of the technical treatment delivery = ‘bricks ’ belonging to a greater ‘wall ’

C-QMS can only be deployed on 3 pillars

1. A formal engagement of the hospital board and its representative (Sr. Med. Manager)
2. A professional of Quality in health care (Quality Manager (QM))
3. A Specific Methodology (Document Management)

Comprehensive Quality Management System (C-QMS)

Document Management



Presents the framework of C-QMS

Describe an organization (with several kinds of personnel, places…)

Describe one specific task

Bring a piece of evidence

➔Knowledge of a QM is key to set-up this particular framework !

C-QMS in summary

Mandatory

A shared culture within your dept.

Diplomatic skills and Commitment of the Hospital Board of Directors required

Based on self-defined objectives and a specific methodology (document management)

An appointed Quality Manager = key to success

➔ Still, the question remains: ‘Why do I need a C-QMS ?’

The need for a C-QMS

C-QMS brings Order

C-QMS brings Transparancy

C-QMS brings Efficiency

The need for a C-QMS

C-QMS brings Order

C-QMS brings Transparancy

C-QMS brings Efficiency

C-QMS brings Order

Defining the scope of C-QMS

Respecting legislation

Recording control checks and error/near-miss reports

Homogenizing practices

C-QMS brings Order

Define the scope of the quality system and its implementation through

Incentive of the Chief Radiation Oncologist assisted by :

- Quality Manager
- Chief-Physicist
- Chief-Technician

A permanent steering committee

An initial audit of strengths and weaknesses of the dept. +/- assistance of external auditors

➔ Write your own *Magna Carta* for Quality*!*

C-QMS brings Order

Obtain any relevant piece of legislation

Read the Law and let no one tell you what lies in it…

Apply the Law and demand means necessary to do that!

Define precisely what is legally mandatory

- schedules (medical, phycists and technicians),
- checks (typology, chalendar, results to be achieved)
- medical records (in-vivo dosimetry, double calculation of dosimetry, end-of-treatment report)

➔ Medical records are 100% in line with the Law!

C-QMS brings Order

Record control checks and error/near-miss reports through adequate documentation

- Checks and reports are prospectively recorded on adequate sheets, forms and databases
- With the assistance of secretary trained by the QM
- Lists of records, reports and corrective actions are maintained, adequately stored and identified

➔Build your own database, always ready for audit!

C-QMS brings Order

Homogenize practices among Physicians

- Who retain the right to be creative…
- Who should be aware that defining a medical goal to achieve is of their responsibility
- Who should be assisted in a way they do not waste time and energy
- Who should be convinced that a procedure for treating common cancer locations is the way forward

➔ First step before transparancy and efficiency!

The need for a C-QMS

C-QMS brings Order

C-QMS brings Transparancy

C-QMS brings Efficiency

The need for a C-QMS

C-QMS brings Order

C-QMS brings Transparancy

C-QMS brings Efficiency

C-QMS brings Transparancy

Responsibilities within the RT dept.

Control checks are recorded properly

Practice is secured

Errors/near-misses are properly analyzed

Communicate with care-givers/providers and patients

C-QMS brings Transparancy

Responsibilities within the RT dept.

- Described in an internal rules document signed by hospital board highest authority (gen. director)
- Clearly states the respective roles and responsibilities of staff
- Clear job descritions are available for the Sr. Medical Manager and yearly revised

➔ Your collaborators know precisely the scope of their actions and responsibilities!

C-QMS brings Transparancy

Control Checks made are recorded properly

- Preventive controls on LINACs are scheduled and recorded
- Double checks on dosimetry are organized
- Checks lists on sensitive treatments
  - SBRT
  - V-MAT
  - Brachytherapy…

➔ Complex treatments are no longer stressful neither for your colleagues nor control authorities!

C-QMS brings Transparancy

Practice is secured

- No one is left alone with excessive risks in his/her hands (especially dosimetrists)
- No treatment can start without medical validation
- Dose delivered is guaranteed ultimately by Physicists' validation
- Security barriers are designed to deal with the level of complexity of treatments (especially on LINACs)

➔ The risk of errors inducing prejudice to the patient is minored!

C-QMS brings Transparancy

Errors/near misses are reported and analyzed

- In a non-punitive, open and fair ambiance
- Report forms are standardized and easy-to-fill in (sheets accessible everywhere, Intranet…)
- Staff is trained to report errors/near misses
- Forms are reviewed monthly in an unformal multidisciplinary committee dedicated to safety
- Some selected incidents, implying a particular risk, are investigated in depth to identify root causes

➔ Corrective actions are decided and followed-up!

C-QMS brings Transparancy

Communicate with care-givers

Newsletter, e-mail to front-line staff

Results of investigation on errors/near misses published monthly

Targeted staff education programmes

➔ Staff can see the results of its commitment to Quality!

C-QMS brings Transparancy

Communicate with patients

Staff accessible to questions, trained to give answers

Satisfaction questionnaires and annual report displayed in waiting room

Quality indicators (ex.: avg. waiting time, delays to start RT,…), commitment statement by hospital highest authority

➔ Patients can feel the *reassuring* ambiance of Quality!

The need for a C-QMS

C-QMS brings Order

C-QMS brings Transparancy

C-QMS brings Efficiency

The need for a C-QMS

C-QMS brings Order

C-QMS brings Transparancy

C-QMS brings Efficiency

C-QMS brings Efficiency

Practice is homogenized

Time/Energy is saved

Staff is properly trained

C-QMS brings Efficiency

Practice is homogenized

Through operational procedures

For instance, only one way to deal with a common cancer location (e.g. prostate cancer)

From prescription by physican

To simulation and dosimetry

To physics control of V-MAT parameters, on dosimetric parameters and at the LINAC

To delivery of treatment on LINAC and imaging control

➔A lot is learned from group work on these procedures!

C-QMS brings Efficiency

Time/Energy is saved

Approx.70% of practice can be translated into procedures
Workflow processing if faster and secured
Each treatment reaches the level of standard practice
Difficult and rare medical scenarios can be addressed more easily

➔ The medical team is productive and creative!

C-QMS brings Efficiency

Staff is properly trained

- New treatment techniques are developped methodically in accordance to medical objectives
- Physicians and Physicists get involved in the training
- Quality and Security is dealt with (training of staff by Quality manager)
- Staff is involved in the process review of practice

➔ Empowered by training, staff works faster and ‘cleaner’, even on complex treatments!

Conclusion
C-QMS benefits

Order

- Some control over practices
- Each staff group ‘owns’ their checks
- Quality issues have their profile raised

Transparancy

- Controls are made and you can easily check for that
- Work in an appeasing ambiance of self-assurance
- Enhance trust within your team and patients

Efficiency

- The Medical staff states its objectives clearly
- New techniques are developped accordingly
- Training of team is carefully monitored

Conclusion
Quality management is a Revolution!

But…

Don’t chop heads off!

Don’t behave like a dictator!

Don’t burn your dept. down to the ground!

➔

Liberty was a succesful export!

Paradoxes of the Enlightenment…again!

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Recommended readings

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The need of setting up a quality system in a radiation therapy department

Dr. Nicolas POUREL

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COMPREHENSIVE QUALITY MANAGEMENT

IN RADIOTHERAPY

BRUSSELS (Belgium) – Monday, October 2nd 2017

Thank you for your attention !

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The link between risk management

And

Quality management

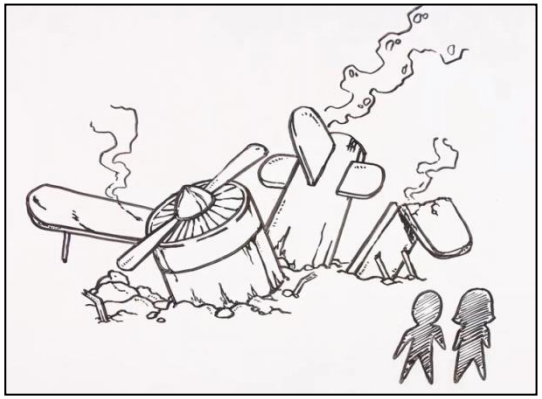
Núria Jornet

Servei de Radiofísica
Hospital Sant Pau,
Barcelona

Learning objectives

- To understand the differences between risk analysis and quality management

An accident has happened…



Focus on a liability assessment
Mitigate consequences

Risk manager

Identify the causes that led to the error/accident

Quality manager

Design formal porcess improvement initiatives
Goal: Improve the quality of patient care

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Retrospective risk evaluation (incident analysis)

LEARNING

Description of the incident

Identification of causes

RISK MANAGEMENT
Priorization and mitigation strategies

RISK ESTIMATION

Causes/hazards

Probability of ocurrence

Severity of impact

Probability of detection/barriers

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Risk manager are skilled investigators

Investigation of sentinel events

Conduct Root Cause Analysis RCA

- Avoid speculations that could bias result.
- Identify special and latent causes of the event
- Provide early risk managment advice to those involveld in the event
- Conduct prompt liability assessment

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Instead of making the analysis of an accident that has occurred risk management can also focus on identifying risk prospectively

Prospective risk estimation (what can go wrong and its impact)

ANTICIPATE

Definition of the situation/problem

Identification of Hazard(s)

RISK MANAGEMENT
Priorization and mitigation strategies

RISK ESTIMATION

Hazard

Probability of ocurrence

Severity of impact

Probability of detection/barriers

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Reactive versus proactive analysis

REACTIVE ANALYSIS

After an incident **has happened** we perform an analysis

ROOT CAUSE ANALYSIS (RCA)

What happened? Why did it happen?

PROACTIVE ANALYSIS

Before an incident **happens** we perform a[illegible]is

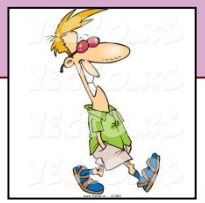
What can go wrong?

What is the probability?

What could be the consequence?

Is there any way to prevent it from happening?

How effective are those methods?



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Reactive versus proactive analysis
RCA and HFMEA

	RCA	FMEA
Timeframe	retrospective	prospective
Focus	Individual case	Process
JCAHO requirements	All incidents/accidents	Annually on a high risk process
Advantages	Asks what has happened and why	Broad impact on the entire process. Does not need an event prior to study. Prevents incidents before they happen
Limitations	Hindhight bias, findings may apply only to one event and may or may not have implications for the entire system.Labour intensive.	Labour intensive

Risk management aim is to guarantee safety

Risk management consists on:

1. Putting tools in place to help us look for risks
2. Assess those risks
3. Take action on the risk

The trick here **is knowing where risk is**, isn't it?

How do we identify risk?

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Risk estimation (what can go wrong and its impact)

Hazards: Potential source of harmful events (cause)

Harms: Resulting damage (effect)

Risk is the combination of the hazard and the harm in a scale.

Quantification of risk will use severity and frequency metrics

How do we identify and quantify risk?

Risk estimation should be done before implementing a new technique or technology

Team work:

Radiation Oncologists
Medical Physicists
Radiation Technologists
Quality manager
Administration

Tris jump in Divergent

http://youtu.be/EQLd_etD5RY

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Proactive risk analysis

What's the point?

Provides a structured way of prioritizing risk

Helps to focus efforts focused to minimize on one side failure and on the other harm

How is it done?

Define the process, process steps and look for possible failures

Give a number that quantifies risk (occurrence probability+harm)

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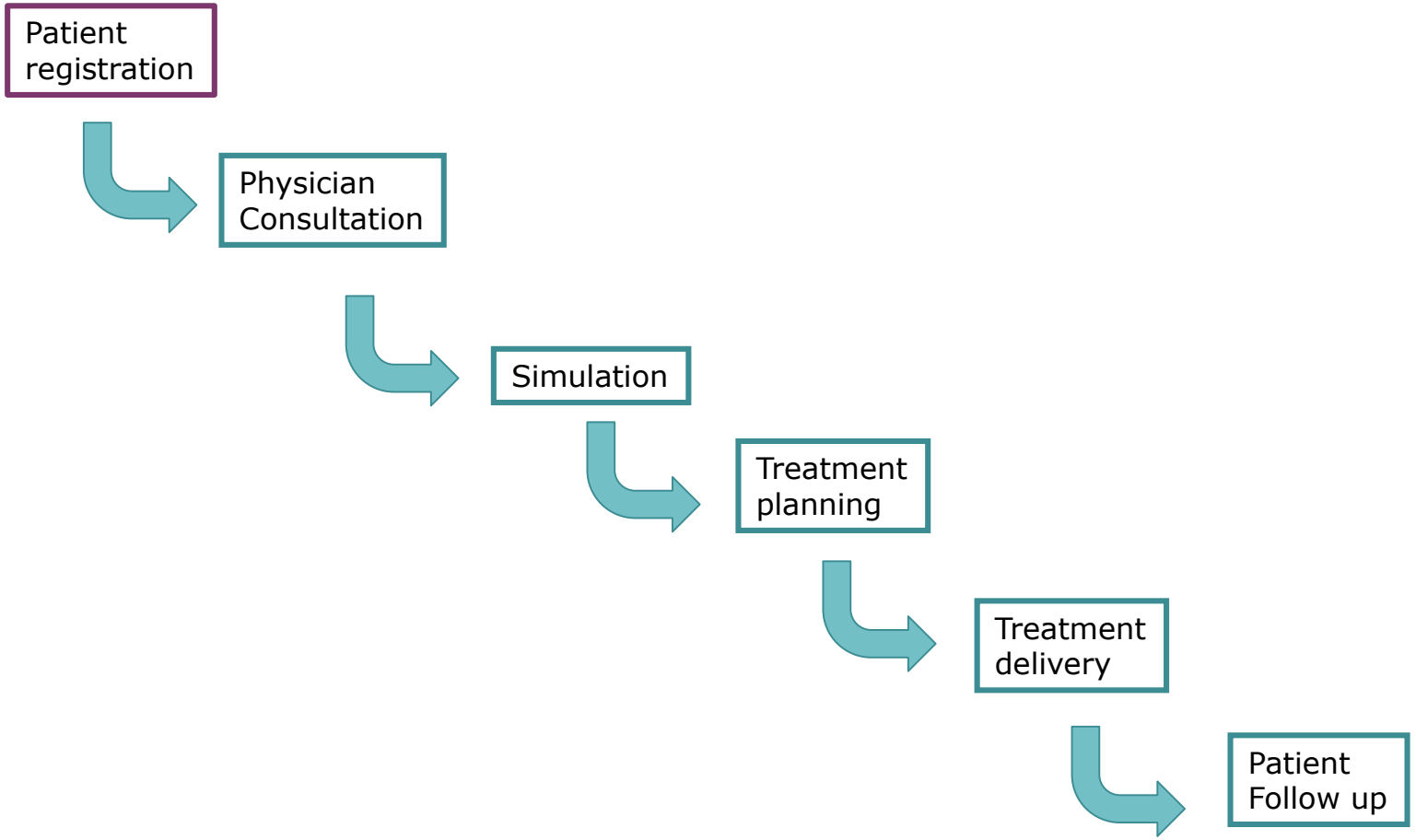
Proactive risk analysis

1. Process mapping



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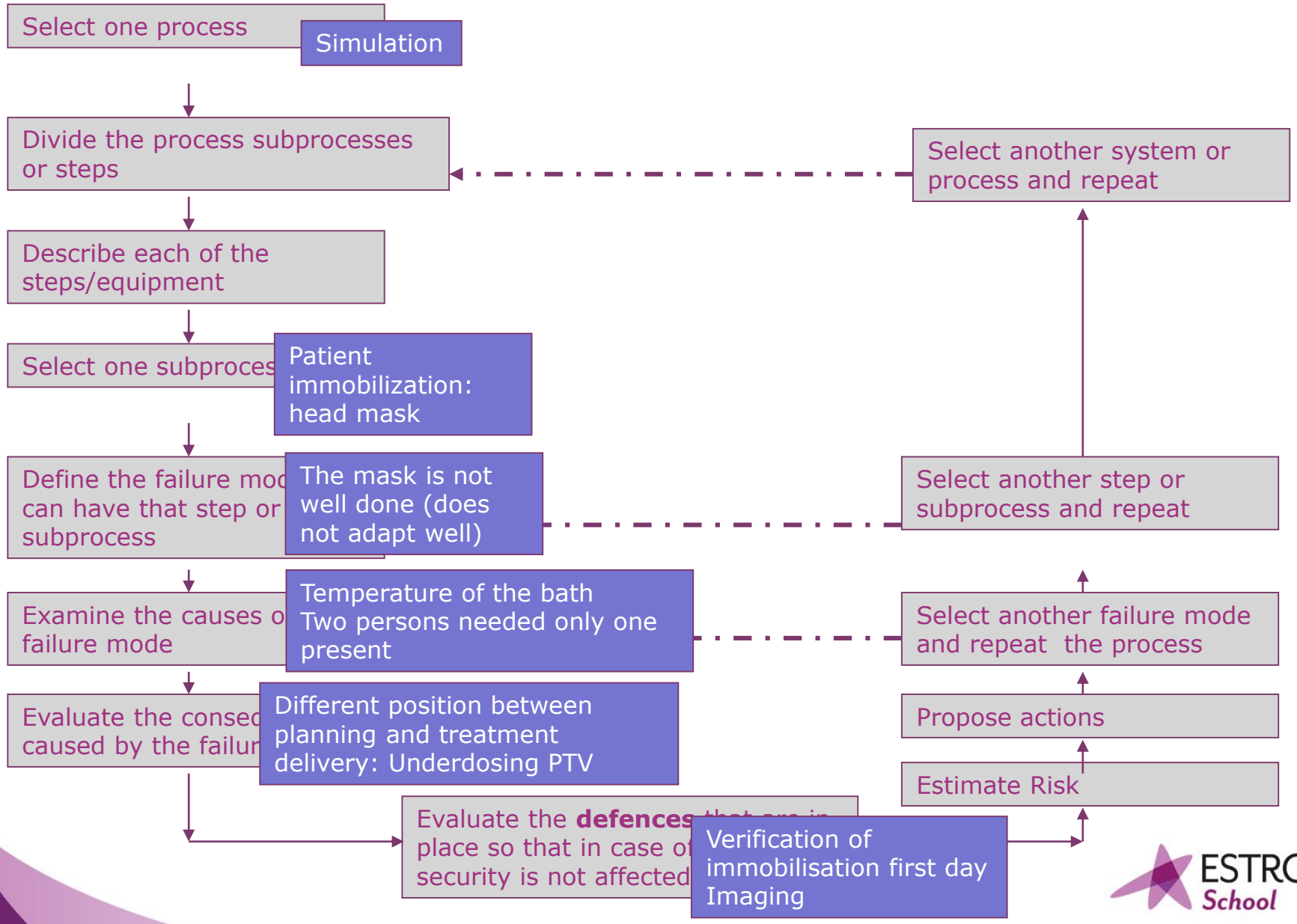
Proactive Risk Analysis



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Example: Getting up and going to work

Example: Waking up

Some questions:

1. What do you think it can go wrong?

I run through the alarm, I continue sleeping

The alarm does not sound, I continue sleeping

2. On a scale 1-10, how severe the consequence would be?

On a working day, a reduction of the month pay of 2% 8 out of 10

3. Could you describe how this would happen?

Alarm brokes

Alarm without battery

Alarm time wrongly set

Clock time wrongly set

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Example: Waking up

Some questions:

4. How likely is the incident to occur? The alarm does not sound, I continue sleeping

It is fairly possible (It has happened before) 6 out of 10

5. How likely is it that we can't stop this from happening?

We can check the battery regularly and change them 2 out of 10

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Example: Waking up

FMEA terminology

What could go wrong? → **Failure mode**

The alarm does not sound, I continue sleeping

How bad would it be? → Severity=8

How this could happen? → **Failure pathway**

The alarm runs out of battery

How likely is this to happen? → Occurrence=6

How unlike are we to prevent it from happening? → "non-detectability"= 2

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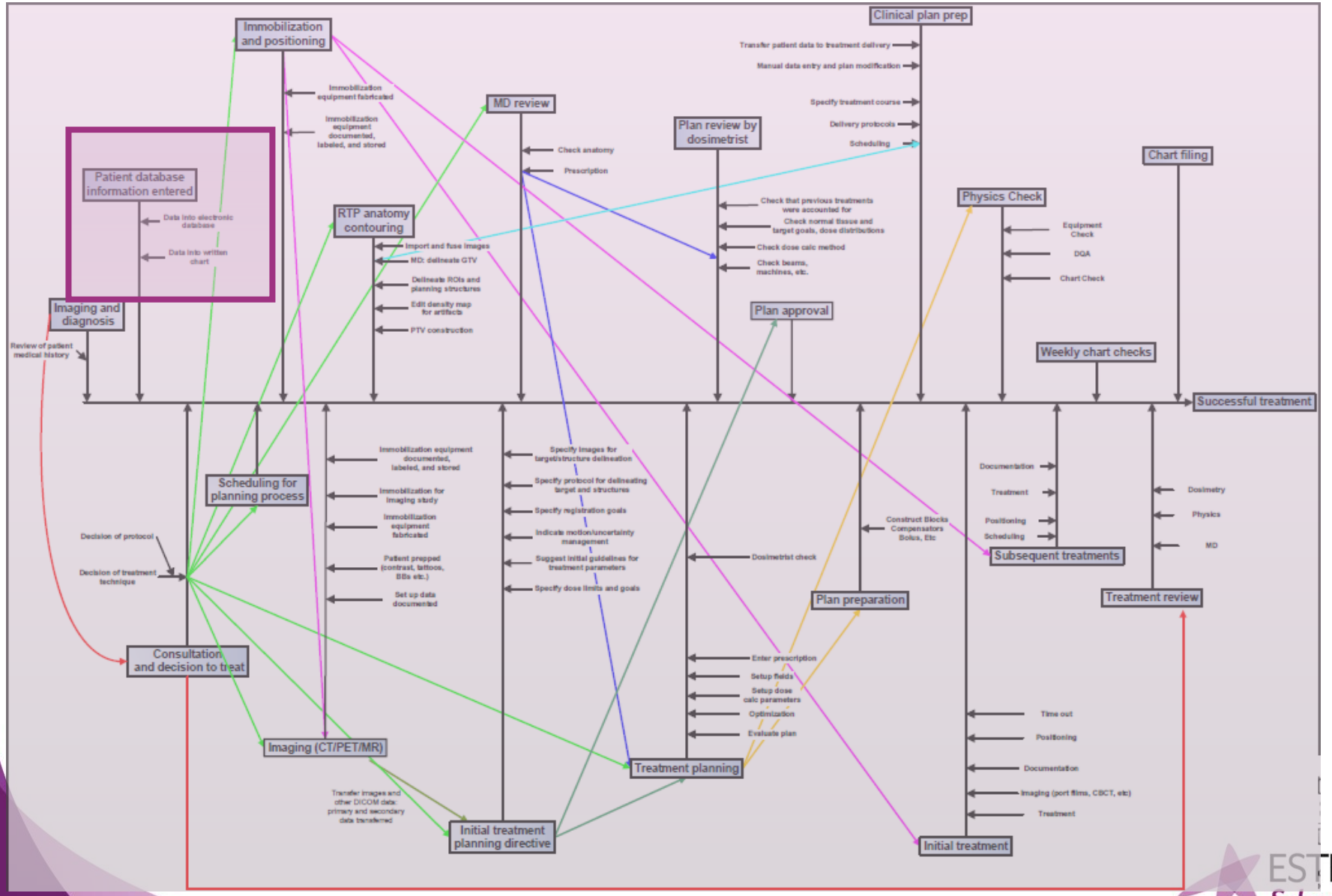
Scoring metrics (FMEA)

Score	Severity	Occurrence	Detectability
1	No effect	Less than 1 time every 5 years	Almost certain detection
2	Not able to have the coffee	Once every 2-5 years	Very High chance of detection
3	Collegues resentment (bad faces)	Once a year	High chance of detection
4	A verbal complaint by my collegues	Several times a year	Moderate high chance of detection
5	A complaint by my boss	Once a month	Moderate chance of detection
6	Need to stay longer to compesate	Several times a month	Low chance of detection
7	Verbal warning	Once a week	Remote chance of detection
8	Writen warning	Several times a week	Remote chance of detection
9	Reduction on salary	Once a day	Very remote chance of detection
10	I get fired	Several times a day	No design control or no chance of detection

TG 100 AAPM: FMEA on IMRT

1. Process mapping



Identification of failure modes; sources

1. Once the process, subprocess has been defined/designed, **ASK**

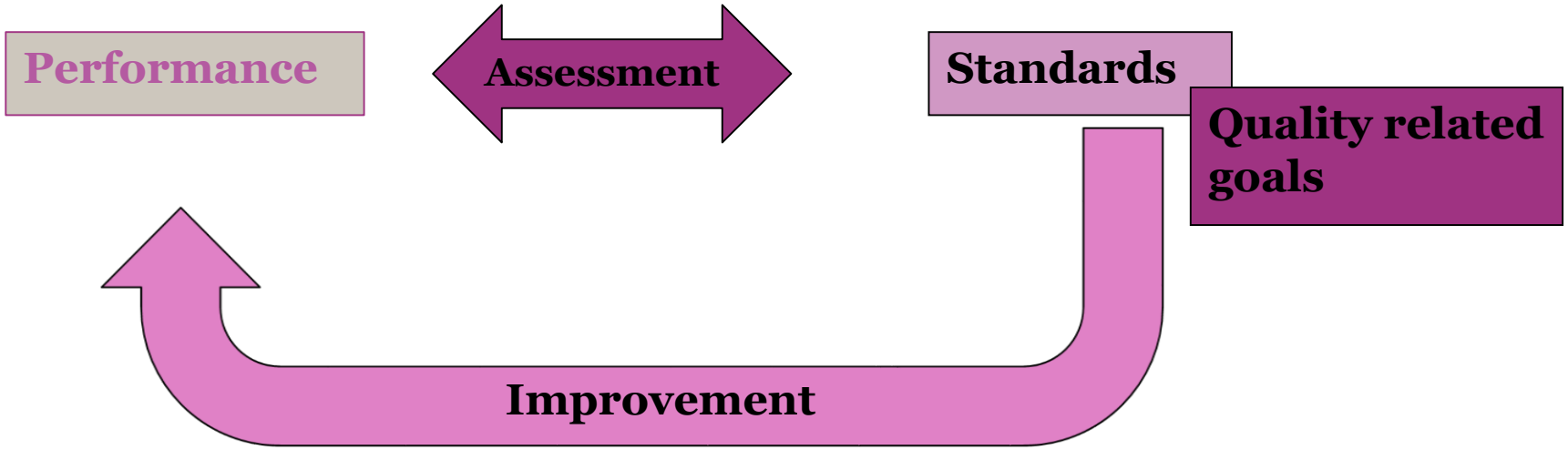
   What can go wrong? Failure mode
   How can this happen? Failure pathway

   Multidisciplinary team brainstorming

2. Use department **incident reporting systems**

3. Use National/International incident reporting systems (ROSIS / SAFRON)

Quality assessment



Safety is not necessarily equal to quality

SAFE:

Risk analysis performed.

Safety interlocks in place

QC performed regularly

GOOD SAFETY

QUALITY (customer):

Not space between rows of seats

Bad Quality of the food served on board

Plane delayed. Lost connection flight

BAD QUALITY

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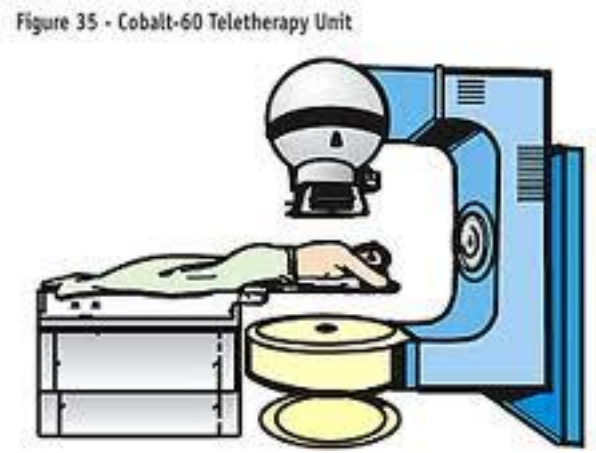
Safety is not necessarily equal to quality



SAFE:

Risk analysis performed.

Safety interlocks in place

QC performed regularly

GOOD SAFETY

QUALITY :

Longer treatment times

No possibility of IMRT treatments

Limited number of fields (Blocks of cerrobend)

…

QUALITY ??

STATE OF THE ART

STANDARD

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Health care organisations...

New standards of perfomance and core quality measures

National patient safety goals to be accomplished every year

Adoption of best practices

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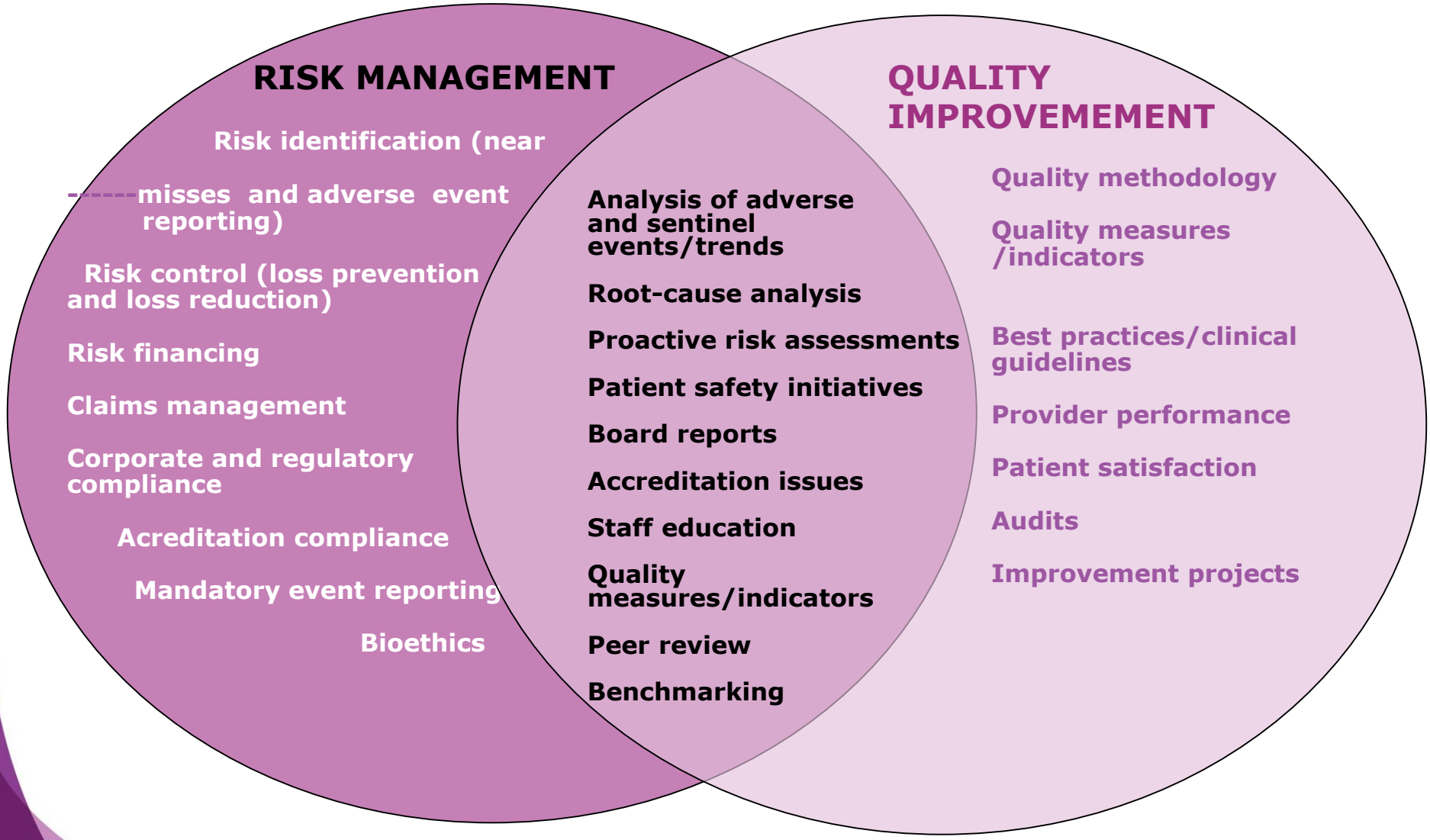

The intersection

Analysis of adverse and sentinel events/trends

Root-cause analysis

Proactive risk assessments

Patient safety initiatives

Board reports

Accreditation issues

Staff education

Quality measures/indicators

Benchmarking

Peer review

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"Today, risk management and quality improvement efforts in healthcare organizations are rallying behind patient safety and finding ways to work together more effectively and efficiently to ensure that their organizations deliver safe, high-quality patient care and continue to minimize risks"

Evolution of quality requirements in Europe and USA: Towards accreditation

Hospital and healthcare accreditation which takes place within national borders

International healthcare accreditation

Quality manager

Quality managers gain recognition and support by executive leaders

→

Affects the finantial streght from an institution

Possibility to recruit talented practitioners

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What do risk management and Quality improvement have in common?

- Both need of a process approach- process maps.
- Both need Quantification

BUT

- Process chart with **barriers** vs process chart with **quality indicators**

- **RISK MANAGEMENT**
  - Will check that **barriers** are robust by monitoring near misses, incidents and accidents reports (reporting system)

Event Report Data

- **QUALITY IMPROVEMENT**
  - Will monitor **quality indicators** to improve process and the quality of treatments which should result in better outcomes

Outcomes

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Example: IMRT optimisation and planning

How can we improve the process?

- Time
- Accuracy
- Compliance to protocols
- Reduce the variability between planners

Do we have quality indicators/metrics and standars?

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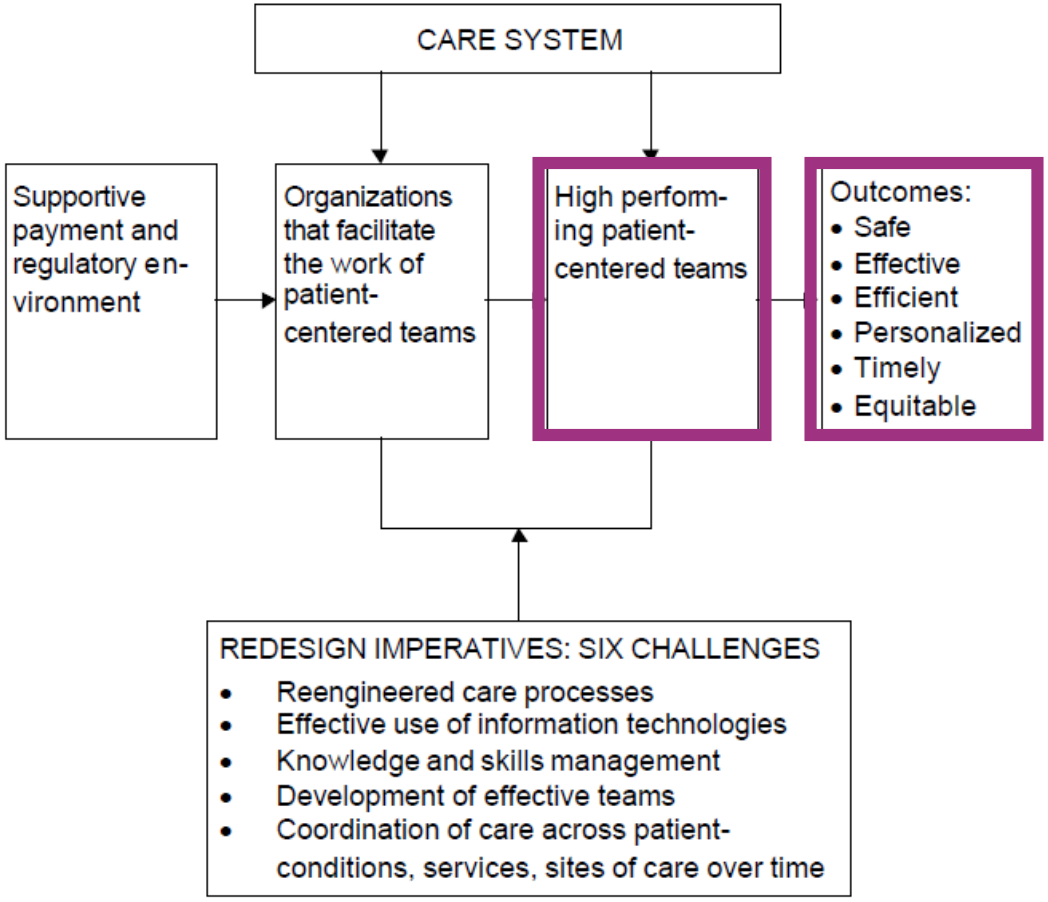
Example: IMRT optimisation and planning

How can we know that the treatment plan is the best we can get?

- Need of quality metrics
- Improving one quality indicator may mean to compromise another quality indicator.

Crossing the quality chasm: A new health system for XXI century



The roles of a Healthcare Organisation manager

- Establish specific quality-related goals to measure the organization's processes and outcomes
- Administer programs that focus on improved outcomes of patient care
- Provide consultative services to departments to assist in achieving regulatory, accreditation, and organizational compliance in quality and performance improvement activities.
- Indentify opportunities for continuous improvement
- Participate in root-cause analyses of events and systems to implement improvements
- Evaluate patient satisfaction and propose actions for improvement

Conclusion

Risk management is part of any quality management programme

Less hazards mean less harm and results in better health care quality

OK for liability

BUT

To improve outcomes we have to go one step further and work on quality metrics linked to those outcomes

The aim of any QUALITY MANAGEMENT system is to deliver safe and high quality patient care

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The Process approach to QM. How to build a process chart. Implementation of process charts in routine in Radiation Oncology

Dr. Nicolas POUREL
ESTRO School

COMPREHENSIVE QUALITY MANAGEMENT
IN RADIOTHERAPY
BRUSSELS (Belgium) – Monday, October 2nd 2017

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The Process approach to QM. How to build a process chart.

Learning objectives

To explain the ‘step-by-step’ building of a process chart

To understand the usefulness of these charts in routine practice

To figure out what kind of preventive actions can be decided through process review

Context

Analysis of Near-Misses and Errors (NM/E)

1. Report near-misses and errors: passive declaratory system
2. CREX: active analytical system '*a posteriori*'
3. Process Review: active analytical system *'a priori'*

Process Review (PR)

An *a priori* analysis of failure modes within any organization

Allowing to set up preventive actions to overcome organisational weaknesses

Failure Mode and Effect Analysis (FMEA)

Industrial Methodology for PR

Based on 4 steps:

1. Description of one process in details
2. Identification of potential risks
3. Rating
4. Setting up corrective actions

Failure Mode and Effect Analysis (FMEA)

Industrial Methodology for PR

Based on 4 steps:

1. Description of one process in details
2. Identification of potential risks
3. Rating
4. Setting up corrective actions

Methods of description

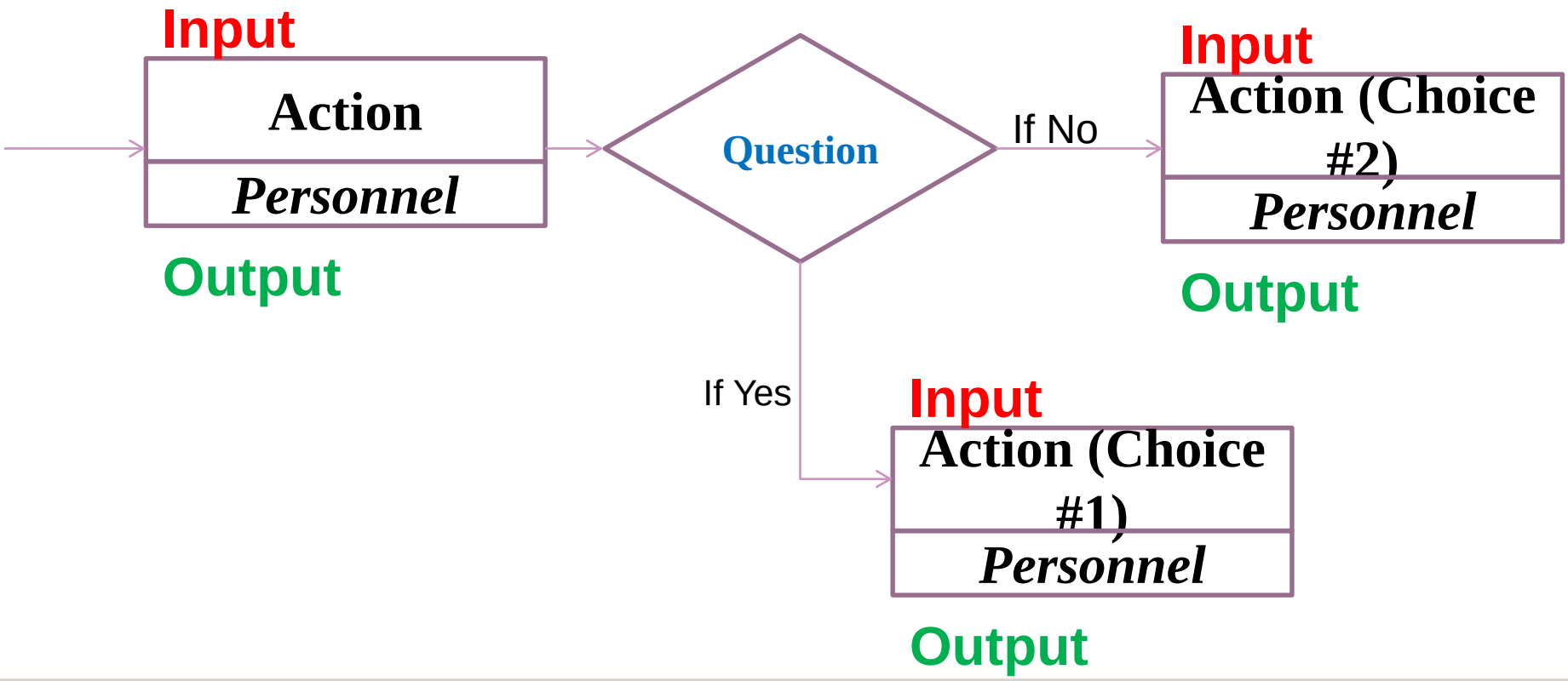
Who ?

Specialists of the methodology
Quality Manager – Trained Physicists
Any other professional trained in the field of QA / RT

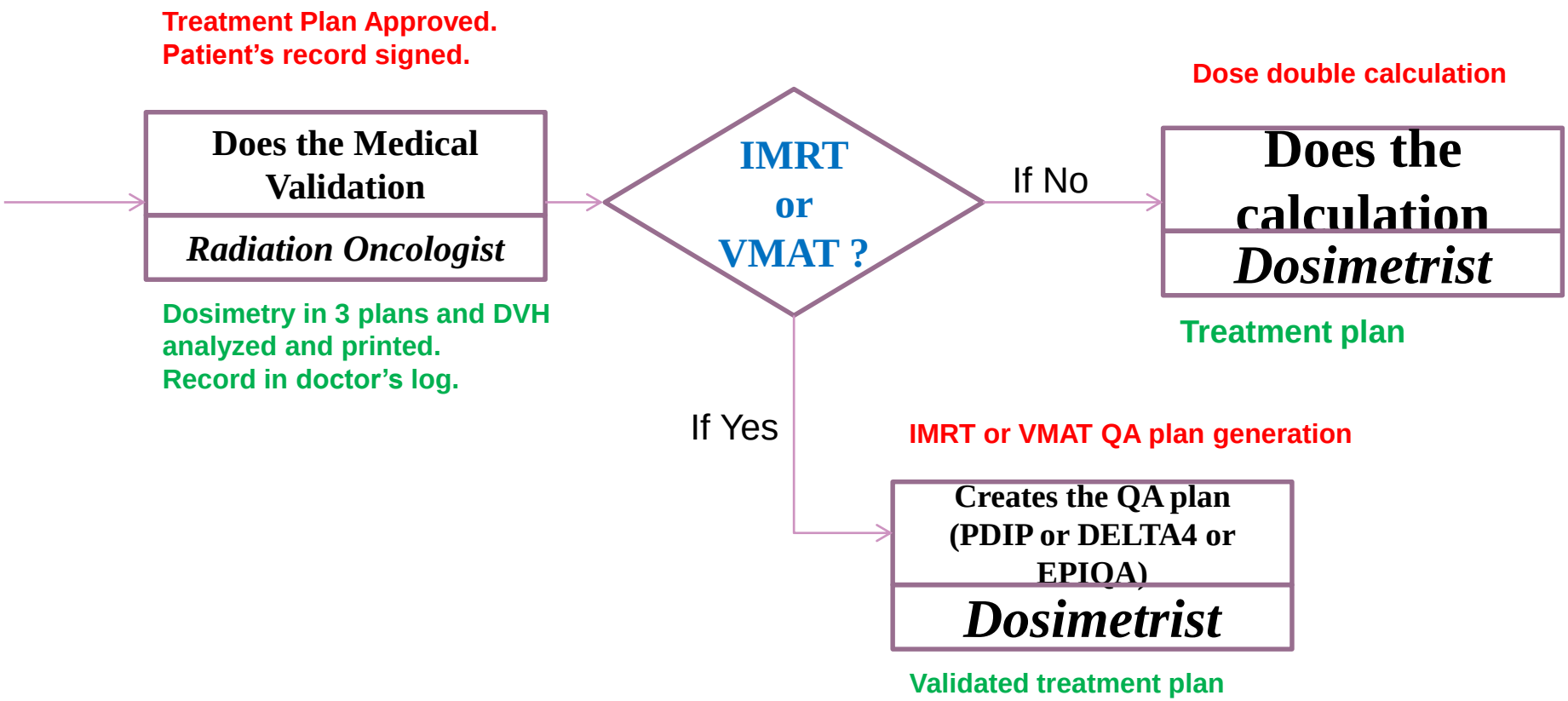
How ?

Repeated short meetings with professionals(1/2-1H)
Limited number of personnel (Max. 6-8)
Periodical meetings (weekly)
Immediate report, displayed to staff

Process Chart Basic Element



‘Dosimetry’ Basic Element



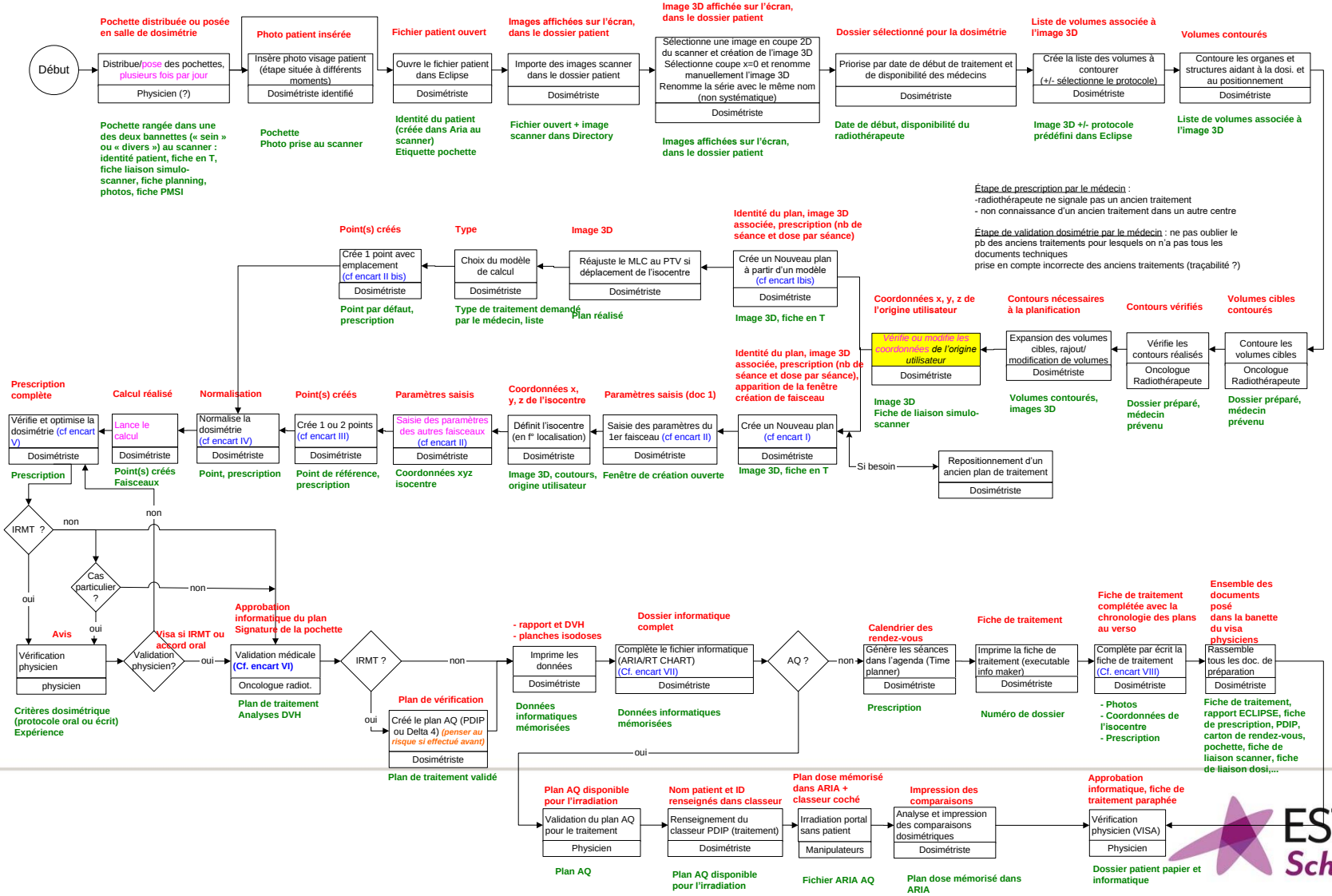
Failure Mode and Effect Analysis (FMEA)

Industrial Methodology for PR

Based on 4 steps:

1. Description of one process in details
2. Identification of potential risks
3. Rating
4. Setting up corrective actions

Process :‘dosimetry’



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Failure Mode and Effect Analysis (FMEA)

Industrial Methodology for PR

Based on 4 steps:

1. Description of one process in details
2. Identification of potential risks
3. Rating
4. Setting up corrective actions

Identification of potential risks

What is a ‘risk factor’ ?

Any present element or danger potentially causing damages or an accident

What is a ‘risk’ ?

Any unexpected situation, potentially causing harm to the patient, resulting from unlikely situations.

Basically, a risk results from the exposition to a danger.

e.g.: Heat (risk factor) can cause dehydration (risk) to elderly patient,
Alcohol intake (risk factor) raises the propability of a car crash (risk).

Identification of potential risks

ANALYSE DES MODES DE DEFAILLANCE, DE LEURS EFFETS ET

Etape	Mode de défaillance potentielle	Effets possibles de la défaillance	Causes possibles de la défaillance	Plan de surveillance actuel ou envisagé
Distribue/pose des pochettes, plusieurs fois par jour	Pochette non prise en charge	Dosimétrie non prête en temps utile	Pochettes éparpillées	-Boost : casier identifié
			Dosimétriste/ physicien non informé de l'urgence	/
Insère photo visage patient (étape située à différents moments)	Photo d'un patient à la place d'un autre	Perte de temps au traitement	Erreur d'identité au scanner	/
	Non insertion de la photo	Risque de confusion de patient au traitement	Photo non réalisée / non enregistrée	/
Ouvre le fichier patient dans Eclipse	Ouverture d'un fichier d'un autre patient pensant que c'est le bon	Réaliser une mauvaise dosimétrie	Erreur de saisie	Message alerte à l'étape suivante
			Pas de message d'alerte si pas de scanner	Vérification au visa
Importe des images scanner dans le dossier patient	Import des images d'un autre patient pensant que c'est le bon	Réaliser une mauvaise dosimétrie	Erreur de saisie	Message alerte, possibilité d'outre passer
	Groupe d'image incomplet	Réaliser une mauvaise dosimétrie	Problème informatique réseau	Contrôle visuel
Sélectionne une image en coupe 2D du scanner et création de l'image 3D Sélectionne coupe x=0 et renomme manuellement l'image 3D Renomme la série avec le même nom (non systématique)	Sélectionner une image d'une autre série (si 2 séries)	Réaliser une dosimétrie sur une référence non correcte	Ne pas savoir quelle série est la bonne	/
			Erreur de sélection de série	/
	Sélectionner une image autre que x=0	aucune csq	Erreur de sélection d'image	pas besoin de plan de surveillance
	Mélange des 2 séries	Perte de temps	Erreur logiciel	Contrôle visuel
	Avoir la mauvaise série	Réaliser une dosimétrie sur une référence non correcte	Envoi de la mauvaise série en provenance du scanner	/
	Si 2 séries, inverse noms des 2 séries	Réaliser une dosimétrie sur une référence non correcte	Erreur dans la nomination	Contrôle visuel

Process Chart 'Dosimetry'
Description of process

Failure Mode and Effects Analyses (FMEA)

Step	Possible failure mode	Possible effects	Possible causes	Surveillance plan
Distributes patients' records several times/day	Record not adressed	Late dosimetry	Disorder in the dosimetry room Physicist not informed of emergency case	Dedicated Log for Emergen
				/
Insère photo visage patient (étape située à différents moments)	Photo d'un patient à la place d'un autre	Perte de temps au traitement		/
	Non insertion de la photo	Risque de confusion de patient au traitement	Photo non réalisée / non enregistrée	/
Ouvre le fichier patient dans Eclipse	Ouverture d'un fichier d'un autre patient pensant que c'est le bon	Réaliser une mauvaise dosimétrie	Erreur de saisie	Message alerte à l'étape suivante
			Pas de message d'alerte si pas de scanner	Vérification au visa
Importe des images scanner dans le dossier patient	Import des images d'un autre patient pensant que c'est le bon	Réaliser une mauvaise dosimétrie	Erreur de saisie	Message alerte, possibilité d'outre passer
	Groupe d'image incomplet	Réaliser une mauvaise dosimétrie	Problème informatique réseau	Contrôle visuel
Sélectionne une image en coupe 2D du scanner et création de l'image 3D Sélectionne coupe x=0 et renomme manuellement l'image 3D Renomme la série avec le même nom (non systématique)	Sélectionner une image d'une autre série (si 2 séries)	Réaliser une dosimétrie sur une référence non correcte	Ne pas savoir quelle série est la bonne	/
			Erreur de sélection de série	/
	Sélectionner une image autre que x=0	aucune csq	Erreur de sélection d'image	pas besoin de plan de surveillance
	Mélange des 2 séries	Perte de temps	Erreur logiciel	Contrôle visuel
	Avoir la mauvaise série	Réaliser une dosimétrie sur une référence non correcte	Envoi de la mauvaise série en provenance du scanner	/
	Si 2 séries, inverse noms des 2 séries	Réaliser une dosimétrie sur une référence non correcte	Erreur dans la nomination	Contrôle visuel

Failure Mode and Effect Analysis (FMEA)

Industrial Methodology for PR

Based on 4 steps:

1. Description of one process in details
2. Identification of potential risks
3. Rating
4. Setting up corrective actions

Rating (PSD)

Probability (F)

Severity (S)

Detection (D)

➔ Risk Level (RL) = (PS)xD

Probability (P)

1	**Extremely unlikely**	Virtually impossible or No known occurrences on similar products or processes, with many running hours
2	**Remote**	Relatively few failures, once in a year max.
3	**Occasional**	Occasional failures, might happen or have happened already (2 to 11 times per year)
4	**Reasonably Possible**	Possible failures, might happen or have happened already (1 to 3 times per month)
5	**Possible**	Possible failures, might happen or have happened already (1 to 2 times a week)
6	**Frequent**	Frequentfailures, might happen or have happened already (10 times + per month), affects almost every tretment session…

Severity (S)

1	**No Relevant effect**	No consequence for the patient dose delivered correct
2	**Very Minor**	No predictable consequence, dosimetry change less than 5%
3	**Minor**	Dosimetry changy more than 5% and/or compensation possible
4	**Moderate**	Risk of moderate side effects
5	**Critical**	Risk of relapse or severe side effects
6	**Catastrophic**	Patient deceased

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Detection (D)

1	**Certain**	Fault will be caught on test by operators or maintainers
2	**Easy**	Fault can easily be caught on test but there is a risk that test is not performed
3	**Hard**	Fault can hardly be caught on test, even if test is performed
4	**Undetectable**	Fault is undetected by operators or maintainers

Risk Level (RL)

P x S / Detection	1	2	3	4	5	6	8	9	10	12	15	16	18	20	24	25	30	36
1	1	2	3	4	5	6	8	9	10	12	15	16	18	20	24	25	30	36
2	2	4	6	8	10	12	16	18	20	24	30	32	36	40	48	50	60	72
3	3	6	9	12	15	18	24	27	30	36	45	48	54	60	72	75	90	108
4	4	8	12	16	20	24	32	36	40	48	60	64	72	80	96	100	120	144

Acceptable = no action needed now

Tolerable = corrective actions to be discussed with staff

Inacceptable = corrective actions to set-up immediately

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To analyze reliability of treatment in Radiation Oncology: Process Review

Charlotte MEYRIEUX[1,2], Robin GARCIA[1], Nicolas POUREL[1], Bernard COMBELLES[3], Alice MEGE[1], Véronique BODEZ[1]

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Cancer Radiother. 2012 Oct;16(7):613-8.
Presented at the 2010 SFRO Annual meeting, Paris – France.

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Process Chart 'Dosimetry'
Rating

Step	Possible failure mode	Possible effects	Possible causes	Surveillance plan /	Rating			
Contoure les volumes cibles	Contourage mal effectué	Traitement erroné	Confusion de patient	Pour le sein : présence du CR opératoire avec la fiche en T	4	2	4	34
			Confusion de choix du volume					
			Confusion de latéralité					
			Manque d'information pour réaliser le contour (IRM,…)					
Vérifie les contours réalisés	Pas de vérification	Contours et DVH erronés	Manque de temps	/	4	4	4	60
			Excès de confiance	/				
			Contours non réalisés	/				
Expansion des volumes cibles, rajout/modification de volumes	Erreur de valeur de marge pour PTV	Traitement erroné	Consignes erronées	/	4	2	2	17
			Erreur de saisie	Inscription par dosimétriste de la marge sur copie de la fiche en T si différent du				
			Confusion					
	Non prise en compte d'une consigne de modification du médecin	Traitement erroné	Oubli	/	4	2	4	32
	Expansion sur un mauvais volume	Traitement erroné	Erreur humaine	Visible sur la dosimétrie	4	4	4	21
				Contrôle du médecin				
	Expansion sur des traces involontairement dessinées en dehors du volume cible	Traitement erroné	Mauvais "clic" sur l'image	+/- Visible sur la dosimétrie	4	3	2	21
		Perte de temps		Contrôle du médecin				
Vérifie ou modifie les coordonnées de l'origine utilisateur	Non réalisation du recalage de l'origine utilisateur	Décalage traitement	Oubli de saisie	/	3	3	2	14
			Information non transmise	Fiche de liaison				
	Saisie de valeurs erronées		Erreur humaine	/	3	3	2	17
			Mauvais prise en compte des coordonnées du 1er traitement	/				
Repositionnement d'un ancien plan de traitement	Mauvais positionnement de l'ancien isocentre	Dosimétrie cumulée erronée	Mauvaise superposition d'image	Parfois vérification autre dosimétriste, physicien ou radiohtérapeute	4	3	3	31
	Mauvaise reproduction des paramètres d'irradiation	Dosimétrie cumulée erronée	Erreur dans la restranscription de l'ancien traitement	/	5	3	4	46

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Process Chart 'Dosimetry' Rating

Step	Possible failure mode	Possible effects	Possible causes	Surveillance plan /	Rating			
Contoure les volumes cibles	Contourage mal effectué	Traitement erroné	Confusion de patient Confusion de choix du volume Confusion de latéralité Manque d'information pour réaliser le contour (IRM,…)	Pour le sein : présence du CR opératoire avec la fiche en T	4	2	4	34
Vérifie les contours réalisés	Pas de vérification	Contours et DVH erronés	Manque de temps Excès de confiance Contours non réalisés	/ / /	4	4	4	60
Expansion des volumes cibles, rajout/modification de volumes	Erreur de valeur de marge pour PTV	Traitement erroné	Consignes erronées Erreur de saisie Confusion	/ Inscription par dosimétriste de la marge sur copie de la fiche en T si différent du	4	2	2	17
	Non prise en compte d'une consigne de modification du médecin	Traitement erroné	Oubli	/	4	2	4	32
	Expansion sur un mauvais volume	Traitement erroné	Erreur humaine	Visible sur la dosimétrie Contrôle du médecin	4	4	4	21
	Expansion sur des traces involontairement dessinées en dehors du volume cible	Traitement erroné Perte de temps	Mauvais "clic" sur l'image	+/- Visible sur la dosimétrie Contrôle du médecin	4	3	2	21
Vérifie ou modifie les coordonnées de l'origine utilisateur	Non réalisation du recalage de l'origine utilisateur	Décalage traitement	Oubli de saisie Information non transmise	/ Fiche de liaison	3	3	2	14
	Saisie de valeurs erronées		Erreur humaine Mauvais prise en compte des coordonnées du 1er traitement	/ /	3	3	2	17
Repositionnement d'un ancien plan de traitement	Mauvais positionnement de l'ancien isocentre	Dosimétrie cumulée erronée	Mauvaise superposition d'image	Parfois vérification autre dosimétriste, physicien ou radiothérapeute	4	3	3	31
	Mauvaise reproduction des paramètres d'irradiation	Dosimétrie cumulée erronée	Erreur dans la restranscription de l'ancien traitement	/	3	3	4	46

Vérifies contours

Lack of Time

No verification

Error on contour and DVH

Excess of confidence

Contours not realized

Repositionning of former treatment

Wrong Repositionning of isocentre

Wrong calculation of Dosimetry

Wrong superposition of images

Wrong reproduction of treatment parameters

Error in tretment parameters re-transcrition

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Failure Mode and Effect Analysis (FMEA)

Industrial Methodology

Based on 4 steps:

1. Description of one process in details
2. Identification of potential risks
3. Rating
4. Setting up corrective actions

Results

The whole PR took 8 weeks

21 steps resulting in 60 failure modes
62 possible effects

Rating (PS)xD

18 acceptable effects
42 tolerable effects
2 unacceptable effects

Corrective Actions

Identification of former RT treatment (within and outside the dept.)
Prescription and Contouring verifications (fractions, side, PET-CT available)

Setting up Preventive Actions

Etape	Mode de défaillance potentielle	Effets possibles de la défaillance	G	F	D	IR	Actions préconisées	Qui, Quand	Mesures prises	G	O	D	IR
Contoure les volumes cibles	Contourage mal effectué	Traitement erroné	4	2	4	34							
Vérifie les contours réalisés	Pas de vérification	Contours et DVH erronés	4	4	4	60							
Expansion des volumes cibles, rajout/modification de volumes	Erreur de valeur de marge pour PTV	Traitement erroné	4	2	2	17							
	Non prise en compte d'une consigne de modification du médecin	Traitement erroné	4	2	4	32							
	Expansion sur un mauvais volume	Traitement erroné	4	4	4	21							
	Expansion sur des traces involontairement dessinées en dehors du volume cible	Traitement erroné Perte de temps	4	3	2	21							
Vérifie ou modifie les coordonnées de l'origine utilisateur	Non réalisation du recalage de l'origine utilisateur	Décalage traitement	3	3	2	14							
	Saisie de valeurs erronées		3	3	2	17							
Repositionnement d'un ancien plan de traitement	Mauvais positionnement de l'ancien isocentre	Dosimétrie cumulée erronée	4	3	3	31							
	Mauvaise reproduction des paramètres d'irradiation	Dosimétrie cumulée erronée	5	3	4	46							

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Setting up Preventive Actions

Step	Potential Failure Mod	Potential Failure Effect / Ratin					Actions foreseen / Who – When / measures taken						
Contoure les volumes cibles	Contourage mal effectué	Traitement erroné	4	2	4	34							
Vérifie les contours réalisés Verifies contours	Pas de vérification No verification	Contours et DVH erronés Error on contour and DVH	4	4	4	60							
Expansion des volumes cibles, rajout/modification de volumes	Erreur de valeur de marge pour PTV	Traitement erroné	4	2	2	17							
	Non prise en compte d'une consigne de modification du médecin	Traitement erroné	4	2	4	32							
	Expansion sur un mauvais volume	Traitement erroné	4	4	4	21							
	Expansion sur des traces involontairement dessinées en dehors du volume cible	Traitement erroné Perte de temps	4	3	2	21							
Vérifie ou modifie les coordonnées de l'origine utilisateur	Non réalisation du recalage de l'origine utilisateur	Décalage traitement	3	3	2	14							
	Saisie de valeurs erronées		3	3	2	17							
Repositionnement d'un ancien plan de traitement Repositionning of former treatment	Mauvais positionnement de l'ancien isocentre Wrong Repositionning of isocentre	Dosimétrie cumulée erronée Wrong calculation of Dosimetry	4	3	3	31							
	Mauvaise reproduction des paramètres d'irradiation Wrong reproduction of treatment parameters	Dosimétrie cumulée erronée Wrong calculation of Dosimetry	5	3	4	46							

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Process Chart
Corrective actions

Acceptable risks are dealt with

- Procedures (like 'Treatment of Prostate Cancer')
- Check-lists (ex.: 3D-CRT or IMRT dosimetry)

Inacceptable risks are dealt with

- Internal Rules (like OPMP or OPRT)
- Dedicated To Do-Lists (ex.: Brain met. Stereo. RT)
- Check-lists on never-events (errors on pt. ID, volume, side or dose)

Results

‘Never-Event’ Check-lists

Simulation

Q : technician
A : patient

‘Never Events’ (Potential errors on…)	Question	Answer
Patient	Patient « Name » ?	OK / Error
Allergy	Are you allergic to iodine contrast ?	Yes or Maybe/No
Metformine Treatment	Do you take Metformine treatment ?	Yes or Maybe/No
Former RT	Have you ever had RT ?	Yes or Maybe/No

Dosimetry

Q : dosimetrist
A : physician

‘Never Events’ (Potential errors on…)	Question	Answer
Patient	Patient « Name » ?	OK / Error
Volume	Volume « Name » ?	OK / Error
Side	R/L/both/none ?	R/L/both/none
Dose	xx Gy/ yy fr./ zz d. ?	xx Gy/ yy fr./ zz d.

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Conclusion

FMEA results in an ‘in depth’ exploration of the radiotherapy processes

Radiation Oncology professionals can set up their own vision of risk analysis

FMEA allows to identify the main weaknesses and propose pertinent preventive actions

Usually through procedures, check-lists, To-Do lists, Never-Event check lists

Recommanded readings

References

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Meyrieux C, Garcia R, Pourel N et al. ‘Analyser la fiabilité des traitements en radiothérapie : la revue de processus’. Cancer Radiother 2012 ; 16(7) : 613-8

Guide de management de la sécurité et de la qualité des soins en radiothérapie. www.asn.fr

Livre Blanc de la Radiothérapie. www.sfro.org

The Process approach to QM. How to build a process chart. Implementation of process charts in routine in Radiation Oncology

Dr. Nicolas POUREL
ESTRO School

COMPREHENSIVE QUALITY MANAGEMENT
IN RADIOTHERAPY
BRUSSELS (Belgium) – Monday, October 2nd 2017

Thank you for your attention !

ESTRO School

Internal Rules, procedures and charts. The writing.

Dr. Nicolas POUREL
ESTRO School

COMPREHENSIVE QUALITY MANAGEMENT
IN RADIOTHERAPY
BRUSSELS (Belgium) – Monday, October 2nd 2017

Internal Rules, procedures and charts. The writing.

Learning objectives

To explain the difference between Internal rules, procedures and charts

To understand the usefulness of them

To figure out what should be comprised in them

Foreword
Internal Rules / Procedures /Charts

What do these words mean?

Beware of skepticism!

…a bureaucratic quagmire

‘You are no lawyer…’

Maintain the spirit of it all…

Internal Rules: ‘…beyond the Law…’

Procedures: ‘…working easily…’

Charts: ‘…mapping the risk…’

Internal Rules
'…beyond the Law…'

Basic principles

Has to be strictly observed
Signed by the highest authority within the hospital
Few of them are needed

Domains of application

Bringing the Law into practice
Permanence of care
Roles and responsibilities

Internal rules

The making of

- Joint writing Rad. Oncol./Med. Phy./Adm. Director
  - Clear statement of roles and responsibilities

  - Organizes permanence of care
    - Presence of Physician/Physicist during treatment
    - Functionning of departement during period of holidays

  - Demanded by french ASN
    - Allocation of Physicists' time to their various activities
    - Priorization of tasks when working in 'degraded conditions ' (missing colleagues: illness, absence for professional obligation or vacation)

- Administrative Director mandatory to deal with the formatting

Internal Rules
OPMP/ OPRT

- OPMP=Organisational Plan for Medical Physics
  - Defines obligations of Medical Physicists
  - Internal Rule (signed by the General Director)
  - Mandatory by ASN decision n° 2008-DC-0103
- OPRT=Organisational Plan for Radio-Therapy
  - Defines obligations of Radiation Oncologists
  - Internal Rule (signed by the General Director)
  - Not mandatory but so useful at our institution !

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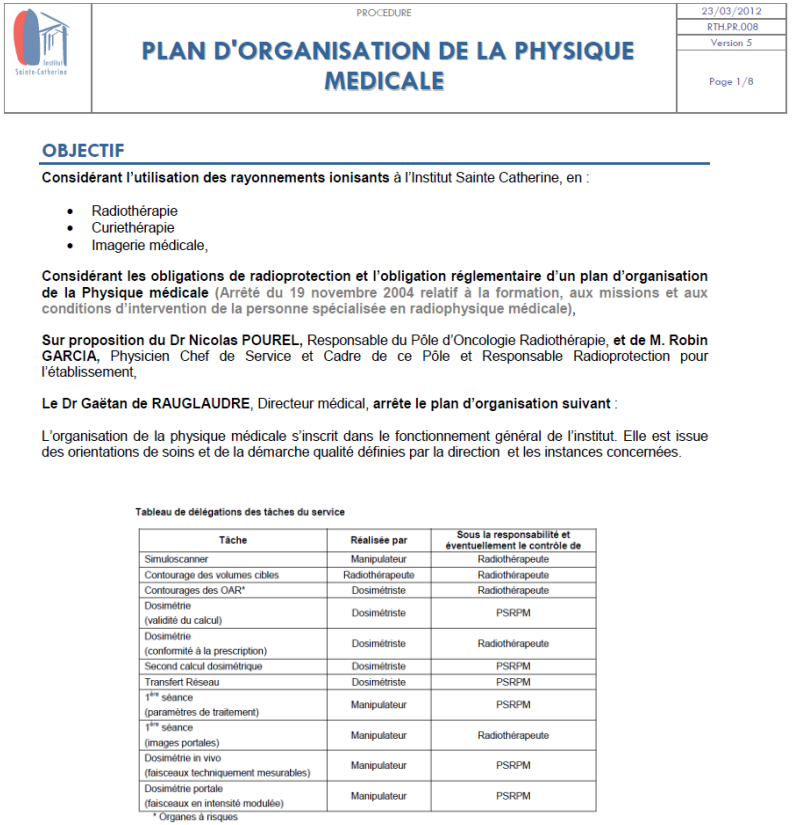
Internal Rule : OPMP

OPMP at *Institut Sainte-Catherine* (ISC)

- Responsibilities clearly defined
- Roles of staff personnel clearly stated
- Written and coherent organization
- Revised annually (by Law)



PROCEDURE

PLAN D'ORGANISATION DE LA PHYSIQUE MEDICALE

23/03/2012
RTH.PR.008
Version 5
Page 1/8

OBJECTIF

Considérant l'utilisation des rayonnements ionisants à l'Institut Sainte Catherine, en :

- Radiothérapie
- Curiethérapie
- Imagerie médicale,

Considérant les obligations de radioprotection et l'obligation réglementaire d'un plan d'organisation de la Physique médicale (Arrêté du 19 novembre 2004 relatif à la formation, aux missions et aux conditions d'intervention de la personne spécialisée en radiophysique médicale),

Sur proposition du Dr Nicolas POUREL, Responsable du Pôle d'Oncologie Radiothérapie, **et de M. Robin GARCIA,** Physicien Chef de Service et Cadre de ce Pôle et Responsable Radioprotection pour l'établissement,

Le Dr Gaëtan de RAUGLAUDRE, Directeur médical, **arrête le plan d'organisation suivant** :

L'organisation de la physique médicale s'inscrit dans le fonctionnement général de l'institut. Elle est issue des orientations de soins et de la démarche qualité définies par la direction et les instances concernées.

Tableau de délégations des tâches du service

Tâche	Réalisée par	Sous la responsabilité et éventuellement le contrôle de
Simuloscanner	Manipulateur	Radiothérapeute
Contourage des volumes cibles	Radiothérapeute	Radiothérapeute
Contourages des OAR*	Dosimétriste	Radiothérapeute
Dosimétrie (validité du calcul)	Dosimétriste	PSRPM
Dosimétrie (conformité à la prescription)	Dosimétriste	Radiothérapeute
Second calcul dosimétrique	Dosimétriste	PSRPM
Transfert Réseau	Dosimétriste	PSRPM
1ère séance (paramètres de traitement)	Manipulateur	PSRPM
1ère séance (images portales)	Manipulateur	Radiothérapeute
Dosimétrie in vivo (faisceaux techniquement mesurables)	Manipulateur	PSRPM
Dosimétrie portale (faisceaux en intensité modulée)	Manipulateur	PSRPM

* Organes à risques

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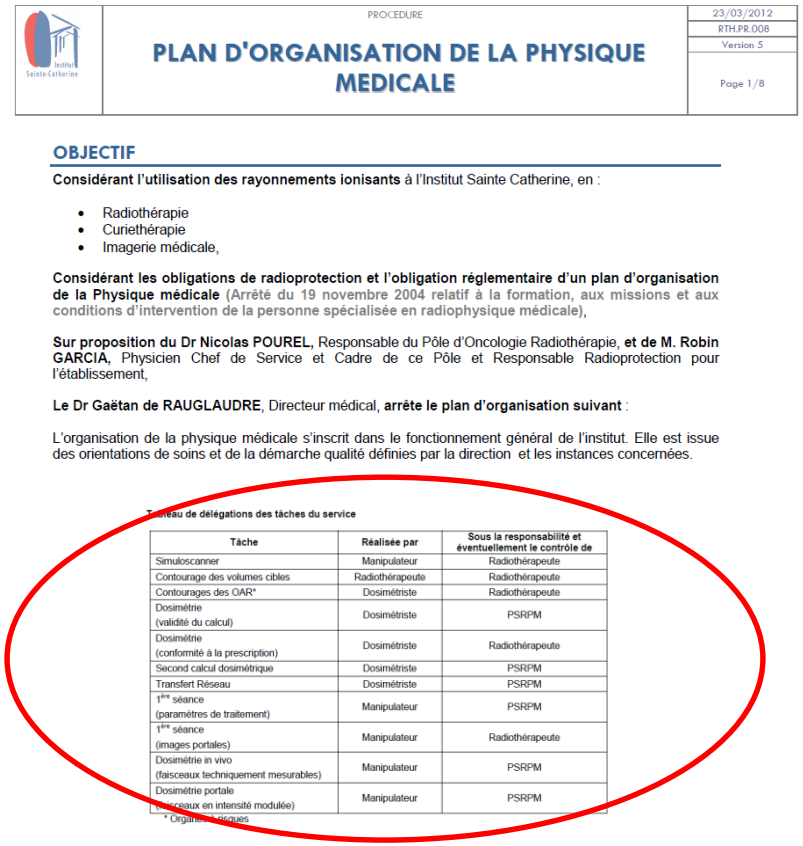

PROCEDURE

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Second calcul dosimétrique	Dosimétriste	PSRPM
Transfert Réseau	Dosimétriste	PSRPM
1ère séance (paramètres de traitement)	Manipulateur	PSRPM
1ère séance (images portales)	Manipulateur	Radiothérapeute
Dosimétrie in vivo (faisceaux techniquement mesurables)	Manipulateur	PSRPM
Dosimétrie portale (faisceaux en intensité modulée)	Manipulateur	PSRPM

* Organes à risques

Internal Rules : OPMP / OPRT

Table: Roles and Responsibilities within the department

Task	Performed by	Under the responsibility and (eventually) direct control of
Simulation CT	Radiographer	Radiation Oncologist
GTV/CTV contouring	Radiation Oncologist / Fellows in RO	Radiation Oncologist
OAR/PRV contouring	Dosimetrist	Radiation Oncologist
Dosimetry (Validity of calculation)	Dosimetrist	Physicist
Dosimetry (Conformity to prescription)	Dosimetrist	Radiation Oncologist
Second dosimetry calculation	Dosimetrist	Physicist
Transfer of data to Record & Verify network	Dosimetrist	Physicist
1st session (parameters of treatment)	Radiographer	Physicist
1st session (imaging control))	Radiographer	Radiation Oncologist
In Vivo Dosimetry (for technically measurable beams)	Radiographer	Physicist
Portal Dosimetry (for modulated beams)	Radiographer	Physicist

➔ **Clear, simple and unequivoqual**

Internal Rule : OPMP

Table: Priorization of basic tasks when working in 'degraded conditions'

Basic tasks guaranteed when:

2 Physicists at work for 1 day

3 Physicists at work for 1 week

Basic Tasks guaranteed
HDR-Brachytherapy source turn-over
Presence during HDR-Brachytherapy treatment session
Calibration of one photon/electron beam energy
Validation of QA controls of LINACs
Validation of a technical intervention on LINACs
Presence during 1st radiotherapy session (new patients)
Validation of dosimetry

➔ **Very useful during summer holidays**

Internal Rule : OPMP

Table: Physicists' time quantification

Basic Tasks	Time Quantification
Brachytherapy	
Presence during treatment sessions	1 to 3h/Week
Weakly Quality Assurance	1h/Week
Radioactive source turn-over	1day/2 months ½
Radiotherapy	
Verification of treatment parameters and pateints' set-up	10h/day
Validation of dosimetry for complex treatments and of multimodality imaging fusion	4h/day
Verification of technical records before the onset of treatment	4 to 8h/day
Dosimetric validation of complex treatment	1h/day
Quality Assurance of equipment	5 to 30h/day
Participation in Experience Return Committee (CREX)	10h/month
Training of fellows in Medical Physics	1 to 4h/day
Teaching and other educational activities	Radiographers' School 15h/year Fellows in RO 20h/year ISC workshop on Innovative treatment techniques 3d/year
Random tasks	
Installation of heavy equipment (LINAC, CT-scan, HDR-source projector)	Variable (weeks to months)
Deployment of new treatment technique	Variable (days to weeks)
Management of Service & Personnel	Unquantifiable !

➔ **Adequation of physicists' time to workload**

Internal Rules
OPMP / OPRT

Roles within the RT-dept.

ACR-ASTRO recommandations

Med. Dosimetrist involved in 1st treatment session!

Radiation Oncologist	Medical Physicist	Medical dosimetrist
Continue management of the patient throughout the course of radiation therapy, including ongoing acquisition, review, and verification of all treatment-related imaging	Consult and participate with the radiation oncologist and other team members in implementing the immobilization/repositioning system for the patient	Be available for the first treatment and assist with verification for subsequent treatments as necessary

Radiographers acquire images to be reviewed by the Radiation Oncologist!

Procedures
'…work easily…'

Basic principles

Has to be observed in general

Allows one to work fast and efficiently

Many are needed

Domains of application

Prepping a patient (e.g.simulation, treatment, *etc*…)

Frequent cancer localizations (e.g. prostate, breast, H&N, etc…)

High precision techniques (e.g. IGRT, SBRT, brachytherapy, etc…)

Procedures

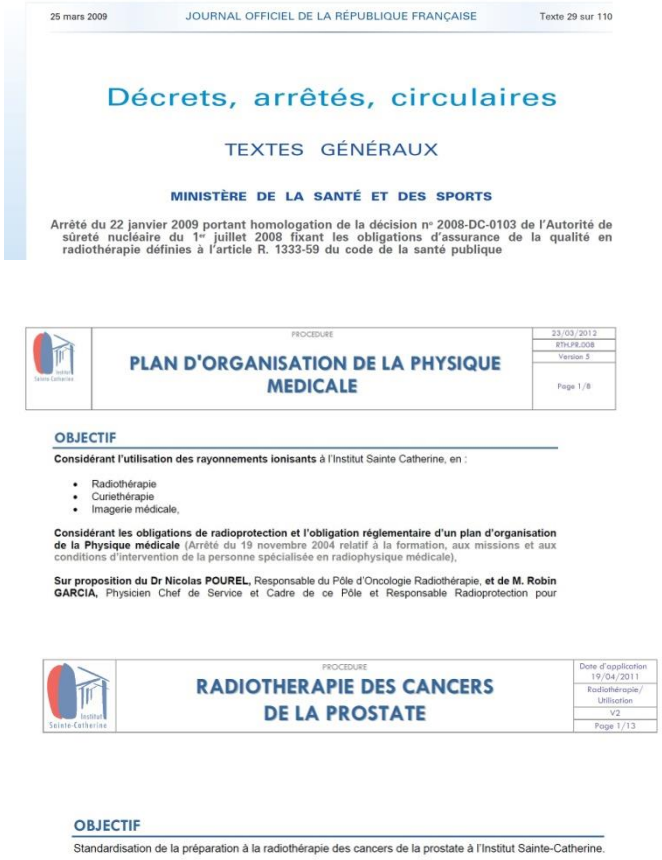
The making of

- Joint writing Rad. Oncol./Med. Phy./Qual. M.
  - Clear medical objective (Rad. Oncol)
    - Predefined clinical scenarios
    - Dosimetric criteria for acceptance of treatment plan
  - Dose delivered guarantied (Med. Phy.)
    - ‘PDIP’ for IMRT
    - ‘Epiqua’ for VMAT
- Quality Manager mandatory to deal with the formatting

Procedures

Concept of procedure

- It is no Law
  - Sometimes, you cannot follow it and it is no crime
- It is no Internal Rule
  - The General Director is not directly involved
- It is a tool for everyday practice
  - To create the greatest amount of outputs
  - Designed with the assistance of QM



25 mars 2009 JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE Texte 29 sur 110

Décrets, arrêtés, circulaires

TEXTES GÉNÉRAUX

MINISTÈRE DE LA SANTÉ ET DES SPORTS

Arrêté du 22 janvier 2009 portant homologation de la décision n° 2008-DC-0103 de l'Autorité de sûreté nucléaire du 1er juillet 2008 fixant les obligations d'assurance de la qualité en radiothérapie définies à l'article R. 1333-59 du code de la santé publique

PROCEDURE

PLAN D'ORGANISATION DE LA PHYSIQUE MEDICALE

23/03/2012 | RTH.PR.008 | Version 5 | Page 1/8

OBJECTIF

Considérant l'utilisation des rayonnements ionisants à l'Institut Sainte Catherine, en :

- Radiothérapie
- Curiethérapie
- Imagerie médicale,

Considérant les obligations de radioprotection et l'obligation réglementaire d'un plan d'organisation de la Physique médicale (Arrêté du 19 novembre 2004 relatif à la formation, aux missions et aux conditions d'intervention de la personne spécialisée en radiophysique médicale),

Sur proposition du Dr Nicolas POUREL, Responsable du Pôle d'Oncologie Radiothérapie, **et de M. Robin GARCIA,** Physicien Chef de Service et Cadre de ce Pôle et Responsable Radioprotection pour

PROCEDURE

RADIOTHERAPIE DES CANCERS DE LA PROSTATE

Date d'application 19/04/2011 | Radiothérapie / Utilisation | V2 | Page 1/13

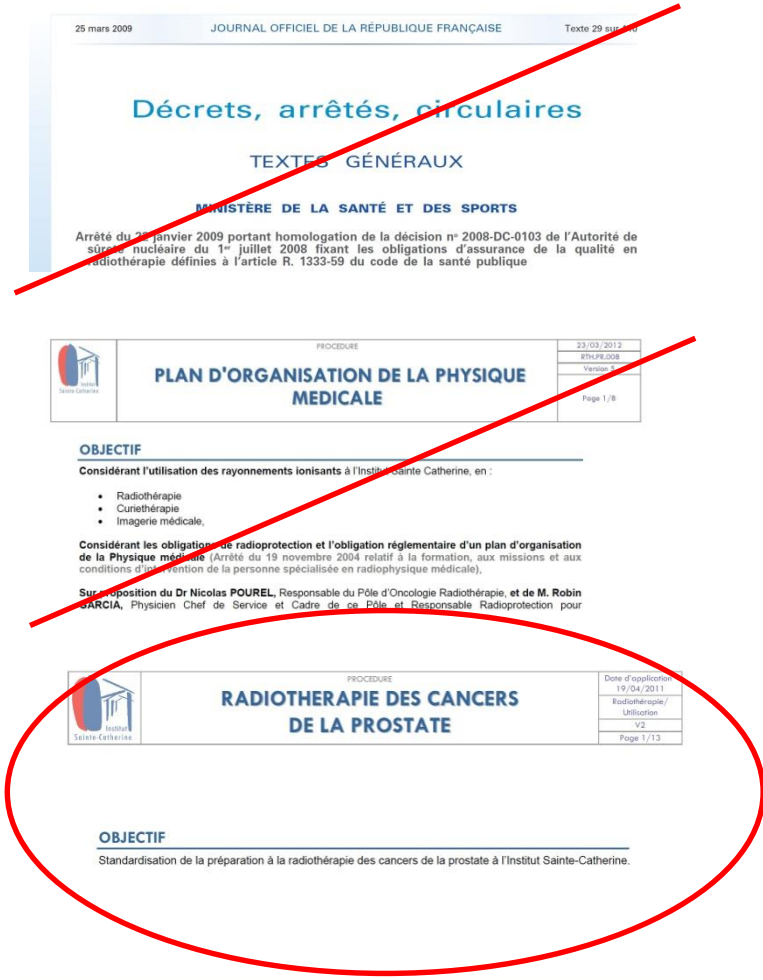
OBJECTIF

Standardisation de la préparation à la radiothérapie des cancers de la prostate à l'Institut Sainte-Catherine.

Procedures

Concept of procedure

- It is no Law
  - Sometimes, you cannot follow it and it is no crime
- It is no Internal Rule
  - The General Director is not directly involved
- It is a tool for everyday practice
  - To create the greatest amount of outputs
  - Designed with the assistance of QM



Procedures

Concept of procedure

Style

Synthetic, Homogeneous

Availability

At hand, Intranet

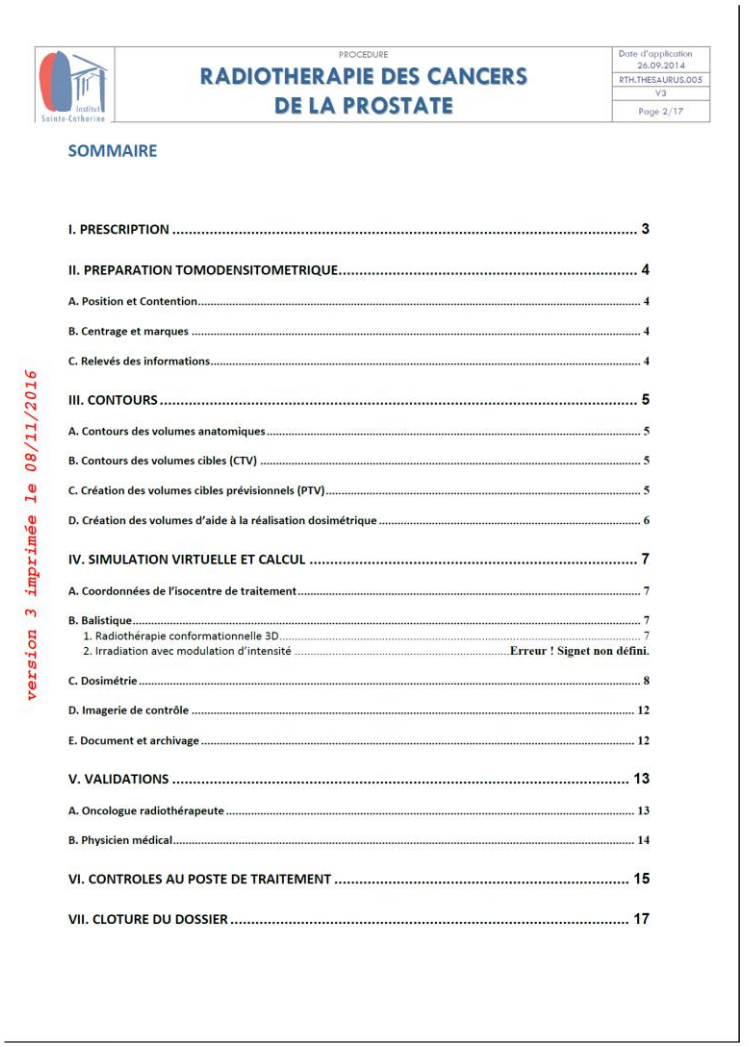
Purpose

Work with efficiency

Serenity

For the whole team of professionnals

➔ Specific framework: assistance of Quality Manager mandatory +++



PROCEDURE

RADIOTHERAPIE DES CANCERS DE LA PROSTATE

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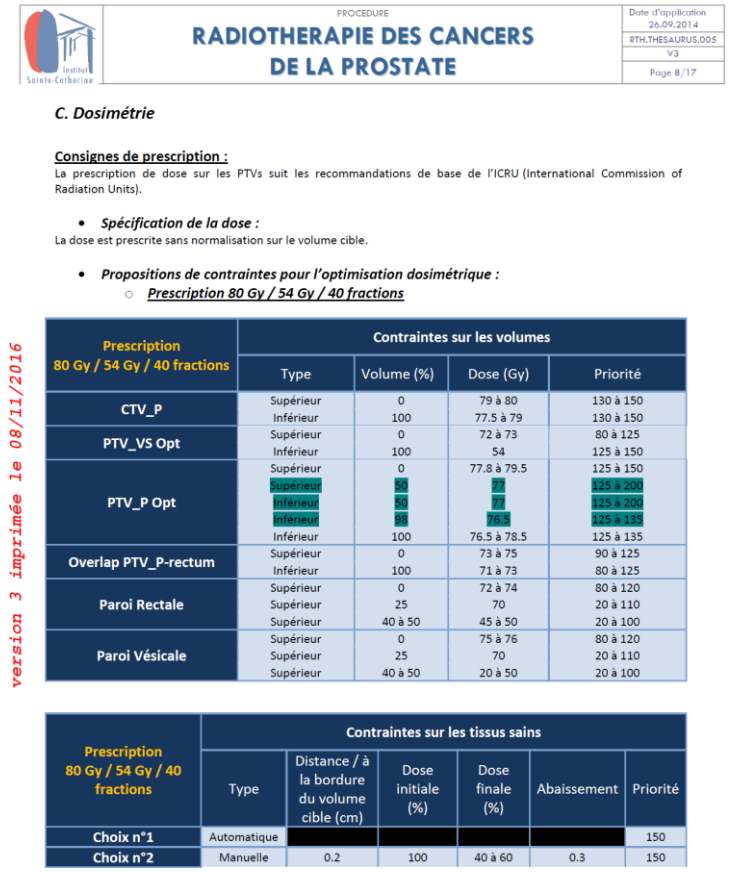
Procedures

Concept of procedure

- Indentify a treatment process
- Belongs to the C-QMS
- C-QMS under control
- Periodic revision
- Ready for Audit

➔ Very much in the views of the French Nuclear Safety Agency!



PROCEDURE

RADIOTHERAPIE DES CANCERS DE LA PROSTATE

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C. Dosimétrie

Consignes de prescription :

La prescription de dose sur les PTVs suit les recommandations de base de l'ICRU (International Commission of Radiation Units).

- ***Spécification de la dose :***

La dose est prescrite sans normalisation sur le volume cible.

- ***Propositions de contraintes pour l'optimisation dosimétrique :***
  - ***Prescription 80 Gy / 54 Gy / 40 fractions***

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Prescription 80 Gy / 54 Gy / 40 fractions	Contraintes sur les volumes			
	Type	Volume (%)	Dose (Gy)	Priorité
CTV_P	Supérieur	0	79 à 80	130 à 150
	Inférieur	100	77.5 à 79	130 à 150
PTV_VS Opt	Supérieur	0	72 à 73	80 à 125
	Inférieur	100	54	125 à 150
PTV_P Opt	Supérieur	0	77.8 à 79.5	125 à 150
	Supérieur	50	77	125 à 200
	Inférieur	50	77	125 à 200
	Inférieur	98	76.5	125 à 135
	Inférieur	100	76.5 à 78.5	125 à 135
Overlap PTV_P-rectum	Supérieur	0	73 à 75	90 à 125
	Inférieur	100	71 à 73	80 à 125
Paroi Rectale	Supérieur	0	72 à 74	80 à 120
	Supérieur	25	70	20 à 110
	Supérieur	40 à 50	45 à 50	20 à 100
Paroi Vésicale	Supérieur	0	75 à 76	80 à 120
	Supérieur	25	70	20 à 110
	Supérieur	40 à 50	20 à 50	20 à 100

Prescription 80 Gy / 54 Gy / 40 fractions	Contraintes sur les tissus sains					
	Type	Distance / à la bordure du volume cible (cm)	Dose initiale (%)	Dose finale (%)	Abaissement	Priorité
Choix n°1	Automatique					150
Choix n°2	Manuelle	0.2	100	40 à 60	0.3	150

ESTRO School

OBJECTIF

Standardisation de la préparation à la radiothérapie des cancers de la prostate à l'Institut Sainte-Catherine.

REFERENCES [textes réglementaires, recommandations,...]

- Guide SFRO 2007
- ICRU 83
- IGROBP Volume76, n°3, pp. S10-S19, 2010

PERSONNES CONCERNEES

- Oncologues radiothérapeutes
- Manipulateurs du simulo-scanner
- Dosimétristes
- Physiciens

DOCUMENTS ASSOCIES

- Dossier du patient
- Fiche de prescription
- Protocole Radiothérapie Guidée par l'Image CB-CT cancers prostatiques

REDACTION	VERIFICATION	APPROBATION
Nom(s) & Fonction(s) Mme Véronique BODEZ, Physicienne Chef Adjoint Dr Lysian CARTIER, Oncologue radiothérapeute M. José PUNTER, Manipulateur Principal M. Guillaume FRANCOIS, Aide Physicien	**Nom :** Docteur Bruno CHAUVET **Fonction :** Oncologue Radiothérapeute	**Nom :** Docteur Nicolas POUREL **Fonction :** Oncologue Radiothérapeute
Date : Mai 2014	**Date :** Août 2014	**Date :** 26.09.2014

version 3 imprimée le 08/11/2016

SOMMAIRE

Clinical Scenarios

I. PRESCRIPTION

Indication	Volume CTV1	Prescription pour CTV1		Volume CTV2	Prescription pour CTV2	
		Dose (Gy)	Nombre de fractions		Dose (Gy)	Nombre de fractions
RT Exclusive / Faible risque	Prostate seule	74	37			
RT Exclusive / Risque intermédiaire et élevé	Prostate + Vésicules séminales	54	40	Prostate	80	40
RT Exclusive / Risque élevé + RT pelvienne	Prostate + Vésicules séminales + Ganglions pelviens	54	40	Prostate	80	40
RT adjuvante	Loge de prostatectomie	64.8	36			
RT de rattrapage	Loge de prostatectomie ou récidive visible	68.4	38			

Dans certains cas, il peut être nécessaire d'adapter la dose (ex : 70 Gy en 35 fractions), ou de traiter les ganglions pelviens dans le cas d'un traitement de loge prostatique.

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II. PREPARATION TOMODENSITOMETRIQUE

A. Position et Contention

- Confection d'une coque en mousse polyuréthane personnalisée.
- Le patient est positionné en décubitus dorsal. Les mains du patient sont croisées sur la poitrine.

B. Centrage et marques

- Administrer un lavement MICROLAX® afin de réaliser une vidange rectale, si nécessaire faire boire le patient et reprendre le scanner une heure plus tard si la vessie a été vidée et qu'il n'y a pas d'injection.
- Pose de la voie veineuse
- Mise en place et alignement du patient

Les marques sont définies de façon à représenter d'emblée l'isocentre de traitement.
Le plan de référence est situé sur le bord supérieur de la symphyse.

- Définition de la zone d'intérêt (du petit trochanter à 5 cm au dessus de S1) et faire le «zéro scanner»
- Injection de 50 ml de produit de contraste concentré à 300 mgI/ml après avoir vérifié l'absence d'allergie connue ou de contre-indication aux produits iodés
- Réalisation d'une hélice tardive (10 mn après l'injection du produit de contraste) afin de faciliter la délinéation de la prostate au niveau de l'apex et de la base
- Réalisation de l'acquisition de la totalité des volumes d'intérêt en coupe de 2 mm ; des crêtes iliaques à la marge anale
- Tracer deux croix latérales et un trait médian sur la coque
- Tatouer les points tibiaux

C. Relevés des informations

- Photographie de la mise en place de face et de profil
- Renseignement de la fiche de liaison avec la dosimétrie et de la fiche unique

Prepping procedure

Standardization of target-volumes, nomenclature

III. CONTOURS

Les volumes anatomiques, dont les organes à risques (OAR), sont contourés par le dosimétriste et validés par l'oncologue radiothérapeute. Les contours des volumes cibles (CTV) sont réalisés par le radiothérapeute. Les volumes cibles prévisionnels sont réalisés par les dosimétristes.

A. Contours des volumes anatomiques

Volumes	Réalisation	Couleur
Paroi Vessie	Délinéation de l'ensemble de la paroi vésicale d'une épaisseur de 7 mm	Orange
Paroi rectum	Délinéation de la paroi rectale d'une épaisseur de 5 mm sur une hauteur comprise entre 2 cm au-dessus et 2 cm en dessous du CTV Prostate et CTV VS ou du CTV loge prostatique. Délinéation sur une hauteur de 2cm en dessous du CTV P, CTV VS, CTV GG jusqu'au sigmoïde dans le cas d'irradiations pelviennes	Vert
Tête fémorale droite	Délinéation du sommet de la tête au sommet du petit trochanter	Bleu foncé
Tête fémorale gauche	Délinéation du sommet de la tête au sommet du petit trochanter	Vert foncé
Anses digestives	Délinéation de la cavité péritonéale dans le cas des irradiations pelviennes jusqu'à 2 cm au-dessus du PTV	Purple

B. Contours des volumes cibles (CTV)

Les volumes cibles sont délinéés manuellement par le radiothérapeute.

Volumes	Réalisation	Couleur
Prostate : CTV_P ou Loge : CTV Loge	Délinéation éventuellement à l'aide d'une IRM de fusion.	Bleu
Vésicules séminales : CTV_VS	Délinéation uniquement si traités.	Cyan
Ganglions pelviens : CTV_Ggls	Délinéation uniquement si traités.	Vert

C. Création des volumes cibles prévisionnels (PTV)

Les volumes cibles prévisionnels (PTV) sont obtenus par expansion automatique autour des volumes cibles (CTV).

Volumes PTV	Droite / Gauche (mm)	Antéro/Postérieur		Tête /Pieds (mm)	Couleur
		Ant (mm)	Post (mm)		
PTV_Prostate Ou PTV_Loge	10	10	5	10	Rouge
PTV_Ggls	7	7	7	7	Magenta
PTV_VS	10	10	5	10	Cyan

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D. Création des volumes d'aide à la réalisation dosimétrique

Les volumes décrits ci-dessous et aidant à la réalisation de la dosimétrie doivent être réalisés dans tous les cas de traitement.

Volumes	Réalisation	Couleur
Produit de Contraste vésical (PC)	Contourage de la zone artéfactée manuellement sur toutes les coupes et affectation d'un nombre UH = 0	Vert
Table de traitement	Insérer et positionner la Table Exact IGRT Epaisse avec -600UH pour la partie externe et -942UH pour la partie interne.	Purple
PTV_P - Paroi rect (pour dosi à 80Gy)	= PTV_P – Paroi rectale	Rouge
PTV_P Opt	= PTV_P– CTV_P (– Paroi rectale si dosi à 80Gy)	Rouge
PTV_Loge Opt	= PTV_Loge– CTV_Loge	
PTV_VS Opt	= PTV_VS – PTV_P	Rose
Overlap PTV_P-rectum	= PTV_P + Paroi rectale	Rouge
PTV_VS+GG Opt	=(PTV_VS Opt+PTV_Ggls)-PTV_P	Rose

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Generation of sub-volumes for dosimetric optimization

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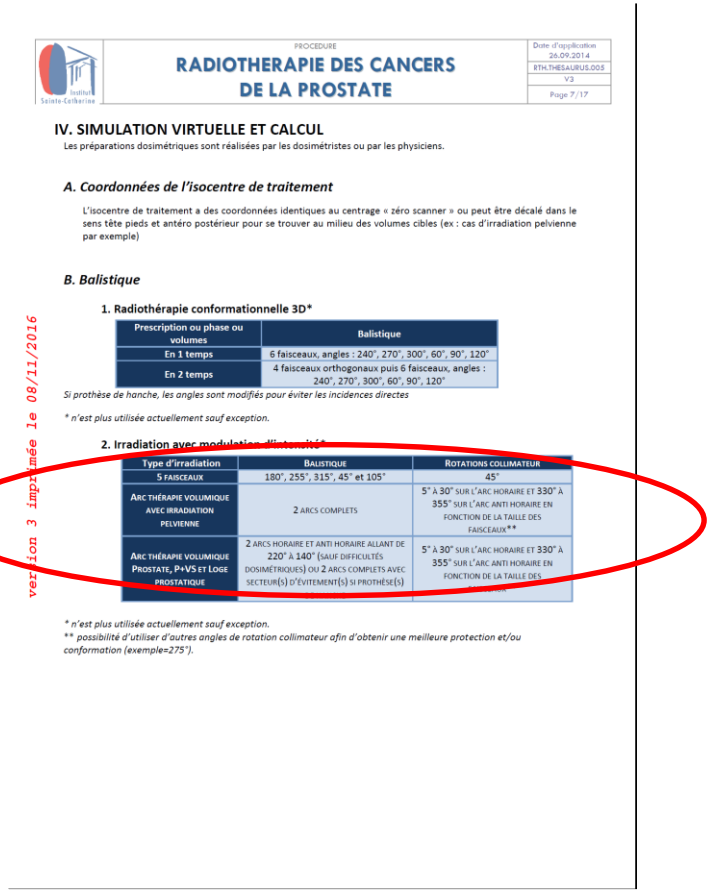

PROCEDURE

RADIOTHERAPIE DES CANCERS DE LA PROSTATE

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IV. SIMULATION VIRTUELLE ET CALCUL

Les préparations dosimétriques sont réalisées par les dosimétristes ou par les physiciens.

A. Coordonnées de l'isocentre de traitement

L'isocentre de traitement a des coordonnées identiques au centrage « zéro scanner » ou peut être décalé dans le sens tête pieds et antéro postérieur pour se trouver au milieu des volumes cibles (ex : cas d'irradiation pelvienne par exemple)

B. Balistique

1. Radiothérapie conformationnelle 3D*

Prescription ou phase ou volumes	Balistique
En 1 temps	6 faisceaux, angles : 240°, 270°, 300°, 60°, 90°, 120°
En 2 temps	4 faisceaux orthogonaux puis 6 faisceaux, angles : 240°, 270°, 300°, 60°, 90°, 120°

Si prothèse de hanche, les angles sont modifiés pour éviter les incidences directes

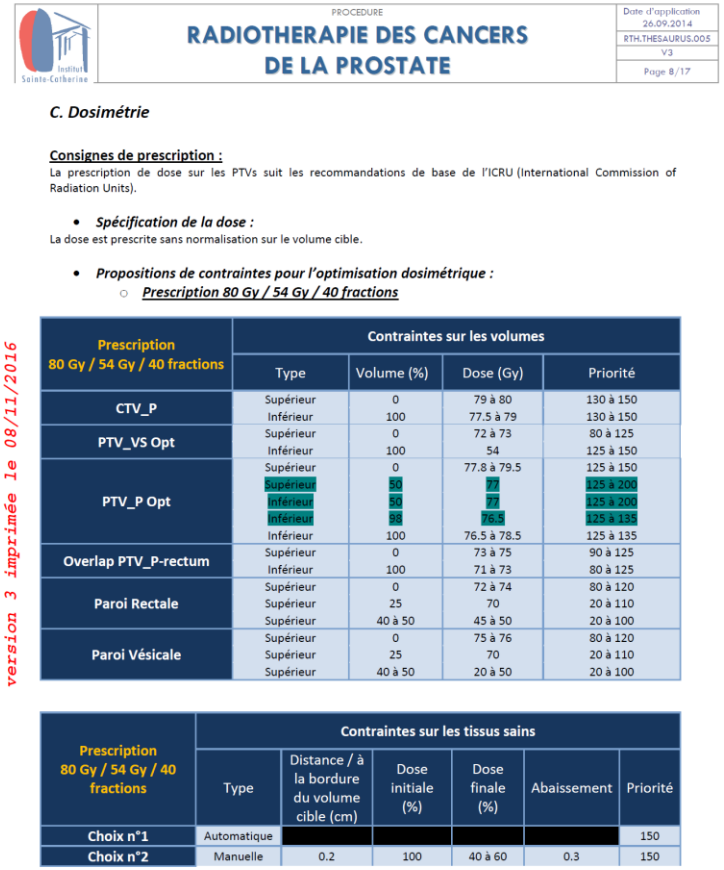
** n'est plus utilisée actuellement sauf exception.*

2. Irradiation avec modulation d'intensité*

Type d'irradiation	Balistique	Rotations collimateur
5 faisceaux	180°, 255°, 315°, 45° et 105°	45°
Arc thérapie volumique avec irradiation pelvienne	2 arcs complets	5° à 30° sur l'arc horaire et 330° à 355° sur l'arc anti horaire en fonction de la taille des faisceaux**
Arc thérapie volumique Prostate, P+VS et Loge prostatique	2 arcs horaire et anti horaire allant de 220° à 140° (sauf difficultés dosimétriques) ou 2 arcs complets avec secteur(s) d'évitement(s) si prothèse(s)	5° à 30° sur l'arc horaire et 330° à 355° sur l'arc anti horaire en fonction de la taille des faisceaux**

** n'est plus utilisée actuellement sauf exception.*

*** possibilité d'utiliser d'autres angles de rotation collimateur afin d'obtenir une meilleure protection et/ou conformation (exemple=275°).*



PROCEDURE

RADIOTHERAPIE DES CANCERS DE LA PROSTATE

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C. Dosimétrie

Consignes de prescription :

La prescription de dose sur les PTVs suit les recommandations de base de l'ICRU (International Commission of Radiation Units).

- ***Spécification de la dose :***

La dose est prescrite sans normalisation sur le volume cible.

- ***Propositions de contraintes pour l'optimisation dosimétrique :***
  - ***Prescription 80 Gy / 54 Gy / 40 fractions***

Prescription 80 Gy / 54 Gy / 40 fractions	Contraintes sur les volumes			
	Type	Volume (%)	Dose (Gy)	Priorité
CTV_P	Supérieur	0	79 à 80	130 à 150
	Inférieur	100	77.5 à 79	130 à 150
PTV_VS Opt	Supérieur	0	72 à 73	80 à 125
	Inférieur	100	54	125 à 150
PTV_P Opt	Supérieur	0	77.8 à 79.5	125 à 150
	Supérieur	50	77	125 à 200
	Inférieur	50	77	125 à 200
	Inférieur	98	76.5	125 à 135
	Inférieur	100	76.5 à 78.5	125 à 135
Overlap PTV_P-rectum	Supérieur	0	73 à 75	90 à 125
	Inférieur	100	71 à 73	80 à 125
Paroi Rectale	Supérieur	0	72 à 74	80 à 120
	Supérieur	25	70	20 à 110
	Supérieur	40 à 50	45 à 50	20 à 100
Paroi Vésicale	Supérieur	0	75 à 76	80 à 120
	Supérieur	25	70	20 à 110
	Supérieur	40 à 50	20 à 50	20 à 100

Prescription 80 Gy / 54 Gy / 40 fractions	Contraintes sur les tissus sains					
	Type	Distance / à la bordure du volume cible (cm)	Dose initiale (%)	Dose finale (%)	Abaissement	Priorité
Choix n°1	Automatique					150
Choix n°2	Manuelle	0.2	100	40 à 60	0.3	150

Predefined ballistic solutions

- ***Prescription 74 Gy / 37 fractions***

Prescription 74 Gy / 37 fractions	Contraintes sur les volumes			
	Type	Volume (%)	Dose (Gy)	Priorité
PTV_P Opt	Supérieur	0	72.5 à 74	125 à 150
	Supérieur	50	71 à 72.5	125 à 150
	Inférieur	50	71 à 72.5	125 à 150
	Inférieur	98	71	125 à 150
	Inférieur	100	70.5 à 73	125 à 150
CTV_Prostate	Supérieur	0	74 à 75	130 à 150
	Inférieur	100	72 à 73.5	130 à 150
Paroi Rectale	Supérieur	0	70 à 74	70 à 100
	Supérieur	25	70	20 à 90
	Supérieur	50	30 à 50	20 à 90
Paroi Vésicale	Supérieur	0	70 à 74	90 à 110
	Supérieur	50	45 à 50	20 à 90
	Supérieur	25	70	20 à 90

Prescription 74 Gy / 37 fractions	Contraintes sur les tissus sains					
	Type	Distance / à la bordure du volume cible (cm)	Dose initiale (%)	Dose finale (%)	Abaissement	Priorité
Choix n°1	Automatique					150
Choix n°2	Manuelle	0.2 à 0.5	100	40 à 60	0.3	150

- ***Prescription 64.8 Gy / 36 fractions***

Prescription 64.8 Gy / 36 fractions	Contraintes sur les volumes			
	Type	Volume (%)	Dose (Gy)	Priorité
PTV Loge	Supérieur	0	64 à 65	125 à 150
	Supérieur	50	62 à 63	125 à 150
	Inférieur	50	62 à 63	125 à 150
	Inférieur	98	64	125 à 150
	Inférieur	100	63 à 64	125 à 150
CTV_Loge	Supérieur	0	66 à 67	125 à 150
	Inférieur	100	64 à 65	125 à 150
Paroi Rectale	Supérieur	0	61 à 62	90 à 100
	Supérieur	50	45 à 50	20 à 90
Paroi Vésicale	Supérieur	0	61 à 62	90 à 100
	Supérieur	50	45 à 50	20 à 90

Prescription 64.8 Gy / 36 fractions	Contraintes sur les tissus sains					
	Type	Distance / à la bordure du volume cible (cm)	Dose initiale (%)	Dose finale (%)	Abaissement	Priorité
Choix n°1	Automatique					150
Choix n°2	Manuelle	0.2 à 0.5	100	40 à 60	0.3	150

- ***Prescription 68.4 Gy / 38 fractions***

Prescription 68.4 Gy / 38 fractions	Contraintes sur les volumes			
	Type	Volume (%)	Dose (Gy)	Priorité
CTV Loge	Supérieur	0	68 à 69	130 à 150
	Inférieur	100	67 à 68	130 à 150
PTV_Loge Opt	Supérieur	0	67.5 à 68	125 à 150
	Supérieur	50	67.5 à 68.5	125 à 150
	Inférieur	50	67.5 à 68.5	125 à 150
	Inférieur	98	67.8 à 68.4	125 à 150
	Inférieur	100	66.5 à 67.5	125 à 150
Paroi Rectale	Supérieur	0	64 à 67.5	90 à 100
	Supérieur	50	45 à 50	90 à 100
Paroi Vésicale	Supérieur	0	64 à 67.5	90 à 100
	Supérieur	50	45 à 50	90 à 100
	Supérieur	50	45 à 50	90 à 100

Prescription 68.4 Gy / 38 fractions	Contraintes sur les tissus sains					
	Type	Distance / à la bordure du volume cible (cm)	Dose initiale (%)	Dose finale (%)	Abaissement	Priorité
Choix n°1	Automatique					150
Choix n°2	Manuelle	0.2 à 0.5	100	40 à 60	0.3	150

Acceptance criteria (PTV coverage, dose to OAR)

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- ***Contraintes à respecter pour valider la dosimétrie :***

Contraintes aux PTV

DP = Dose Prescrite

PTV_P PTV_Loge PTV_VS PTV_Ggls	80 Gy contraintes pour le volume (PTV_P-paroi rectale)	54 Gy	54 Gy	74 Gy contraintes pour le volume PTV_P	68.4 Gy contraintes pour le volume PTV_Loge	64.8 Gy contraintes pour le volume PTV_Loge
D98%	≥ 76 Gy	≥ 54 Gy	≥54 Gy	≥ 70.3 Gy	≥ 65 Gy	≥ 61.6 Gy
D50%	80 (± 0.2) Gy	ND	ND	74 (± 0.2) Gy	68.4 (± 0.2) Gy	64.8 (± 0.2) Gy
D2%	< 105% DP = 84 Gy	ND	ND	< 105% DP = 77.7 Gy	< 105% DP = 71.8 Gy	< 105% DP = 68 Gy
D95%	≥ 95% DP = 76 Gy (dans le volume PTV_P)	ND	ND	ND	ND	ND
D max ponctuelle	< Dmax CTV	N/A	N/A	N/A		

Contraintes aux CTV

CTV_P CTV_Loge	80 Gy	74 Gy	68.4 Gy	64.8 Gy
D98%	≥ 98% DP = 78.4 Gy	≥ 98% DP = 72.5 Gy	≥ 98% DP = 67 Gy	≥ 98% DP = 63.5 Gy
D2% *	< 105% DP = 84 Gy	< 105% DP = 77.7 Gy	< 105% DP = 71.8 Gy	< 105% DP = 68 Gy
D max ponctuelle	< 107 % DP = 85.6 Gy	N/A	N/A	N/A

Contraintes aux OAR

Prescription OAR		80 Gy Si Ggls à 54 Gy	74 Gy	68.4 Gy	64.8 Gy
Paroi rectale	D2%	< 76 Gy	< 74 Gy	< 68.4 Gy	< 64.8 Gy
	D25%	< 70 Gy	< 70 Gy	N/A	N/A
	D50%	< 50 Gy	< 50 Gy	< 50 Gy	< 50 Gy
Paroi Vésicale	D2%	< 80 Gy	< 105%DP = 77.7 Gy	<105%DP = 71.8 Gy	< 105%DP = 68 Gy
	D25%	< 70 Gy	< 70 Gy	< 70 Gy	N/A
	D50%	< 50 Gy	< 50 Gy	< 50 Gy	< 50 Gy
Têtes fémorales	D5%	< 55 Gy	< 55 Gy	< 55 Gy	< 55 Gy
Anses Digestives - PTV	V40 Gy	< 200 cc			

- ***Présentation du plan de dosimétrie :***

Les HDV seront affichés et imprimés dès lors qu'ils sont délinéés pour les volumes suivants : CTV_VS, CTV_Ggs, CTV_P, PTV_P, PTV_P-Rectum, PTV_VS, PTV_Ggs

D. Imagerie de contrôle

Pour tous les types d'irradiation, créer les faisceaux de positionnement suivants :

Faisceaux	Angle du bras	Angle du collimateur	Taille du champ	
			X (cm)	Y (cm)
KV Lat Droit	270	0	26.6	20
KV Post	180	0	26.6	20
KV CBCT	0	0	26.6	20

Les images CBCT sont réalisées de façon quotidienne pour les prostates en place et les images kV/kV sont réalisées quotidiennement pour les loges prostatiques.

E. Document et archivage

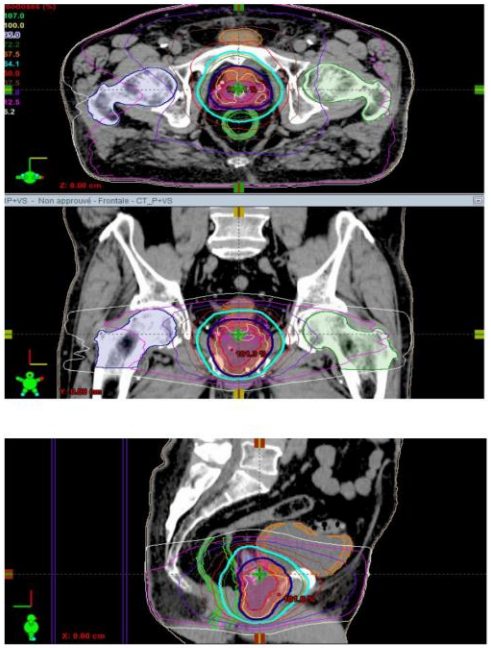
- Les fichiers terminés (c'est-à-dire après validation médicale de la dosimétrie) sont archivés systématiquement dans le serveur ARIA® (plans de traitement, images de scanner, images de référence (DRR), images de contrôle).
- Les impressions papier des courbes isodoses, des DVHs faisant apparaître les doses moyennes à tous les CTV et PTV et du plan de traitement sont archivées dans le dossier médical.

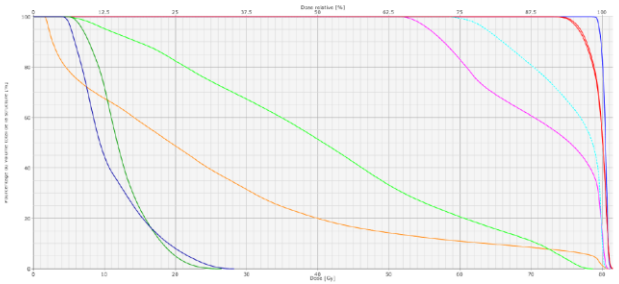
Acceptance criteria (PTV coverage, dose to OAR)

V. VALIDATIONS

A. Oncologue radiothérapeute

La validation de la dosimétrie par l'oncologue radiothérapeute s'appuie sur les histogrammes dose - volume et la dosimétrie résumée en 3 plans de l'espace.





Remarque :

- **Les Isodoses affichées sont celles des modèles prévus**
- **Exemples :**
  - **Modèle Prostate 80 Gy**

La validation informatique de la dosimétrie est réalisée par l'oncologue radiothérapeute avec son code personnel.

B. Physicien médical

Les dosimétristes regroupent l'ensemble des documents de préparation du traitement de chaque patient. Le physicien effectue une vérification exhaustive de tous les paramètres.
La validation informatique du traitement dans sa globalité est réalisée par le physicien avec son code personnel. Cette validation donne accès aux fichiers de traitement pour l'irradiation sur l'accélérateur.

version 3 imprimée le 08/11/2016

Standardized presentaion of treatment plan, DVHs & ctrl. imaging

version 3 imprimée le 08/11/2016

PROCEDURE

RADIOTHERAPIE DES CANCERS DE LA PROSTATE

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VI. CONTROLES AU POSTE DE TRAITEMENT

Technique	Localisation	Fréquence des images	Structures pour recalage antérieur	Corrections en antérieur	Structures pour recalage latéral	Corrections en latéral	Particularités	Code
Conformationnel 3D	Prostate Prostate + VS Prostate + VS +GG Loge de prostatectomie	Portal 1ère, 2ème et 3ème séance + Hebdomadaire * n'est plus utilisé sauf exception	Symphyse Branches ilio-pubiennes Branches ischio-pubiennes	**Décalage :** si écart ≥ 5 mm (avec contention) **Décalage :** si écart ≥ 8 mm (sans contention)	Symphyse Sacrum	**Décalage :** si écart ≥ 5 mm (avec contention) **Décalage :** si écart ≥ 8 mm (sans contention)	**Les décalages se font en P3** Sauf si l'écart ≥ 5 mm (avec contention)	A1
Modulation d'intensité	Loge de prostatectomie	kV – kV quotidien		**Décalage :** si écart ≥ 3 mm (avec contention)		**Décalage :** si écart ≥ 3 mm (avec contention)		
Modulation d'intensité	Prostate Prostate + VS Prostate + VS +GG	CBCT quotidien	Cf. Protocole Radiothérapie guidée par l'Image CBCT					

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PROCEDURE

RADIOTHERAPIE DES CANCERS DE LA PROSTATE

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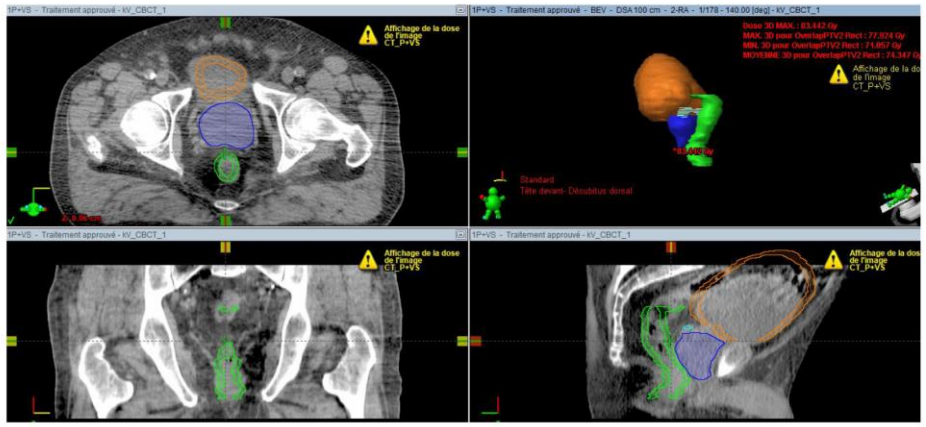


Positionning instructions for RTTs

ESTRO School

Process Charts
'…mapping the risk…'

Basic principles

Process Review (PR) is a proactive analysis of failure modes within any organization

PR allows to set up preventive actions to overcome organisational weaknesses identified doing so

Domains of application

New treatment technique within the dept. (i.e. SBRT, IGRT…)

Any complex process with multiple care providers involved (i.e. dosimetry, BT, cCRT…)

Process Charts

The 4 principles

1. Description of one process in details
2. Identification of potential risks
3. Rating
4. Setting up corrective actions

➔ The example of FMEA

(Failure Mode and Effect Analysis)

Process Charts

The making of

Rad. Oncol/Med. Phy./Technicians

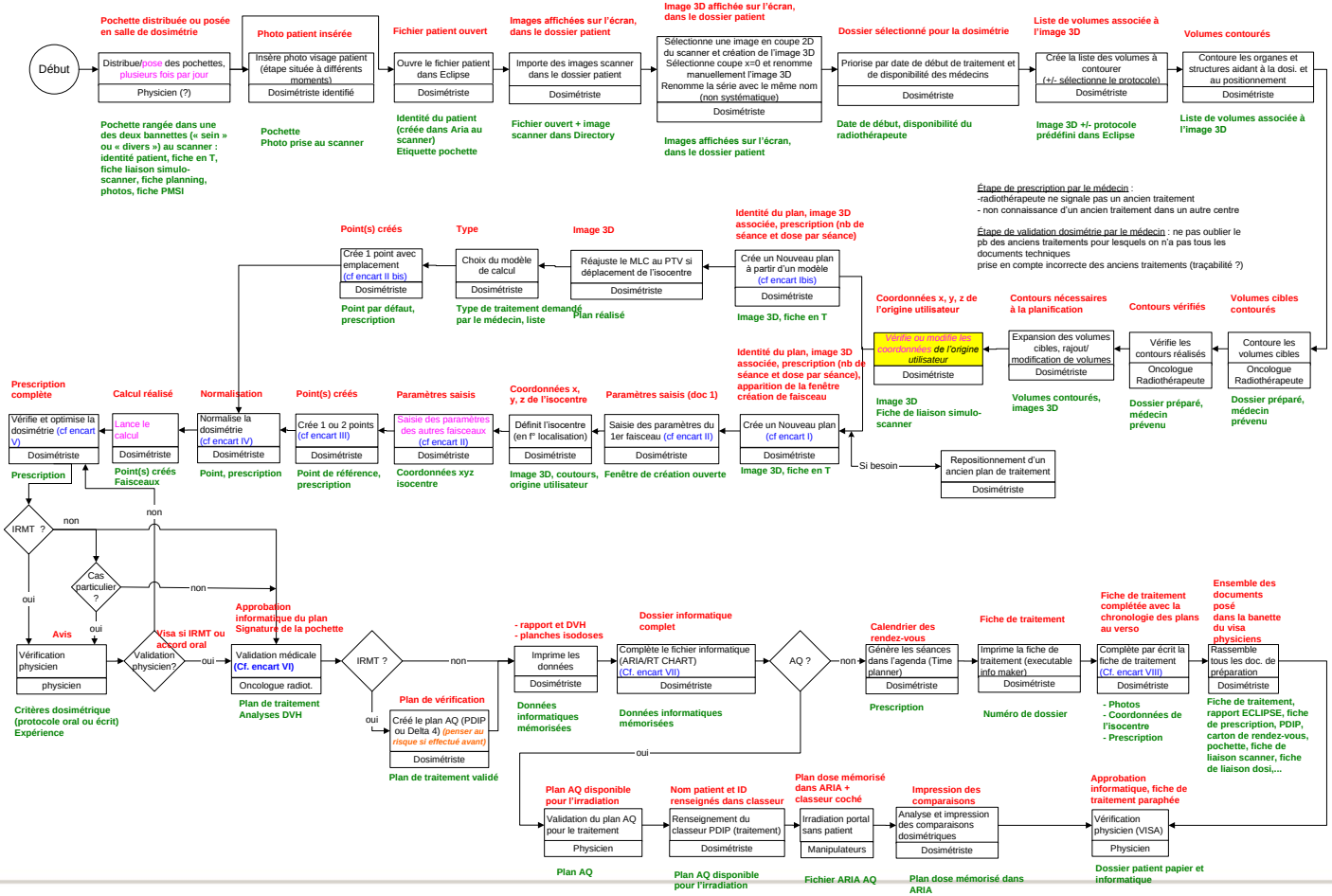
Choice of theme is crucial! (Dosimetry+++, SBRT++, IGRT+)

Industrial methodology (like FMEA)

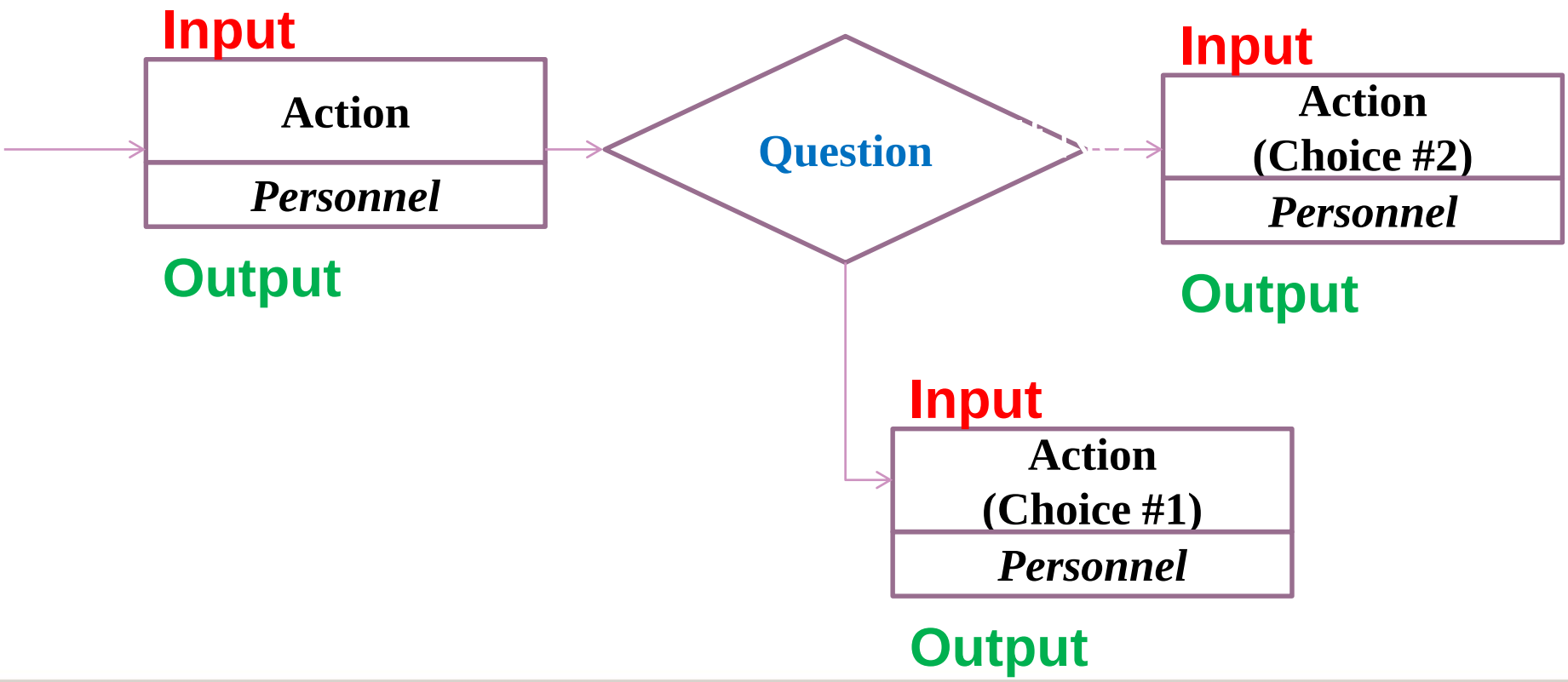
Multidisciplinary meetings (short and repeated on a fixed process)

Technical assistance of Consultants / QM for the formatting

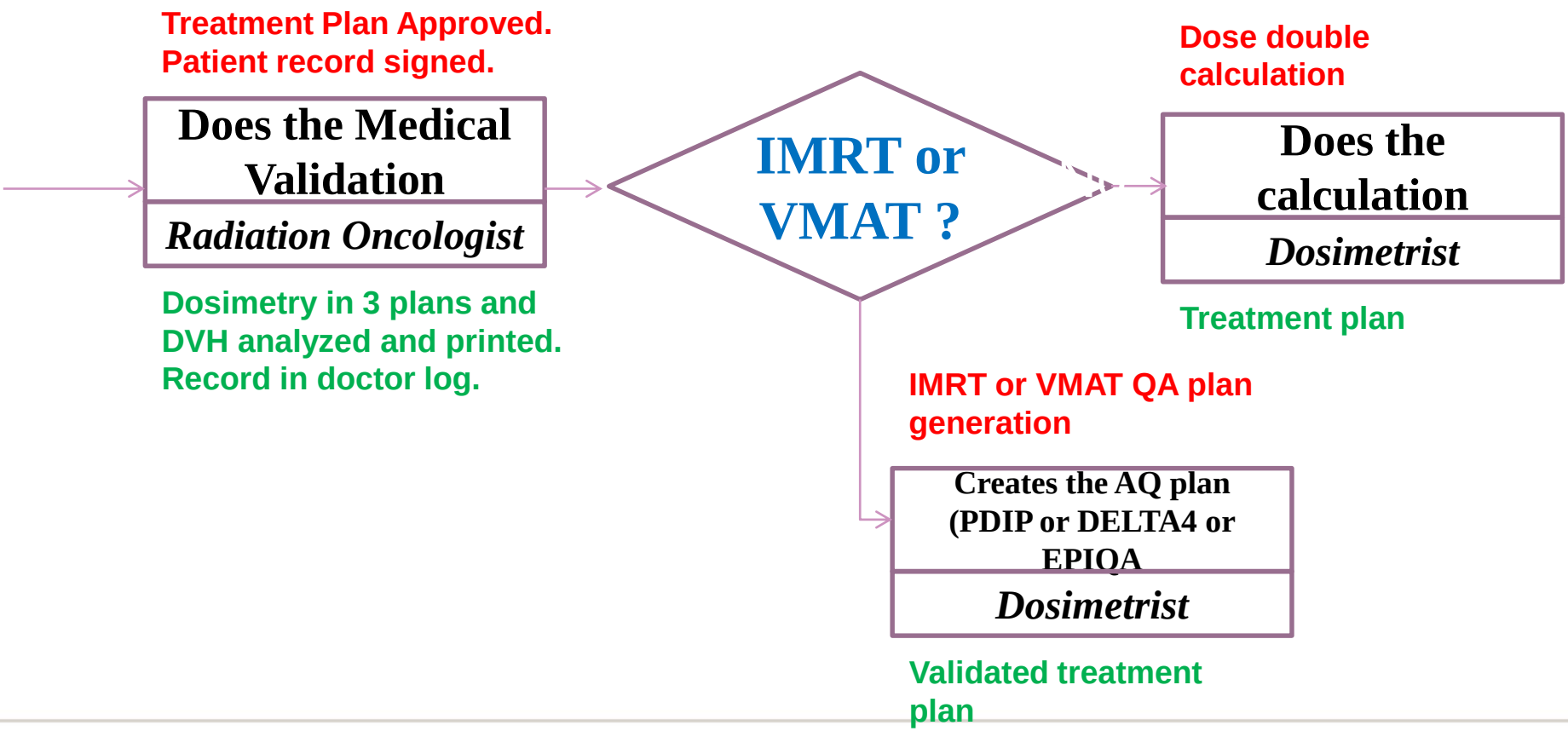
Process Chart 'Dosimetry'
Risk Mapping



Process Chart ‘Dosimetry’



Process Chart ‘Dosimetry’



Process Chart 'Dosimetry'
Description of process

ANALYSE DES MODES DE DEFAILLANCE, DE LEURS EFFETS ET

Etape	Mode de défaillance potentielle	Effets possibles de la défaillance	Causes possibles de la défaillance	Plan de surveillance actuel ou envisagé
Distribue/pose des pochettes, plusieurs fois par jour	Pochette non prise en charge	Dosimétrie non prête en temps utile	Pochettes éparpillées	-Boost : casier identifié
			Dosimétriste/ physicien non informé de l'urgence	/
Insère photo visage patient (étape située à différents moments)	Photo d'un patient à la place d'un autre	Perte de temps au traitement	Erreur d'identité au scanner	/
	Non insertion de la photo	Risque de confusion de patient au traitement	Photo non réalisée / non enregistrée	/
Ouvre le fichier patient dans Eclipse	Ouverture d'un fichier d'un autre patient pensant que c'est le bon	Réaliser une mauvaise dosimétrie	Erreur de saisie	Message alerte à l'étape suivante
			Pas de message d'alerte si pas de scanner	Vérification au visa
Importe des images scanner dans le dossier patient	Import des images d'un autre patient pensant que c'est le bon	Réaliser une mauvaise dosimétrie	Erreur de saisie	Message alerte, possibilité d'outre passer
	Groupe d'image incomplet	Réaliser une mauvaise dosimétrie	Problème informatique réseau	Contrôle visuel
Sélectionne une image en coupe 2D du scanner et création de l'image 3D	Sélectionner une image d'une autre série (si 2 séries)	Réaliser une dosimétrie sur une référence non correcte	Ne pas savoir quelle série est la bonne	/
			Erreur de sélection de série	/
	Sélectionner une image autre que x=0	aucune csq	Erreur de sélection d'image	pas besoin de plan de surveillance
Sélectionne coupe x=0 et renomme manuellement l'image 3D	Mélange des 2 séries	Perte de temps	Erreur logiciel	Contrôle visuel
	Avoir la mauvaise série	Réaliser une dosimétrie sur une référence non correcte	Envoi de la mauvaise série en provenance du scanner	/
Renomme la série avec le même nom (non systématique)	Si 2 séries, inverse noms des 2 séries	Réaliser une dosimétrie sur une référence non correcte	Erreur dans la nomination	Contrôle visuel

Process Chart 'Dosimetry'
Description of process

Failure Mode and Effects Analyses (FMEA)

Step	Possible failure mode	Possible effects	Possible causes	Surveillance plan / Rating
Distributes patients' records several times/day	Record not adressed	Late dosimetry	Disorder in the dosimetry room Physicist not informed of emergency casey	Dedicated Log for Emergen
				/
Insère photo visage patient (étape située à différents moments)	Photo d'un patient à la place d'un autre	Perte de temps au traitement		/
	Non insertion de la photo	Risque de confusion de patient au traitement	Photo non réalisée / non enregistrée	/
Ouvre le fichier patient dans Eclipse	Ouverture d'un fichier d'un autre patient pensant que c'est le bon	Réaliser une mauvaise dosimétrie	Erreur de saisie	Message alerte à l'étape suivante
			Pas de message d'alerte si pas de scanner	Vérification au visa
Importe des images scanner dans le dossier patient	Import des images d'un autre patient pensant que c'est le bon	Réaliser une mauvaise dosimétrie	Erreur de saisie	Message alerte, possibilité d'outre passer
	Groupe d'image incomplet	Réaliser une mauvaise dosimétrie	Problème informatique réseau	Contrôle visuel
Sélectionne une image en coupe 2D du scanner et création de l'image 3D Sélectionne coupe x=0 et renomme manuellement l'image 3D Renomme la série avec le même nom (non systématique)	Sélectionner une image d'une autre série (si 2 séries)	Réaliser une dosimétrie sur une référence non correcte	Ne pas savoir quelle série est la bonne	/
			Erreur de sélection de série	/
	Sélectionner une image autre que x=0	aucune csq	Erreur de sélection d'image	pas besoin de plan de surveillance
	Mélange des 2 séries	Perte de temps	Erreur logiciel	Contrôle visuel
	Avoir la mauvaise série	Réaliser une dosimétrie sur une référence non correcte	Envoi de la mauvaise série en provenance du scanner	/
	Si 2 séries, inverse noms des 2 séries	Réaliser une dosimétrie sur une référence non correcte	Erreur dans la nomination	Contrôle visuel

Process Chart 'Dosimetry'
Rating

Step	Possible failure mode	Possible effects	Possible causes	Surveillance plan /	Rating			
Contoure les volumes cibles	Contourage mal effectué	Traitement erroné	Confusion de patient	Pour le sein : présence du CR opératoire avec la fiche en T	4	2	4	34
			Confusion de choix du volume					
			Confusion de latéralité					
			Manque d'information pour réaliser le contour (IRM,…)					
Vérifie les contours réalisés	Pas de vérification	Contours et DVH erronés	Manque de temps	/	4	4	4	60
			Excès de confiance	/				
			Contours non réalisés	/				
Expansion des volumes cibles, rajout/modification de volumes	Erreur de valeur de marge pour PTV	Traitement erroné	Consignes erronées	/	4	2	2	17
			Erreur de saisie	Inscription par dosimétriste de la marge sur copie de la fiche en T si différent du				
			Confusion					
	Non prise en compte d'une consigne de modification du médecin	Traitement erroné	Oubli	/	4	2	4	32
	Expansion sur un mauvais volume	Traitement erroné	Erreur humaine	Visible sur la dosimétrie	4	4	4	21
				Contrôle du médecin				
	Expansion sur des traces involontairement dessinées en dehors du volume cible	Traitement erroné	Mauvais "clic" sur l'image	+/- Visible sur la dosimétrie	4	3	2	21
		Perte de temps		Contrôle du médecin				
Vérifie ou modifie les coordonnées de l'origine utilisateur	Non réalisation du recalage de l'origine utilisateur	Décalage traitement	Oubli de saisie	/	3	3	2	14
			Information non transmise	Fiche de liaison				
	Saisie de valeurs erronées		Erreur humaine	/	3	3	2	17
			Mauvais prise en compte des coordonnées du 1er traitement	/				
Repositionnement d'un ancien plan de traitement	Mauvais positionnement de l'ancien isocentre	Dosimétrie cumulée erronée	Mauvaise superposition d'image	Parfois vérification autre dosimétriste, physicien ou radiohtérapeute	4	3	3	31
	Mauvaise reproduction des paramètres d'irradiation	Dosimétrie cumulée erronée	Erreur dans la restranscription de l'ancien traitement	/	5	3	4	46

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Process Chart 'Dosimetry' Rating

Step	Possible failure mode	Possible effects	Possible causes	Surveillance plan /	Rating			
Contoure les volumes cibles	Contourage mal effectué	Traitement erroné	Confusion de patient Confusion de choix du volume Confusion de latéralité Manque d'information pour réaliser le contour (IRM,…)	Pour le sein : présence du CR opératoire avec la fiche en T	4	2	4	34
Vérifie les contours réalisés	Pas de vérification	Contours et DVH erronés	Manque de temps Excès de confiance Contours non réalisés	/ / /	4	4	4	60
Expansion des volumes cibles, rajout/modification de volumes	Erreur de valeur de marge pour PTV	Traitement erroné	Consignes erronées Erreur de saisie Confusion	/ Inscription par dosimétriste de la marge sur copie de la fiche en T si différent du	4	2	2	17
	Non prise en compte d'une consigne de modification du médecin	Traitement erroné	Oubli	/	4	2	4	32
	Expansion sur un mauvais volume	Traitement erroné	Erreur humaine	Visible sur la dosimétrie Contrôle du médecin	4	4	4	21
	Expansion sur des traces involontairement dessinées en dehors du volume cible	Traitement erroné Perte de temps	Mauvais "clic" sur l'image	+/- Visible sur la dosimétrie Contrôle du médecin	4	3	2	21
Vérifie ou modifie les coordonnées de l'origine utilisateur	Non réalisation du recalage de l'origine utilisateur	Décalage traitement	Oubli de saisie Information non transmise	/ Fiche de liaison	3	3	2	14
	Saisie de valeurs erronées		Erreur humaine Mauvais prise en compte des coordonnées du 1er traitement	/ /	3	3	2	17
Repositionnement d'un ancien plan de traitement	Mauvais positionnement de l'ancien isocentre	Dosimétrie cumulée erronée	Mauvaise superposition d'image	Parfois vérification autre dosimétriste, physicien ou radiothérapeute	4	3	3	31
	Mauvaise reproduction des paramètres d'irradiation	Dosimétrie cumulée erronée	Erreur dans la restranscription de l'ancien traitement	/	3	3	4	46

Vérifies contours

Lack of Time

No verification

Error on contour and DVH

Excess of confidence

Contours not realized

Repositionning of former treatment

Wrong Repositionning of isocentre

Wrong calculation of Dosimetry

Wrong superposition of images

Wrong reproduction of treatment parameters

Error in tretment parameters re-transcrition

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Process Chart
Corrective actions

Acceptable risks are dealt with

- Procedures (like 'Treatment of Prostate Cancer')
- Check-lists (ex.: 3D-CRT or IMRT dosimetry)

Inacceptable risks are dealt with

- Internal Rules (like OPMP)
- Dedicated To Do-Lists (ex.: Brain met. Stereo. RT)
- Check-lists on never-events (errors on pt. ID, volume, side or dose)

Process Chart
Check lists – 3D-CRT or IMRT

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Liste de vérifications avant mise en traitement 3D conformationnel

NIP : **Date :** / /20 **Physicien :** **Localisation :**

DOCUMENTS NECESSAIRES A LA VALIDATION

O Prescription médicale	O Rapport de dosimétrie ARIA
O Fiche de liaison de simulation	O Histogramme dose-volume + Impression dosimétrie
O Fiche de traitement + photos + BEV (vue à la peau)	O/NA Fiche set-up et vue à la peau
O Rapport double calcul (IMSURE)	O/NA Fiche de repositionnement

INFORMATIONS GENERALES

du patient	O identité du patient	O NIP du patient	O Radiothérapeute référent
de simulation	O oui /O non : Informations de simulation et notes OK O/NA Si traitement en BIP : le litrage du patient	O oui /O non : Décalage laser O Photos identité/position/contention/tatouage	O oui /O non/NA : Si oui, report sur la dosimétrie O/NA Traitement 4D
de traitement	O Cohérence ARIA/fiche de traitement : nombre de séances/rendez-vous O Cohérence ARIA/fiche de traitement : appareil déclaré O Oui /O Non : Ancien traitement O/NA Si oui, fiche « ancien traitement » remplie et signée	O Cohérence ARIA/fiche de traitement : Dates des rendez-vous O/NA Si plusieurs parties, chronologie rendez-vous conforme O/NA Repositionnement non nécessaire	O/NA Cohérence ARIA/fiche traitement : Date du CT de réduction
de dosimétrie in vivo	O oui /O non/NA : Alerte DIV créée pour la 2eme séance	O oui /O non/NA : Informations sur les faisceaux mesurables fournies	

FICHE DE TRAITEMENT

O Feuille de traitement adapté	O Nombre de séances (recto et verso)	O Nombre de RDV complété
O Modalités et périodicités de l'IGRT	O/NA Si plusieurs parties, conforme	O Oui /O Non/NA : Repos entre les parties signalé + RDVs OK

Planification de radiothérapie – ECLIPSE -

Général	O/NA Ancien(s) dossier(s) traitement et AQ clos	O / NA Si nécessaire séance à blanc prévue	O / NA Têtière mobile nécessaire
Prescription	Dose totale (Gy) ... Gy	Dose par séance (Gy) ... Gy	Nombre de fractions ...
Origine utilisateur / isocentre	O/NA Si décalage laser, report sur la dosimétrie O/NA Si monoisocentre position OK O/NA POST en 180°E (si nécessaire) O/NA Si autre CT pour réduction ou modification, isocentre OK	O Vérification du zéro CT/ billes O/NA Si FinF, nombre d'UM par sous faisceaux > 5 UM O/NA Si Isocentre non médian et/ou HT élevée, spécification du risque collision O/NA Repositionnement(s) réalisé(s) conforme(s)	O Position de l'isocentre report OK sur fiche de TTT
Contourage	O/NA Contour externe O/NA Présence de la table	O/NA Contours des OAR O/NA UH affectés à la table OK	O/NA Marge(s) CTV – PTV O/NA Position de la table OK
Etude des champs	O Cohérence nom/numéro/ angle du bras O Projections entrée et sortie des faisceaux O/NA Si BIP, débit 600 UM/min sauf pour les faisceaux filtrés et FinF O Isocentre identique pour l'ensemble des faisceaux	O/NA Conformation des lames / PTV	O/NA Faisceaux filtrés : nom du champ, >21UM O/NA Pertinence de l'utilisation du filtre O/NA Fuite si nécessaire (exemple TGI-TGE) O Energie choisie pertinente
Etude des points	O Cohérence nom(s)/numéro(s) des point(s) O/NA Si 2 parties : création du point alerte	O Position du point (build-up, zone homogène, 2 cm bord des lames, si FinF 0.7 cm ss-champs) O/NA Deux points (xC et xP) créés si prescription sur isodose autre que 100%	
Etude en dose	Remarque(s) :		
Imagerie de positionnement	O Faisceaux de positionnement adaptés O Optimisation angulations fx de position	O Taille de champ fx de position O Optimisation des DRR	O Position de l'isocentre OK

Version 1 mise en ligne le 19/05/2013

ENREGISTREMENT — Date d'application 14/05/2013 — RTH.EN.009 — Version 1 — Page 1/2

Liste de vérifications avant mise en traitement par RCMI

NIP : **Date :** / / 20 **Physicien :** **Localisation :**

DOCUMENTS NECESSAIRES A LA VALIDATION

O Prescription médicale	O Rapport de dosimétrie ARIA O/NA Feuilles validation stéréo.
O Fiche de liaison de simulation	O Histogramme dose-volume + Impression dosimétrie
O Fiche de traitement + photos + BEV (vue à la peau)	O/NA Rapport EPIQA
O Rapport double calcul (IMSURE)	O/NA Fiche de repositionnement

INFORMATIONS GENERALES

du patient	O identité du patient	O NIP du patient	O Radiothérapeute référent
de simulation	O oui /O non : Informations de simulation et notes OK O/NA Si traitement en BIP : le litrage du patient O/NA Stéréotaxie intracrânienne	O oui /O non : Décalage laser O Photos identité/position/contention/tatouage O/NA Stéréotaxie extracrânienne	O oui /O non/NA : Si oui, report sur la dosimétrie O/NA Traitement 4D
de traitement	O Cohérence ARIA/fiche de traitement : nombre de séances/rendez-vous O Cohérence ARIA/fiche de traitement : appareil déclaré O Oui /O Non : Ancien traitement O/NA Si oui, fiche « ancien traitement » remplie et signée	O Cohérence ARIA/fiche de traitement : Dates des rendez-vous O/NA Si plusieurs parties, chronologie rendez-vous conforme O/NA Repositionnement non nécessaire	

FICHE DE TRAITEMENT

O Feuille de traitement adapté	O Nombre de séances (recto et verso)	O Nombre de RDV complété
O/NA Modalités et périodicités de l'IGRT	O/NA Si plusieurs parties, conforme	O Oui /O Non/NA : Repos entre les parties signalé + RDVs OK

Planification de radiothérapie – ECLIPSE -

Général	O Ancien(s) dossier(s) traitement et AQ clos	O/NA Si nécessaire traitement l'impose séance à blanc prévue	
Prescription	Dose totale (Gy) ... Gy	Dose par séance (Gy) ... Gy	O Nombre de fractions ...
Origine utilisateur / isocentre	O/NA Si décalage laser, report sur la dosimétrie O Position de l'isocentre cohérente/PTV O/NA Si autre CT pour réduction ou modification, isocentre OK	O Vérification du zéro CT/ billes O/NA Si Isocentre non médian et/ou HT élevée, spécification du risque collision O/NA Repositionnement(s) réalisé(s) conforme(s)	O Position de l'isocentre report OK sur fiche de TTT
Contourage	O Contour externe O/NA Présence de la table O/NA Volumes d'optimisation (PTV opt/overlap)	O Contours des OAR O/NA UH affectés à la table OK O/NA Peau + 3mm	O Marge(s) CTV - PTV O/NA Position de la table OK O/NA Contour rectum 4 coupes / PTV
Etude des champs	O Cohérence nom/numéro/ angles du bras O Géométrie des arcs OK (angle départ/fin, nombre) O Isocentre identique pour l'ensemble des faisceaux	O Position des machoires / PTV	O Machine, énergies, débits OK O Oui /O Non : rotations de collimateurs optimales O Nombre d'UM cohérent par arc
Optimisation	O Pertinence des critères d'opt. choisis	O/NA Objectifs tissus sains	O Oui /O Non Présence de petits segments
Etude des points	O Cohérence nom/numéro du point	O Point de référence virtuel	O/NA Si 2 parties : création du point alerte
Etude en dose	O Remarques :		
Imagerie de positionnement	O Faisceaux de positionnement adaptés O Optimisation angulations fx de position	O Taille de champ fx de position. O Optimisation des DRR	O Position de l'isocentre OK

Version 1 mise en ligne le 19/05/2013

ESTRO School

Process Chart
Check lists – 3D-CRT or IMRT

Exhaustive and passive

Made of critical points to handle carefully <u>before</u> the onset of RT

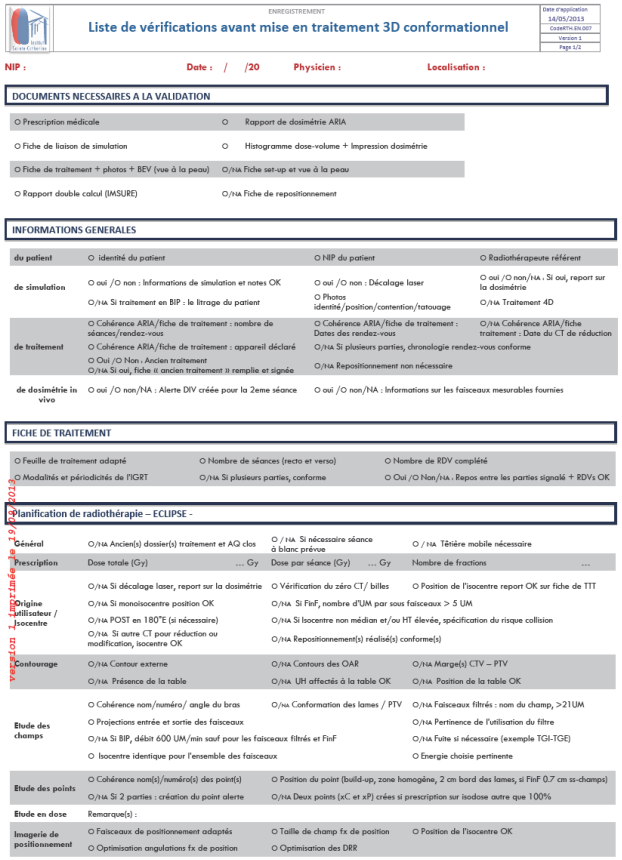
Cross-control of one dosimetrist work by the Physicist

Derives from

- Internal rules and Procedures
- CREX expertise and Process review

Dynamic

- Can evolve with time
- Collegial piece of work
- Adapted to one department



ENREGISTREMENT

Liste de vérifications avant mise en traitement 3D conformationnel

Date d'application 14/05/2013 — CodeRTH.EN.007 — Version 1 — Page 1/2

NIP : Date : / /20 Physicien : Localisation :

DOCUMENTS NECESSAIRES A LA VALIDATION

O Prescription médicale	O Rapport de dosimétrie ARIA
O Fiche de liaison de simulation	O Histogramme dose-volume + Impression dosimétrie
O Fiche de traitement + photos + BEV (vue à la peau)	O/NA Fiche set-up et vue à la peau
O Rapport double calcul (IMSURE)	O/NA Fiche de repositionnement

INFORMATIONS GENERALES

du patient	O identité du patient	O NIP du patient	O Radiothérapeute référent
de simulation	O oui /O non : Informations de simulation et notes OK O/NA Si traitement en BIP : le litrage du patient	O oui /O non : Décalage laser O Photos identité/position/contention/tatouage	O oui /O non/NA : Si oui, report sur la dosimétrie O/NA Traitement 4D
de traitement	O Cohérence ARIA/fiche de traitement : nombre de séances/rendez-vous O Cohérence ARIA/fiche de traitement : appareil déclaré O Oui /O Non : Ancien traitement O/NA Si oui, fiche « ancien traitement » remplie et signée	O Cohérence ARIA/fiche de traitement : Dates des rendez-vous O/NA Si plusieurs parties, chronologie rendez-vous conforme O/NA Repositionnement non nécessaire	O/NA Cohérence ARIA/fiche traitement : Date du CT de réduction
de dosimétrie in vivo	O oui /O non/NA : Alerte DIV créée pour la 2eme séance	O oui /O non/NA : Informations sur les faisceaux mesurables fournies	

FICHE DE TRAITEMENT

O Feuille de traitement adapté	O Nombre de séances (recto et verso)	O Nombre de RDV complété
O Modalités et périodicités de l'IGRT	O/NA Si plusieurs parties, conforme	O Oui /O Non/NA : Repos entre les parties signalé + RDVs OK

Planification de radiothérapie – ECLIPSE -

Général	O/NA Ancien(s) dossier(s) traitement et AQ clos	O / NA Si nécessaire séance à blanc prévue	O / NA Tête mobile nécessaire
Prescription	Dose totale (Gy) ... Gy	Dose par séance (Gy) ... Gy	Nombre de fractions ...
Origine utilisateur / isocentre	O/NA Si décalage laser, report sur la dosimétrie O/NA Si monoisocentre position OK O/NA POST en 180°E (si nécessaire) O/NA Si autre CT pour réduction ou modification, isocentre OK	O Vérification du zéro CT/ billes O/NA Si FinF, nombre d'UM par sous faisceaux > 5 UM O/NA Si Isocentre non médian et/ou HT élevée, spécification du risque collision O/NA Repositionnement(s) réalisé(s) conforme(s)	O Position de l'isocentre report OK sur fiche de TTT
Contourage	O/NA Contour externe O/NA Présence de la table	O/NA Contours des OAR O/NA UH affectés à la table OK	O/NA Marge(s) CTV – PTV O/NA Position de la table OK
Etude des champs	O Cohérence nom/numéro/ angle du bras O Projections entrée et sortie des faisceaux O/NA Si BIP, débit 600 UM/min sauf pour les faisceaux filtrés et FinF O Isocentre identique pour l'ensemble des faisceaux	O/NA Conformation des lames / PTV	O/NA Faisceaux filtrés : nom du champ, >21UM O/NA Pertinence de l'utilisation du filtre O/NA Fuite si nécessaire (exemple TGI-TGE) O Energie choisie pertinente
Etude des points	O Cohérence nom(s)/numéro(s) des point(s) O/NA Si 2 parties : création du point alerte	O Position du point (build-up, zone homogène, 2 cm bord des lames, si FinF 0.7 cm ss-champs) O/NA Deux points (xC et xP) créés si prescription sur isodose autre que 100%	
Etude en dose	Remarque(s) :		
Imagerie de positionnement	O Faisceaux de positionnement adaptés O Optimisation angulations fx de position	O Taille de champ fx de position O Optimisation des DRR	O Position de l'isocentre OK

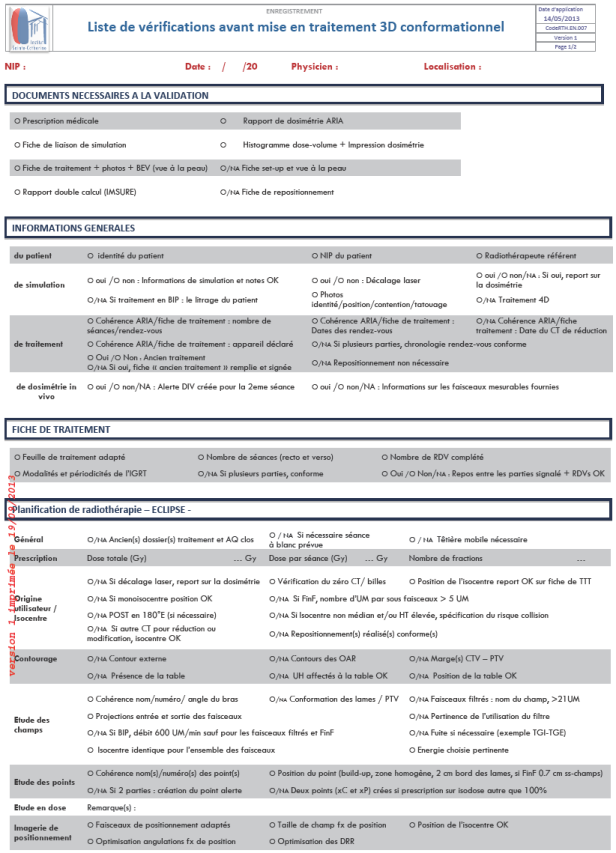
version 1 imprimée le 19/05/2013

➔ NEVER COPY AND PASTE

ESTRO School

Process Chart
Check lists – 3D-CRT or IMRT

- Is a procedure *per se*
- Made by a physicist who did not get involved in prepping the plan
- Mandatory before starting any treatment
- Generic Points to be verified
  - Documentation
  - Prescription
  - Previous Radiation Therapy
  - ARIA® Report on RT Chart ®
  - Signatures



ENREGISTREMENT

Liste de vérifications avant mise en traitement 3D conformationnel

Date d'application 14/05/2013 — CodeETH.EN.007 — Version 1 — Page 1/2

NIP : Date : / /20 Physicien : Localisation :

DOCUMENTS NECESSAIRES A LA VALIDATION

O Prescription médicale	O Rapport de dosimétrie ARIA
O Fiche de liaison de simulation	O Histogramme dose-volume + Impression dosimétrie
O Fiche de traitement + photos + BEV (vue à la peau)	O/NA Fiche set-up et vue à la peau
O Rapport double calcul (IMSURE)	O/NA Fiche de repositionnement

INFORMATIONS GENERALES

du patient	O identité du patient	O NIP du patient	O Radiothérapeute référent
de simulation	O oui /O non : Informations de simulation et notes OK O/NA Si traitement en BIP : le litrage du patient	O oui /O non : Décalage laser O Photos identité/position/contention/tatouage	O oui /O non/NA : Si oui, report sur la dosimétrie O/NA Traitement 4D
de traitement	O Cohérence ARIA/fiche de traitement : nombre de séances/rendez-vous O Cohérence ARIA/fiche de traitement : appareil déclaré O Oui /O Non : Ancien traitement O/NA Si oui, fiche ci ancien traitement ci remplie et signée	O Cohérence ARIA/fiche de traitement : Dates des rendez-vous O/NA Si plusieurs parties, chronologie rendez-vous conforme O/NA Repositionnement non nécessaire	O/NA Cohérence ARIA/fiche traitement : Date du CT de réduction
de dosimétrie in vivo	O oui /O non/NA : Alerte DIV créée pour la 2eme séance	O oui /O non/NA : Informations sur les faisceaux mesurables fournies	

FICHE DE TRAITEMENT

O Feuille de traitement adapté	O Nombre de séances (recto et verso)	O Nombre de RDV complété
O Modalités et périodicités de l'IGRT	O/NA Si plusieurs parties, conforme	O Oui /O Non/NA : Repos entre les parties signalé + RDVs OK

Planification de radiothérapie – ECLIPSE -

Général	O/NA Ancien(s) dossier(s) traitement et AQ clos	O / NA Si nécessaire séance à blanc prévue	O / NA Tâtière mobile nécessaire
Prescription	Dose totale (Gy) ... Gy	Dose par séance (Gy) ... Gy	Nombre de fractions ...
Origine utilisateur / isocentre	O/NA Si décalage laser, report sur la dosimétrie O/NA Si monoisocentre position OK O/NA POST en 180°E (si nécessaire) O/NA Si autre CT pour réduction ou modification, isocentre OK	O Vérification du zéro CT/ billes O/NA Si FinF, nombre d'UM par sous faisceaux > 5 UM O/NA Si isocentre non médian et/ou HT élevée, spécification du risque collision O/NA Repositionnement(s) réalisé(s) conforme(s)	O Position de l'isocentre report OK sur fiche de TTT
Contourage	O/NA Contour externe O/NA Présence de la table	O/NA Contours des OAR O/NA UH affectés à la table OK	O/NA Marge(s) CTV – PTV O/NA Position de la table OK
Etude des champs	O Cohérence nom/numéro/ angle du bras O Projections entrée et sortie des faisceaux O/NA Si BIP, débit 600 UM/min sauf pour les faisceaux filtrés et FinF O Isocentre identique pour l'ensemble des faisceaux	O/NA Conformation des lames / PTV	O/NA Faisceaux filtrés : nom du champ, >21UM O/NA Pertinence de l'utilisation du filtre O/NA Fuite si nécessaire (exemple TGI-TGE) O Energie choisie pertinente
Etude des points	O Cohérence nom(s)/numéro(s) des point(s) O/NA Si 2 parties : création du point alerte	O Position du point (build-up, zone homogène, 2 cm bord des lames, si FinF 0.7 cm ss-champs) O/NA Deux points (xC et xP) crées si prescription sur isodose autre que 100%	
Etude en dose	Remarque(s) :		
Imagerie de positionnement	O Faisceaux de positionnement adaptés O Optimisation angulations fx de position	O Taille de champ fx de position O Optimisation des DRR	O Position de l'isocentre OK

version 1 imprimée le 19/06/2013

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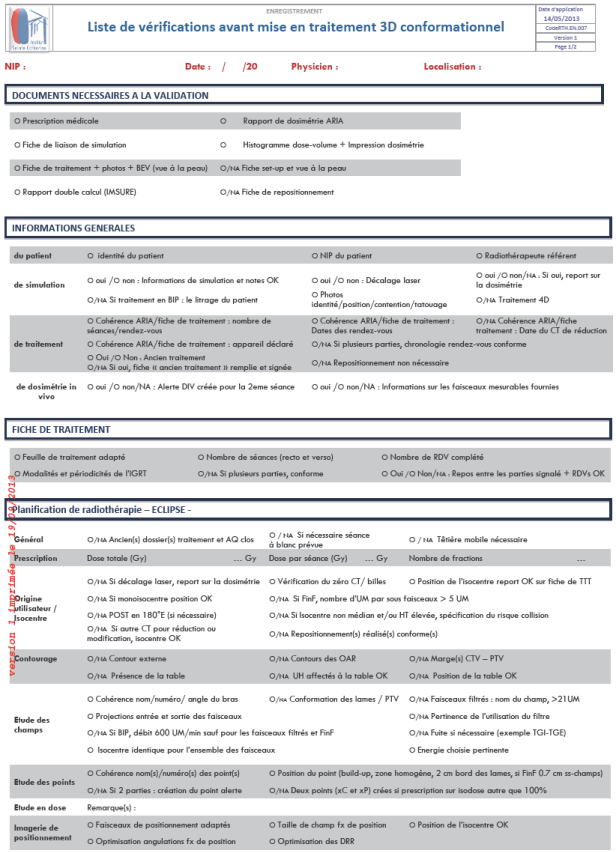
Process Chart
Check lists – 3D-CRT or IMRT

Specific points checked For 3D-CRT

- Checks on isocenter and table position
- Ballistics and choice of Energy
- Fields 'in-field' or wedge filter optimization

Double dose calculation

- With IMSure®
- Mandatory by Law



ENREGISTREMENT

Liste de vérifications avant mise en traitement 3D conformationnel

Date d'application 14/05/2013 | CodeITN.EN.007 | Version 1 | Page 1/2

NIP : **Date : / /20** **Physicien :** **Localisation :**

DOCUMENTS NECESSAIRES A LA VALIDATION

O Prescription médicale	O Rapport de dosimétrie ARIA
O Fiche de liaison de simulation	O Histogramme dose-volume + Impression dosimétrie
O Fiche de traitement + photos + BEV (vue à la peau)	O/NA Fiche set-up et vue à la peau
O Rapport double calcul (IMSURE)	O/NA Fiche de repositionnement

INFORMATIONS GENERALES

du patient	O identité du patient	O NIP du patient	O Radiothérapeute référent
de simulation	O oui /O non : Informations de simulation et notes OK O/NA Si traitement en BIP : le litrage du patient	O oui /O non : Décalage laser O Photos identité/position/contention/tatouage	O oui /O non/NA : Si oui, report sur la dosimétrie O/NA Traitement 4D
de traitement	O Cohérence ARIA/fiche de traitement : nombre de séances/rendez-vous O Cohérence ARIA/fiche de traitement : appareil déclaré O Oui /O Non : Ancien traitement O/NA Si oui, fiche « ancien traitement » remplie et signée	O Cohérence ARIA/fiche de traitement : Dates des rendez-vous O/NA Si plusieurs parties, chronologie rendez-vous conforme O/NA Repositionnement non nécessaire	O/NA Cohérence ARIA/fiche traitement : Date du CT de réduction
de dosimétrie in vivo	O oui /O non/NA : Alerte DIV créée pour la 2eme séance	O oui /O non/NA : Informations sur les faisceaux mesurables fournies	

FICHE DE TRAITEMENT

O Feuille de traitement adapté	O Nombre de séances (recto et verso)	O Nombre de RDV complété
O Modalités et périodicités de l'IGRT	O/NA Si plusieurs parties, conforme	O Oui /O Non/NA : Repos entre les parties signalé + RDVs OK

Planification de radiothérapie – ECLIPSE -

Général	O/NA Ancien(s) dossier(s) traitement et AQ clos	O / NA Si nécessaire séance à blanc prévue	O / NA Tâtière mobile nécessaire
Prescription	Dose totale (Gy) ... Gy	Dose par séance (Gy) ... Gy	Nombre de fractions ...
Origine utilisateur / isocentre	O/NA Si décalage laser, report sur la dosimétrie O/NA Si monoisocentre position OK O/NA POST en 180°E (si nécessaire) O/NA Si autre CT pour réduction ou modification, isocentre OK	O Vérification du zéro CT/ billes O/NA Si FinF, nombre d'UM par sous faisceaux > 5 UM O/NA Si isocentre non médian et/ou HT élevée, spécification du risque collision O/NA Repositionnement(s) réalisé(s) conforme(s)	O Position de l'isocentre report OK sur fiche de TTT
Contourage	O/NA Contour externe O/NA Présence de la table	O/NA Contours des OAR O/NA UH affectés à la table OK	O/NA Marge(s) CTV – PTV O/NA Position de la table OK
Etude des champs	O Cohérence nom/numéro/ angle du bras O Projections entrée et sortie des faisceaux O/NA Si BIP, débit 600 UM/min sauf pour les faisceaux filtrés et FinF O Isocentre identique pour l'ensemble des faisceaux	O/NA Conformation des lames / PTV	O/NA Faisceaux filtrés : nom du champ, >21UM O/NA Pertinence de l'utilisation du filtre O/NA Fuite si nécessaire (exemple TGI-TGE) O Energie choisie pertinente
Etude des points	O Cohérence nom(s)/numéro(s) des point(s) O/NA Si 2 parties : création du point alerte	O Position du point (build-up, zone homogène, 2 cm bord des lames, si FinF 0.7 cm ss-champs) O/NA Deux points (xC et xP) créés si prescription sur isodose autre que 100%	
Etude en dose	Remarque(s) :		
Imagerie de positionnement	O Faisceaux de positionnement adaptés O Optimisation angulations fx de position	O Taille de champ fx de position O Optimisation des DRR	O Position de l'isocentre OK

version 1 imprimée le 19/12/2013

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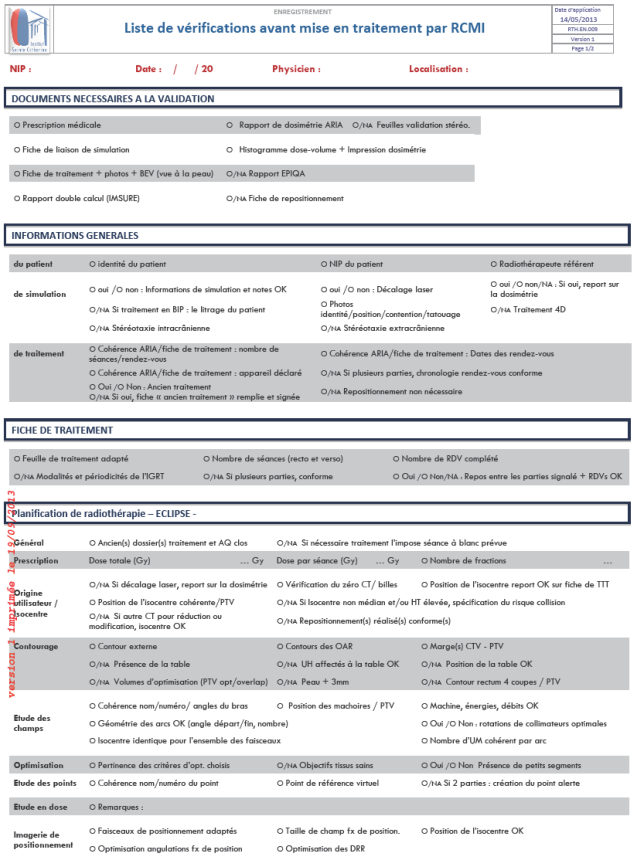
Process Chart
Check lists – 3D-CRT or IMRT

Specific points checked For IMRT

- Checks on planification are re-inforced (isocenter contouring)
- Collimator rotation
- Mouvements of MLC visually checked for coherence
- Optimisation criteria and dose to OAR is verified

Double dose calculation

- With gamma analysis (IM Sure®)
- Mandatory by Law



ENREGISTREMENT

Liste de vérifications avant mise en traitement par RCMI

Date d'application 14/05/2013 | RTH.EN.009 | Version 1 | Page 1/2

NIP : **Date :** / / 20 **Physicien :** **Localisation :**

DOCUMENTS NECESSAIRES A LA VALIDATION

O Prescription médicale	O Rapport de dosimétrie ARIA O/NA Feuilles validation stéréo.	
O Fiche de liaison de simulation	O Histogramme dose-volume + Impression dosimétrie	
O Fiche de traitement + photos + BEV (vue à la peau)	O/NA Rapport EPIQA	
O Rapport double calcul (IMSURE)	O/NA Fiche de repositionnement	

INFORMATIONS GENERALES

du patient	O identité du patient	O NIP du patient	O Radiothérapeute référent
de simulation	O oui /O non : Informations de simulation et notes OK O/NA Si traitement en BIP : le lit-rage du patient O/NA Stéréotaxie intracrânienne	O oui /O non : Décalage laser O Photos identité/position/contention/tatouage O/NA Stéréotaxie extracrânienne	O oui /O non/NA : Si oui, report sur la dosimétrie O/NA Traitement 4D
de traitement	O Cohérence ARIA/fiche de traitement : nombre de séances/rendez-vous O Cohérence ARIA/fiche de traitement : appareil déclaré O Oui /O Non : Ancien traitement O/NA Si oui, fiche « ancien traitement » remplie et signée	O Cohérence ARIA/fiche de traitement : Dates des rendez-vous O/NA Si plusieurs parties, chronologie rendez-vous conforme O/NA Repositionnement non nécessaire	

FICHE DE TRAITEMENT

O Feuille de traitement adapté	O Nombre de séances (recto et verso)	O Nombre de RDV complété
O/NA Modalités et périodicités de l'IGRT	O/NA Si plusieurs parties, conforme	O Oui /O Non/NA : Repos entre les parties signalé + RDVs OK

Planification de radiothérapie – ECLIPSE -

Général	O Ancien(s) dossier(s) traitement et AQ clos	O/NA Si nécessaire traitement l'impose séance à blanc prévue	
Prescription	Dose totale (Gy) ... Gy	Dose par séance (Gy) ... Gy	O Nombre de fractions ...
Origine Utilisateur / Isocentre	O/NA Si décalage laser, report sur la dosimétrie O Position de l'isocentre cohérente/PTV O/NA Si autre CT pour réduction ou modification, isocentre OK	O Vérification du zéro CT/ billes O/NA Si Isocentre non médian et/ou HT élevée, spécification du risque collision O/NA Repositionnement(s) réalisé(s) conforme(s)	O Position de l'isocentre report OK sur fiche de TTT
Contourage	O Contour externe O/NA Présence de la table O/NA Volumes d'optimisation (PTV opt/overlap)	O Contours des OAR O/NA UH affectés à la table OK O/NA Peau + 3mm	O Marge(s) CTV - PTV O/NA Position de la table OK O/NA Contour rectum 4 coupes / PTV
Etude des champs	O Cohérence nom/numéro/ angles du bras O Géométrie des arcs OK (angle départ/fin, nombre) O Isocentre identique pour l'ensemble des faisceaux	O Position des machoires / PTV	O Machine, énergies, débits OK O Oui /O Non : rotations de collimateurs optimales O Nombre d'UM cohérent par arc
Optimisation	O Pertinence des critères d'opt. choisis	O/NA Objectifs tissus sains	O Oui /O Non Présence de petits segments
Etude des points	O Cohérence nom/numéro du point	O Point de référence virtuel	O/NA Si 2 parties : création du point alerte
Etude en dose	O Remarques :		
Imagerie de positionnement	O Faisceaux de positionnement adaptés O Optimisation angulations fx de position	O Taille de champ fx de position. O Optimisation des DRR	O Position de l'isocentre OK

version imprimée le 10/05/2013

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Process Chart
To Do list – Brain Met. Stereo. RT

Patient out of dressing room (hh.mm)	
	Done (Y/N)
Place treatment beams and positionning beams in correct order	
Select CB-CT	
Place a radio-opaque marker on carbon fiber head support	
Install patient	
Carve up mask above contralateral eyebrows.	
Place mask et radio-opaque marker on patient	
Perform shifts and markings	
Place a radio-opaque marker on mask at isocenter	
Acquire CBCT and perform 3D-registration of table shifts 3D	
Acquire kV image 'Ant Head-AP' (270°-Arm) Record distances of points to graduation axis	
Acquire KV image 'Post Head-AP' (90°-Arm) Record distances of points to graduation axis	
Deliver first transverse Arc Table at 0°	
Select KV-270° (90°-Arm)	
Entrer room	
Measure table height / laser Table at 0°	
Shift arm to 0°	
Turn table to 270°	
Check for table height / laser Table at 270°	
Acquire KV Post image Check for Distances from points to graduation axis et compare to values recorded for table at 0°	
Retract OBI	
Deliver non coplanar Arc Table at 270°	
Select beam KV 315° (90°-Arm)	
Enter room	
Shift arm to 0°	
Turn table to 315°	
Check for table height / laser Table at 315°	
Shift arm to 270 °	
Acquire KV Post image Check for Distances from points to graduation axis et compare to values recorded for table at 0°	
Retract OBI	
Deliver non coplanar Arc Table at 315°	
Select KV-45° (270°-arm)	
Enter room	
Shift arm to 0°	
Turn table to 45°	
Check for table height / laser	
Shift arm to 90°	
Acquire KV Ant image Check for Distances from points to graduation axis et compare to values recorded for table at 0°	
Retract OBI	
Delivre non coplanar arc Table at 45°	
Enter room and help patient out	
Patient back in dressing room (hh/mm)	

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Process Chart
To Do list – Brain Met. Stereo RT

Is a part of a treatment procedure

Made by a Physicist who is involved in treating the patient

The Physician signs the document 'on-line'

And participates in the session

Mandatory <u>while doing</u> any Stereo RT at our center (brain, lung or bone met.)

Each action is performed in a specific order ('*modus operandi*')

- Patient installation
- Table positioning
- Control imaging
- Treatment arcs delivery
- Medical validation

Patient out of dressing room (hh.mm)	
	Done (Y/N)
Place treatment beams and positionning beams in correct order	
Select CB-CT	
Place a radio-opaque marker on carbon fiber head support	
Install patient	
Carve up mask above contralateral eyebrows.	
Place mask et radio-opaque marker on patient	
Perform shifts and markings	
Place a radio-opaque marker on mask at isocenter	
Acquire CBCT and perform 3D-registration of table shifts 3D	
Acquire kV image 'Ant Head-AP' (270°-Arm) Record distances of points to graduation axis	
Acquire KV image 'Post Head-AP' (90°-Arm) Record distances of points to graduation axis	
Deliver first transverse Arc Table at 0°	
Select KV-270° (90°-Arm)	

Process Chart
Check List on 'Never Events'

Is a part of a treatment procedure

Made by a dosimetrist controlling actions of the Physician!

Short questions and few of them ➔ Short and unequivoqual answers

Typically, before the medical validation of a treatment plan

Patient, Volume, Side, Dose (errors on those items : inacceptable)

Interrupted check-list must be restarted from the beginning

'Never Events' (Potential errors on…)	Question	Answer
Patient	Patient « Name » ?	OK / Error
Volume	Volume « Name » ?	OK / Error
Side	R/L/both/none ?	R/L/both/none
Dose	xx Gy/ yy fr./ zz d. ?	xx Gy/ yy fr./ zz d.

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Recommanded readings

References

‘Towards Safer Radiotherapy.’ U.K. Dept. Of Health. www.rcr.ac.uk

‘From technical quality assurance of radiotherapy to a comprehensive quality of service management system.’ Kehoe T, Rugg LJ. Radiat Oncol 1999 ; 51 : 281-90

Meyrieux C, Garcia R, Pourel N et al. ‘Analyser la fiabilité des traitements en radiothérapie : la revue de processus’. Cancer Radiother 2012 ; 16(7) : 613-8

Guide n° 20 de l’ASN/SFPM pour la rédaction du plan d’organisation de la physique médicale (POPM). www.sfpm.asso.fr

Internal Rules, procedures and charts. The writing.

Dr. Nicolas POUREL
ESTRO School

COMPREHENSIVE QUALITY MANAGEMENT
IN RADIOTHERAPY
BRUSSELS (Belgium) – Monday, October 2nd 2017

Thank you for your attention !

Quality Indicators in the IMRT-IGRT era

Pietro Gabriele MD
Radiation Oncology Department
Candiolo Cancer Center
IRCCS-FPO Candiolo (Turin – Italy)

Fondazione del Piemonte per l'Oncologia

ISTITUTO DI CANDIOLO

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Learning objectives and Outline

- Definition and classifications of Quality Indicators
- Methods to define indicators
- Old indicators for 2D-3D Radiotherapy and New indicators for volumetric radiotherapy
- Applications of Quality Indicators in the clinical practice
- Take home message

- Introduction
- Historic background:he long road to perform Quality Indicators
- Definitions and classifications
- How you can made an indicator?
- Why new indicators?
- The QI in the IMRT-IGRT era
- Considerations
- Conclusions

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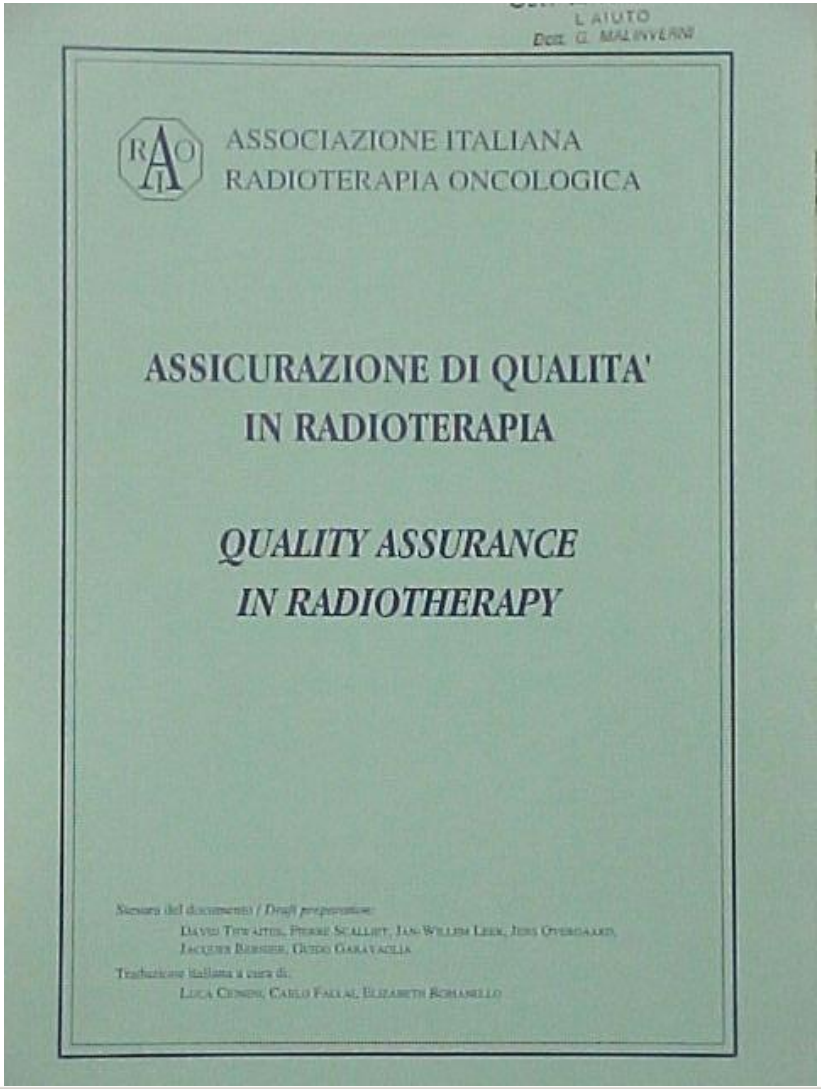
Historic background



The Italian new law on protection against ionizing radiations 1995

1995: The first Italian document translated from ESTRO document

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Historic background: The activity of the first group Quality in Radiotherapy (1998-2003)

This was the first activity to know the state of the art in Italy in order to successively define guideliness of Quality in Radiotherapy

Courses on Quality Controls in Radiotherapy (1998-99)

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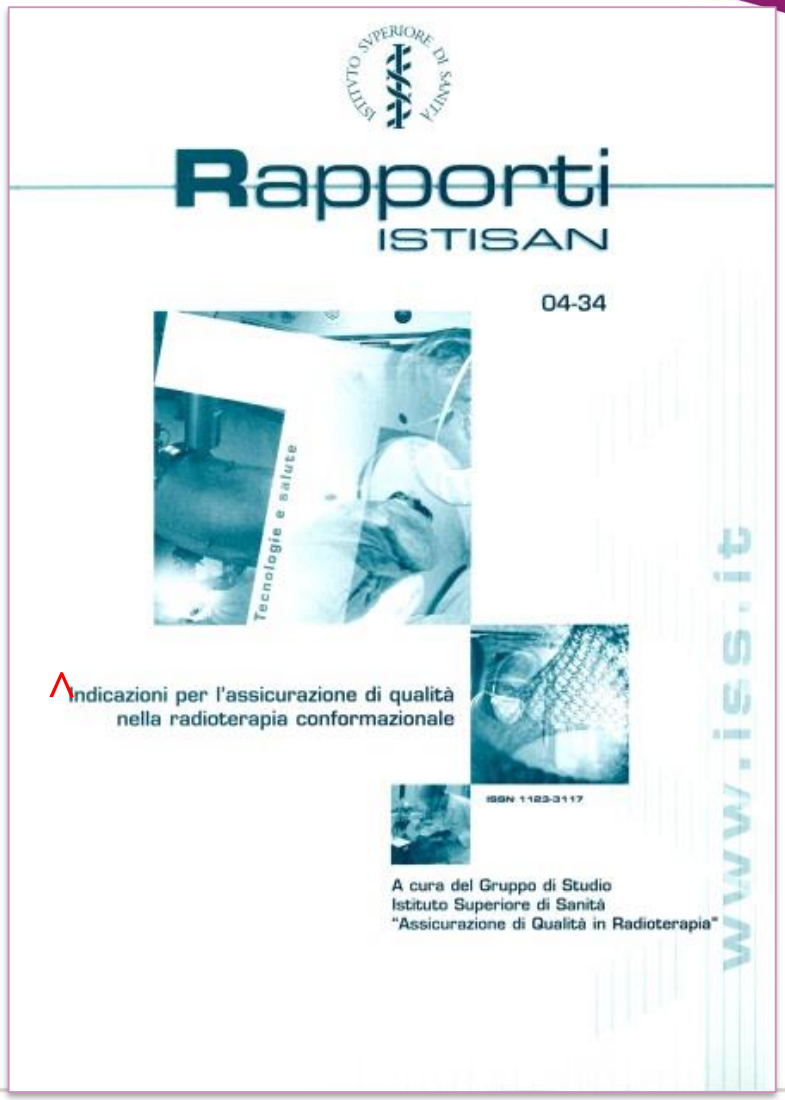
Historic background: the reports by National Health Institute

ISTITUTO SUPERIORE DI SANITÀ

* **Garanzia di qualità in radioterapia. Linee guida in relazione agli aspetti clinici e tecnologici**

Gruppo di studio Istituto Superiore di Sanità
"Assicurazione di Qualità in Radioterapia"

ISSN 1123-3117
Rapporti ISTISAN 02/20



***Guidelinees for Quality Assurance in Radiotherapy (2002)**

^Quality Assurance in 3DCRT (2004)

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The second Italian working group for QA in RT with the aim to built Quality Indicators (2003-2007)

Secondo Gruppo di studio Istituto Superiore di Sanità "Assicurazione di qualità in radioterapia"

M. Benassi (Roma)
A. Bonini (Milano)
L. Conte (Varese)
G. Gardani (Monza)
M. Morelli (Ravenna)
P. Olmi (Milano)
A. Rosi (ISS)
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L. Raffaele (Catania)
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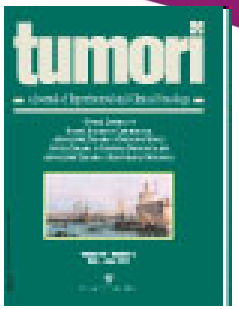
V. Viti (ISS)

Our first paper on the use of QI in the clinical practice



Tumori, 92: 496-502, 2006

ARE QUALITY INDICATORS FOR RADIOTHERAPY USEFUL IN THE EVALUATION OF SERVICE EFFICACY IN A NEW BASED RADIOTHERAPY INSTITUTION?

Pietro Gabriele[1], Giuseppe Malinverni[1], Cristina Bona[1], Manuela Manfredi[2], Elena Delmastro[1], Marco Gatti[1], Giovanni Penduzzu[1], Barbara Baiotto[3], and Michele Stasi[3]

[1]Radiation Therapy Unit, [2]Psychology Service and [3]Medical Physics Unit, Institute for Cancer Research and Treatment, IRCC, Candiolo (Turin), Italy

Table 1 - Quality indicators according to the Italian Institute of Health

Indicator 1	Appropriate number of staff members/patients treated per year
Indicator 2	Waiting list
Indicator 3	Number unplanned equipment stop/year
Indicator 4	Appropriate equipment facilities
Indicator 5	Appropriateness of quality-control programs (quality assurance)
Indicator 6	Case-history accuracy
Indicator 7	Multidisciplinary approach in the study of clinical cases/total number of cases
Indicator 8	Number of CT treatment plans/overall treatments number
Indicator 9	Number of fields performed per fraction/overall treatment fraction
Indicator 10	Number of conformed fields/fraction
Indicator 11	Number of treatments verified by portal imaging/overall treatments
Indicator 12	Number of patients treated/hour
Indicator 13	Patient satisfaction verified by questionnaires filled

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The formal final paper of the Italian group about QI

Radiotherapy and Oncology 82 (2007) 191–200
www.thegreenjournal.com

Quality indicators

Quality indicators in radiotherapy

Luca Cionini[a], Gianstefano Gardani[b], Pietro Gabriele[c], Secondo Magri[d], Pier Luigi Morosini[e], Antonella Rosi[f], Vincenza Viti[f,*], Italian Working Group General Indicators[1]

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Abstract

***Background and purpose*: There is a widespread and increasing tendency to develop hospital performance indicators in the field of accreditation/certification systems and quality benchmarking. A study has been undertaken to develop a set of performance indicators for a typical radiotherapy Centre and to evaluate their ability to provide a continuous quality improvement.**

***Materials and methods*: A working group consisting of radiation oncologists, medical physicists and radiation technologists under the coordination of experts in health technology assessment has elaborated a set of general indicators able to monitor performances and the quality level of a typical radiotherapy Centre.**

The work has been carried out through four steps: a preliminary set of indicators was selected; data on these indicators were collected in a number of Italian radiotherapy Centres and medical physics Services; problems in collection and analysis of data were discussed; a final set of indicators was developed.

***Results*: A final set of 13 indicators is here presented. They concern general structural and/or operational features, health physics activities and accuracy and technical complexity of the treatment.**

***Conclusions*: The indicators tested in a few Italian Centres of radiotherapy and medical physics Services are now ready to be utilized by a larger community.**

Keywords: Quality; Indicators; Radiotherapy

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The application of QI in the QA of 3D-CRT

ELSEVIER

Critical Reviews in Oncology/Hematology 70 (2009) 24–38

CRITICAL REVIEWS IN
Oncology
Hematology
Incorporating Geriatric Oncology

www.elsevier.com/locate/critrevonc

Quality assurance of 3D-CRT: Indications and difficulties in their applications

Luisa Begnozzi[a], Marcello Benassi[b], Mario Bertanelli[c], Antonio Bonini[d], Luca Cionini[e], Leopoldo Conte[f], Claudio Fiorino[d], Pietro Gabriele[g], Gianstefano Gardani[h], Alessandra Giani[i], Secondo Magri[j], Maria Morelli[k], Brunello Morrica[l], Patrizia Olmi[m], Roberto Orecchia[n], Giovanni Penduzzu[g], Luigi Raffaele[o], Antonella Rosi[p,q], M. Antonella Tabocchini[p,q], Riccardo Valdagni[r], Vincenza Viti[p,q,□]

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Accepted 18 July 2008

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Critical review of international literature about QI

International Journal of Radiation Oncology biology • physics

www.redjournal.org

Critical Review

Quality Indicators in Radiation Oncology

Jeffrey M. Albert, MD, MPH, and Prajnan Das, MD, MS, MPH

Department of Radiation Oncology, The University of Texas MD Anderson Cancer Center, Houston, Texas

Received May 9, 2012, and in revised form Aug 28, 2012. Accepted for publication Aug 29, 2012

The primary information source was the National Center for Biotechnology Information PubMed database. All searches were performed in early February 2012. An initial search using the terms "radiation oncology" and "quality" revealed 3080 matching articles. Similarly, "radiotherapy" and "quality" resulted in 13,512 matches, with most results not relevant for the purposes of this review. Thus, more specific terms were used; for example, "radiation oncology" was used in separate searches with the terms "quality indicators," "quality improvement," "quality assessment," "quality measures," and "quality metrics" to search for potentially relevant articles. Next, all of the above-cited search terms were used with the variant term "radiotherapy." Reference lists of identified studies were also reviewed for pertinent articles. Of note, the new journal *Practical Radiation Oncology*, which has a scope that specifically includes quality and safety issues, has not yet been indexed for MEDLINE, so that journal was reviewed manually.

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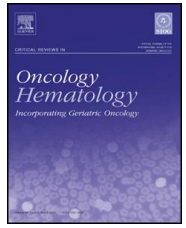
Quality Indicators in the IMRT/IGRT radiotherapy era

Critical Reviews in Oncology/Hematology 108 (2016) 52–61

Contents lists available at ScienceDirect

Critical Reviews in Oncology/Hematology

journal homepage: www.elsevier.com/locate/critrevonc



Quality indicators in the intensity modulated/image-guided radiotherapy era

P. Gabriele (MD)[a,*], A. Maggio[b], E. Garibaldi[a], C. Bracco[b], E. Delmastro[a], D. Gabriele[c], A. Rosi[d], F. Munoz[e], N. Di Muzio[f], R. Corvò[g], M. Stasi[b]

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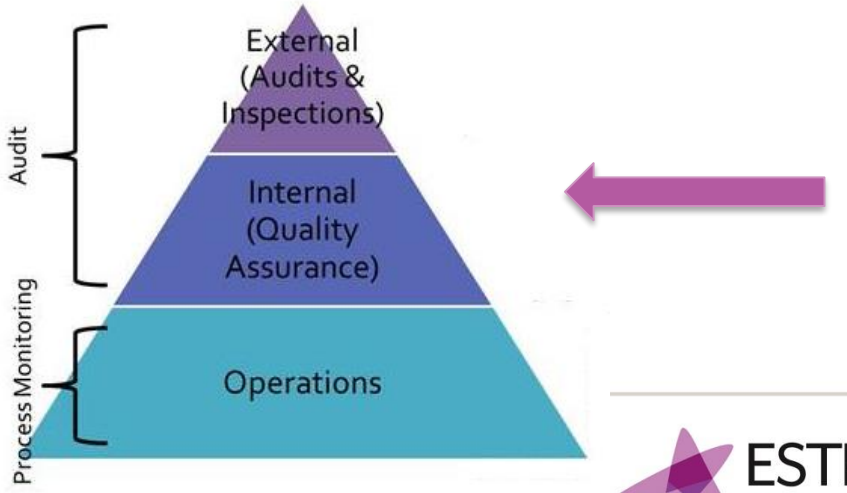
Definition of Quality Indicator

The indicator is an instrument that makes a *"picture"* of a department and allows us to compare the activity of the center with other centers.

The indicators allow us to understand our actions and improve ourselves stimulating the staff with a new *"forma mentis"* to make an *improvement in the quality of the service*.



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Aim of Quality Indicators

The indicators urge us to achieve our objectives by stimulating critical ability to see our strengths and weaknesses and eliminating any false presumption of omnipotence or damaging sense of impotence.

All indicators can guarantee quality concerning technical and clinical aspects of the treatment and organizational training program.

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Type of Indicators

Structure indicators

Process indicator

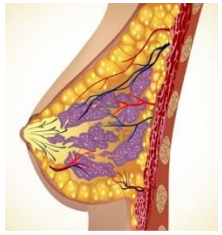
- general indicators

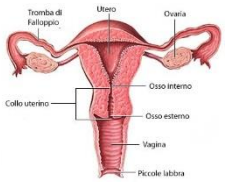
or

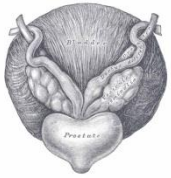
- site specifics indicators

Outcome indicators

- hospital organization
- surgery
- radiotherapy
- medical oncology
- .....







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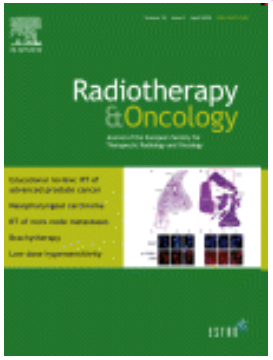
The method to define Indicators

Radiotherapy and Oncology 82 (2007) 191–200
www.thegreenjournal.com

Quality indicators



Quality indicators in radiotherapy

Luca Cionini[a], Gianstefano Gardani[b], Pietro Gabriele[c], Secondo Magri[d], Pier Luigi Morosini[e], Antonella Rosi[f], Vincenza Viti[f,*], Italian Working Group General Indicators[1]

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Table 1
Grid used to define indicators [10]

Items	Definitions
Topic	What you measure
Rationale	Why you measure, which are advantages and the relevance in terms of quality
Type of indicator	Structure, process, outcome
Numerator	Parameter value
Denominator	Reference population
Stratification	Recommended categories for the indicator application
Standard	Reference value
Data collection	Type (population or sample), time period for data collection, frequency, responsible of data collection, of data analysis and interpretation

In general from literature or sometimes new

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The new volumetric radiotherapy: the need for new process indicators (2010)

Why New Indicators?

"Radiation oncology has a long history of leadership in quality of care assessment and continues to work toward defining consensus QIs and appropriate metrics derived from QIs. This is complicated by the continual introduction of complex quality and safety issues by the rapidly emerging technologies that are central to the field».

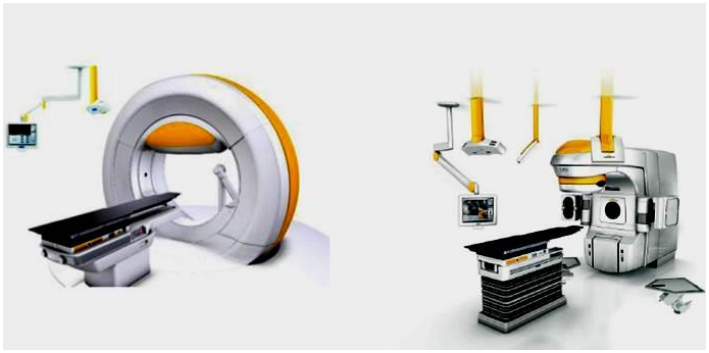
The new volumetric radiotherapy (SBRT & IGRT, IMRT & IGRT, VMAT, robotic RT), contrary to 2D and 3D radiotherapy, is not based on number of fields per treatment, shaped fields od portal vision feasibility because all these features are in the concept of volumetric radiotherapy; because that, we need for new indicators.

2D –> 3DCRT→ IMRT→ Volumetric radiotherapy

«Volumetric radiotherapy is an arc based dose delivery approach that produces highly conformal dose distributions «similar» to dose generated with static gantry IMRT: allows to delivery different high doses at different volumes with maximun sparing of OARs».

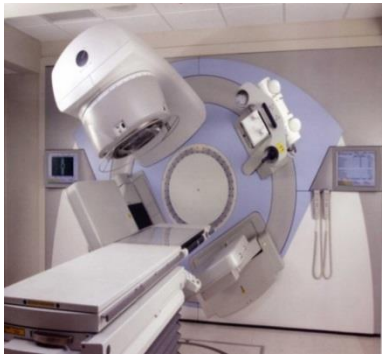
Tomotherapy

Cyberknife

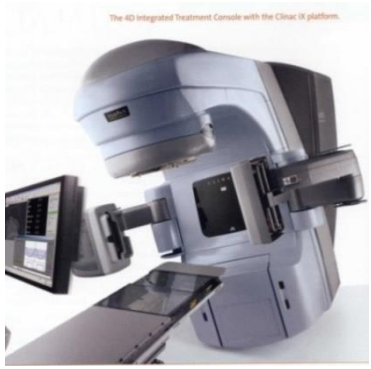


VERO

Brain-Lab



Elekta volumetric



Varian volumetric

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From old (for 2D-3D) to new (for volumetric RT) Quality Indicators

Table 1 - Quality indicators according to the Italian Institute of Health

Indicator 1	Appropriate number of staff members/patients treated per year
Indicator 2	Waiting list
Indicator 3	Number unplanned equipment stop/year
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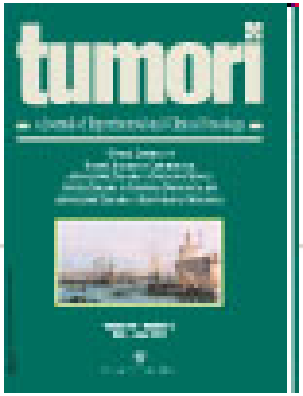
Indicator 13	Patient satisfaction verified by questionnaires filled

Proposed Quality Indicators. Bold, cursive and normal indicate the new proposed indicators, the indicators with new proposed standard and the indicators with now change, respectively.

Indicator 1	*Adequacy of equipment for IMRT/IGRT radiotherapy*
Indicator 2	*Workload*
Indicator 3	*Multidisciplinary approach to patient care*
Indicator 4	**Adequacy of the multi-modality imaging**
Indicator 5	Clinical record quality
Indicator 6	Waiting time
Indicator 7	*Appropriateness of Quality Control programs (quality assurance–QA)*
Indicator 8	**Number of dosimetric controls on patients treated by IMRT/IGRT**
Indicator 9	**Number of MV o CBCT control versus number of RT sessions**
Indicator 10	Number of clinical controls of patient during treatment
Indicator 11	**Number of Adaptive RT**
Indicator 12	**Treatment room occupation time**
Indicator 13	**Number of patients treated in clinical studies**
Indicator 14	**Machine Uptime**



(2003-2010)

(2011-2016)

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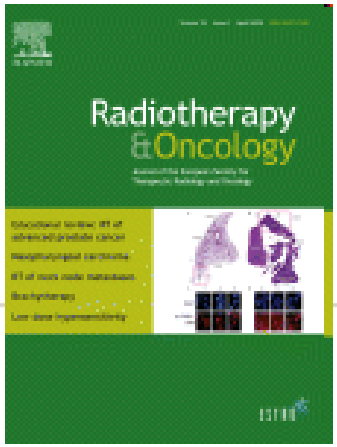
Type of Indicators: Structure Indicators

STRUCTURE INDICATORS

• They assess house, human and technological resources availability



•In figurative language:

"Has our house a defined perimeter?"
"Who and how many peoples are living indoors?"

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Indicator 1– Adequacy of equipment for radiotherapy

Indicator 1	
Topic	Kind of treatment delivered to the patients
Type of indicator	Structure
Numerator	Number of IMRT/IGRT machines
Denominator	Total number of radiotherapy machines
Standard	At least 73%*
Time period for data collection, frequency of analysis	To be checked at least once before clinical activity of the new IMRT/IGRT machine starts.

* The standard is defined according the median number of IMRT machines available in 872 facilities in 27 countries (Grau et al., 2014b).

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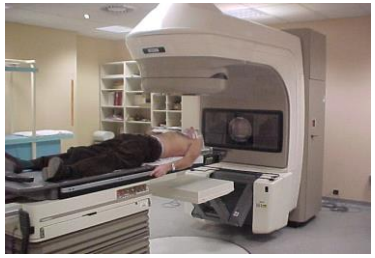
Equipment for Radioherapy

Tomotherapy HD:
installed in march 2012

Tomotherapy Hi Art:
installed in march 2010



Varian 600 Millennium:
installed
November 1999

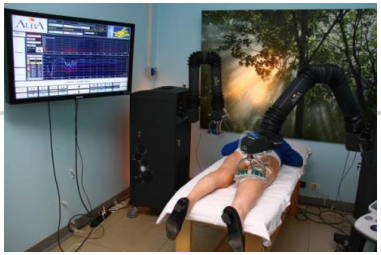
➔

Varian True Beam :
installed July 2014

Toshiba large bore CT:
installed in march 2010

3DHDR :
installed in
march 2012

Double antennas
Hyperthermia
Unit: installed in
march 2012



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Global personnel staff in 2014

Physicians (Radiation Oncol): 1+ 6

Physicist dedicated to RO (1 (pt) + 4

RO Technicians: 1+ 12 (2pt)

RO Nurses: 2

Secretaries: 2 pt

29 (25 full time)

Patients: 1350

Pts x MD: 190

Pts x Ph: 295

Pts x RTT: 108

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Indicator – Workload

Indicator 2	
Topic	Human resources' productivity
Type of indicator	Structure
Numerator	Total number of patients treated in 1 year
Denominator	Number of workers: (a) Radiation Oncologist (MD) (b) Medical Physicist (MP) Medical Physicist (MP) (c) Radiation Technologist (RTT)
Definitions and Specifications	Number of workers should be expressed as full-time equivalents. For the standard definition of the radiation oncologists' workload, only the time dedicated to treatments has been considered
Standard*	MD average 208.9 courses per year* MP average 303.3 courses per year* RTT average 76.8 per year*
Time period for data collection, frequency of analysis	1 year, repeated every 2 years

*The standard reported refers to ESTRO-HERO survey (Lievens et al., 2014b)

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Process Indicators

PROCESS INDICATORS

They offer a scientific approach to increase and evaluate "the organization" of a patient's clinical course

In a figurative language:
" What about the organization in the privacy of our home?"

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Indicator 3 – Multidisciplinary approach to patient care

Indicator 3	
Topic	MDM of diagnostic and therapeutic path of the patient
Type of indicator	Process
Numerator	Number of patients discussed in MDM
Denominator	Total number of treated patients
Standard	80%*
Time period for data collection, frequency of analysis	1 year, repeated every 2 years

*The standard proposed is the average percentage value considering the VC centers data.

When MDM?	Weekly or every two weeks?
Actors?	Only RO, Surgeon and Med oncol or also diagnostic people?
Presence of patient ?	Yes or not?
With other personnel?	Secretary, Nurse

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Patients seen in MDMs in the VC.

Disease	% patient seen in MDM
Breast	88% (range: 65%–100%)
Head and Neck	84% (range: 70%–100%)
Hematology	68% (range: 21%–100%)
Gastrointestinal	86% (range: 60%–100%)
Genitourinary	75% (range: 60%–100%)
Gynecology	75% (range: 50%–100%)
Lung/thorax	88% (range: 80%–100%)
Palliation	34% (range: 20%–70%)
Sarcoma	85% (range: 70%–100%)

Palliation not reached the minimum of the standard in any of the centers. > It means that it is very difficult to organize a multidisciplinary meeting in this topic, in particular because more than 7 different medical specialization are involved.

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Experience of MDM in urology during 2014

Overall patients

Patients n°	Prostate	Bladder	Kidney	Testicle	Penis
218	145	14	45	12	2

Imaging provided by the patient for prostate cancer

Staging by imaging	TR-US	CT scan	Bone scan	Multiparam-MRI	Choline-PET
114	1	15	16	28	54*

Decisions arising from MDM

Change of staging at the MDM	9/145 (6%)
Change of strategy at the MDM	14/145 (10%)
Watchful waiting	6/145 (4%)

*more than 50% of patients are in restaging

Indicator 4 – Adequacy of the multi-modality imaging

Indicator 4	
Topic	Information Accuracy
Type of indicator	Process
Numerator	Number of patients undergoing radical RT receiving multi-parametric MRI, CT-PET and/or SPECT.
Denominator	Total number of patients treated with radical RT
Standard	15%*
Time period for data collection, frequency of analysis	1 year, or at least 6 months; repeated every 2 years

*The standard proposed is the average percentage value considering the VC centers data.

Radical = Radical radiotherapy for primary, recurrent, nodal or oligometastases if the dose was >60 Gy

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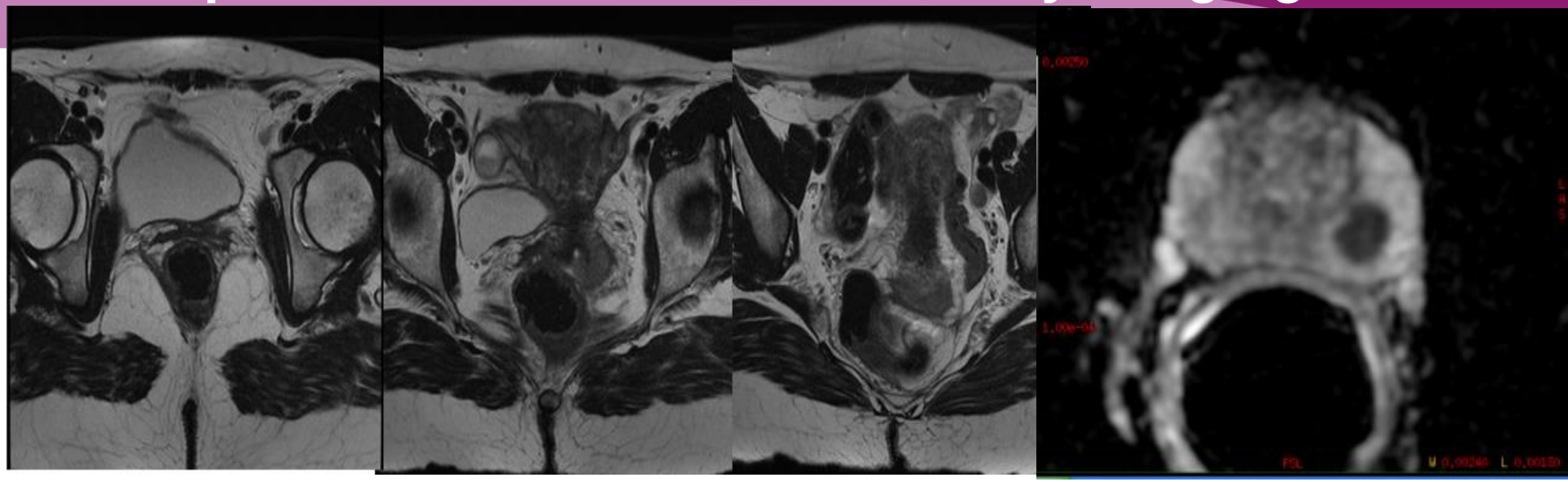
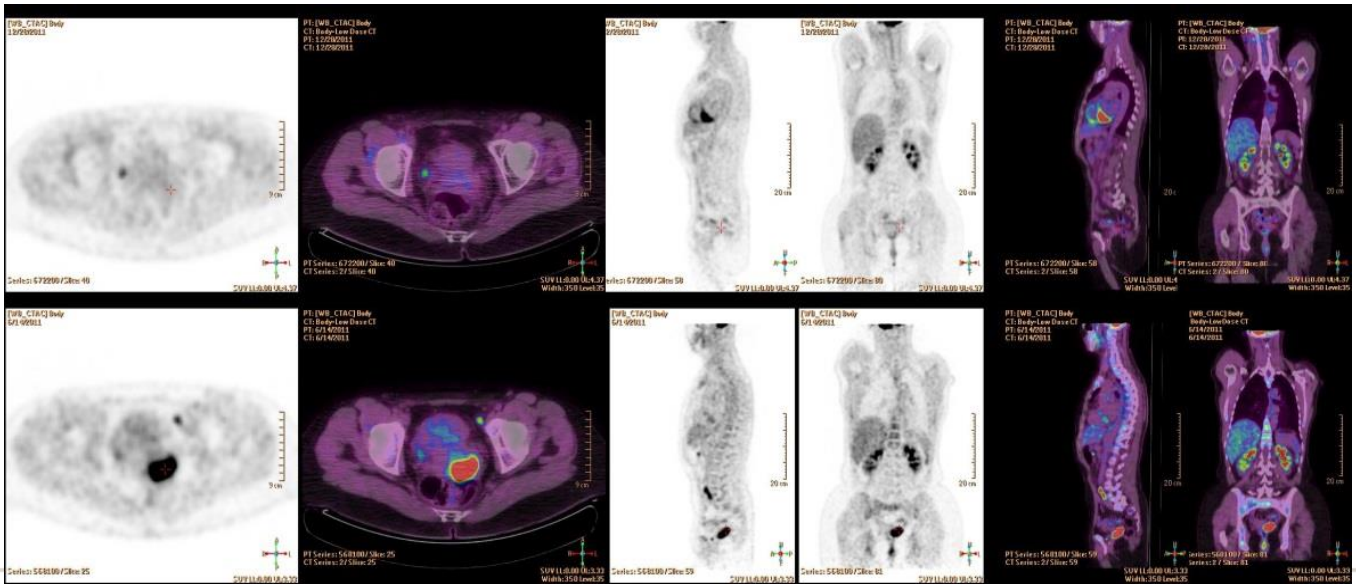
Specification about multimodality imaging



- RM with minimum 2 different imaging: ex: T2 and DWE; better also spectroscopy (if indicated)
- PET-CT FDG and choline PET or PSMA PET for prostate cancer



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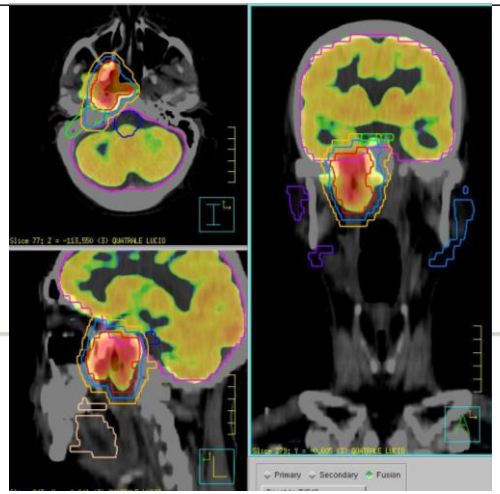
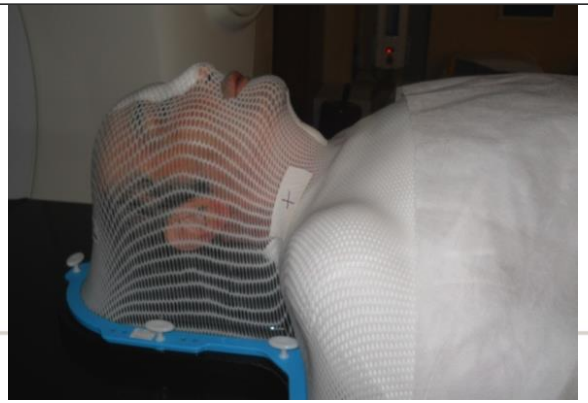
Average and range of percentage of patients submitted to PET-CT and or SPECT and MRI imaging procedures in the VC.

Pathologies treated with IMRT/IGRT	18-FDG/CHOLINE/PSMA PET and/or SPECT	MRI
Head and neck cancers (overall)	43% (18%–66%)	38% (4%–56%)
Radical head and neck cancers	38% (18%–59%)	33% (4%–49%)
Re-irradiations	10% (3%–18%)	5% (3%–7%)
Prostate cancers (overall)	21% (6%–35%)	59% (3%–89%)
High/very high risk/oligometastatic patients	14% (11%–19%)	27% (3%–65%)
Escalation dose protocol (dominant intraprostatic lesion)	11%	5% (3%–8%)
Biochemical/locoregional nodal recurrences	14% (11%–20%)	9% (3%–13%)
Postoperative patients	7% (5%–11%)	24% (3%–86%)
Rectal cancers (overall)	14% (9%–18%)	25% (4%–50%)
Preoperative with concomitant boost	14% (9%–18%)	23% (4%–50%)
Oligometastases/complex palliations	23% (10%–35%)	6% (4%–9%)
Lung cancers	31% (15%–52%)	1%
Breast cancers with inframammary/supraclavicular nodes	12% (7%–19%)	4% (1%–7%)
Pancreas/biliary/liver/gastric/esophageal cancers	38% (16%–99%)	–
Sarcomas/melanomas	8% (1%–18%)	8% (4%–13%)
Cervical cancers	14% (12%–15%)	11% (3%–19%)
Mesothelioma/thymomas	7% (5%–11%)	1%
Anal cancers	13% (8%–18%)	9% (4%–16%)
Vulvar cancers	10% (1%–18%)	3% (1%–4%)
Penile cancers	7% (1%–18%)	2% (1%–4%)
Craniospinal irradiation	1%	7% (1%–12%)





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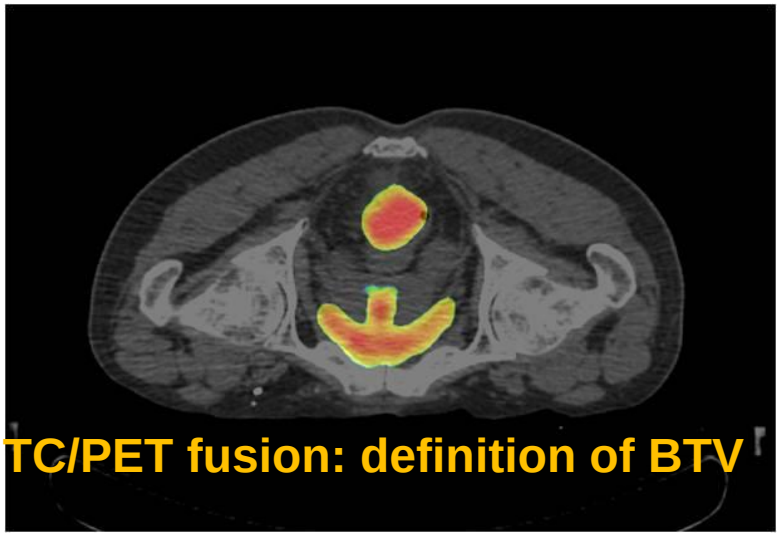
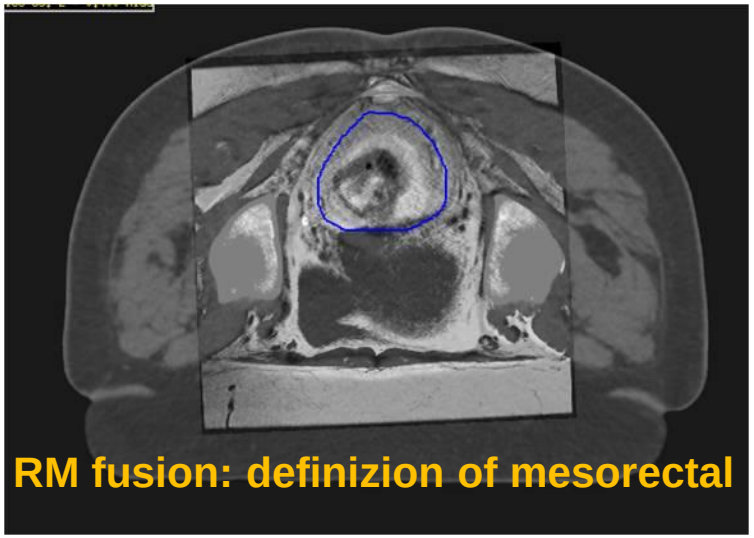
Also imaging for definition of Radiotherapy volumes are part of this Indicator

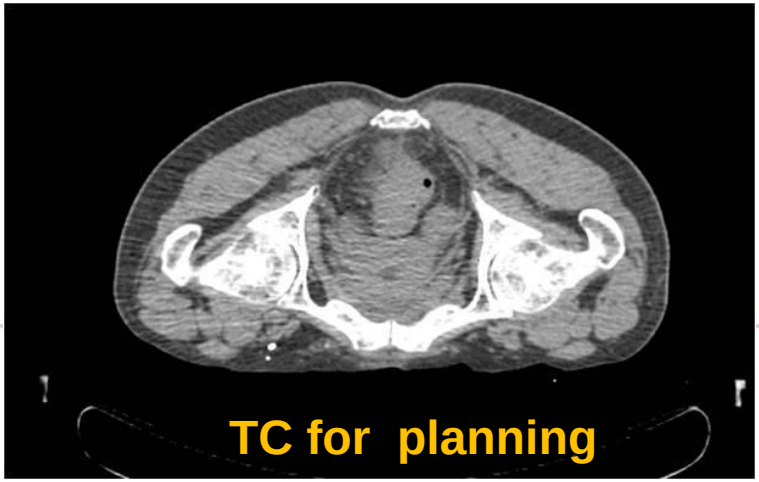
GTV definition with multimodal imaging

TC + PET + MR





This part can be a second part of the previous indicator or in future can be a totally new indicator



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Indicator 6 – Waiting time

Indicator 6	
Topic	Mean waiting time
Type of indicator	Process
Numerator	TWT = sum of the waiting times (in days) WT1, WT2, WT3
Denominator	Number of treated patients
Recommended stratification	According to the treatment objective TWT Standard according to the recommended stratification (Cionini, 2007): (1) Curative/radical ≤ 30 days per patient; (2) Palliative/symptomatic ≤ 10 days per patient; (3) Pre-operative adjuvant ≤ 15 days per patient; (4) Post-operative adjuvant ≤ 60 days per patient deviations are possible in specific conditions.
Time period for data collection, frequency of analysis	At least 3 months, at least every 2 years

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Effect of treatment delay

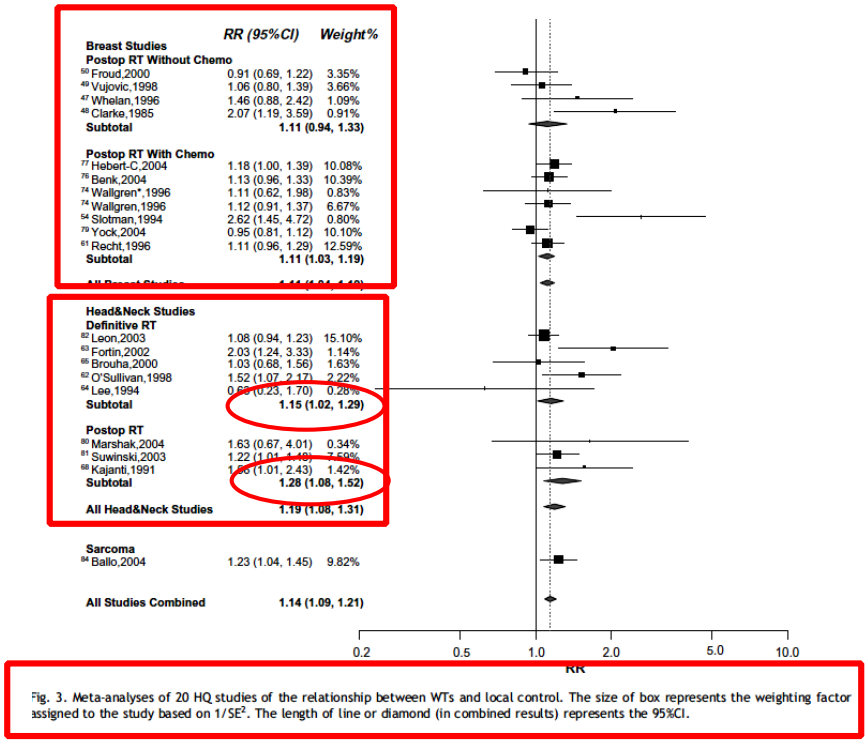

Fig. 3. Meta-analyses of 20 HQ studies of the relationship between WTs and local control. The size of box represents the weighting factor assigned to the study based on $1/SE^2$. The length of line or diamond (in combined results) represents the 95%CI.

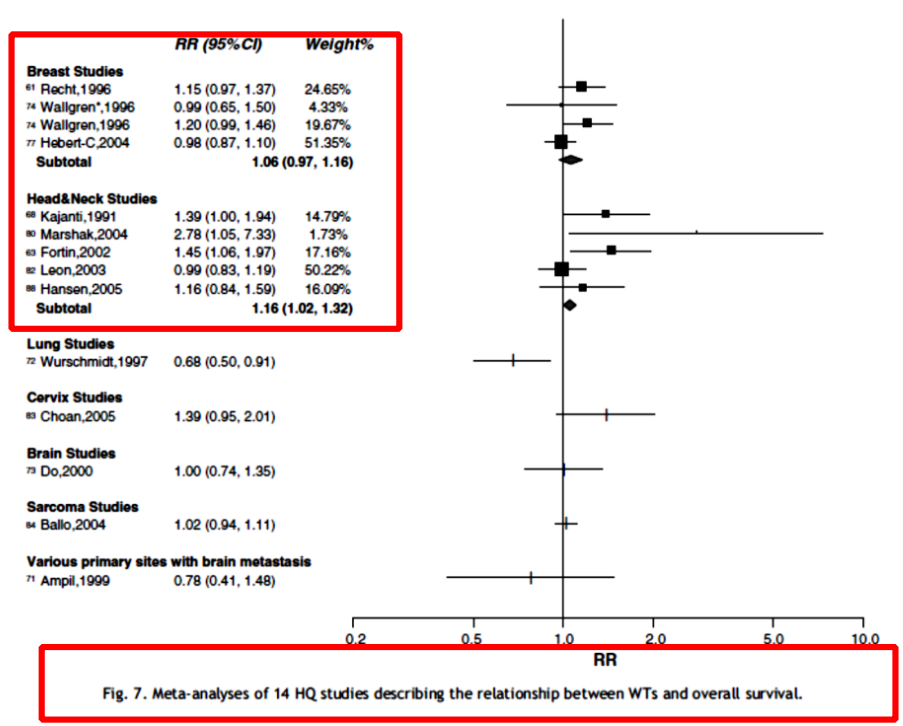

Fig. 7. Meta-analyses of 14 HQ studies describing the relationship between WTs and overall survival.

Conclusions:

1. The risk of local recurrence increases with increasing WTs for RT.
2. The increase in local recurrence rate may translate into decreased survival in some clinical situations (as H&N).
3. WTs for RT should be as short as reasonably achievable.

The relationship between waiting time for radiotherapy and clinical outcomes: A systematic review of the literature

Zheng Chen[a], Will King[a], Robert Pearcey[b], Marc Kerba[a], William J. Mackillop[a,*]

[a]Queen's Cancer Research Institute, Queen's University, Kingston, Ont., Canada, [b]Cross Cancer Institute, Edmonton, Alta., Canada

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Indicator 8 – Number of dosimetric controls on patients treated by IMRT/IGRT

Indicator 8	
Topic	Frequency of pre-treatment verifications
Type of indicator	Process
Numerator	number of QA pre-treatments performed
Denominator	total number of treated patients with IMRT/IGRT
Standard	100%: each plan should be checked prior to delivery (Alber et al., 2016).
Time period for data collection, frequency of analysis	2 months per year

Application of Indicator 8: In the VC the pre-treatment specific IMRT quality assurances were performed for each treated patient.

First consultation → set-up and CT(PET) simulation → contouring → treatment plannning → approval → pretreatment verification → set-up and treatment → CT/MV cone beam

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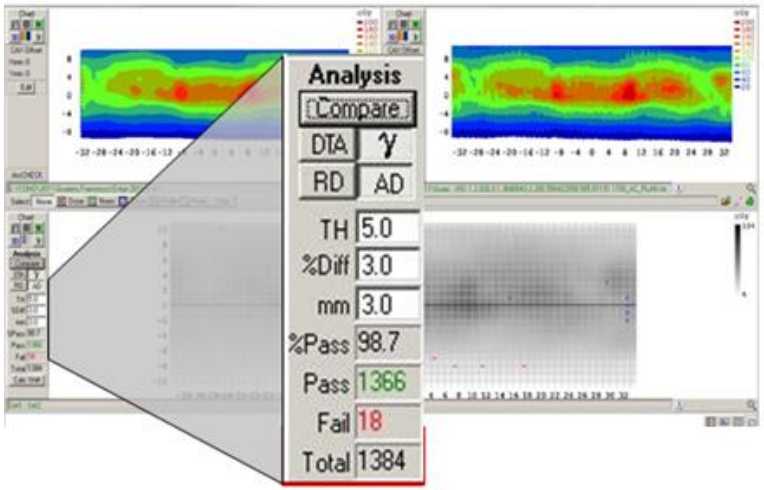
Control set-up Tomotherapy

Designed for Helical & Arc Delivery
RapidArc®, TomoTherapy®, VMAT

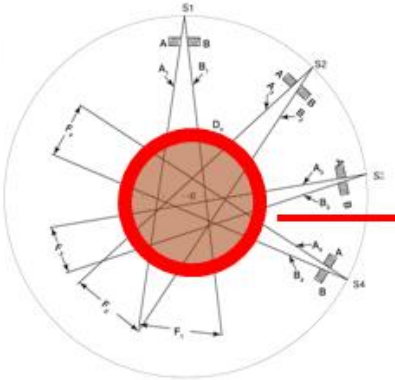
Consistent and coherent measurement geometry regardless of gantry angle

1386 diodes in a helical geometry

21 cm diameter, 21 cm length



SNC patient software



Diodes array set in helicoidal geometry

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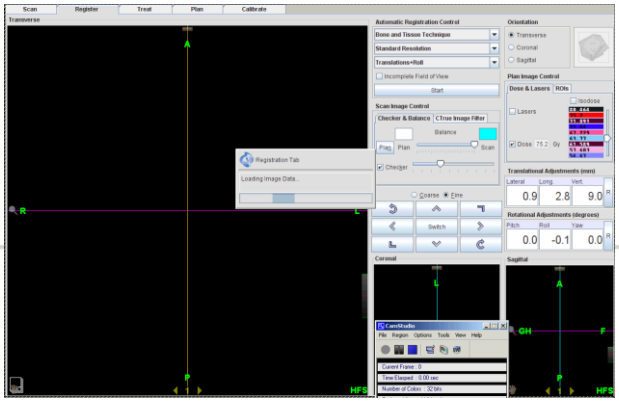
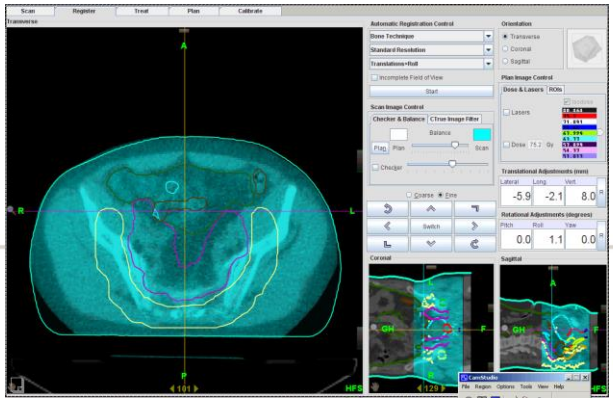
Indicator 9 – Number of MV or CBCT control versus number of RT sessions

Indicator 9	
Topic	Frequency of MVCT or CBCT during the RT
Type of indicator	Process
Numerator	Number of volumetric images performed
Denominator	Total number of RT fractions
Standard	100%: at least once per fraction when off-line protocols are not implemented
me period for data collection, Frequency of analysis	One month every six months

Application of Indicator 9: For the VC, at least one image per fraction was acquired.





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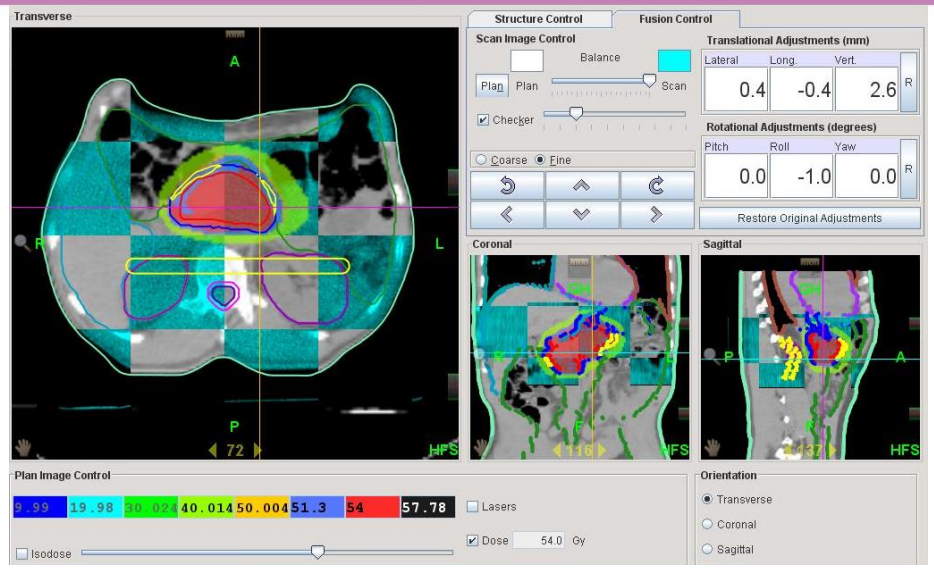
Open questions in IGRT controls

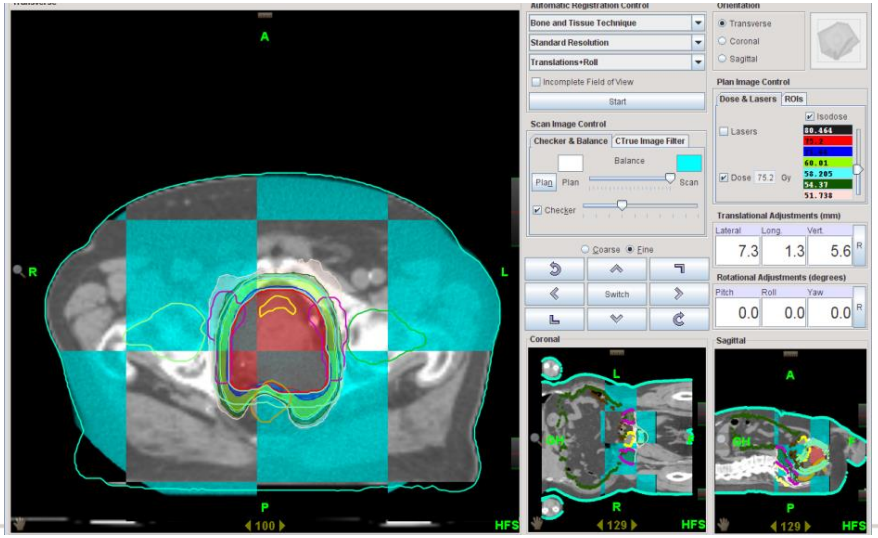


Cone beam timing:

- Daily
- Bi-weekly
- Weekly

Issues:

- Who evaluate Cone Beam: RO, RTT or a joung doctor?
- Intervention level: defined from Quality manual, guidelines or only oral tradition?
- Evaluation in different pathologies?
- Data published?



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Indicator 10 – Number of clinical controls of patient during treatment

Indicator 10	
Topic	Timing of clinical monitoring during treatment
Type of indicator	Process
Numerator	Number of clinical examinations carried out for each patient
Denominator	Total number of RT sessions
Standard	1 clinical examination every 5 RT sessions (1 per week) = 100%
Time period for data collection, frequency of analysis	At least 1 year, repeated every 2 years

Indicator 10:

VISITA IN CORSO DI TRATTAMENTO *(MDQ CANDIOLO – ACCORDING TO ISO9001)*

"Le visite durante il trattamento sono svolte ogni 5-7 sedute di terapia e vengono effettuate a turno dai vari medici strutturati durante tutto l'arco dell'orario di servizio oppure su richiesta del paziente stesso o dei famigliari. Ci si accerta della tolleranza al trattamento radiante in corso mediante un colloquio ed eventualmente un esame clinico del paziente; possono essere richiesti esami particolari ed impostati i provvedimenti terapeutici necessari per la prosecuzione della cura. In caso di effetti collaterali acuti di particolare gravità il radioterapista può sospendere temporaneamente o definitivamente il trattamento o proporre il ricovero ospedaliero. L'infermiera esegue la terapia".

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Indicator 11 – number of Adaptive RT

Indicator 11	
Topic	Maximization in customization of the RT treatment
Type of indicator	Process
Numerator	Number of Adaptive Radiotherapies performed
Denominator	Total number of treatments performed by IMRT/IGRT
Standard	10%*
Time period for data collection, frequency of analysis	At least 1 year; every year

*The standard proposed is the average percentage value considering the CV centers data.

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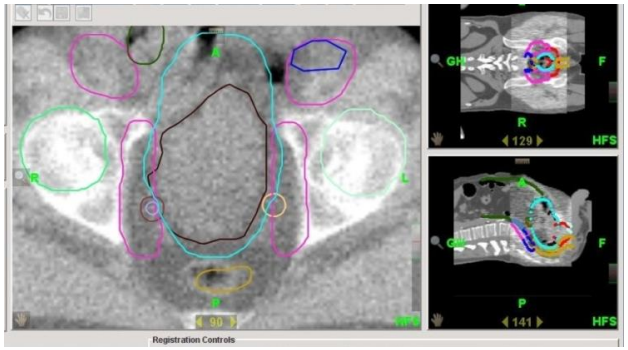
Number of Adaptive in 410 treated patients

Between October 2010 and October 2012 we treated with Tomo 410 patients. 27 were replanned (about 6% of total patients), 2 of these were replanned 2 times, in different sites with different volumes and dose prescriptions.

Tumor site	Patient number
Head & neck	12
Prostate	4
Thorax	2
Soft tissues	2
Gynecological	2
Pancreas	1
Metastasis	1
Anal canal	1
Tot	**25**



Volumes & dose prescriptions

Volumes	Total Doses (Gy)	Doses per fraction (Gy)
PTV Gross Tumor Tolumes (T&N+)	60-75.2	2-2.35
PTV N- (prophylactic nodal volumes)	51-54.4	1.7-1.8
Fraction number	28-32	

Updated October 2012

Indicator 12 – treatment room occupation time

Indicator 12	
Topic	Increasing the number of treated patients
Type of indicator	Process
Definitions and specifications	The total treatment time (called TTT) can be subdivided into the five intervals: URT (undressing room time), ST (set-up time), IT (imaging set-up time), SAT (set-up approval time) and BOT (beam on time)
Numerator	60 min
Denominator	TTT = sum of URT, ST, IT, SAT and BOT
Standard	Depending on the IMRT/IGRT machine it should be at least 2.4 patients/hour
Time period for data collection, frequency of analysis	One month every year

*The standard proposed is the minimun number of patients treated per hour in the VC.

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Time of bunker occupation

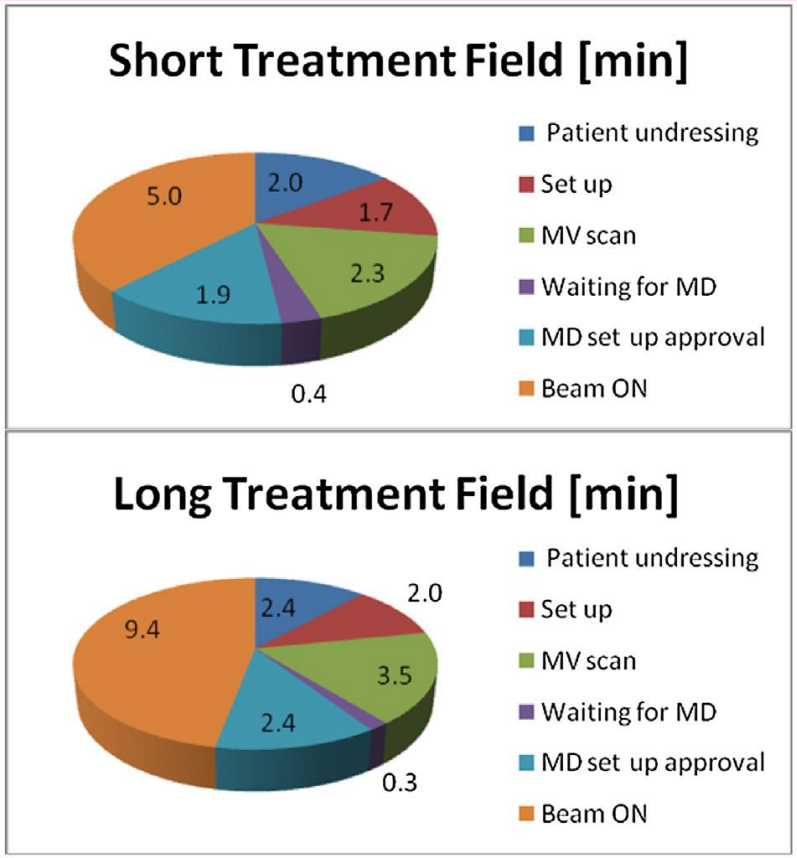

Fig. 1. Treatment at Tomotherapy unit 1: bunker occupation time for short treatment field (13.3 min) and for long treatment field (19 min).

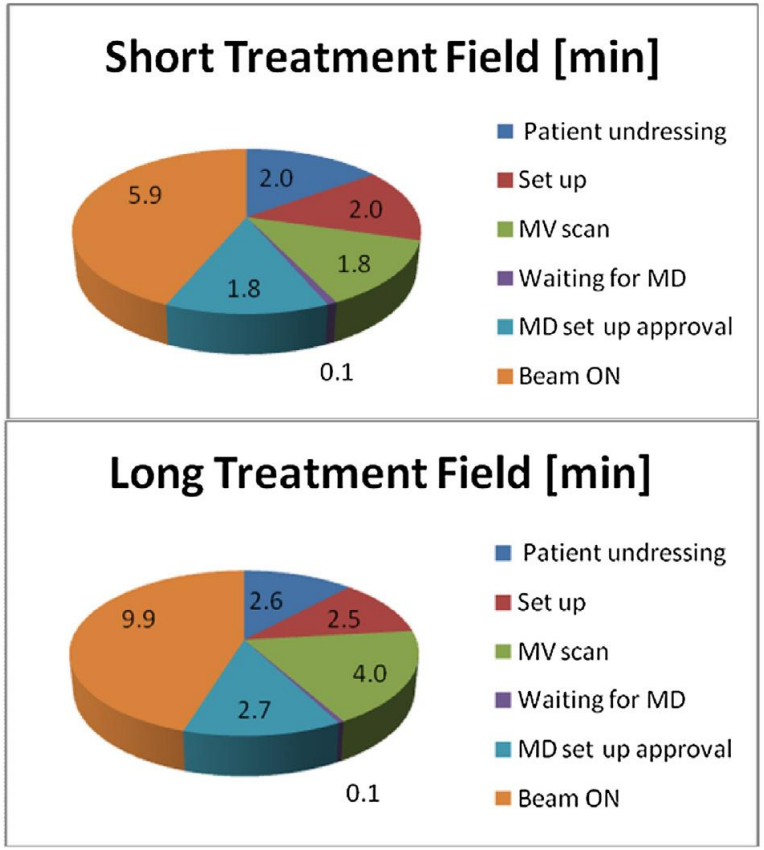

Fig. 2. Treatment at Tomotherapy unit 2: bunker occupation time for short treatment field (21.8 min) and for long treatment field (13.6 min).

Tomo 1: 13.3 or 19 minutes vs 13.6 or 21.8 minutes Tomo (+ 2% - + 15%)

H&N, lung, pancreas prostate, gynecology

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Why the time difference between Tomo 1 and Tomo 2?

Preparation problems of prostate/gynecology patients

about rectum emptying

Treatment mean time all population
MT: **15,9**
SD: **3,8**

about bladder filling

but with inadequate preparation:

	Total treatment time for pts with full rectum and empty bladder
Mean (minutes)	**27 (+11 minutes!)**
SD	**6**

Bladder empty/Rectum full	total fractions	% fractions
54	352	15%

P. Gabriele et al: ESTRO meeting, 2014

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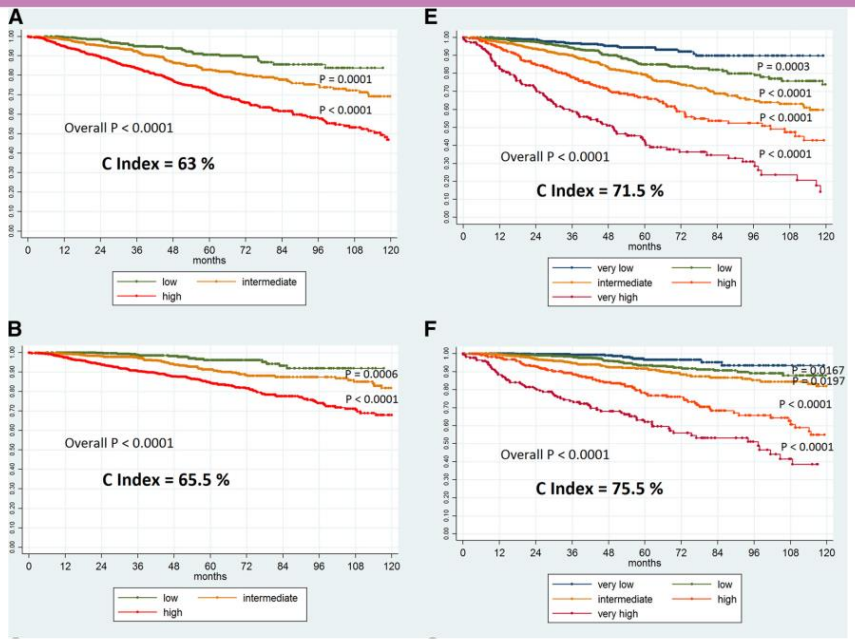
OUTCOME INDICATORS

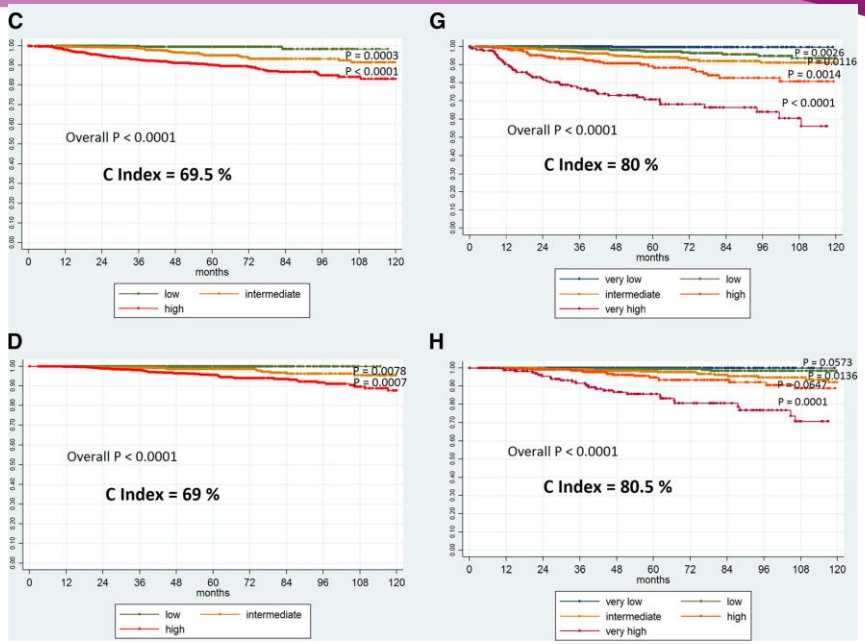
They evaluate the final results relative to structural and procedural phases and they are used to align employee performances with customers expectations.

In other words: " Has the patient been treated in our center with our tools (technical, clinical and emotional) and has been he satisfied with the quality of our service?

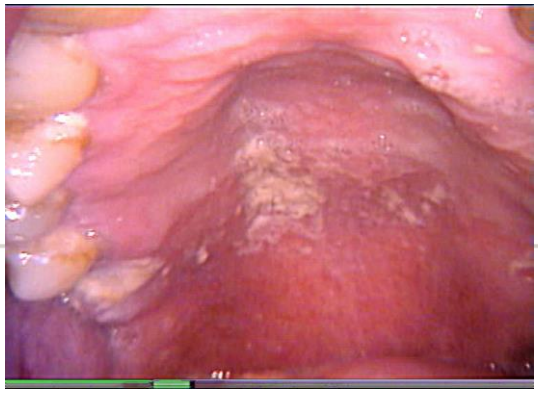
Has the service joined the mean of international expected results?

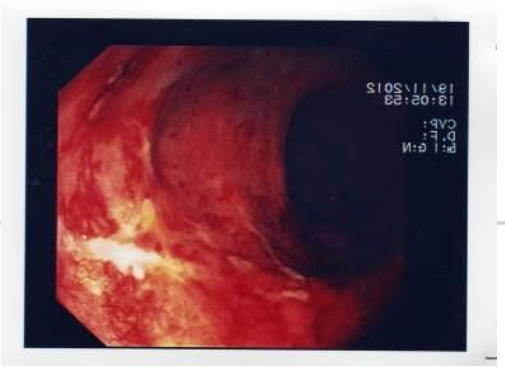
True Indicators and Surrogate Indicators





The outcome true indicators are, of course, 5/10 years loco-regional control, 5-10 y disease free survival, 5-10 y overall survival and global adverse events incidence.





True Indicators and Surrogate Indicators

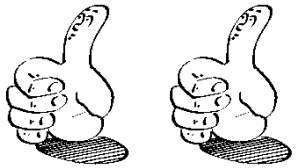
Because of numerous confounding factors that get difficult to obtain these data:

- time of prolonged follow-up
- casistic composition related to age, performance status and comorbidities,
- aggressiveness of therapy in indication
- associate therapies as surgery and/or chemotherapy and/or hormons

Surrogate Outcome Indicators

Surrogate outcome indicators consist in indicators that circumvent the problem of clinical results (in term of control, survival and adverse events) and give an alternative criteria for its evaluation.

The most important surrogate indicators are:

- patients opinion 

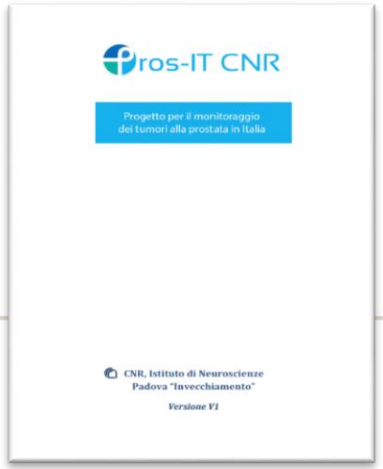
- collegues opinion 

- treatment (procedure) cost evaluation 

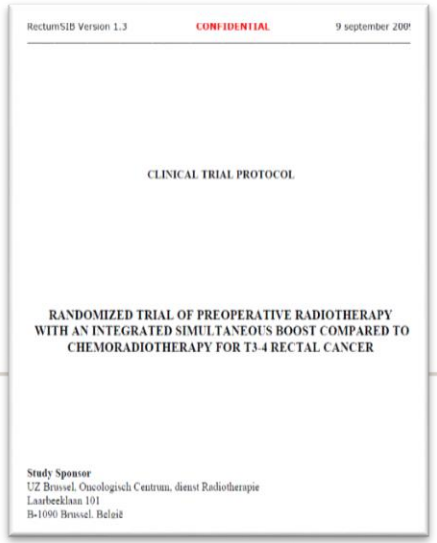
Indicator 13 – number of patients treated in clinical studies

Indicator 13	
Topic	Quality improvement of patient management
Type of indicator	Outcome
Numerator	Number of patients included in controlled clinical trials
Denominator	Total number of treated patients
Standard	13%*
Time period for data collection, frequency of analysis	1 year, every year

*The standard proposed is the average percentage value considering the VC centers data.



Observation national multicentric study of Pca diagnosis and therapy and 2 y FU



Prospectic Phase III Multicentric International study on RT-CT vs RTSIB for rectal cancer. With imaging review and molecular biology.

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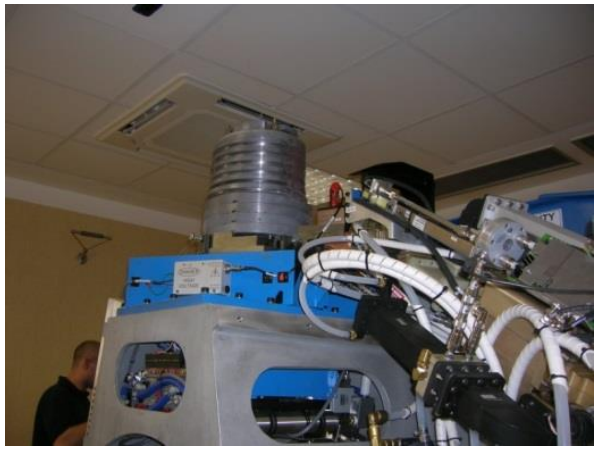
Indicator 14–Machine Uptime

Indicator 14 Topic	Days of unplanned RT treatment unit down each year.
Type of indicator	Outcome
Numerator	*BaseTime* − *DownTime* − *Over All Delay Time*
Denominator	*BaseTime*
Definitions and specifications	*BaseTime* is the nominal amount of days per year useful to RT treatment delivery, *DownTime* is the days of treatment suspension because of unplanned LINAC breakdown, and *Over All Delay Time* is the days of treatment interruption due to issues non attributable to LINAC malfunction (Goli and Yang, 2011).
	
Standard	≥95%
Time period for data collection, frequency of analysis	1 year, every year

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Proposed new QI for volumetric Radiotherapy

Indicator 1	*Adequacy of equipment for IMRT/IGRT radiotherapy*
Indicator 2	*Workload*
Indicator 3	*Multidisciplinary approach to patient care*
Indicator 4	**Adequacy of the multi-modality imaging**
Indicator 5	Clinical record quality
Indicator 6	Waiting time
Indicator 7	*Appropriateness of Quality Control programs (quality assurance–QA)*
Indicator 8	**Number of dosimetric controls on patients treated by IMRT/IGRT**
Indicator 9	**Number of MV o CBCT control versus number of RT sessions**
Indicator 10	Number of clinical controls of patient during treatment
Indicator 11	**Number of Adaptive RT**
Indicator 12	**Treatment room occupation time**
Indicator 13	**Number of patients treated in clinical studies**
Indicator 14	**Machine Uptime**

Proposed Quality Indicators. Bold, cursive and normal indicate the new proposed indicators, the indicators with new proposed standard and the indicators with now change, respectively.

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Quality Indicators for Centers comparison to protocol adherence

TABLE 1. Quality control indicators evaluated

#1: Waiting time and compliance
- 1.1 Time from pathological diagnosis to initial consultation.
- 1.2 Time from the first visit to start the treatment
- 1.3. Existence of protocol for unplanned curative treatment interruptions
- 1.4 Compliance to the prescribed overall treatment time.

#2: Existence of a multidisciplinary treatment approach

#3: Portal Verification
- 3.1 Existence of protocol for periodic verification of treatment fields
- 3.2. Number of portal verifications per preoperative course of radiotherapy

#4: Informed consent
- 4.1 Existence of signed consent form in patient records
- 4.2 Availability of detailed information about treatment & side-effects

#5. In vivo dosimetry
- 5.1 Existence of protocol and recommendations for checking the entrance dose
- 5.2 Number of in vivo dosimetric verifications per preoperative course of radiotherapy.

#6: Guidelines used for diagnostics and therapy.

#7. Monitoring & review of rectal cancer patients during the treatment period.

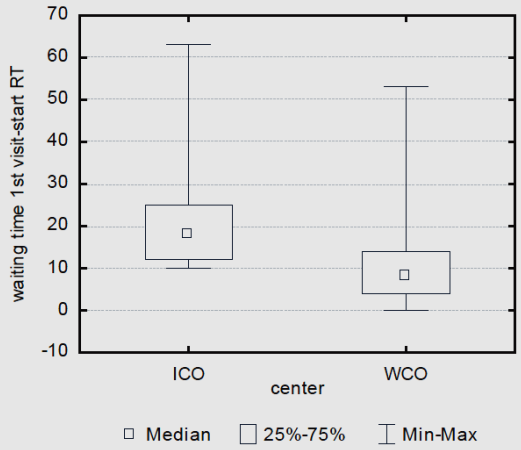

FIGURE 1. Waiting time from the first visit to start the treatment. RT = radiotherapy

TABLE 2. Portal imaging

	Acceptable N (%)	Unacceptable N (%)	Not performed N (%)
ICO	35 (51%)	31 (46%)	2 (3%)
GPCC	78 (83%)	15 (16%)	1 (1%)

N = number; ICO = Catalan Institute of Oncology; GPCC = Greater Poland Cancer Centre

TABLE 3. Percent of patient medical records containing a signed informed consent form

	ICO		GPCC	
Informed consent	Pts	[%]	Pts	[%]
Yes	61	89.7	94	100
No	7	10.3	0	0

Preoperative radiotherapy for rectal cancer: a comparative study of quality control adherence at two cancer hospitals in Spain and Poland

Magdalena Fundowicz[1], Miguel Macia[2], Susanna Marin[2], Marta Bogusz-Czerniewicz[3], Ewelina Konstanty[4], Ignaci Modolel[5], Julian Malicki[4,6], Ferran Guedea[2]

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Technical Conclusions (I)

1. An evaluation of the Radiotherapy Center should be performed when the techniques and the number of patients is at least as expected, more so if the number of patients and the waiting list is higher than expected

2. Prior to administration of Indicators is necessary to produce the internal quality manual with a list of every person, present material and Radiotherapy techniques of the Center

3. The first administration of Indicators may also be minimal (at least 10, of which at least 7 of process)

4. When the center changes equipment, techniques and personnel, a new administration of indicators would be mandatory

5. For the new radiotherapy (IMRT & IGRT-SBRT- robotic RT) new Indicators are needed.

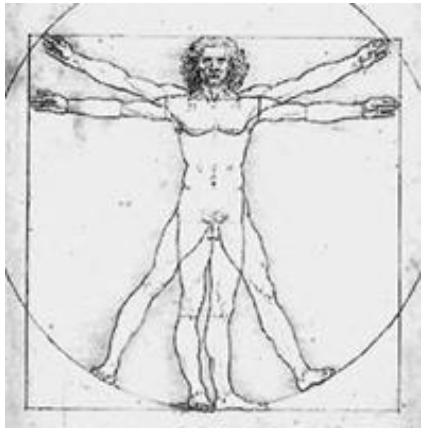
General Conclusion

1. Topic in evolution…..

2. Very important for University Hospitals and Clinical Research Centers (Cancer Centers) needing formal accreditation. In this case the indicators were done by the accreditation organization (ISO 9001 or others).

3. At the end is a form of respect for the staff and……..

…….. the PATIENT



Recommended references

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- Lievens, Y., Defourny, N., Coffey, M., 2014b. Radiotherapy staffing in the European countries: final results from the ESTRO-HERO survey. Radiother. Oncol. 112, 178–186.

Thank you for your attention

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Quality standards in Multidisciplinary setting

Pietro Gabriele, MD

Candiolo Cancer Center

IRCCS-FPO Candiolo, Italy

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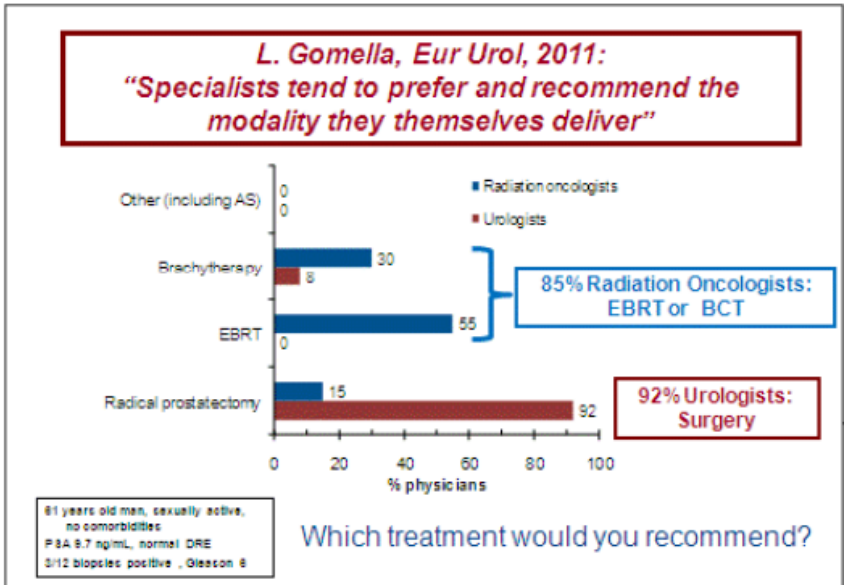
Learning objectives

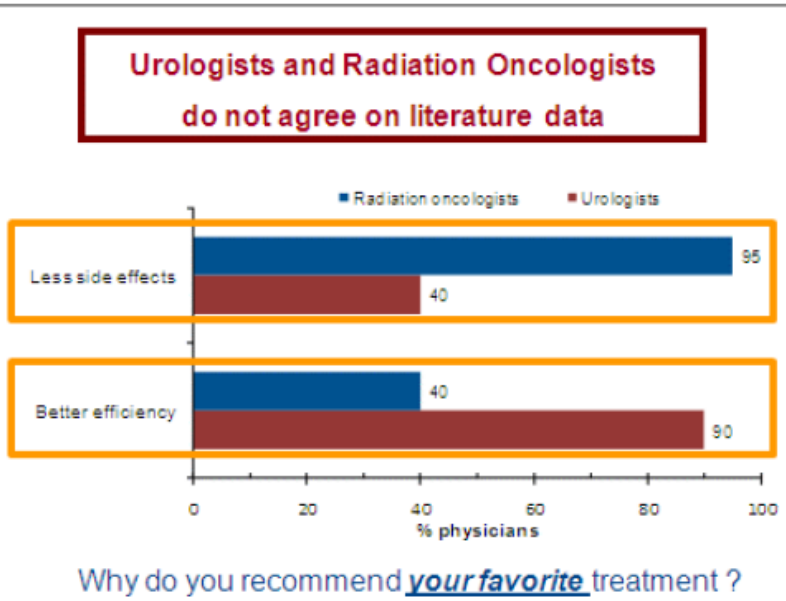
- Definition and organization of Multidisciplinary meeting (MDM)
- Quality standard for MDMs
- MDM improves the care management for individual patients:
- Evidence to decrease waiting time to treatment
- Evidence of changing treatments attitude/rate of intervention
- Evidence of effectiveness of MDMs in Survival
- What is the role of the patient

Outline

- Background
- Definition of Multidisciplinary setting
- Definition of Multidisciplinary Meeting (MDM) and difference with Tumor Board
- What about the quality standard? Minimum, mean and maximum standards
- Example of application of MDM in head and neck, prostate and breast cancers
- Second opinions
- Cost, cost-effectiveness and legal issues of MDM
- Summary of the evidence of the effectiveness of MDM
- Conclusions and future directions

There is evidence that …….single specialist prefers his own modality





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Background (I): Multidisciplinary Approach in Oncology

Theoric PROS

1.Decreases the waiting time to treatment by reducing errors, duplicate tests, fragmentation, variability among Medical Doctors
2.Improves diagnostic/therapeutic paths → ensure application of guidelines
3.Changes treatments' attitude and rate of intervention
4.Facilitates timely access to physical/phycho-emotional rehabilitation programs
5.Helps and improves management of disease recurrence and timely access to support and palliative care
6.Helps enrollement in innovative and experimental therapies
7.Improves the education of professionals involved in patients care
8.Increases patients satisfaction
9.Improves survival
10.Guarantees a minor risk of law suits

FM Boyle et al: J Clin Oncol 2005, A Fleissig et al Lancet Oncol 2006, MA Sidhom et al Lancet Oncol 2006, CS Sternberg et al BJU int 2007, LE Horvath et al Lancet Oncol 2010, J Walsh et al BMC Heakth Serv Res 2010, EM Kesson et al BMJ 2012

Background (II)

It is well acknowledged that the multidisciplinary decision-making process is able to greatly reduce the wide variations in decisions made by professionals acting indipendently

There are some recommendations and guidelines for multidisciplinary team-working like in Canada, Australia or in the UK, but there is no universally accepted model of multidisciplinary care.

Laura Horvath et al, J Oncol Pract, 2010

Options …… from literature
… and experience on the battle field

1. Multidisciplinary clinics (Specific Cancer Units eg: Prostate Cancer Units, Breast Cancer Units and so on)

2. Multidisciplinary meetings with patient's presence

3. Multidisciplinary meetings without patient's presence

4. Multidisciplinary discussions just of the difficult cases

5. Second opinions

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Multidisciplinary Meeting: definition

Mostly are tumour specific meetings known by different titles:

- multi-disciplinary meeting (MDM)
- multi-disciplinary teams (MDT)
- tumour boards (TB)
- cancer conferences (CC)

Because MDM and MDT are quite the same, and also Tumor Board and Cancer Conference are quite the same

from now we propose to use only the acronym «MDM» (for MultiDisciplinary Meeting) and "TB" (for Tumor Board)

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Current Perspective

The multidisciplinary meeting: An indispensable aid to communication between different specialities

Thomas Ruhstaller[a,b,*], Helen Roe[b], Beat Thürlimann[a], Jonathan J. Nicoll[b]

[a]Division of Oncology-Haematology, Kantonsspital St. Gallen, Rorschacherstr. 107, CH-9007, Switzerland

[b]Department of Clinical Oncology, Cumberland Infirmary, Carlisle CA2 7HY, UK

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The Organization of Multidisciplinary Care Teams: Modeling Internal and External Influences on Cancer Care Quality

TB vs MDM

Table 1. Comparing tumor boards and multidisciplinary care teams

Dimension	Tumor boards	Multidisciplinary treatment care teams
Stage of cases	Newly diagnosed; complex cases	Newly diagnosed, complex cases, plus "repeat" cases at later stages
Approach	Consultative; advice provided to lead MD	Collaborative, consultation between all members of team
Focus	Treatment only	Treatment and patient's quality of life (rehabilitation; psychosocial needs; long-term care)
Primary purpose	Education and training	Planning treatment and care management
Participants	Open to any practitioner	Focused on care team responsible for managing patient care for specific disease site
Timing	At one point in time	Multiple points along treatment pathway
Case review	Retrospective; prospective planning potential more recently	Prospective
Functioning	Face-to-face only	In-person or virtual
Treatment decision process	Physician in charge	Consensus
Patient	Absent	Encouraged to be present

Conclusion: For oncologic use MDM is better than Tumor Board!

Mary L Fennell, Irene Prabhu Das, Steven Clauser, Nicholas Petrelli, Andrew Salner

J Natl Cancer Inst Monogr 2010;40:72–80

Actors (members) of the MDM

The three therapeutic modalities of surgery, radiotherapy and medical oncology form the core members of the team

It is beneficial to have representatives from the diagnostic specialties, i.e. radiology, pathology, nuclear etc.

Extended members of an MDM :

- clinical trials coordinator (CTO)
- psycho-oncologist
- member of the palliative care team
- nurse
- Patient

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Actors of MDM on prostate cancer in USA

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Seminars in RADIATION ONCOLOGY

Multidisciplinary Care and Management Selection in Prostate Cancer

Ayal A. Aizer, MD, MHS,* Jonathan J. Paly, BS,† and Jason A. Efstathiou, MD, DPhil†

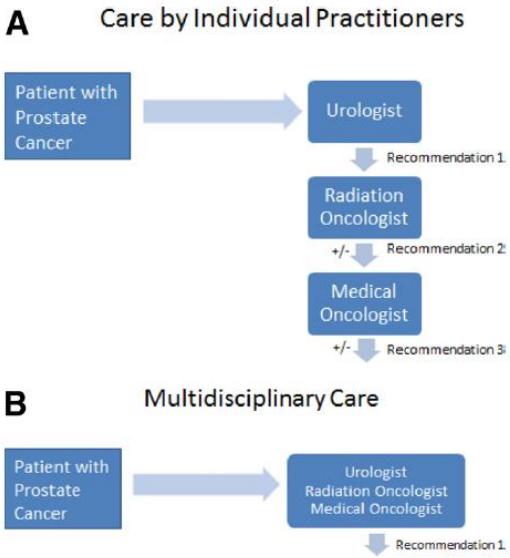

Table 1 Published Experiences With Multidisciplinary Prostate Cancer Care

Institution	Year Published	Multidisciplinary Care in Existence Since at Least	Oncology Physicians Involved
Jefferson Medical College[44]	2010	1996	Urologist, radiation oncologist, medical oncologist
Center for Prostate Disease Research[45]	2009	2000	Urologist, radiation oncologist, andrologist
Duke[46]	2012	2005	Urologist, radiation oncologist, medical oncologist
Harvard affiliated[37]	2012	1990	Urologist, radiation oncologist, medical oncologist
Instituto Nazionale dei Tumori, Milan[47]	2012	2005	Urologist, radiation oncologist, medical oncologist
William Beaumont Cancer Center[48]	2012	2010	Urologist, radiation oncologist, medical oncologist

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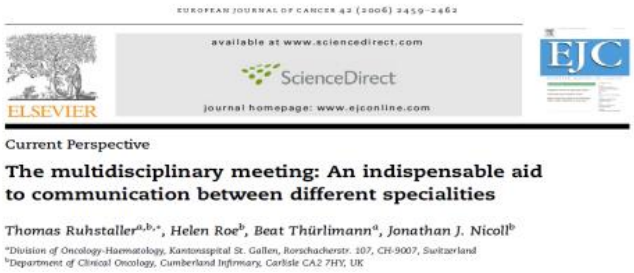
The goals of MDM's (I)

1. The primary goal of an MDM is to improve the care management for individual patients
2. Another important and often overlooked benefit of MDM's is the improvement in communication between different specialities

---

3. The third important issue is the position of the participants:

- each representative must be able to make independent decisions
- all members have an equal voice in the meeting and require the ability to demonstrate real expertise in their field rather than be a specific grade.



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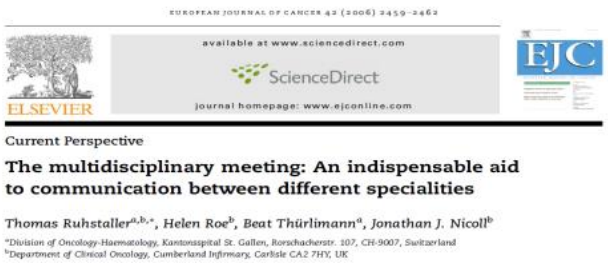
Decisions (II)

Therefore, it is possible to categorise the decisions made into two groups:

1. Firstly, the decision of the MDM is only a recommendation for the caring doctor, by which this doctor is not necessarily bound.

2. Secondly, the MDM makes a final decision, which can only be changed with a very good reason, for example, if the patient refused the recommended treatment plan.



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The MDM needs adequate communications tools ……

In the meeting room there must be:

- a telephone
- a computer connected with the different hospital services and for bibliographic research
- a printer
- a projector for presentations

Optional

- oncology library

and the internal RT meeting, in order to translate the MDM decisions in the RT practice

Internal meeting of the staff of Radiotherapy (MD: 8 people, Physics: 6 people and RTT's head)

Workings of an MDM (I)

1. *Announcement of an MDM*

Any specialty can bring cases for discussion at the MDM, in particular those cases which are diagnosed outside the 'normal pathway'

It is helpful if a **coordinator** is appointed to collect the cases together, write and disseminate the agenda before the meeting so that all participants know beforehand which patients will be discussed, allowing for notes to be organized and reviewed

2. *How should cases be presented?*

- All relevant patient information should be presented in the most efficient and concise way;
- Presentations can be verbal but should be backed up by projection.

- MDM is time consuming: thus the presentations would become **standardized.**

Teamwork and Team Decision-making at Multidisciplinary Cancer Conferences: Barriers, Facilitators, and Opportunities for Improvement

Table 1 Adequacy of information presentation at MCCs

Question—Are the following types of information adequately presented at the MCC?		
Parameter	Answer to question/no.	Representative quotes from MCC members
Information type ($n = 19$)		
Case history	Yes/12	It's the consultant [surgeon] usually, will likely present his own cases (S3)
	No/7	It depends … we have to have the notes in the clinics so that we can go back and double check (O4)
Radiological images	Yes/12	The most positive aspect is having radiology (O3)
	No/7	A lot of the time we're just working off reports, which is obviously not adequate (S3)
Pathology slides	Yes/7	Very often yes, there's an agreement not to discuss every G2, G1 TCC (O2)
	No/12	If there's anything really interesting he will actually put these slides up (N2)
Co-morbidities: psychological and social problems	Yes/10	The patient's social, domestic, or psychological circumstances may have a bearing on what we would recommend (S4)
	No/9	If you're asking whether they're [co-morbidities] discussed on the majority of patients, no they're not (S3)
Patients' wishes	Yes/11	If they [the patient] have a strong preference, then, yes, we normally would say (N3)
	No/8	Not overall, not generally speaking (S4)

MCC multidisciplinary cancer conferences, *S* surgeons, *O* oncologist, *N* nurse, *C* MCC coordinator, *G* grade, *TCC* traditional cell carcinoma

World Journal of Surgery

World J Surg (2011) 35:1970–1976

Benjamin W. Lamb · Nick Sevdalis · Sonal Arora · Anna Pinto · Charles Vincent · James S. A. Green

Teamwork and Team Decision-making at Multidisciplinary Cancer Conferences: Barriers, Facilitators, and Opportunities for Improvement

Table 2 Barriers to reaching a clear treatment plan at MCCs

Question—At the MCC, what are the barriers to reaching a clear treatment plan?

Emerging themes ($n = 19$)	No.	Representative quotes from MCC members
Lack of clinical or staging information	11	Patients are rediscussed because the MCC may say "well, we need another scan or we need further information or … a biopsy or something else" (S2)
Lack of personal knowledge of patient	5	If you've never met them [the patient], I think that does hamper the discussion and sometimes you can't come to a proper decision (O3)
Lack of information on co-morbidities	3	Often that [referring to another meeting] will be because it's a very complicated patient … somebody who's got complex co-morbidities that again you need the notes to be able to assess it (O4)
Poor attendance	3	Our one big problem is getting people, getting everybody there every week (S1)
Disagreement	3	Sometimes there's disagreement over what the best course of action to take is between the consultants (M2)
Complex cases	1	[About] 70% of cases include a treatment plan … it [failing to make a plan] is really about information, complexity of case (S3)

work to be done before MDM !

patient must be present !

Workings of an MM (III)

3. The presentation of the investigations should follow: professionals attending MM's must ensure that their contribution remains relevant and concise

A good team leader is essential to stop too long-winded speeches

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Teamwork and Team Decision-making at Multidisciplinary Cancer Conferences: Barriers, Facilitators, and Opportunities for Improvement

Table 3 Ideal qualities and skills of a MCC chairperson

Question—What are the ideal qualities and skills of an MCC chairperson?		
Emerging themes ($n = 19$)	No.	Representative quotes from MCC members
Time management	8	To try to ensure the thing runs to time.... Time can be really important (O2)
Gathering opinions	6	The role of a chair really is to ensure that all voices are heard (N1)
Leadership	6	As a leader, it is having to take charge (M3)
Forming a plan	5	If there's any sticking point, to be able to make a casting decision (M2)
Clinical experience	5	Without clinical knowledge it would be very difficult, because you are dealing with difficult complex patients (S2)
Camaraderie	4	We all trust each other and I think the chair ... doesn't need to be terribly, terribly formal (O1)
Facilitation	2	I think to facilitate the actual meeting (N3)
Respect of peers	2	They need to be well respected within their team (S2)
Coordinate meeting	1	The ideal role of the chair is to try [to] coordinate the meeting (N4)

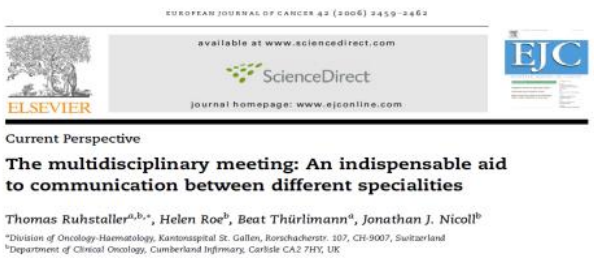
Workings of an MDM (IV)

5. The preference is for difficult cases

It makes no sense to show histological slides of standard colon cancers, but to define an exact stage of a locally advanced NSCLC it is crucial to show and discuss a CT-scan with a PET-scan in detail, if CT-PET-fusion is not already available .

With the attendance of the diagnostic specialties, it will also allow for discussion to establish the best method of obtaining the necessary tissue.

A very useful consequence of these discussions between diagnostic/therapeutic specialties is that it allows clinicians to learn about their abilities and limitations!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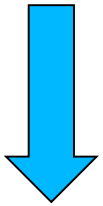
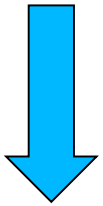
Are there Quality standards for MDMs?

Yes, there are standards or better, proposal of standard for MDMs of some tumors (breast, prostate, lung, colorectal cancers, head and neck cancers, onco-hematology)



The compliance to standard can be measured



The result, in form of score, can be considered a Quality Standard

Proposed standard for MDM of breast cancer. Canadian proposal (2009) reviewed in 2015 by Turkish group

1. MDMs for breast cancer should gather at least once every two weeks (with specified date and time) and should not last for less than one hour.
2. It is required to have a written protocol for a MDM.
3. The list of participants should be recorded at every meeting.
4. Every MDM should include one chairman (and one coordinator) in charge of the management and organization of the meeting.
5. It is more appropriate if the physician managing the discussed patient participates at the MDM of breast cancer.
6. The patient information should be presented in an efficient and concise manner; the presentation may be oral, or supported by projection. The person who makes the presentation needs to have full knowledge of the case.
7. The fact that the patient (present) talks to different specialists at the same time prevents the potential bias during the communication of the decision.
8. One representative from the departments of medical oncology, radiation oncology, surgery/surgical oncology must be present at MDM;
9. Pathology, radiology and nursing should be present at the MDM to make sure that the opinions of all specialists are heard
10. The data obtained from the MDM for breast cancer should be stored interactively in the computerized environment.

Wright FC et al: Expert Panel on Multidisciplinary Cancer Conference Standards. Multidisciplinary cancer conferences: a systematic review and development of practice standards. Eur J Cancer 2007; 43: 1002-1010. Multidisciplinary breast cancer teams and proposed standards - Review. Ulusal Cer Derg 2015; 31: 39-41 2015

An History (1998-1999) and actors of MDMs

- 324 patients evaluables of the 329 patients that partecipated in the MDM for HeN cancers
- The primary tumour could be TNM-classified and staged in 220 (68%) patients, of whom the majority had a cancer stage III or IV (n/127)
- Staging was not performed in the remaining 104 (32%) patients

---

- All participating specialists were registered during, the MDM meetings.

  Most meetings were attended by 3 ENT surgeons, 2 oncologists, 1 pathologist, 1 dental surgeon and 1 radiologist; one-third of the meetings were also attended by a general surgeon and in one-fifth of the meetings a thoracic surgeon was present

  And the radiation oncologist? And the nurse?

Acta Oto-Laryngologica, 2007; 127: 82–87

informa
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ORIGINAL ARTICLE

Quality assessment of a multidisciplinary tumour meeting for patients with head and neck cancer

JOACIM STALFORS, M.D., CHRISTER LUNDBERG, M.D., professor, &
THOMAS WESTIN, M.D. Ph.D.

Department of Otolaryngology, Head and Neck Surgery, Sahlgrenska University Hospital, Gothenburg, Sweden

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Results (I)

- A diagnosis and treatment plan could be established for 236 (73%) of 324 patients at the first meeting and were regarded as successes
- 88 (27%) patients needed complementary workup before a diagnosis or treatment plan could be established and were regarded as failures
- The score of success was 77% in inpatients, patient present at MDM and when telemedicine was in use
- The score of success was only 50% for the patients outside the hospital, non present at MDM or when telemedicine was not in use

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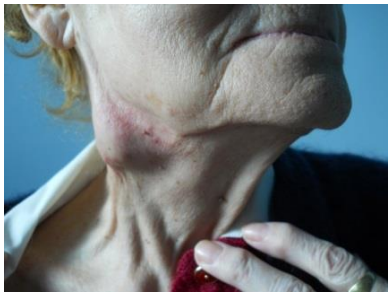

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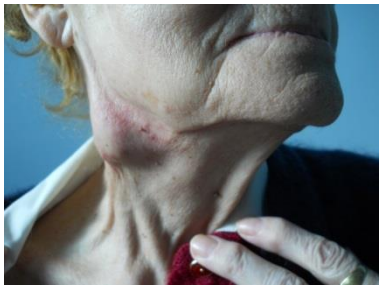
Reasons of failure

1. Lack of proper imaging (42%)
2. Need for investigations regarding tumour extension with or without biopsy (30%)
3. Histological re-evaluation (7%)
4. Uncertainty regarding general cardiovascular status (6%)
5. Lack of complementary information concerning more than one of the above categories (16%)

MDM specialists deemed palpation necessary for a patient presented via telemedicine and for one presented by case notes. These patients were requested to personally attend a later meeting.

MDM have better results if patient is present !



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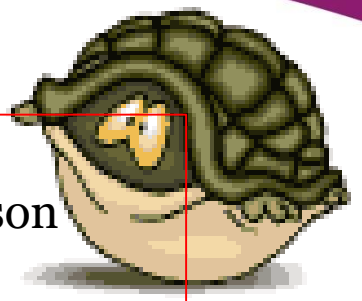
Delay in treatment (telemedicine worse for 5-6 days)



- The median number of days until surgery was performed at the ENT department was 14 days for patients presented in person and 19 days for patients presented via telemedicine (+5 days)

- The median number of days until treatment at the oncology department was 32 days for patients presented in person and 38 days for patients presented via telemedicine (+6)

- Globally mean waiting time to treatment was better for patients presented in person (-5.5 days) for surgery or chemotherapy treatment vs patients via telemedicine (and data for radiations?)

Acta Oto-Laryngologica, 2007; 127: 82–87

informa
healthcare

ORIGINAL ARTICLE

Quality assessment of a multidisciplinary tumour meeting for patients with head and neck cancer

JOACIM STALFORS, M.D., CHRISTER LUNDBERG, M.D., professor, & THOMAS WESTIN, M.D. Ph.D.

Department of Otolaryngology, Head and Neck Surgery, Sahlgrenska University Hospital, Gothenburg, Sweden

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Waiting time

National Comprehensive Cancer Network®

NCCN Guidelines Version 2.2017
Cancer of the Oral Cavity

NCCN Guidelines Index
Table of Contents
Discussion

PRINCIPLES OF RADIATION THERAPY[1]

POSTOPERATIVE:

RT

- **Preferred interval between resection and postoperative RT is ≤6 weeks.**
- **PTV**
  - **High risk: Adverse features such as positive margins (see footnote i on OR-3)**
    - **60–66 Gy (2.0 Gy/fraction); daily Monday–Friday in 6–6.5 weeks**
  - **Low to intermediate risk: Sites of suspected subclinical spread**
    - **44–50 Gy (2.0 Gy/fraction) to 54–63 Gy (1.6–1.8 Gy/fraction)**[3]

POSTOPERATIVE CHEMORADIATION:

- **Concurrent systemic therapy**[6-10]

Either IMRT or 3-D conformal RT is recommended.

Radical RT: as soon as possible

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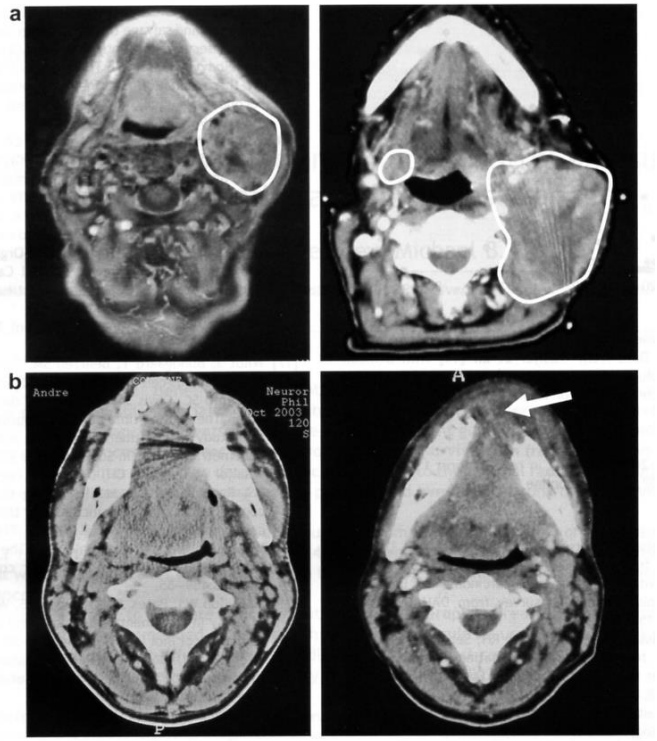
Effect of treatment delay



a) N-stage. Patient with 47 days between scans. Growth of lymph node metastasis and appearance controlateral metastasis.

b) T-stage. Patient with 19 days between scans. Progressive bone destruction.

Interpretation: This study shows a negative impact of waiting time in patients with SCCHN. Within an average time of 4 weeks the majority of the patients developed significant signs of tumor progression. It was not possible to define a threshold for acceptable time intervals in order to avoid volume changes, or to define a subgroup.

Tumor progression in waiting time for radiotherapy in head and neck cancer

Anni Ravnsbæk Jensen[a,b,*], Hanne Marie Nellemann[c], Jens Overgaard[a]

[a]Department of Experimental Clinical Oncology, [b]Department of Oncology, and [c]Department of Radiology, Aarhus University Hospital, Denmark

Radioter Oncol 2007

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Conclusions on MDM on H&N oncology

- The quality of decisions made at the MDM were good, but there is a need to improve the quality of the workups

- The mode of presentation of the patients at the MDM (patient present vs telemedicine) was not decisive for the accuracy of diagnoses and treatment plans but influences the waiting time period

- The study demonstrates the importance of quality assurance of MDM meetings in head and neck oncology

theoric score: 5.5

Acta Oto-Laryngologica, 2007; 127: 82–87

informa
healthcare

ORIGINAL ARTICLE

Quality assessment of a multidisciplinary tumour meeting for patients with head and neck cancer

JOACIM STALFORS, M.D., CHRISTER LUNDBERG, M.D., professor, &
THOMAS WESTIN, M.D. Ph.D.

Department of Otolaryngology, Head and Neck Surgery, Sahlgrenska University Hospital, Gothenburg, Sweden

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MDMs on prostate cancer in USA

Impact of a Prostate Multidisciplinary Clinic Program on Patient Treatment Decisions and on Adherence to NCCN Guidelines

The William Beaumont Hospital Experience

Howard Korman, MD, Thomas Lanni, Jr, MBA,† Chirag Shah, MD,† Jan Parslow, RN,‡ Joyce Tull, RN, MS,§ Mihai Ghilezan, MD,† Daniel Krauss, MD,† Savitha Balaraman, MD,‖ Kenneth Kernen, MD,* Matthew Cotant, MD,‖ Jeffrey Margolis, MD,¶ and Frank A. Vicini, MD, FACR†*

American Journal of Clinical Oncology • ■ 2012

The experience of the Beaumont Hospital, Royal Oak
Start: March 2010 (March 2010 March 2011: 182 pts)

- MD approach: greater awareness of the patient toward the disease, the therapeutic-observational options, the therapy induced side effects
- Better compliance of the patient toward the choice
- Correct application of guidelines, thus better outcome
- More objectivity in the proposal of the options (fewer robot assisted surgery in low and high risk patients, more patients on active surveillance)

theoric score: 7.25

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MDMs on prostate cancer in USA

The experience of the MD Prostate Cancer Clinics at Harvard Medical School (MGH, BWH, BIDMC), Boston
Analysis: Jan - Dec 2009: 701 pts

Aim: to determine whether MDC consultation is associated with the selection of Active Surveillance for low risk patients

- Selection of Active Surveillance in patients seen at a MDM was double than patients seen by individual practitioners: 43% vs 22%
- Patients treated with RP or RT decreased by ~ 30%
- Consultation at MDC vs monodisciplinary was significantly associated with pursuit of Active Surveillance: p=0.02

theoric score: 7.75

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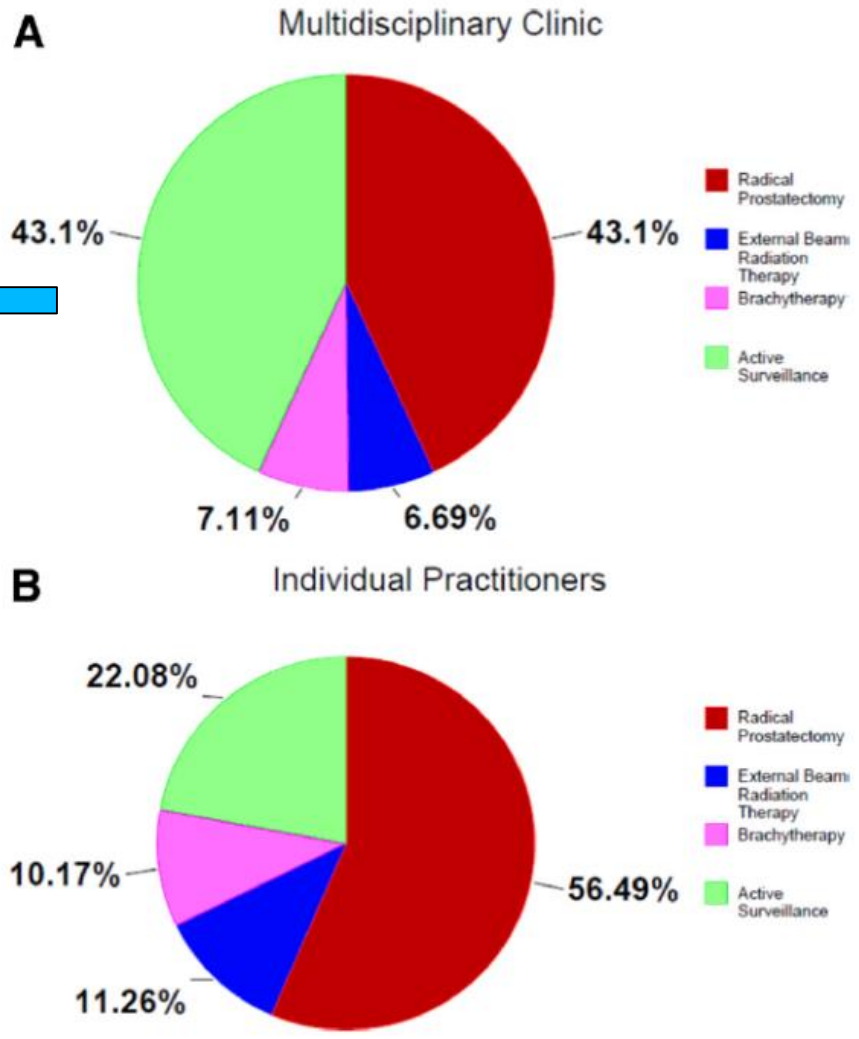
MDMs on prostate cancer in USA

More active surveillance

and

Less Radical Prostatectomies



ELSEVIER

Seminars in RADIATION ONCOLOGY

Multidisciplinary Care and Management Selection in Prostate Cancer

Ayal A. Aizer, MD, MHS,* Jonathan J. Paly, BS,† and Jason A. Efstathiou, MD, DPhil†

ESTRO School

MDMs on prostate cancer in USA

The experience of the Thomas Jefferson University, Philadelphia
Data analysis 1996-2010: MD approach pros

- **Better survival rate in high risk prostate cancer compared to SEER data**
- Expertise of fully integrated multidisciplinary clinicians
- Simultaneous care (beside urologists, radiation oncologists and medical oncologists, rehab professionals, psychologists and supportive care specialists)
- Timely identification of patients who might benefit from combined therapies or inclusion in clinical protocols

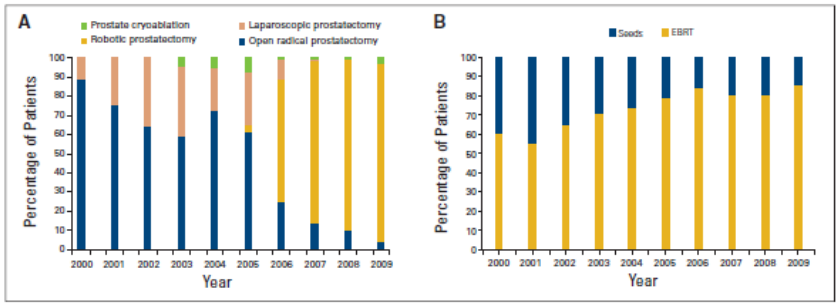


Figure 2. Treatment changes over time, in surgical method (A) and radiation treatment type (B). EBRT, external beam radiation therapy.

Table 2. Patient Satisfaction Survey Concerning the Multidisciplinary Clinic Experience: Percentage of "Good" and "Very Good" Responses

Survey Item	Percentage of Responses		
	Nov 2008 to Jan 2009	June 2009 to Sept 2009	Oct 2009 to Jan 2010
Waiting time for appointment	94	95	90
Explanation of what to expect	94	96	93
Waiting time in center	91	90	86
Treatment with respect and dignity	97	98	100
Treatment option explained by doctors	100	98	100
Likelihood of recommending	93	98	93

theoric score: 7.80

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The experience of National Cancer Institute of Milano

The experience of the Fondazione IRCCS Istituto Nazionale dei Tumori, Milano
2005-2012: 2260 MD clinics (consultations, second opinions)

- Improved application of diagnostic/therapeutic guide-lines
  - partial or inappropriate therapeutic indications for patients examined in MD clinics (vs NCCN/EAU): 59%
  - wrong prescriptions (vs NCCN/EAU): 11%
- Histologic reclassification (from low to intermediate risk class): 8%
- Improved accrual in Active Surveillance protocols
- Better identification of patients to be enrolled in clinical trials
- High patients satisfaction

theoric score: 7.5

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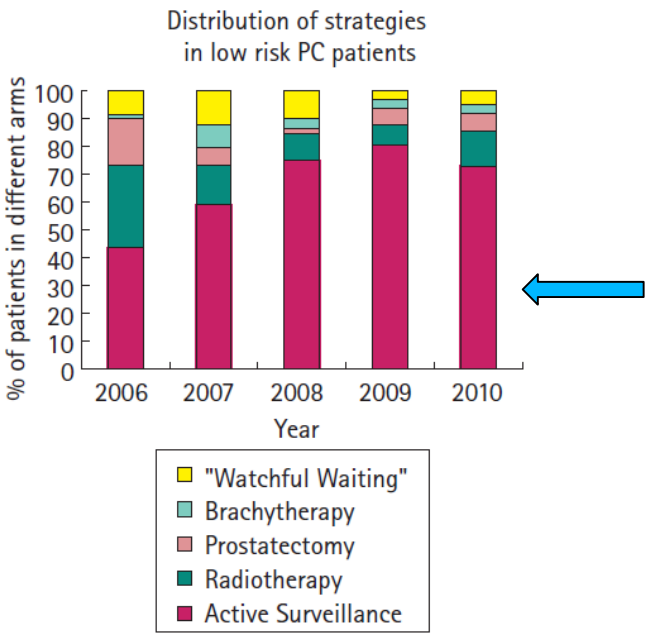
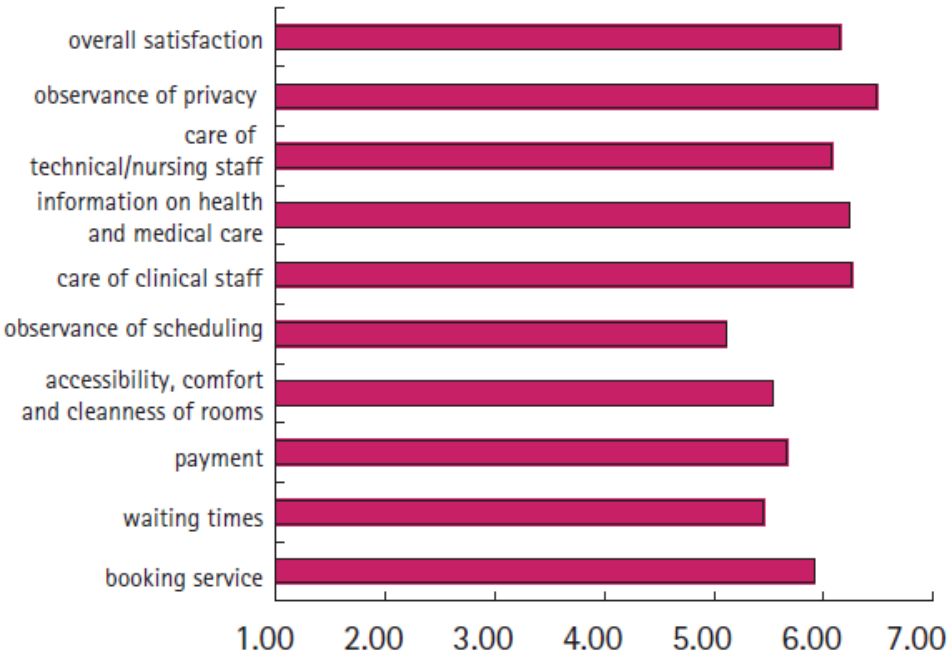
Other experiences: prostate in Italy





BJUI
BJU INTERNATIONAL

The 6-year attendance of a multidisciplinary prostate cancer clinic in Italy: incidence of management changes

Tiziana Magnani*, Riccardo Valdagni*†, Roberto Salvioni‡, Sergio Villa†, Lara Bellardita§, Simona Donegani§, Nicola Nicolai‡, Giuseppe Procopio¶, Nice Bedini†, Tiziana Rancati* and Nadia Zaffaroni††

**Prostate Cancer Programme, Scientific Director's Office, †Division of Radiation Oncology 1, ‡Division of Urology, §Prostate Cancer Program, Psychology Service, ¶Division of Medical Oncology 2, ††Division of Molecular Pharmacology, Fondazione IRCCS Istituto Nazionale dei Tumori, Milan, Italy*

Accepted for publication 9 November 2011

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MDM on breast cancer in USA (I)

The Impact of A Multidisciplinary Breast Cancer Center on Recommendations for Patient Management

The University of Pennsylvania Experience

AJCC Clinical Stage as Determined by the Outside Institution for 77 Breast Lesions Compared with the Clinical Stage Determined by the Breast Cancer Evaluation Center

	Outside institution		Breast Cancer Evaluation Center	
AJCC clinical stage	Number	Percentage	Number	Percentage
0				
LCIS	4	5	2	3
DCIS	13	17	12	16
I	30	39	32	42
IIA	13	17	13	17
IIB	9	12	9	12
IIIA	2	3	2	3
IIIB	2	3	2	3
Other[a]	2	3	2	3
No cancer	2	3	3	4

AJCC: American Joint Committee on Cancer; LCIS: lobular carcinoma in situ; DCIS: ductal carcinoma in situ.

[a] Includes one patient with angiosarcoma of the breast and another patient with an anaplastic spindle and giant cell carcinoma.

Comparison of Outside Pathologic Diagnoses with Breast Cancer Evaluation Center Pathology Review[a]

	Breast Cancer Evaluation Center diagnosis				
Outside diagnosis	LCIS	DCIS	Invasive carcinoma	Angiosarcoma	No cancer
LCIS	2	—	1[a]	—	1[a]
DCIS	—	12	1[a]	—	—
Invasive carcinoma	—	—	57	—	—
Angiosarcoma	—	—	—	1	—
No cancer	—	—	—	—	2

LCIS: lobular carcinoma in situ; DCIS: ductal carcinoma in situ.

[a] Major difference in interpretation on pathologic review in 3 (4%) of the 77 breast lesions.

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Breast cancer in USA (II): concordance of treatment

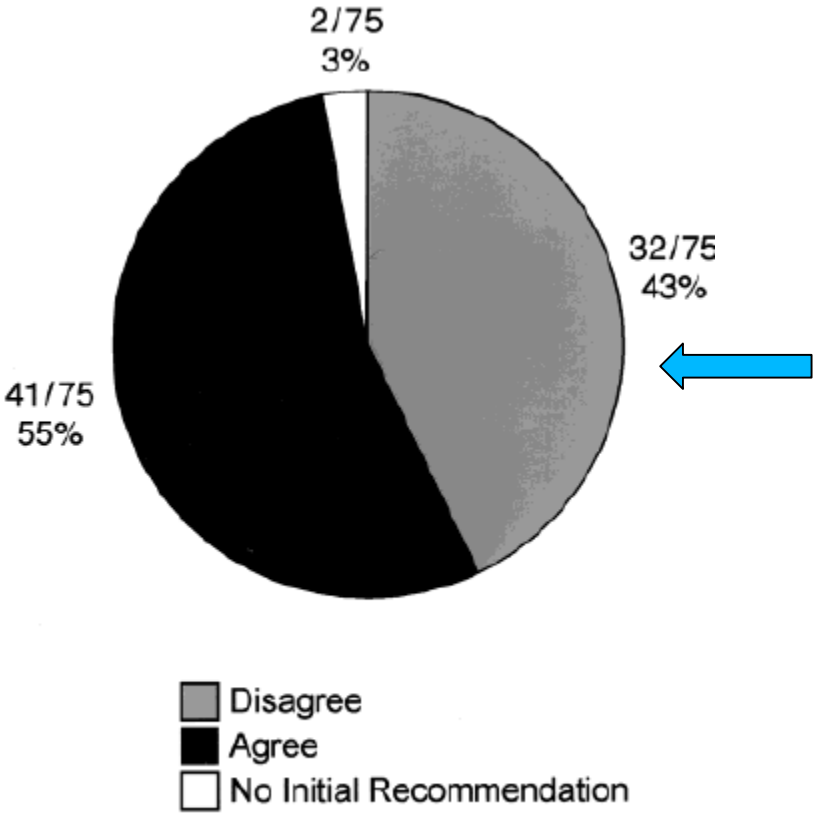

FIGURE 1. Concordance of treatment recommendations by the multidisciplinary breast cancer center panel of physicians with the outside physicians.

Differences in Treatment Recommendations for the 32 Patients Who Had a Difference in Management Recommendations

Outside hospital recommendation	Breast Cancer Evaluation Center recommendation	Number	Percentage
Mastectomy VS	Breast-conservation treatment	13	41
Immediate definitive treatment	Further workup	10	31
Mastectomy and adjuvant chemotherapy	Mastectomy, adjuvant chemotherapy, and postmastectomy radiation treatment	3	9
Recommendation based on outside pathology	Recommendation based on change in pathology requiring change in management	3	9
Reexcision	Breast conservation treatment	2	6
Chemotherapy	Chemotherapy and hormonal therapy	1	3
Breast-conservation treatment	Mastectomy	0	0

The Impact of A Multidisciplinary Breast Cancer Center on Recommendations for Patient Management

The University of Pennsylvania Experience

theoric score: 7.6

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Multidisciplinary meetings in Candiolo: time to implement the whole organization

From the first to the last MDM organization a period of 9 years was needed

- 1. Breast cancer MDM (weekly)
- 2. Prostate cancer MDM (w)
- 3. Colorectal and GI cancers MDM (w)
- 4. Head and Neck cancers MDM (w)
- 5. Thoracic diseases MDM (w)
- 6. Gynecological cancers MDM (w)
- 7. Haematological diseases MDM (every two ws)
- 8. Skin, MM and sarcomas MDM (every two ws)
- 9. Palliation (osteo-oncology) MDM (w)

Prostate, Breast and GI MDMs

- Established: january 2002
- Frequency: every week (48 w/y)
- Number of patients discussed per y: *200-250
- Coordinator: radiotherapist (P. Gabriele)
- Participants: urologist (1), radiotherapist (2), medical oncologists (2-3), radiologist (1), nuclear medicine specialist (1), nurse (1), **patient**

Problem: pathologist

- Established: march 2000
- Frequency: every week (50 w/y)
- Number of patients discussed per y: 250-300
- Coordinator: medical oncologist (F. Montemurro)
- Participants: breast surgeons (2), radiotherapist (2), medical oncologists (2-3), radiologist (1), nuclear medicine specialist (1), nurse (1), sometime pathologist ,nurse, **patient**

Problem : ----------

- Established: march 2000
- Frequency: every week (50 w/y)
- Number of patients discussed per y: 200-250
- Coordinator: surgeon (M. De Simone)
- Participants: surgeons (2), radiotherapist (1), medical oncologists (2), radiologist (1), nuclear medicine specialist (1), nurse (1)
- *Issue : pathologist and patient*

results of 2010-2013 presented at SIUrO 2014

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Percentage of pts discussed in MDM (personal data)

Indicator 3 – Multidisciplinary approach to patient care	
Indicator 3	
Topic	MDM of diagnostic and therapeutic path of the patient
Type of indicator	Process
Numerator	Number of patients discussed in MDM
Denominator	Total number of treated patients
Standard	80%*
Time period for data collection, frequency of analysis	1 year, repeated every 2 years

*The standard proposed is the average percentage value considering the VC centers data.

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Critical Reviews in Oncology/Hematology

journal homepage: www.elsevier.com/locate/critrevonc

Quality indicators in the intensity modulated/image-guided radiotherapy era

P. Gabriele (MD)[a,*], A. Maggio[b], E. Garibaldi[a], C. Bracco[b], E. Delmastro[a], D. Gabriele[c], A. Rosi[d], F. Munoz[e], N. Di Muzio[f], R. Corvò[g], M. Stasi[b]

Patients seen in MDMs in the VC.

Disease	% patient seen in MDM
Breast	88% (range: 65%–100%)
Head and Neck	84% (range: 70%–100%)
Hematology	68% (range: 21%–100%)
Gastrointestinal	86% (range: 60%–100%)
Genitourinary	75% (range: 60%–100%)
Gynecology	75% (range: 50%–100%)
Lung/thorax	88% (range: 80%–100%)
Palliation	34% (range: 20%–70%)
Sarcoma	85% (range: 70%–100%)

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Evaluation of MDMs in Candiolo

1. The role and the presence of pathologist (only in 1/9 MDMs)
2. The presence of radiologist (only in 5/9 MDMs)
3. The presence of the patient (only in 5/9 MDMs)
4. Only two paper published (more than 6.000 patients seen in the nine MDM during the last 7 years period!)

1. Optimization of staging protocols in prostate (mpMR and choline PET) and GI cancers (echo vs CT vs MR vs FDG PET for rectal cancer and pancreas cancer)
2. Reduction of waiting times to start therapy for preoperative RT(CT) and concomitant chemoradiation (GY-H&N)
3. More easily participation to international / national protocols
3. Introduction of second opinion for radiological and pathological initial assessment of tumor when absent radiologist or pathologist

theoric score: 6.75 (4 MDMs) to 7.75 (5 MDMs)

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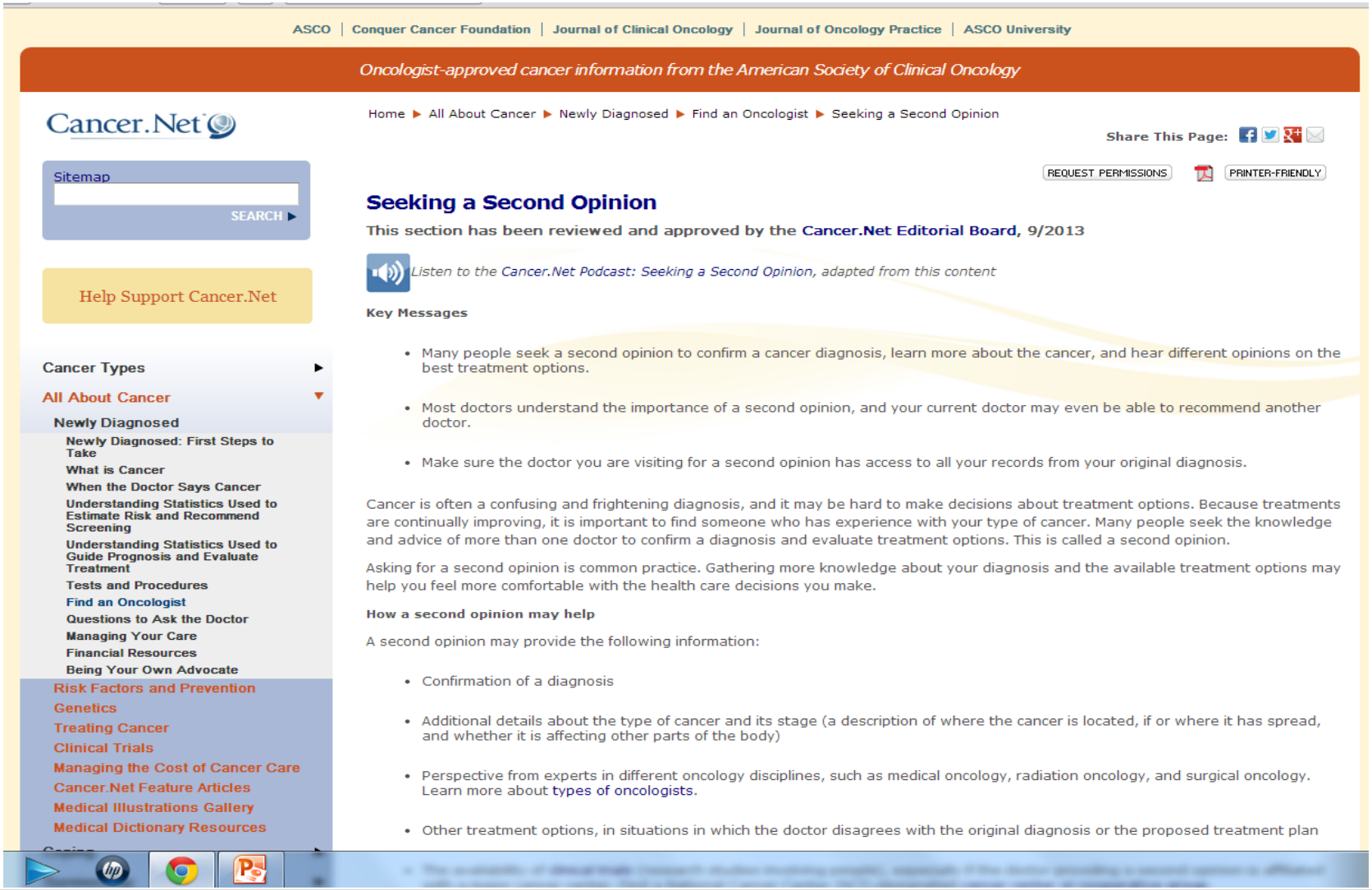
Seeking a second opinion …… the ASCO solution



ASCO | Conquer Cancer Foundation | Journal of Clinical Oncology | Journal of Oncology Practice | ASCO University

Oncologist-approved cancer information from the American Society of Clinical Oncology

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Seeking a Second Opinion

This section has been reviewed and approved by the Cancer.Net Editorial Board, 9/2013

Listen to the Cancer.Net Podcast: Seeking a Second Opinion, adapted from this content

Key Messages

- Many people seek a second opinion to confirm a cancer diagnosis, learn more about the cancer, and hear different opinions on the best treatment options.
- Most doctors understand the importance of a second opinion, and your current doctor may even be able to recommend another doctor.
- Make sure the doctor you are visiting for a second opinion has access to all your records from your original diagnosis.

Cancer is often a confusing and frightening diagnosis, and it may be hard to make decisions about treatment options. Because treatments are continually improving, it is important to find someone who has experience with your type of cancer. Many people seek the knowledge and advice of more than one doctor to confirm a diagnosis and evaluate treatment options. This is called a second opinion.

Asking for a second opinion is common practice. Gathering more knowledge about your diagnosis and the available treatment options may help you feel more comfortable with the health care decisions you make.

How a second opinion may help

A second opinion may provide the following information:

- Confirmation of a diagnosis
- Additional details about the type of cancer and its stage (a description of where the cancer is located, if or where it has spread, and whether it is affecting other parts of the body)
- Perspective from experts in different oncology disciplines, such as medical oncology, radiation oncology, and surgical oncology. Learn more about types of oncologists.
- Other treatment options, in situations in which the doctor disagrees with the original diagnosis or the proposed treatment plan

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Pathological review as second opinion

Am J Surg Pathol. 2008 May;32(5):732-epub 31815a04f5.

Mandatory second opinion in surgical pathology referral material: clinical consequences of major disagreements.

Manion E Cohen MB Weydert J

Department of Pathology, University of Iowa Carver College of Medicine, Iowa City, IA, USA.

Eur Urol. 2013 Aug;64(2):193-8.. Epub 2013 Mar 17.

Phase 3 study of adjuvant radiotherapy versus wait and see in pT3 prostate cancer: impact of pathology review on analysis.

Bottke D Golz R Störkel S Hinke A Siegmann A Hertle L Miller K Hinkelbein W Wiegel T

Department of Radiation Oncology, University Hospital Ulm, Ulm, Germany. dirk.bottke@uniklinik-ulm.de

Radiological review as second opinion

AJNR Am J Neuroradiol 23:1622–1626, November/December 2002

Reinterpretation of Cross-Sectional Images in Patients with Head and Neck Cancer in the Setting of a Multidisciplinary Cancer Center

Laurie A. Loevner, Adina I. Sonners, Brian J. Schulman, Kerstin Slawek, Randal S. Weber, David I. Rosenthal, Gul Moonis, and Ara A. Chalian

RESULTS: Change in interpretation occurred in 56 patients (41%) (95% CI: 33–49%, $P < .001$). Forty-six patients (34%) had a change in T, N, and/or M staging (26–42%, $P < .001$). Change in T stage occurred in 27 cases (20%) (13–27%, $P < .001$) (upstaged in 22, downstaged in five), and a change in N stage in 26 cases (19%) (12–26%, $P < .001$) (upstaged in 20, downstaged in six). Two patients (1.5%) had missed systemic metastases. Three patients with an initial diagnosis of cancer were found to be cancer-free, and six patients had a diagnosis of new second primary cancers that were missed at original interpretation. One patient had a missed middle cerebral artery aneurysm. Changes in image interpretation altered treatment in 55 (98%) of 56 patients and affected prognosis in 53 patients (95%) ($P < .001$).

CONCLUSION: Reinterpretation of cross-sectional images in the setting of a multidisciplinary cancer center has a significant effect on staging, management, and prognosis in patients with head and neck cancer.

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Second opinions: pro vs contra

Second opinions for patients with cancer

Can give peace of mind but should be used wisely

Second opinions can give much greater peace of mind for patients with cancer and their doctors, and occasionally they can lead to a radical reappraisal of the suggested plan of treatment. But it is vital that they are used wisely and are not seen as an essential requirement before treatment can begin. In most cases they are unlikely to make much overall difference to the success or otherwise of treatment, and their impact should be closely audited.

KAROL SIKORA
Professor of clinical oncology

ICRF Oncology Unit,
Royal Postgraduate Medical School,
Hammersmith Hospital,
London W12 0NN

"If you want a second opinion, I'll ask my computer."

Second opinion (theoric score: 4): it can't be considered as multidisciplinary approach but it will be useful if added to MDM!

ESTRO School

Are MDMs cost effective? Advantages of MDMs

There were two non-randomised studies that reported results of **MDMs in cancer care:**

- Fader et al (1998): with **melanoma, the costs of health care were 33% to 50% lower** in patients whose management decisions were made by an MDM

- Hagiwara et al. (2011): team for patients with **haematologic malignancies.** It was found that incidences of hepatic complications, hyperglycemia, and central venous catheter infection were lower in the 'after' group than in the 'before' group, and **costs fell by about 20%**

RESEARCH Open Access

Are multidisciplinary teams in secondary care cost-effective? A systematic review of the literature

K Melissa Ke[1*], Jane M Blazeby[2,3], Sean Strong[2], Fran E Carroll[2], Andy R Ness[1] and William Hollingworth[2]

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Issues of MDMs

- None of the included studies in this review has accounted for the full costs of administering, preparing for and attending an MDM

- An audit conducted at a large teaching hospital/cancer centre estimated that the average annual cost of MDMs in salaries alone was about £1 million

Fosker CJ, Dodwell D: The cost of the MDT (2010)

The omission of the associated costs in any cost-effectiveness analysis of MDM could lead to an underestimation of costs

RESEARCH Open Access

Are multidisciplinary teams in secondary care cost-effective? A systematic review of the literature

K Melissa Ke[1*], Jane M Blazeby[2,3], Sean Strong[2], Fran E Carroll[2], Andy R Ness[1] and William Hollingworth[2]

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Medicolegal implications of MDMs

Multidisciplinary care in oncology: medicolegal implications of group decisions

Mark A Sidhom, Michael G Poulsen

Figure: Multidisciplinary teams can provide comprehensive cancer care, but doctors remain individually liable

Question: What is the implication of individual responsability?

Consensus is growing that multidisciplinary meetings (MDMs) provide the best means of formulating comprehensive treatment plans for patients with cancer. Although many doctors attend MDMs and contribute to the decision-making process, only a few will become involved in a patient's care after the team meeting. Despite this, if a patient was grieved by a decision made in a MDM and wished to recover damages, all doctors present at the meeting would be personally accountable for decisions related to their area of expertise. Doctors should be made aware of the legal implications of their participation in such meetings. A greater awareness of these responsibilities and improved team dynamics should optimise outcomes for patients while limiting exposure of the participants to legal liability. Special attention should be given to providing patients with adequate information in this combined speciality setting.

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Teamwork and Team Decision-making at Multidisciplinary Cancer Conferences: Barriers, Facilitators, and Opportunities for Improvement

Table 4 Positive aspects of MCCs and aspects requiring improvement:

Question—What are the positive aspects of MCCs, and which aspects require improvement?

Emerging themes ($n = 19$)	No.	Representative quotes from MCC members
Positive aspects		
Camaraderie and consensus	5	We all feel very comfortable … which is why I think it works well (O1)
Clinical discussion	4	Probably the best part of the process is the clinical discussion (N1)
Attendance of specialists	3	It's [MCC meeting] very well attended in the sense that we always have pathological cover, radiological cover, and oncological cover (S1)
High standard of care	2	The patients clinically are managed well in that good, sound clinical decisions are discussed and ultimately formulated (N1)
Patient-centered	2	We know the patients well, their morbidities, their preferences (S3)
Efficiency	1	They're quite fast, I think just that it's more organized (M1)
Preparation	1	I think the fact that we prepare all our cases before the MCC (N3)
Video-conferencing facilities	1	With the hospitals 20 to 30 miles apart … the good AV, the high-quality AV facilities help us (S1)
Aspects requiring improvement		
More time	5	More time. Our meetings are far too short (M3)
Working in a more structured way	4	When everybody's chipping in it, gets quite heated.… I think there should be more set rules (M1)
Better preparation	3	I think the time for the specialist MCC is adequate. It's just [that] the preparation by all departments is not good enough (S3)
Better case selection/fewer cases	3	Bring to the specialist MCC those cases that are actually clinically problematic, which would cut it down tremendously (S4)
Improved IT and video-conferencing	3	The video link-up could be better (M2)
Better attendance	2	Better time management of all individuals that should be at the MCC—i.e., allowing them time to attend the MCC (S3)
More patient-centered	2	I think the patient's views need to be represented a bit more (N4)

IT information technology, *AV* audio-video

Summary of the evidence of the effectiveness of MDM

Outcomes assessed	Study	E*	Total cases	Cancer type	Difference in MDT meeting arm and control arm with respect to the outcome
Survival	[7]	2b	88	Lung	NSD
	[8]	3b	67	Glioma	NSD (18.7 versus 11.9 months, $P = 0.11$)
	[9]	4	240	Lung	NSD
	[10]	4	144	Oesophageal	5 years (52% versus 10%, $P < 0.001$)
	[11]	4	243	Lung	Median (6.6 months versus 3.2 months)§
	[12]	4	533	Ovarian	In favour of MDT group§
	[13]	4	16035	All cancers	5 years (71% versus 63%, $P < 0.001$)
	[14]	4	—	Lung	1 year (23.5% versus 18.3%)§
Quality of life	[7]	2b	88	Lung	NSD
Patient experience	[7]	2b	88	Lung	Improved in MDT group, $P = 0.01$
	[15]	4	269	Breast	Improved in MDT group, $P < 0.001$
Rate of intervention	[11]	4	243	Lung	Patients receiving chemo (23% versus 7%)§
	[16]	4	112	Lung	30% ↑ in resection in favour of MDT
	[8]	3b	67	Glioma	Patients having chemo (55% versus 17%)§
	[9]	4	240	Lung	↑ in resection (23.4 % versus 12.2%)§
	[17]	3b	2935	Colorectal	↑ in trial recruitment (10.3 versus 5.1%)§
Time to intervention	[15]	4	269	Breast	Time to treatment (29.6 versus 42.2 days)§
	[16]	4	112	Lung	NSD
	[8]	3b	67	Glioma	NSD
Staging accuracy	[18]	3b	118	Upper GI	MDT improved staging accuracy§
Costs per patients	[19]	4	208	Melanoma	MDT saved $1600 per patient
Decision quality as prediction of accuracy	[20]	4	50	Lung	NSD, Team discussion did not improve the quality of decision making overall.
Psychological morbidity of team members	[21]	5	72	Breast	lower prevalence of psychiatric morbidity (15.7% versus 26.6% $P < 0.005$)

*E**: levels of evidence as defined by Oxford Centre for Evidence-Based Medicine (1a: systematic review of RCTs, 1b: individual RCT (with narrow Confidence Interval), 1c: all or none, 2a: systematic review of cohort studies, 2b: individual cohort study (including low quality RCT), 2c: "Outcomes" Research, 3a: systematic review of case-control studies, 3b: individual Case-Control Study, 4: case-series (and poor quality cohort and case-control studies), 5: expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"), NSD: no significant difference found in both groups, §statistically significant differences, and chemo: chemotherapy.

6/8 studies

0/1 studies

2/2 studies

5/5 studies

1/3 studies

3/4 studies

17/23 studies

International Journal of Breast Cancer 2012

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Summary of the evidence of the effectiveness of MDMs (2*)

7 other studies (5 prostate, 1 H&N, 1 breast)	
Increase survival	2/7
Increase QoL	2/7
Decrease Waiting time	1/7
Rate of intervention	1/7
Changing treatment's attitude	5/7
Patients satisfaction	2/7

*Studies not computed in the previous slides reported in the last slide

Challenges in realising the full potential of MDMs

Review Article

Cancer Multidisciplinary Team Meetings: Evidence, Challenges, and the Role of Clinical Decision Support Technology

Vivek Patkar,[1,2] Dionisio Acosta,[2] Tim Davidson,[1] Alison Jones,[1] John Fox,[3] and Mohammad Keshtgar[1,2]

[1] *Breast Unit, Royal Free Hospital, London NW3 2QG, UK*
[2] *University College London, London W1W 7EJ, UK*
[3] *Department of Engineering Science, Oxford University, Oxford OX1 3PJ, UK*

From a theoric point of view MDM can do numerous advantages; but, for obtain some of these advantages we need to:

Table 2: Challenges in realising the full potential of cancer MDT meeting.

Establishing robust mechanisms for prospective assessment of MDT performance
Ensuring MDT recommendations are followed in the practice
Ensuring adherence with standards including evidence-based guidelines
Establishing reliable interfaces with primary care to ensure continuity of care
Ensuring active patient participation
Achieving right balance of educational and care delivery objectives of this forum
Ensuring the consistent collection of crucial data such as disease staging and outcomes
Limiting exposure of the MDT members to medicolegal liability

International Journal of Breast Cancer 2012

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Exemple of a tool developed for breast cancer MDM

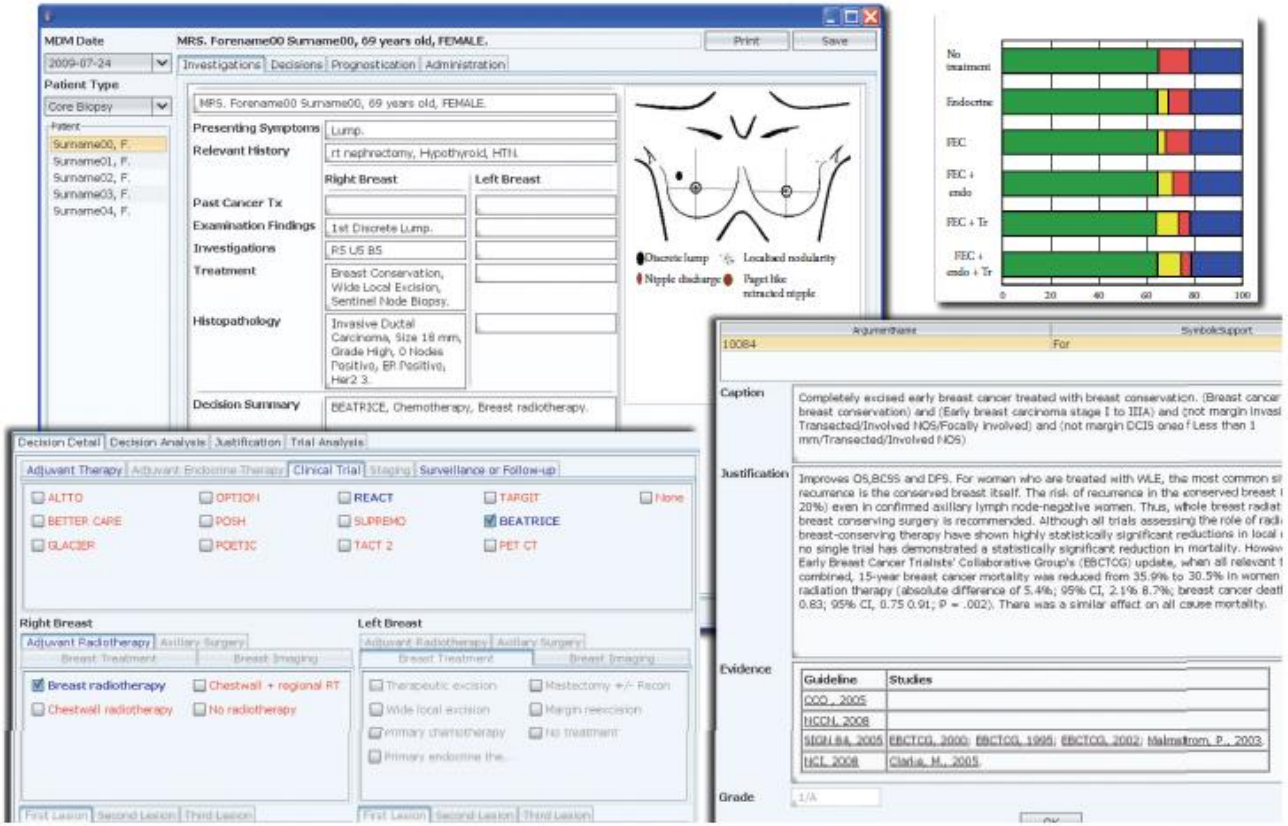

FIGURE 1: Composite screenshot describing some of the functionalities of an example CDS tool developed for breast cancer MDT meeting. Upper left: the summary screen for the patient. Upper right: one of the many prognostication tools available, Lower left: decision panel where system recommendations and eligible clinical trials are highlighted in blue. Lower right: the evidential justification for each recommended option.

A score for MDMs

1. Multidisciplinary clinics (Specific Cancer Units: ex: Prostate or Breast Cancer units: the best option (theoric score: 9)

1. **Multidisciplinary meetings with patient's presence (theoric score: 8)**

2. Multidisciplinary meetings without patient's presence (score: 7)

4. Multidisciplinary discussions just of the difficult cases (score: 6)

5. Second opinions (score: 4)

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Conclusion: Demonstrated PROS for MDMs

1. **Decreases waiting time to treatment** for H&N, pancreas, anus-rectal and gynecological cancers
2. Improves diagnostic/therapeutic paths and ensure application of guidelines: yes for prostate, breast and glioma
3. **Changes treatments attitude and rate of intervention:** yes for lung, breast and prostate
4. Garantees/facilitates timely access to physical/phycho-emotional rehabilitation programs: yes for prostate and breast
5. Helps and improves management of disease recurrence and timely access to support and palliative care
6. Helps enrollement in innovative and experimental therapies: yes for colo-rectal cancers, breast and prostate
7. Improves the education of professionals involved in patients care
8. Increases patients satisfaction: yes for prostate and breast
9. **Improves survival:** yes for lung, oesophageal, ovarian and HR prostate cancers
10. Guarantees a minor risk of law suits

FM Boyle et al: J Clin Oncol 2005, A Fleissig et al Lancet Oncol 2006, MA Sidhom et al Lancet Oncol 2006, CS Sternberg et al BJU int 2007, LE Horvath et al Lancet Oncol 2010, J Walsh et al BMC Heakth Serv Res 2010, EM Kesson et al BMJ 2012

Future directions: Specific Cancer Units (example: Prostate Cancer Units)

EUROPEAN UROLOGY 60 (2011) 1197–1199

available at www.sciencedirect.com
journal homepage: www.europeanurology.com

European Association of Urology

Editorial

The Prostate Cancer Unit: A Multidisciplinary Approach for Which the Time Has Arrived

Leonard G. Gomella *

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EUROPEAN JOURNAL OF CANCER 47 (2011) 1–7

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journal homepage: www.ejconline.com

Current perspective

The requirements of a specialist Prostate Cancer Unit: A discussion paper from the European School of Oncology

Riccardo Valdagni [a,b,*], *Peter Albers* [c], *Chris Bangma* [d], *Lawrence Drudge-Coates* [e], *Tiziana Magnani* [b], *Clare Moynihan* [f], *Chris Parker* [g], *Kathy Redmond* [a], *Cora N. Sternberg* [h], *Louis Denis* [i], *Alberto Costa* [a]

Table 1 – Prostate cancer units: main requirements*

	Requirements
General recommendations	Able to provide care for patients with prostate cancer at all stages Research and teaching activities as essential interests Setup of a European certification process based on agreed-upon requirements
Mandatory requirements	
Critical mass	Able to cover a population of at least 300 000 people Able to have >100 newly diagnosed cases under its care (for treatment or observation) Able to carry out treatments and observational strategy protocols under the guidance of the unit's multidisciplinary team
Documentation/audit	Recording of basic data (including side-effects and complications) Able to provide data for yearly audit in which quality indicators and protocols are reviewed Able to have written protocols for diagnosis and management of prostate cancer at all stages
Core team	Members with specialist training in prostate disorders, spending an agreed-upon amount of time working with prostate cancer, attending multidisciplinary meetings for case management and audit purposes, and undertaking continuing professional education on a regular basis
Clinical director	Responsible for coordination
Uropathologist	One or more, responsible for prostate pathology reports
Urologist	Two or more, each carrying out ≥25 prostatectomies per year (≥50 prostatectomies per unit per year)
Radiation oncologist	Two or more, each performing radiotherapy on ≥25 patients per year (≥50 treatments per unit per year); at least 15 brachytherapy procedures (high or low dose rate)
Medical oncologist	One or more, each seeing ≥30 patients per year
Nurse specialist in prostate cancer	At least one, able to provide care for patients at different stages
Data manager	One or more, responsible for entering data
Documentation representative	One, responsible for the documentation system, monitoring the compilation of patient data, and supporting staff in compilation
Associated services and noncore personnel	Additional professional services available in the various European countries under different professional headings
Radiologist	One or more, spending at minimum 20–30% time on prostate disease
Medical physicist	One or more, each carrying out radiation treatment planning on ≥40 treatments per year
Radiation therapy technologist	Two or more, each carrying out simulation and treatment on 25 radiotherapy treatments per year
Physiotherapist	One or more, trained in rehabilitation
Palliative care specialist	One or more, responsible for palliative therapy and supportive care
Professional offering psychological support	Experienced in seeing prostate cancer patients to offer support after the diagnosis, during therapy, or in decision making
Sexologist/andrologist	Able to provide counselling about changes in sexual function
Geriatrician	Trained in the care of elderly patients with prostate cancer
Clinical trials coordinator	One or more, responsible for all clinical trials and research protocols
Patient advocate and advocacy group	To offer information on the disease and its multiple facets To help improve the quality of care offered
Organisation	
Multidisciplinary case management	Held weekly, attended by the core personnel and possibly by the noncore personnel Aimed at discussing ≥90% of all cases
Relation to the patient	Respect of patients' right to information and self-determination Offer of clear and easy-to-understand written and oral information
Clinics	
Multidisciplinary clinics for newly referred patients	At least one clinic per week Appointment within 10 working days of receipt of referral Depending on risk class, urologist, radiation oncologist, and medical oncologist, synchronously or in rapid succession
Follow-up clinics	Supervision by one of the prostate cancer unit core teams responsible for initial treatment
Recurrent/advanced prostate cancer clinics	Held at least every 2 wk Urologist, radiation oncologist, and medical oncologist, synchronously or in rapid succession

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The new role of the patient in MDMs «No decision about me without me»

Involving patients in decisions about their treatment is central to UK health policy and embedded in the National Health Service (NHS) Constitution, with the current government using the phrase “No decision about me without me” to describe their aspiration for the NHS.

This study aim:

- To explore what current cancer patients know, and need to know, about the MDMs involved in their care to ensure effective involvement in decision-making.
- To examine cancer MDM members’ views on how best to ensure that patients are involved in decision-making
- To gain patient and MDM members views on how to overcome any barriers identified and improve current practice.

Design and sample

Semi-structured interviews were conducted with current upper gastrointestinal and gynaecological cancer patients from one cancer centre and with MDM members

Taylor *et al. BMC Health Services Research* 2014, **14**:488
http://www.biomedcentral.com/1472-6963/14/488

BMC Health Services Research

RESEARCH ARTICLE Open Access

“No decision about me without me” in the context of cancer multidisciplinary team meetings: a qualitative interview study

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The patients said: «No decision about me without me» (2)

Results

Characteristics of participants:

Twenty-one interviews were conducted. This included nine GI and GY patients aged 25–80 years. Twelve MDM members were interviewed.

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Patients	Patients
• Current out-patients who have completed primary treatment for Upper GI or Gynaecological cancer within the previous two months	• Aged 17 or under
	• Unable to speak English
	• Unable to cope either physically or emotionally, with the research protocol
• Able to give informed consent	• Patients with major communication or cognitive problems (i.e. degenerative illness or other condition affecting cognition and/or comprehension).
• Sufficient understanding of written and spoken English to enable participation	
MDT members	
• Core MDT member	
• Responsible for communication about treatment (including Oncologists, Surgeons and Clinical Nurse Specialists)	

Conclusions

1. Patients had limited knowledge of MDMs or opportunities to input to MDM meeting discussions.
2. There is a need to ensure MDM processes are both efficient and patient-centred.
3. The operationalization of “No decision about me without me” in the context of MDM models of care requires further consideration.
4. Methods for ensuring that patients are actively integrated into the MDM processes are required to ensure patients have an informed choice regarding engagement, and to ensure recommendations are based on the available patient-based & clinical evidence.

Recommended references

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- No decision about me without me" in the context of cancer multidisciplinary team meetings: a qualitative interview study. Taylor et al. BMC Health Services Research 2014, 14:488
- Multidisciplinary breast cancer teams and proposed standards Sertaç Ata Gu¨ler1, N. Zafer Cantu¨rk. Ulusal Cer Derg 2015; 31: 39-41

Thank you for your attention

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Institut de Cancérologie de Lorraine

Alexis Vautrin

Ensemble, construisons l'avenir

METHODS FOR MONITORING QUALITY INDICATORS

Karine HERLEVIN-GERARD, Physicist PhD

- Institut de Cancérologie de Lorraine (ICL), Nancy (France) -

OUTLINE

I. INTRODUCTION

❖ Need for a method to monitor and analyze the abundant data in Radiation Oncology.

⇒ Statistical Process Control (SPC)

II. ESSENTIAL CONCEPTS TO START WITH STATISTICAL PROCESS CONTROL (SPC)

❖ Goal: reaching the target with minimal variation

III. STATISTICAL PROCESS CONTROL IN PRACTICE

❖ Steps to set up a SPC analysis

❖ The key tools of SPC:
- ➢ Capability indicators
- ➢ Control charts

❖ Application to pre-treatment quality controls in IMRT

IV. CONCLUSION

LEARNING OBJECTIVES

✓ To understand **variability,** its impact and behavior (differentiate random and special causes).

✓ To describe the **DMAICS** method to introduce a SPC analysis.

✓ To explain the difference between **specifications** and **natural variation**.

✓ To understand the interest of **performance indicators** and **control charts**.

I. INTRODUCTION

1. Continuous improvement of quality in healthcare

- **Quality indicators in healthcare**
  - ❑ developed recently (compared to industry)
  - ❑ → data has become **abundant**.

- **New challenges and aims**
  - ❑ to analyze the data rigorously and objectively in order to obtain reliable information to take:
    - ✓ right and effective decisions
    - ✓ based on facts and not only on impressions or opinions.

- **Process approach (= GLOBAL view)**
  - ❑ A process is a complex set of tasks to follow to achieve an activity.

- **Most of the methods used in healthcare**

  = « **picture** » of quality at a precise moment
  - ❑ *Ex*: *clinical audit, healthcare facilities accreditation process…*

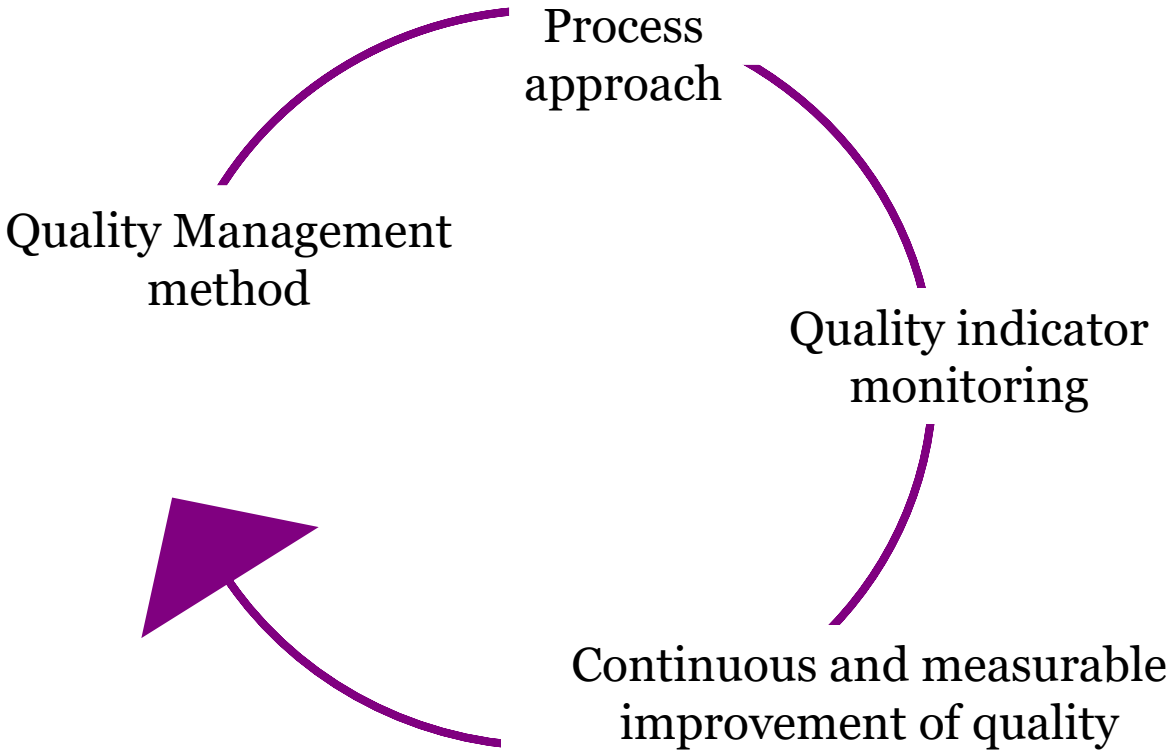
2. Requirements to choose the best adapted method to our needs

Part 1 :
Introduction to SPC

Part 2 :
Essential concepts to start with SPC

Part 3 :
SPC in practice

Part 4
Conclusion



= STATISTICAL PROCESS CONTROL (SPC)

II. ESSENTIAL CONCEPTS TO START WITH SPC

1. Understanding variation

Part 1 :
Introduction to SPC

Part 2 :
Essential concepts to start with SPC

Part 3 :
SPC in practice

Part 4
Conclusion

• All things vary: no two things are exactly the same.

• All variations have a source.

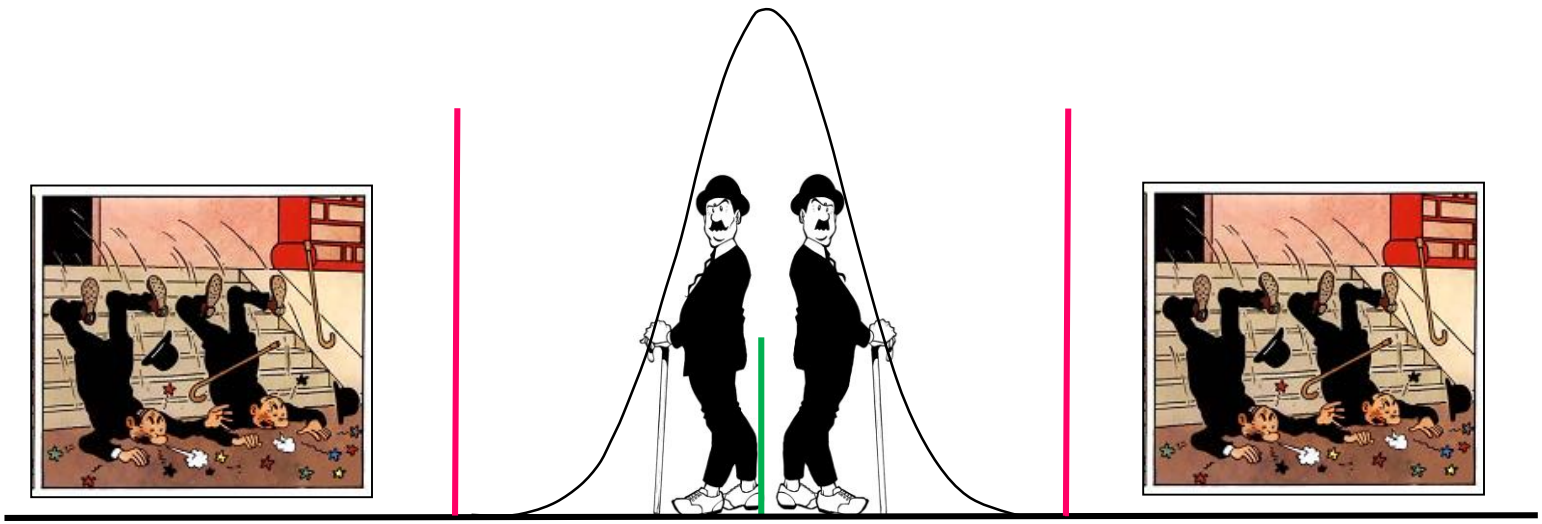
• The cause of poor performance is unmanaged sources of variation.

• We can **manage/control variations** by identifying and removing the source.

(No more stairs...)

1. Understanding variation

TRADITIONAL VIEW OF VARIATION



LSL **Target** **USL**

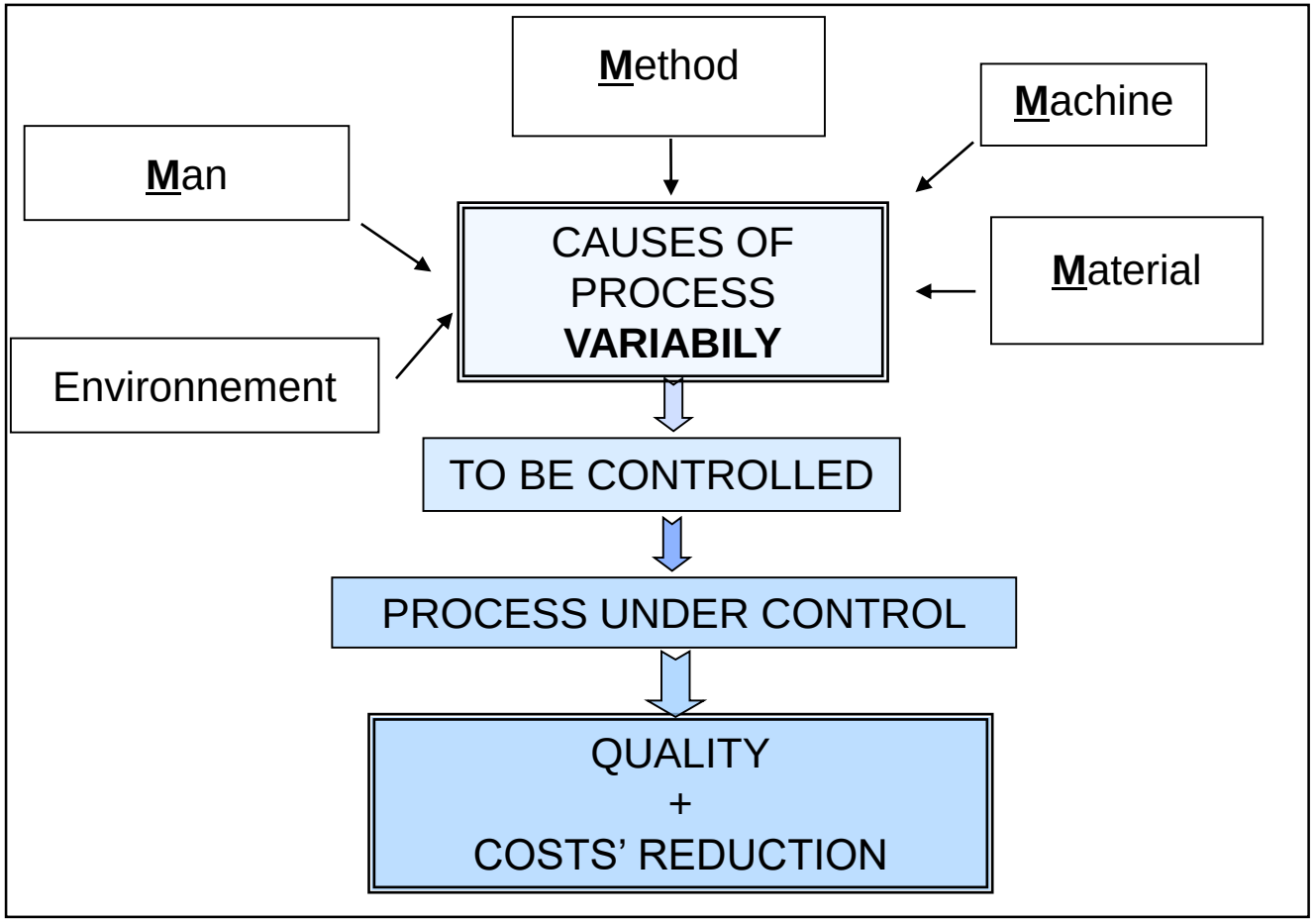
=Lower Specification Limit **=Upper Specification Limit**

⇒ Binary analysis

⇒ The global performance of the process is not improved.

2. Quality's ennemy: process variability

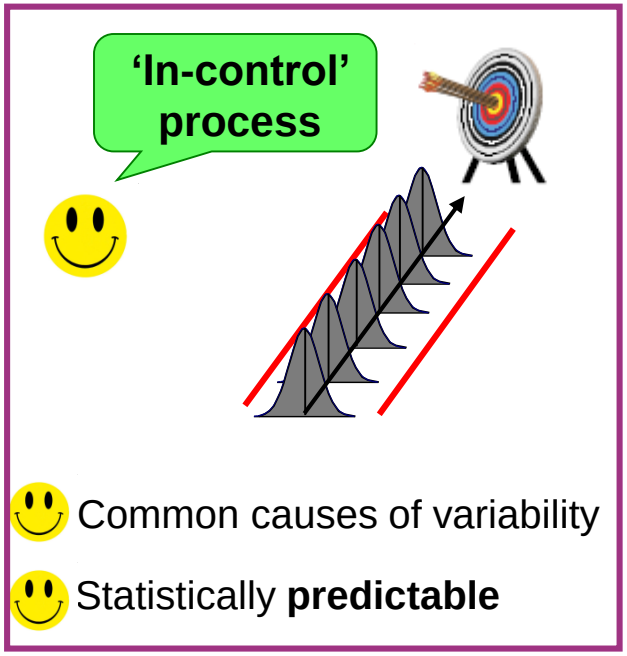
Quality: a set of characteristics that ensure that a product or a service is meeting customer requirements (tolerances, specifications).



⇒ *Understanding the causes of process variability: key to improvement.*

3. Goal: Reaching the target with minimal variation

- **Two types of causes of variability:**
  - → **Common causes** (or random causes)
    Inherent in the process, responsible from small variations
  - → **Special causes** (or assignable causes)
    Not inherent in the process, their effects significantly disturb the normal evolution of the process

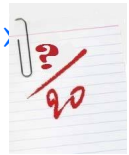


Aim of SPC: to make processes in control

4. Two fundamental tools of SPC

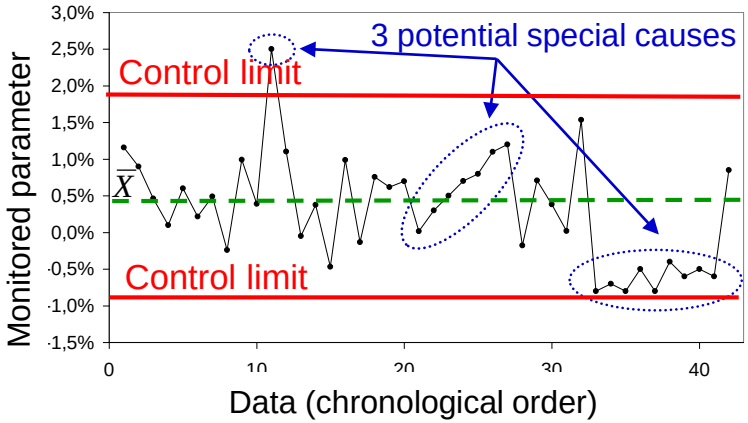
1. Capability indicators:

= rate the performance



Quantify the ability of a process to produce data that are within specifications, at a precise moment.

2. Control charts:



Monitor the process over time.

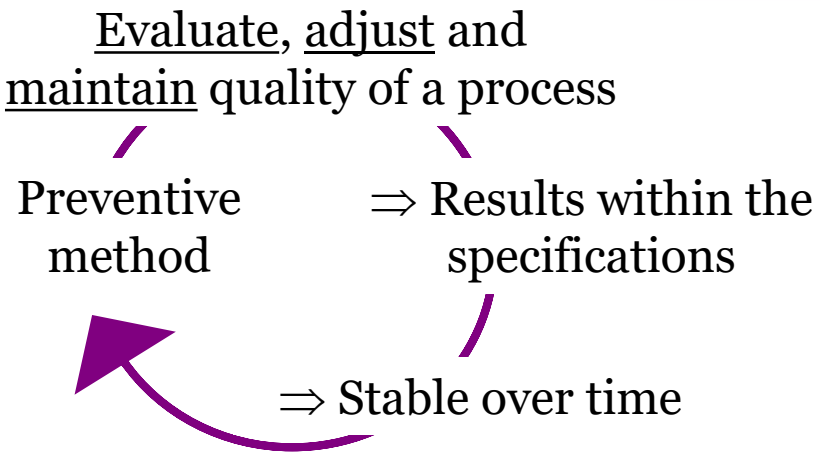
⇒ detect significant changes.
⇒ effects of special causes can be reduced or removed.

III. SPC IN PRACTICE

1. Statistical Process Control (SPC)

- **Definition:**

Measurable *and* ***continuous*** *improvement of quality*



- **Applications:**

– widely used in industry since 1950 in Japan and 1970 in the USA and in Europe (ex. food industry, automotive industry…)

– Radiotherapy: essentially since 2005 with a growing interest in 2012.

Pawlicki *et al.* (2005), Vega *et al.* (2012), Lopez-Tarjuelo *et al. (2015),* Lopez-Tarjuelo *et al. (2016)*	Linear accelerators quality controls. Ionization chambre stability
Pawlicki *et al.* (2008), Nordström *et al.* (2012)	Clinical trials, multicenter study.
Breen *et al.* (2008), Gérard *et al.* (2009), Pawlicki *et al.* (2009), Villani *et al.* (2010), Palaniswaamy *et al.* (2012) Sanghangthum *et al* .(2012), Gagneur *et al.* (2014), Bellec *et al.* (2017)	IMRT / Cyberknife patient-specific quality verification.
Pawlicki *et al.* (2012)	The systematic application of SPC in clinical radiation oncology.

2. Introducing a SPC analysis: DMAICS method*

* From a Six sigma approach

Part 1 :
Introduction to SPC

Part 2 :
Essential concepts to start with SPC

Pa
SP
pra

Pa
Conc

CONTINUOUS IMPROVIEMENT

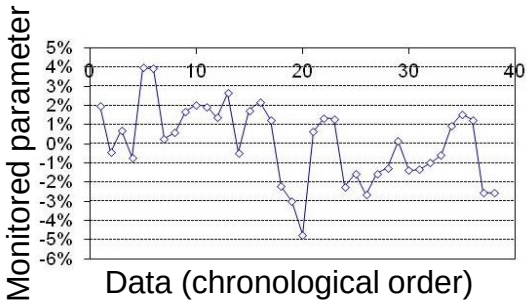
DEFINE

Choice of relevant quality indicators to monitor

MEASURE

1. Verification of the measurement system 's **capability**
2. Characterization of the data distribution
3. Observation of the process

Building a control chart without limits



ANALYZE

Calculation of the process **performance** indicators
Choice of control charts and calculation of control limits

ANALYZE

Searching the **sources of variability**
(Ishikawa)

CONTROL

Process monitoring using control charts
Detection of special causes
Is the process 'under control'?

IMPROVE

Reduction of variability
(5 WHY, Design of Experiments)

STANDARDIZE

Optimization of the process, maintain the gain
Reduction of the frequency of controls?

3. What to measure?

- Choice of relevant indicators, target and specifications.
- *Examples*: (Pawlicki *et al* (2012))

= 'Voice of the customer'

Indicator	Measure	Process Target	Specification limits
Complications for H&N patients	% of patients that need a feeding tube	10%	+5%
Overall attention to patient care	% of patients with quality of life assessments obtained	95%	-5%
Clinical process efficiency	Time from simulation to first treatment	5 working days	+1 working day
Practice consistency	% of replans or field changes during treatment	10%	+5%
Patient-specific QA	% of points passing the 3%/3mm gamma index criteria for IMRT/VMAT plans	100%	-95%

Patient-related

Clinical practice-related

'Quality measures need to be objective, unambigous, clear and quantitative before they can be used effectively. '

4. Verification of the capability of the measurement system

Without being able to measure, impossible to quantify changes.

Part 1 : Introduction to SPC

Part 2 : Essential concepts to start with SPC

Part 3 : SPC in practice

Part 4 Conclusion

Observed dispersion = True dispersion of the process + Dispersion of the measurement system

Consider the measurement as a process itself

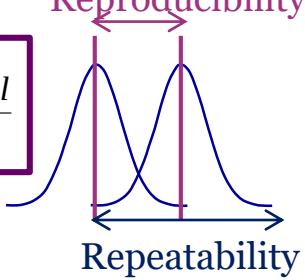
- **Capability of the measurement system (Cpc)**

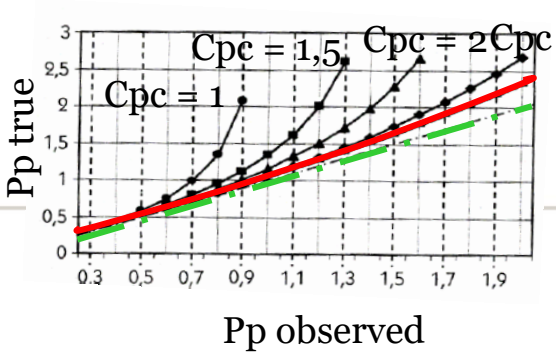
⇒ *Repeatability and Reproducibility study (Gage R&R))*

N° faisceau	Opérateur 1				Opérateur 2			
	1ère mesure Δ(%)	2ème mesure Δ(%)	$\bar{X}$	R	1ère mesure Δ(%)	2ème mesure Δ(%)	$\bar{X}$	R
1	-0,59%	-0,39%	-0,49%	0,20%	-0,76%	-0,44%	-0,60%	0,32%
2	-0,21%	-0,13%	-0,17%	0,08%	-0,44%	-0,34%	-0,39%	0,10%
3	-0,17%	-0,19%	-0,18%	0,02%	-0,70%	-0,47%	-0,59%	0,23%
4	-1,19%	-1,09%	-1,14%	0,10%	-1,19%	-0,99%	-1,09%	0,20%
5	-0,24%	-0,40%	-0,32%	0,16%	-0,36%	-0,59%	-0,48%	0,22%
6	0,17%	0,20%	0,19%	0,03%	-0,03%	-0,26%	-0,14%	0,23%
7	-0,67%	-0,77%	-0,72%	0,10%	-0,85%	-0,81%	-0,83%	0,04%
8	-0,91%	-0,66%	-0,78%	0,24%	-1,09%	-1,07%	-1,08%	0,02%
9	-1,35%	-1,25%	-1,30%	0,10%	-1,39%	-1,43%	-1,41%	0,04%
10	-0,44%	-0,24%	-0,34%	0,21%	-0,75%	-0,71%	-0,73%	0,04%

$$Cpc_{measure\ system} = \frac{Specification\ interval}{6 \cdot \sigma_{measure\ system}}$$

$$\sigma_{measure\ system} = \sqrt{\sigma^2_{repeatability} + \sigma^2_{reproducibility}}$$





CONCLUSION: $Cpc_{measure\ system} \geq 4$

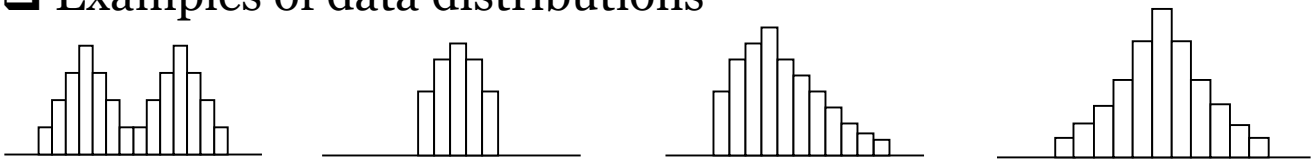
⇒ Observed dispersion ≈ True Dispersion

⇒ **Measure system statistically capable**

M. Pillet (2005)

5. Characterization of the data distribution

- **Build the histogram of the data:**
  - ❑ Examples of data distributions



  - ❑ Understand the shape of your data distribution. Was it expected?

- **Studied case: normal distribution**
  - ❑ Why?
    - ✓ Most of radiotherapy processes follow a normal distribution.
    - ✓ SPC's traditional formulas: based on the hypothesis of a normal distribution.

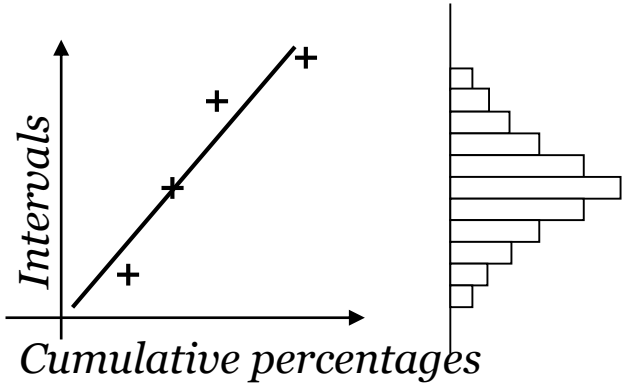
- Important comment: with certain precautions*, it remains possible to use SPC tools for non normal distributions

(no more link between limits of control charts and the α risk, no more link between capability and % of data out of specifications)*

5. Characterization of the data distribution

- **Statistical tests to verify the normality of the data**

❑ Graphical method: Henry line, Quantile-Quantile plot (Q-Q plot)



✓ Aligned points
⇒ Hypothesis of a normal distribution

✓ Can be done without any particular sofware.

✓ Not as powerful as numerical tests.

❑ Numerical methods: Shapiro-Wilk test, Anderson-Darling test, Kolmogorov test…

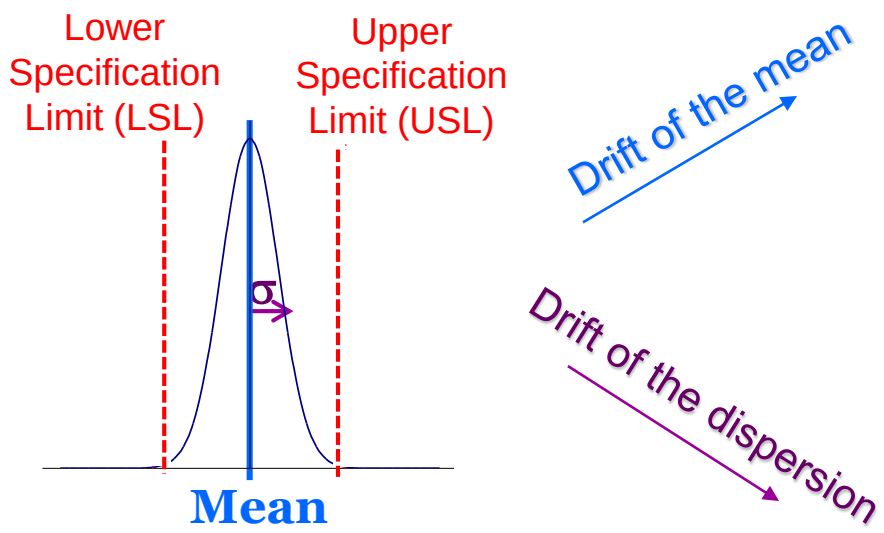
✓ Choice depends on your data

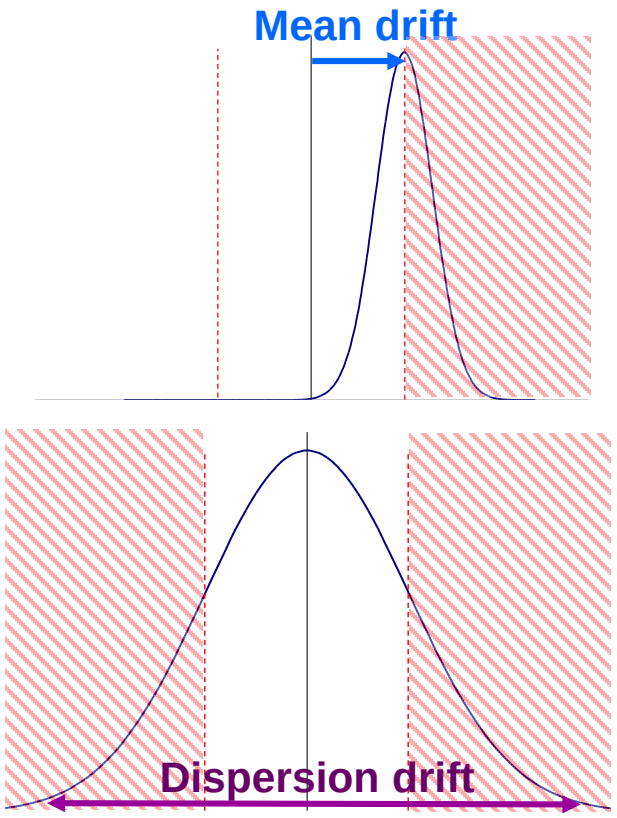
✓ Statistical softwares can easily do those tests

✓ The value of p-value measures how far the data is from a normal distribution.

6. Effects of variability on the process

- A normal distribution is fully characterized with only two parameters:
  - ❑ The **mean**: information on process' **position.**
  - ❑ The **standard deviation σ**: information on process' **dispersion**.





2 causes increasing the proportion of data out of the specification limits

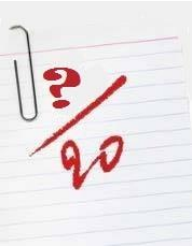
⇒ monitor their evolution

7. Capability assessment

- **Definition of capability:**

= ability of a process to produce data that meet the specifications.

= rate the performance of the process, at a precise moment.

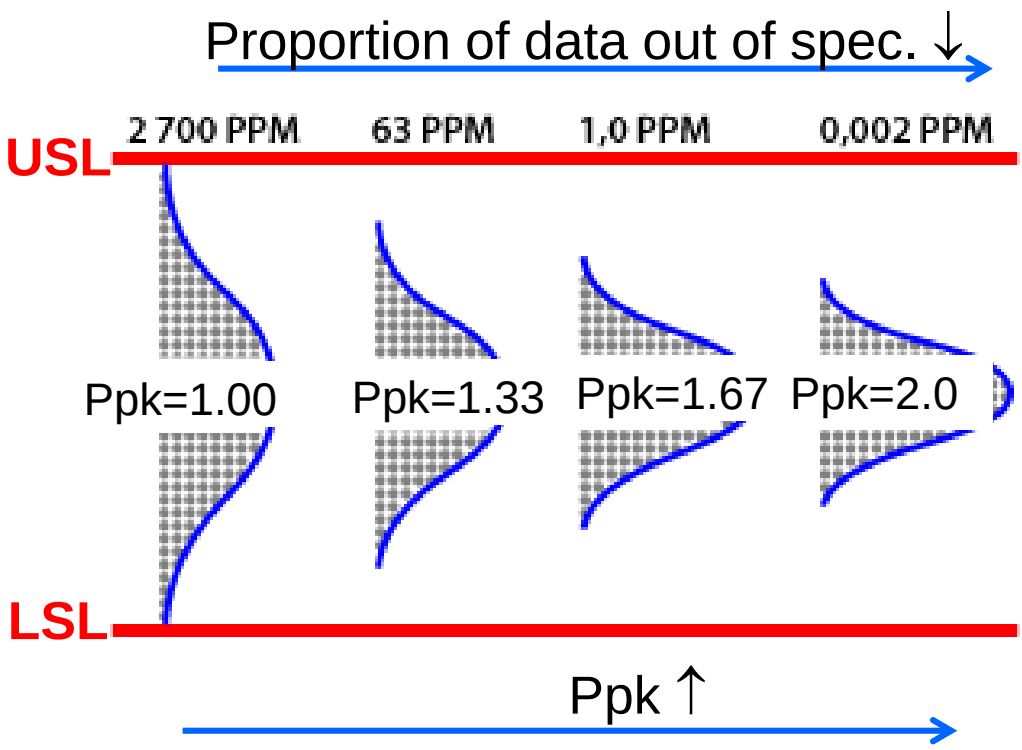


High capability

Low capability

8. Calculation of the performance indicators

Related to the specifications

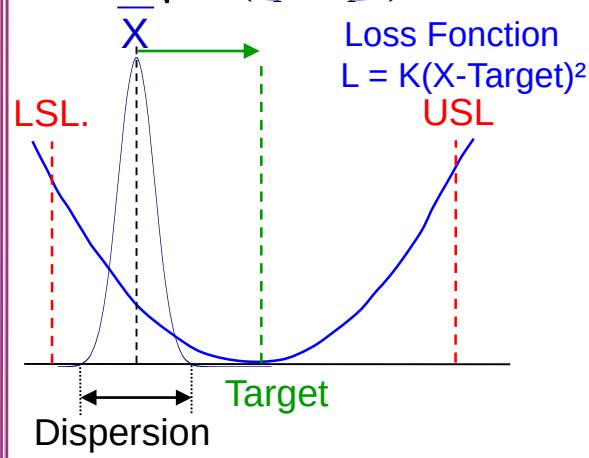


Related to the target

Ppm

$$Ppm = \frac{Specification\ Interval}{6\sqrt{\sigma^2 + \left(\overline{X} - target\right)^2}}$$

$$Ppm = \frac{Pp}{\sqrt{1 + 9(Pp - Ppk)^2}}$$



Ex.: Ppm < 1

- ✓ Aim: to get indicators as high as possible.
- ✓ Calculate the three indicators to be able to identify the reason why data are outside the specifications.

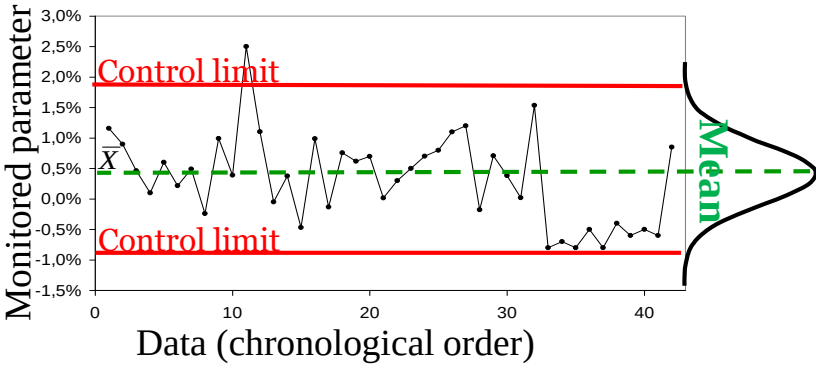
9. Control charts

• Definition:

❑ monitor processes over time.

❑ **a centerline**

❑ **2 statistical control limits** *(based on the natural variation of the process)*.



• Objectives:

❑ Monitor process and maintain under control;

❑ Adjustments **only** when necessary and with caution not to over adjust.

⇒ To take decisions on the process.

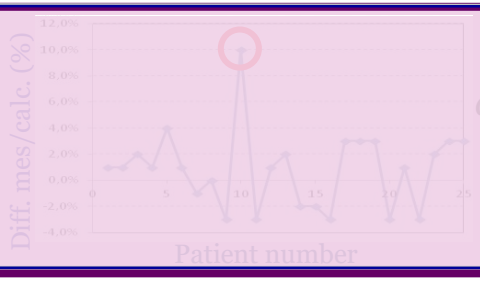
❑ Predictive tool.

⇒ Use of STATISTICAL CONTROL LIMITS to detect **special causes** that disturb the process **before** the results are out of the specifications.

10. Process monitoring: choice of control chart

Type of drifts to detect		Control charts
Large and Fast	*Ex.: wrong adjustment of linac's parameters, errors during measurement…*	**Individual value /** Moving Range (I-MR)

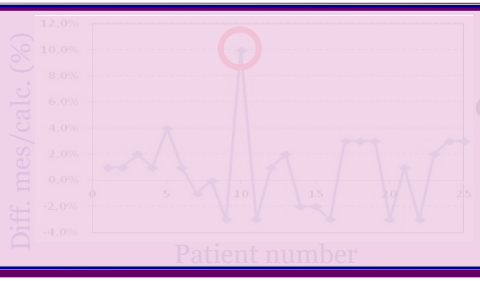
11. Control charts building: Individual value

Type of drifts to detect	Control charts
Large and Fast  *Ex.: wrong adjustment of linac's parameters, errors during measurement…*	**Individual value / Moving Range (I-MR)**

Patient # / Beam #	1	2	3	4	5
1	1,00%	-1,80%	1,68%	-1,07%	3,20%
2	2,02%	-1,27%	-1,15%	-0,55%	3,58%
3	0,20%	2,10%	2,83%	-0,52%	5,49%
4	2,11%	-2,06 %	0,64%	-	3,68%
5	4,61%	0,78%	-0,39%	-	-

Example of a measurement logbook

11. Control charts building: Individual value

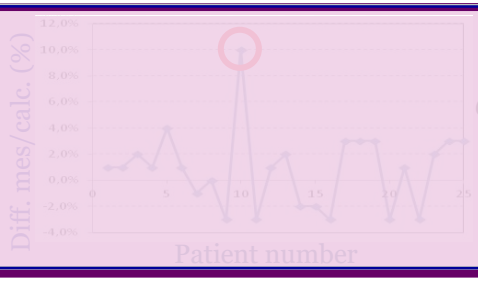
Type of drifts to detect	Control charts
Large and Fast  *Ex.: wrong adjustment of linac's parameters, errors during measurement…*	**Individual value** / Moving Range (I-MR)

B7 =MOYENNE(B2:B6)

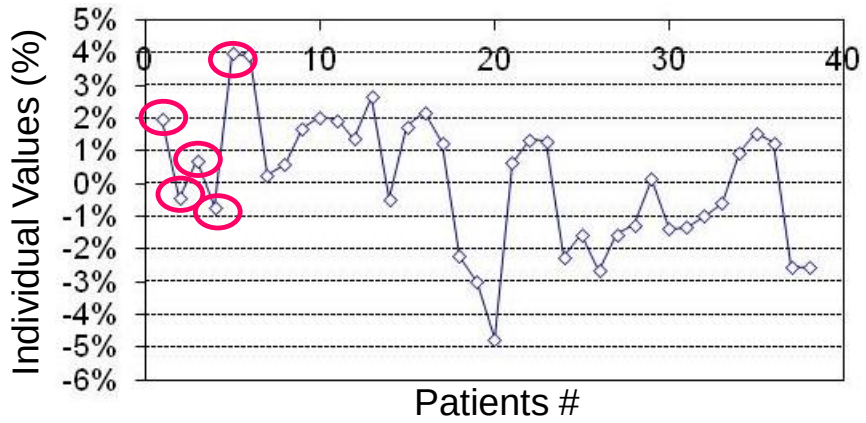
	A	B	C	D	E	F
1	Patient # / Beam #	1	2	3	4	5
2	1	1,00%	-1,80%	1,68%	-1,07%	3,20%
3	2	2,02%	-1,27%	-1,15%	-0,55%	3,58%
4	3	0,20%	2,10%	2,83%	-0,52%	5,49%
5	4	2,11%	-2,06%	0,64%	-	3,68%
6	5	4,61%	0,78%	-0,39%	-	-
7	MEAN	1,99%	-0,45%	0,72%	-0,71%	3,99%

Example of a measurement logbook

11. Control charts building: Individual value

Type of drifts to detect	Control charts
Large and Fast  *Ex.: wrong adjustment of linac's parameters, errors during measurement…*	**Individual value** / Moving Range (I-MR)

Beam # \ Patient #					
1					
2					
3					
4					
5					
MEAN	**1,99%**	**-0,45%**	**0,72%**	**-0,71%**	**3,99%**



Individual Value control chart

Individual values

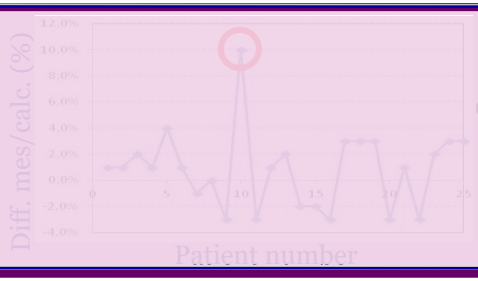
12. Control charts building: Moving-Range

Type of drifts to detect	Control charts
Large and Fast  *Ex.: wrong adjustment of linac's parameters, errors during measurement…*	Individual value / **Moving Range** (I-**MR**)

Beam # \ Patient #	1	2	3	4	5
1	1,00%	-1,80%	1,68%	-1,07%	3,20%
2	2,02%	-1,27%	-1,15%	-0,55%	3,58%
3	0,20%	2,10%	2,83%	-0,52%	5,49%
4	2,11%	-2,06 %	0,64%	-	3,68%
5	4,61%	5 0,78%	-0,39%	-	-
MEAN	**1,99%**	**-0,45%**	**0,72%**	**-0,72%**	**3,99%**

Example of a measurement logbook

12. Control charts building: Moving-Range

Type of drifts to detect	Control charts
Large and Fast  *Ex.: wrong adjustment of linac's parameters, errors during measurement…*	Individual value / **Moving Range** (I-**MR**)

C17 | =ABS(B16-C16)

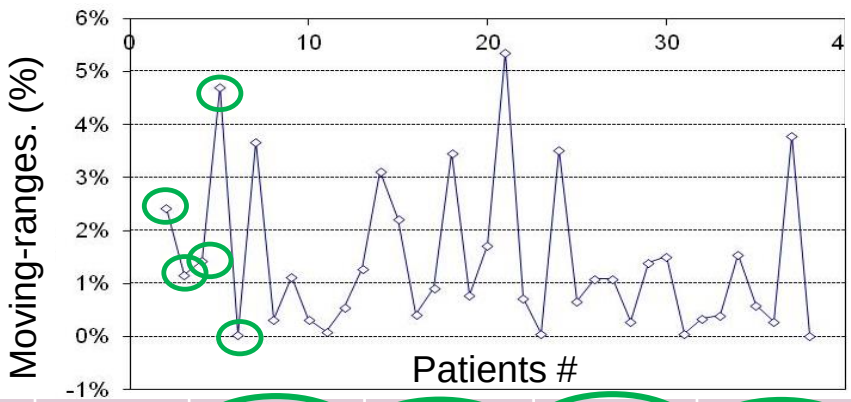
	A	B	C	D	E	F
10	Patient # / Beam #	1	2	3	4	5
11	1	1,00%	-1,80%	1,68%	-1,07%	3,20%
12	2	2,02%	-1,27%	-1,15%	-0,55%	3,58%
13	3	0,20%	2,10%	2,83%	-0,52%	5,49%
14	4	2,11%	-2,06%	0,64%	-	3,68%
15	5	4,61%	0,78%	-0,39%	-	-
16	MEAN	1,99%	-0,45%	0,72%	-0,72%	3,99%
17	MOVING-RANGES	-	2,44%	1,17%	1,44%	4,71%

Example of a measurement logbook

12. Control charts building: Moving-Range

Type of drifts to detect	Control charts
Ex.: wrong adjustment of linac's parameters, errors during measurement…	Individual value / **Moving Range** (I-**MR**)

Beam # \ Patient #	1	2	3	4	5
MEAN					
MOVING-RANGES	-	2,44%	1,17%	1,44%	4,70%



Moving-range control chart

13. Control charts building: EWMA

Type of drifts to detect	Control charts
Small and slow *Ex.: drift of the detector's dose response*	EWMA - Exponentially Weighted Moving Average -

$$M_i = \lambda x_i + (1-\lambda) M_{i-1}$$

coefficient coefficient

Current value — Previous values

Building EWMA control chart

Ex: $\lambda = 0.2$

$\Rightarrow$ Importance of 20% for x_i (current value)

$\Rightarrow$ Importance of 80% for M_{i-1} (previous values)

$M_i = 0.2 \times current\ value + 0.8 \times previsous\ values$

13. Control charts building: EWMA

Type of drifts to detect	Control charts
Small and slow *Ex.: drift of the detector's dose response*	EWMA - Exponentially Weighted Moving Average -

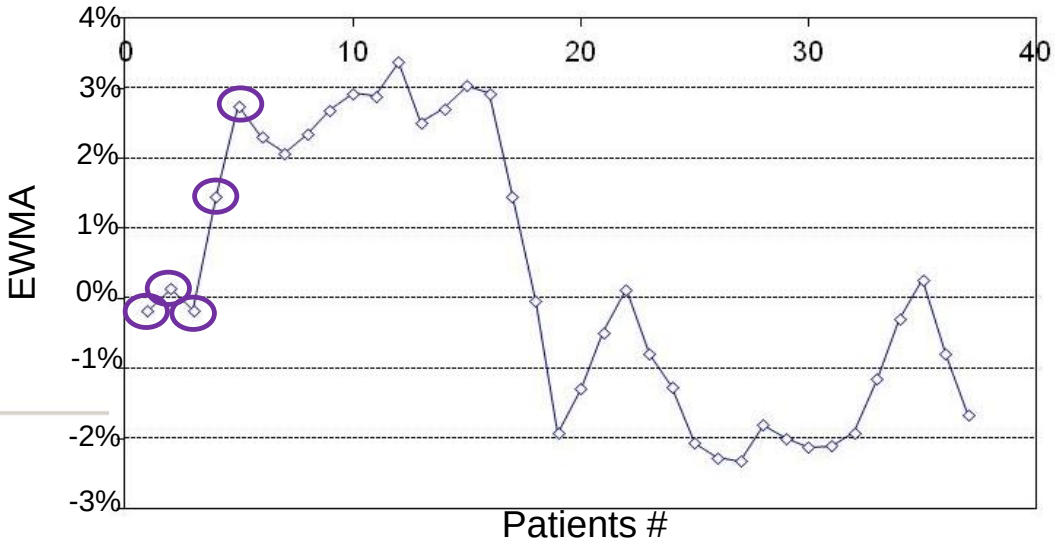
C26 | =(0,2*C25)+0,8*B26

	A	B	C	D	E	F
19	Patient # / Beam #	1	2	3	4	5
20	1	1,00%	-1,80%	1,68%	-1,07%	3,20%
21	2	2,02%	-1,27%	-1,15%	-0,55%	3,58%
22	3	0,20%	2,10%	2,83%	-0,52%	5,49%
23	4	2,11%	-2,06%	0,64%	-	3,68%
24	5	4,61%	0,78%	-0,39%	-	-
25	MEAN	1,99%	-0,45%	0,72%	-0,71%	3,99%
26	Mi	1,28%	0,94%	0,89%	0,57%	1,26%

EWMA control chart

13. Control charts building: EWMA

Type of drifts to detect	Control charts
Small and slow *Ex.: drift of the detector's dose response*	EWMA - Exponentially Weighted Moving Average -



EWMA control chart

14. Control charts building: calculation of control limits

- **Control limits** (= natural limits of the process = "voice of the process") :

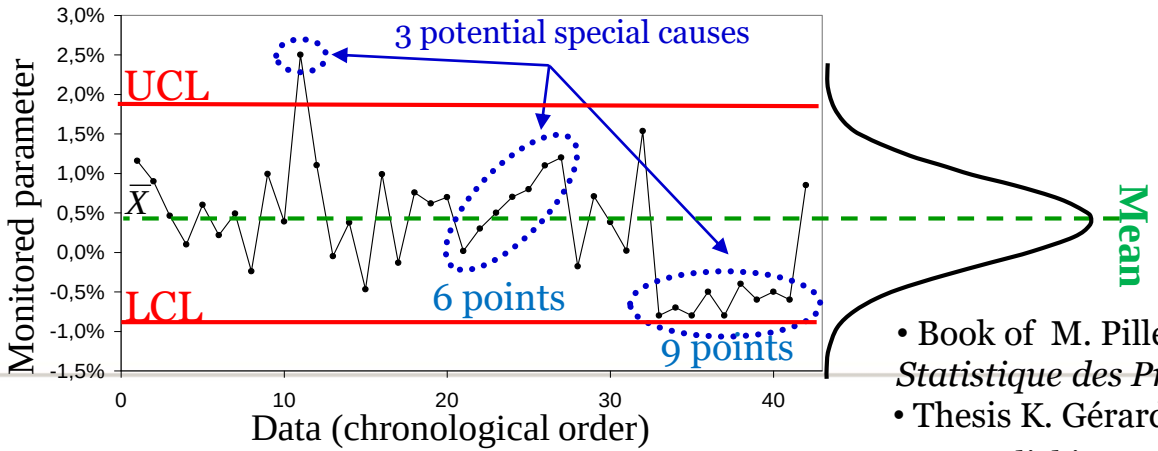
❑ Process's production is not always identical

⇒**Normal distribution** (central limit theorem)

⇒ To be checked.

A point falls outside the natural limits: common causes special cause with certain **α risk (0.27%)**

- **Analysis of control charts**



Details of limits' calculation

- Book of M. Pillet, *Appliquer la Maitrise Statistique des Processus* (2005)
- Thesis K. Gérard (2008)
- T. Pawlicki, SPC for radiotherapy QA (2005)
- ESTRO Practical exercise, Torino (2015)

15. Key points to keep in mind

CONTROL CHARTS

- **Graphics**: more easily understandable to human spirit than tables of data, can reveal interesting structures in the data.
- Take into account the variability of data.
- Filter the **probable noise** in order to detect a **potential signal** in the data.
- **Predictive** tool.

MANAGEMENT

- The voice of the process defines what we have.
- Control chart reflects the **voice of the process**.
- The **voice of the customer** defines what we want to have.
- Role of management is to align the voice of the process on the voice of the customer.

III. SPC IN PRACTICE (NEXT)

- Application to pre-treatment quality controls in IMRT -

(Example of the 'Institut de Cancérologie de Lorraine', Nancy (France))

Institut de Cancérologie de Lorraine
Alexis Vautrin
Ensemble, construisons l'avenir

1. Aim and Method

- **Aim:** **To increase the efficiency (performance and workload) of pre-treatment quality controls in IMRT.**

  ⇒ In increasing the performance of the dose delivery *process.*

  ⇒ To ensure an optimal security of each patient treatment.

Statistical Process Control (SPC)

- **Method:** **Performance of the dose delivery process**: assessed using the results of pre-treatment QC performed for all patients.

- Homogeneous series
- Interesting conclusions

Drifts :

→ *Linac?*

→ *Type of treatment?*

→ *TPS ?*

2. Introducing a SPC analysis: DMAICS method*

* From a Six sigma approach

Part 1 :
Introduction to SPC

Part 2 :
Essential concepts to start with SPC

Pa
SP
pra

Pa
Conc

CONTINUOUS IMPROVIEMENT

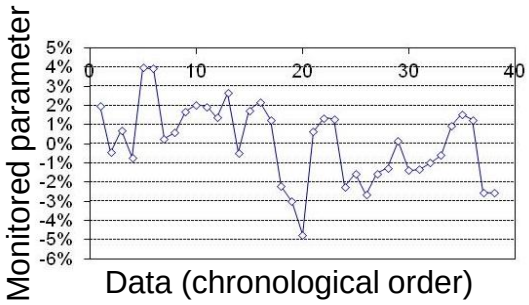
DEFINE

Choice of relevant quality indicators to monitor

MEASURE

1. Verification of the measurement system 's **capability**
2. Characterization of the data distribution
3. Observation of the process

Building a control chart without limits



ANALYZE

Calculation of the process **performance** indicators
Choice of control charts and calculation of control limits

ANALYZE

Searching the **sources of variability**
(Ishikawa)

CONTROL

Process monitoring using control charts
Detection of special causes
Is the process 'under control'?

IMPROVE

Reduction of variability
(5 WHY, Design of Experiments)

STANDARDIZE

Optimization of the process, maintain the gain
Reduction of the frequency of controls?

2. Introducing a SPC analysis: DMAICS method*

* From a Six sigma approach

Part 1 :
Introduction to SPC

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Pa
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CONTINUOUS IMPROVIEMENT

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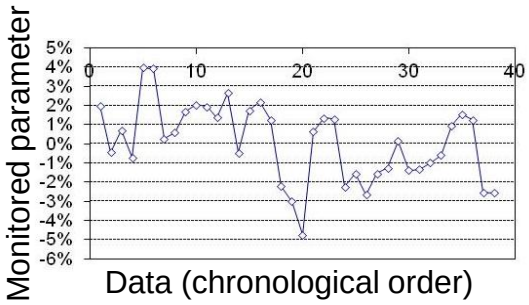
Building a control chart without limits



ANALYZE

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ANALYZE

Searching the **sources of variability**
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CONTROL

Process monitoring using control charts
Detection of special causes
Is the process 'under control'?

IMPROVE

Reduction of variability
(5 WHY, Design of Experiments)

STANDARDIZE

Optimization of the process, maintain the gain
Reduction of the frequency of controls?

3. The IMRT pre-treatment QC process

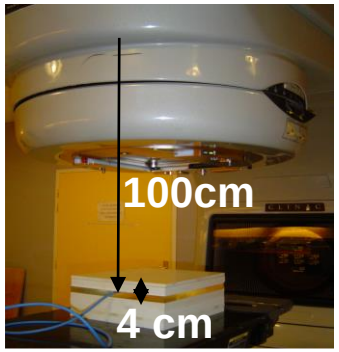
MEASURE

ANALYSIS

MEASURE IN 1D

- **Detector:** IC PTW Semiflex (0.125cm^3)
- **Method:**
  - Absolute dose in 1 pt
  - Field by field

    (gantry at 0°)



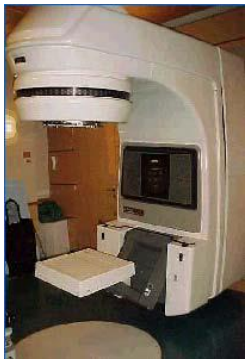
- **Indicator of comparison:**

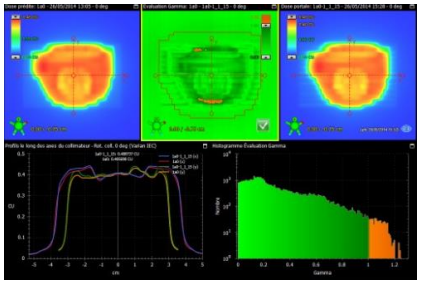
$$Difference = \Delta(\%) = \frac{D_{calculated} - D_{measured}}{D_{calculated}} \times 100$$

- **Target:** $\Delta(\%) = 0\ \%$
- **Clinical specifications:** $\Delta(\%) = \pm 4\ \%^{*}$

MEASURE IN 2D

Portal Dosimetry — AS 500 Exact Arm





Gamma index (γ) passing rate

γ criteria : 4% / 3mm

100%

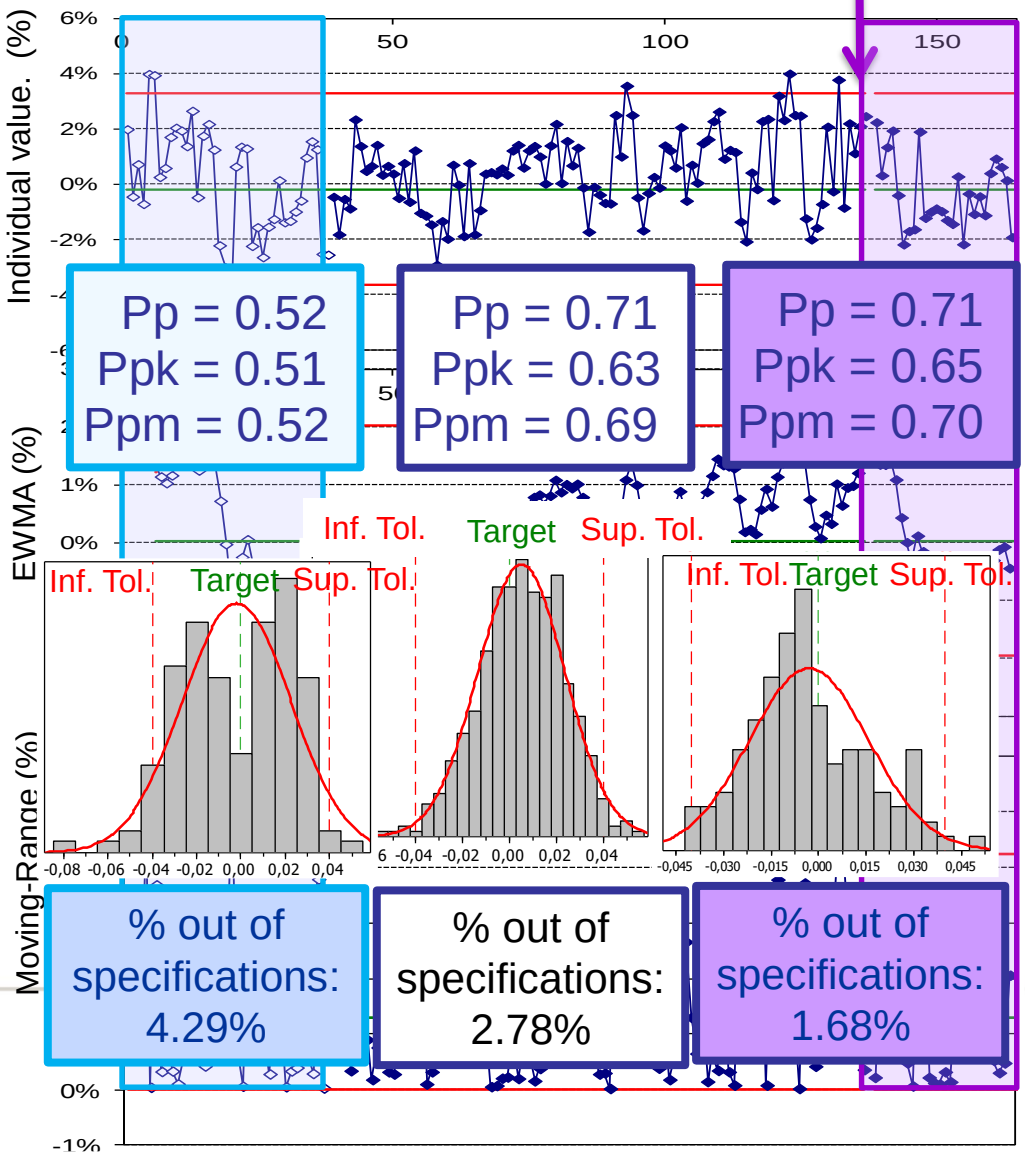
$\geq$ 95%

* Zefkili, “Recommendations for a head and neck IMRT quality assurance protocol” *Cancer/Radiother* (2004)

4. IMRT QC results (IC) monitored with SPC

- Head-and-neck treatments -

Reduction of the number of controls: 1 patient / 3



- In daily practice at ICL:

→ *Control charts:*
Process under control

→ *Performance indicators:*
Stable or even superior

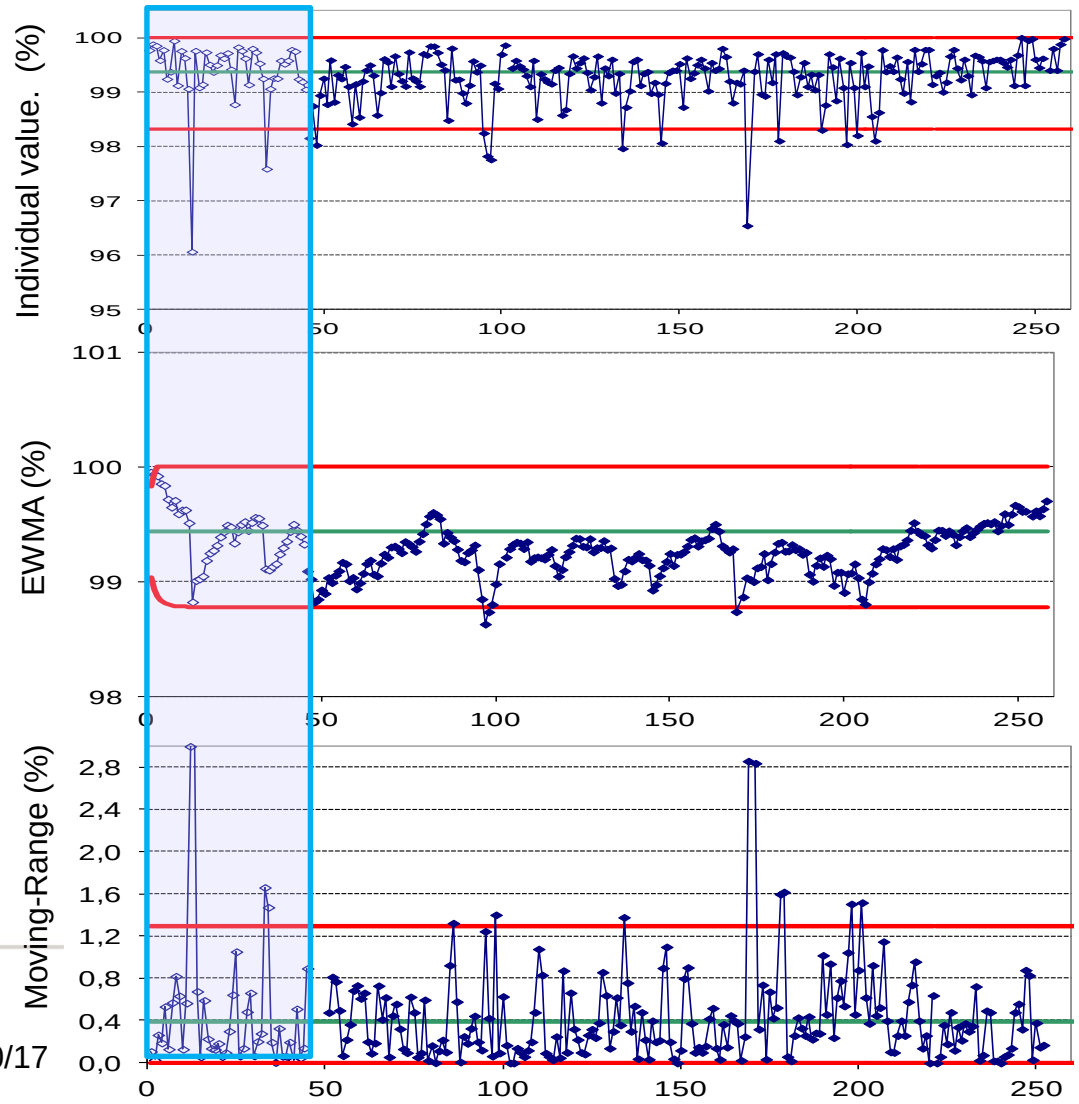
→ Reduction of controls
1 patient / 3 for IC

→ *2D measurements**
- for all patients
- monitored with SPC

* N. Villani *et al. Cancer/Radiotherapie (2010)*

5. IMRT QC results (portal dosimetry) monitored with SPC

- Head-and-neck treatments -



- In daily practice at ICL:

Importance of the choice of data to calculate the limits

→ **Homogenous data**

✓ ∅ changes on the process (∅ special cause)

✓ Outliers removed

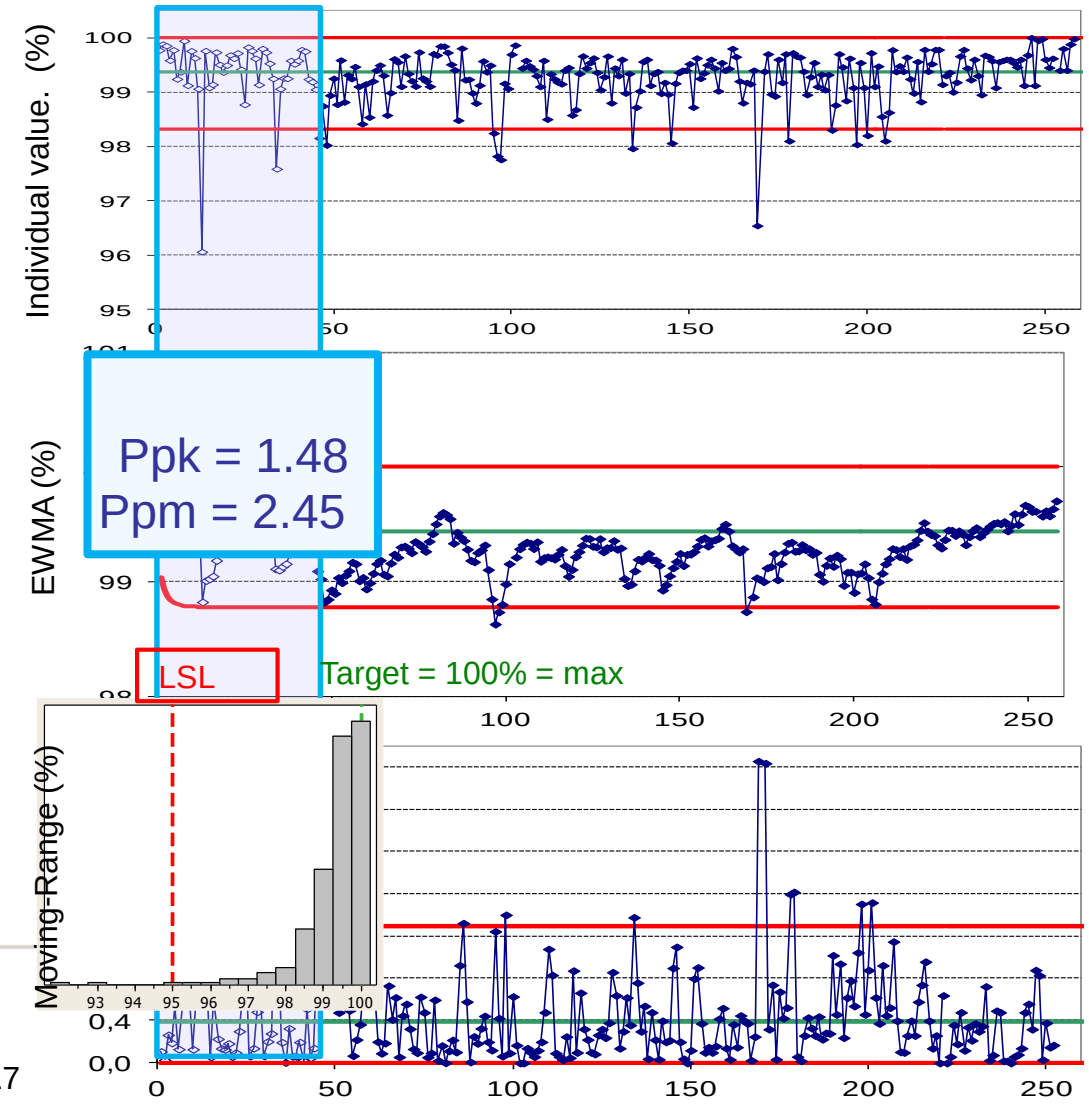
→ **Statistically representative**

→ **Normal distribution**

(α risk = 0.27%)

5. IMRT QC results (portal dosimetry) monitored with SPC

- Head-and-neck treatments -



- In daily practice at ICL:

γ Index particularities

→ **Physical limit at 100%**

⇒ Non normal distrib.

⇒ α risk ≠ 0.27%

→ **Lower Spec. Lim. only**

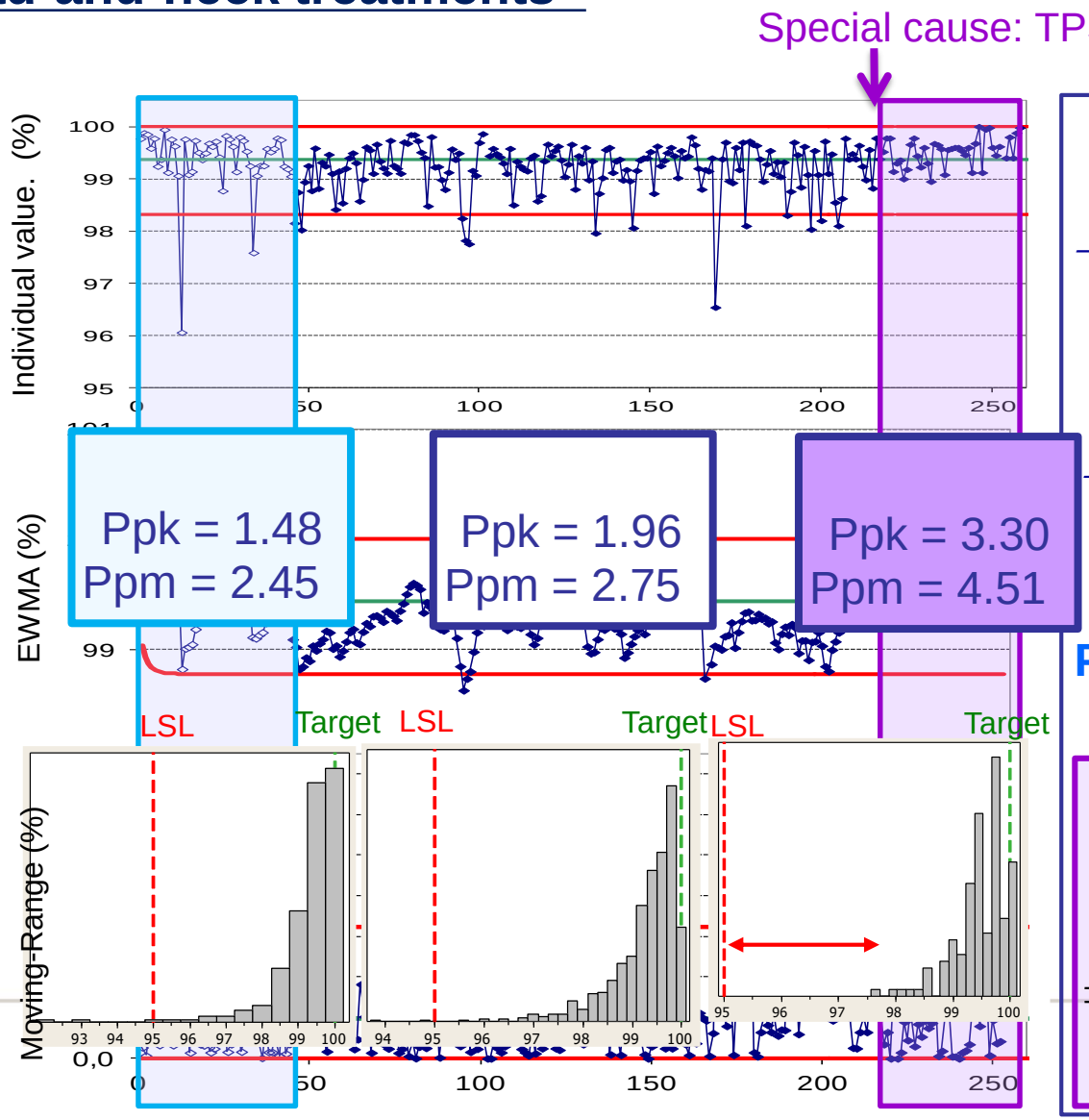
⇒ ∅ Pp

⇒ Ppk, Ppm:

M. Pillet *et al. Quality Engineering (1997)*

5. IMRT QC results (portal dosimetry) monitored with SPC

- Head-and-neck treatments -



- In daily practice at ICL:

→ *Control charts*

< 5% points out of limits

⇒ Process under control

→ *Performance indicators*

Stable or superior

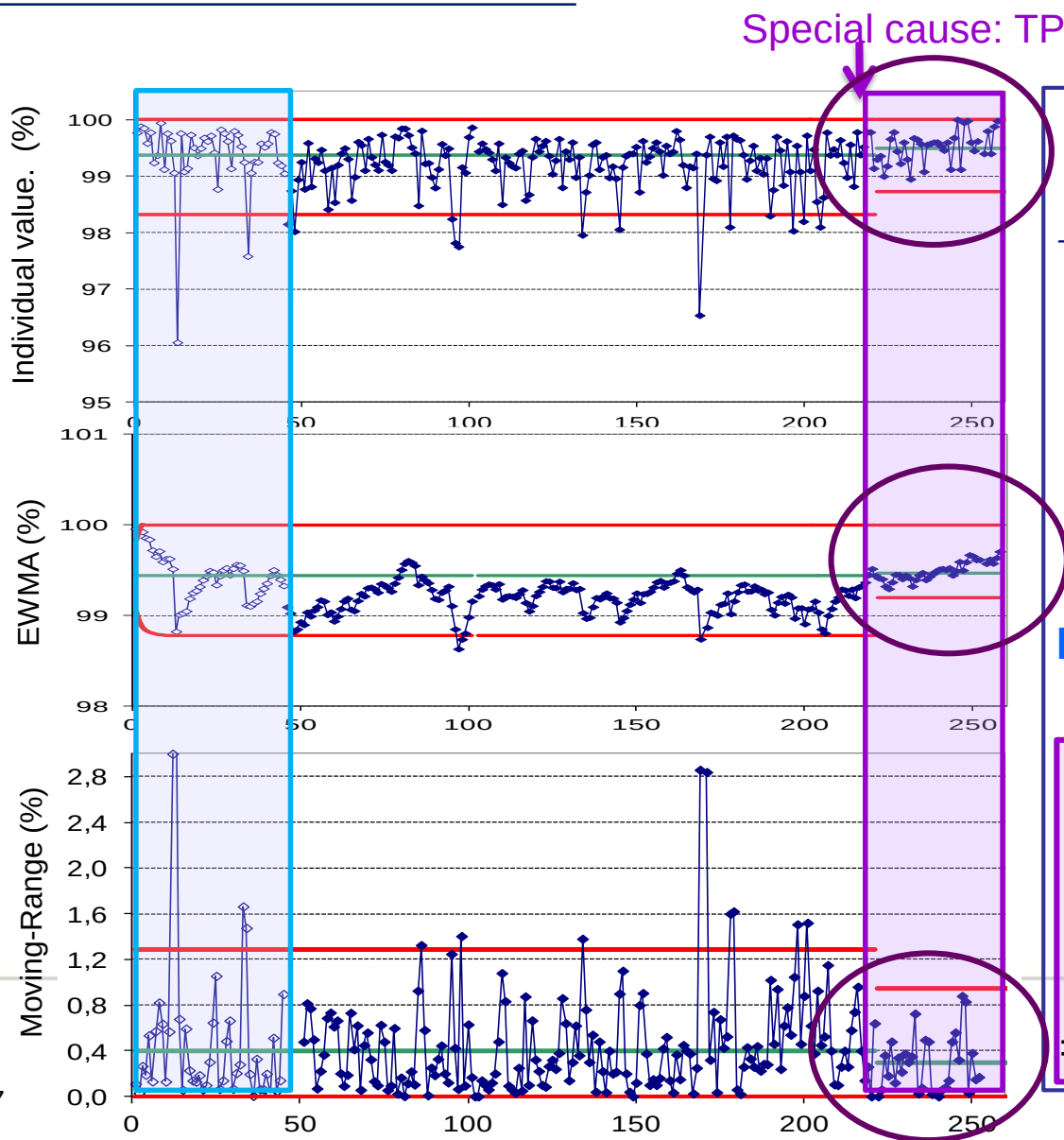
Process under control and statistically capable

→ Special cause identified
- ↑ mean
- ↓ dispersion

⇒ Performance indicators ↑

5. IMRT QC results (portal dosimetry) monitored with SPC

- Head-and-neck treatments -



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→ *Performance indicators*

Stable ou superior

Process under control and statistically capable

→ Special cause identified
- ↑ mean
- ↓ dispersion

⇒ Performance indicators ↑

⇒ **New limits**

IV. CONCLUSION

CONCLUSION - TAKE HOME MESSAGE -

STATISTICAL PROCESS CONTROL (SPC)

Part 1 : Introduction to SPC

Part 2 : Essential concepts to start with SPC

Part 3 : SPC in practice

Part 4 Conclusion

• **Common language** to evaluate and compare processes' performance.

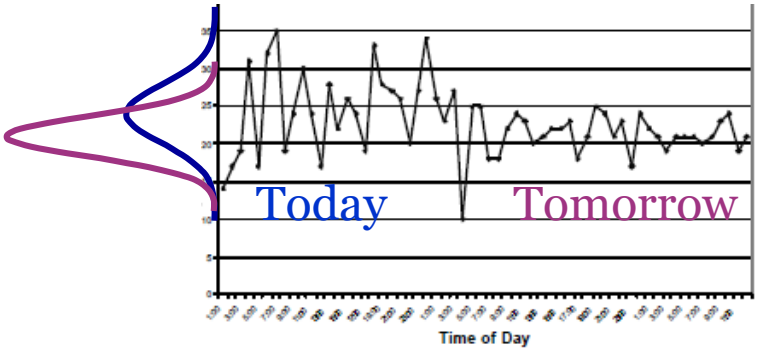
⇒ Key tools: **performance indicators** and **control charts**

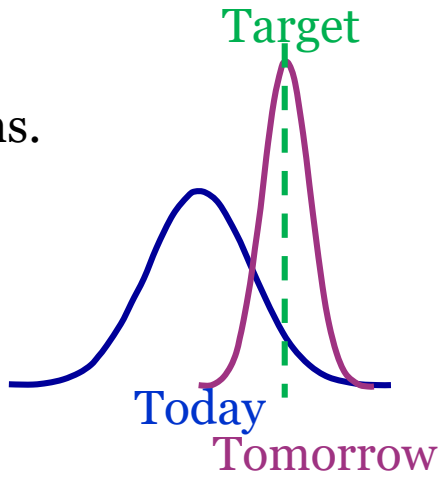
⇒ DMAICS method

• SPC is applied in order to **monitor** and **control** a process.

⇒ Help reducing the variability of the process.

⇒ Decrease the number of data out of specifications.





• **Secure** and **improve** continuously the **quality** of numerous processes in radiotherapy.

- SPC = A method, a tool, a culture -

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• http://www.six-sigma-material.com

THANKS FOR YOUR ATTENTION

TOLERANCE and ACTION LIMITS

Núria Jornet

Servei de Radiofísica i Radioprotecció

Hospital Sant Pau

Barcelona

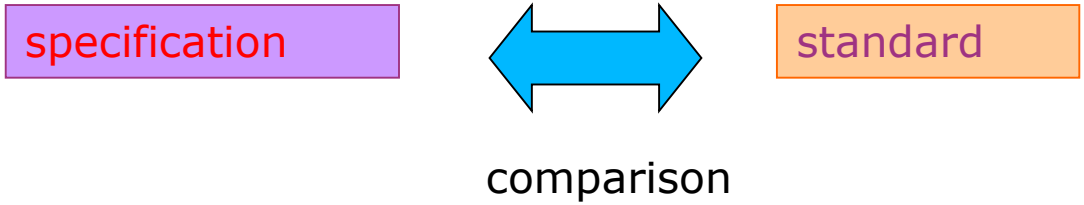
Learning objectives

- To review the different methods to set tolerance and action limits
- To discuss the clinical meaning of tolerance and action limits
- To revise how tolerance limits, action limits and uncertainties are related

Outline

- Definitions of tolerance limit and action limit
- How to set tolerance and action limits value driven
- How to set tolerance limits event driven

Some definitions: Tolerance limits and action limits



"Performance within the tolerance level gives acceptable accuracy in any situation"

"Peformance outside the action level is unacceptable and demands action to remedy the situation"

TOLERANCE LIMITS

Boundary within which a process is considered to be operating normally

Measurements outside ot a Tolerance Limit provide a warning that the system is deviating

ACTION LIMITS

Degree to which the quality measures are allowed to vary

Thresholds for when an action is required

Based on clinical judgement

Some definitions: Tolerance limits and action limits

Example:

Daily measurement of the dose rate constancy:

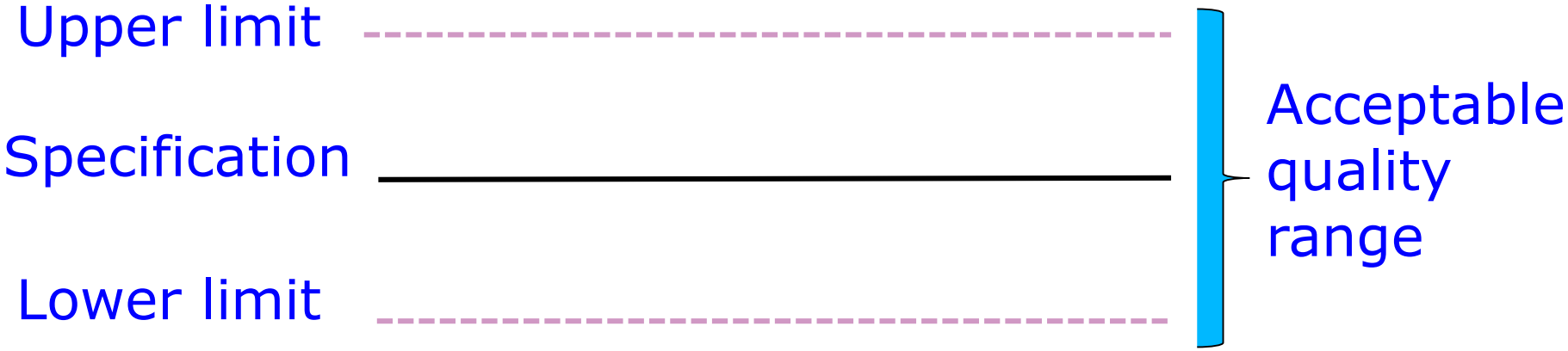
Within tolerance: No action is required

Exceeds the action level: immediate action necessary. Machine cannot be used until the problem is solved

Falls between tolerance and action level: considered acceptable till next measurement

Repeated measurements between tolerance and action level: Adjustment required

Value driven tolerance limits



Specification = standard = base line or a specific value

Value driven tolerance limits – RP162

Suspension Level	Definition
Type A	This is based on an international standard or a formal international or national regulation.
Type B	This is based on formal recommendations by scientific, medical or professional bodies.
Type C	This is based on material published in well-established peer reviewed scientific or medical journals and/or (exceptionally) based on reviewed recommendations from the drafting group. For Types A/C and B/C, see the text.
Type D	The need for a Type D suspension level arises when it has not been possible to make recommendations for explicit suspension levels (see text).

"Failure to meet a suspension level will establish that the operation of the equipment involved is sufficiently poor to raise an alarm indicating action is required"

SUSPENSION LEVEL = ACTION LIMIT

Criteria for Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy. RP 162 (European Commission), 2013

Value driven tolerance limits – RP162

Physical Parameter	Suspension Level	Reference (IEC (2007, 2008c) clause numbers unless stated)	Type
Symmetry of electron fields (max/min ratio)	>1.05		A
Maximum ratio of absorbed dose (max/min ratio)	1.09 See IEC		A
Dose monitoring system		7	
Weekly calibration check	>2 %		A
Reproducibility	>0.5 %		A
Proportionality	>2 %		A
Dependence on angular position of gantry and beam limiting device	>3 %		A
Dependence on gantry rotation	>2 % - electron radiation >3 % - X-radiation		A
Stability throughout the day	>2 %		A
Stability in moving beam radiotherapy	See IEC		A

Criteria for Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy. RP 162 (European Commission), 2013

Value driven tolerance limits – TG

TABLE I. Daily.

Procedure	Machine-type tolerance		
	Non-IMRT	IMRT	SRS/SBRT
Dosimetry			
X-ray output constancy (all energies)			
Electron output constancy (weekly, except for machines with unique e-monitoring requiring daily)		3%	
Mechanical			
Laser localization	2 mm	1.5 mm	1 mm
Distance indicator (ODI) @ iso	2 mm	2 mm	2 mm
Collimator size indicator	2 mm	2 mm	1 mm
Safety			
Door interlock (beam off)		Functional	
Door closing safety		Functional	
Audiovisual monitor(s)		Functional	
Stereotactic interlocks (lockout)	NA	NA	Functional
Radiation area monitor (if used)		Functional	
Beam on indicator		Functional	

Klein et al. TG 142:QA of Medical Accelerators. Med.Phys. 36(9), 2009

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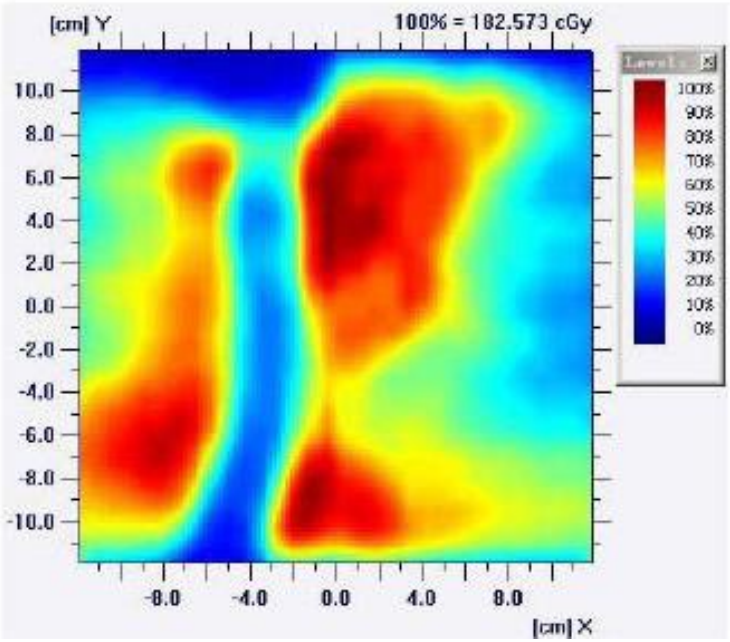
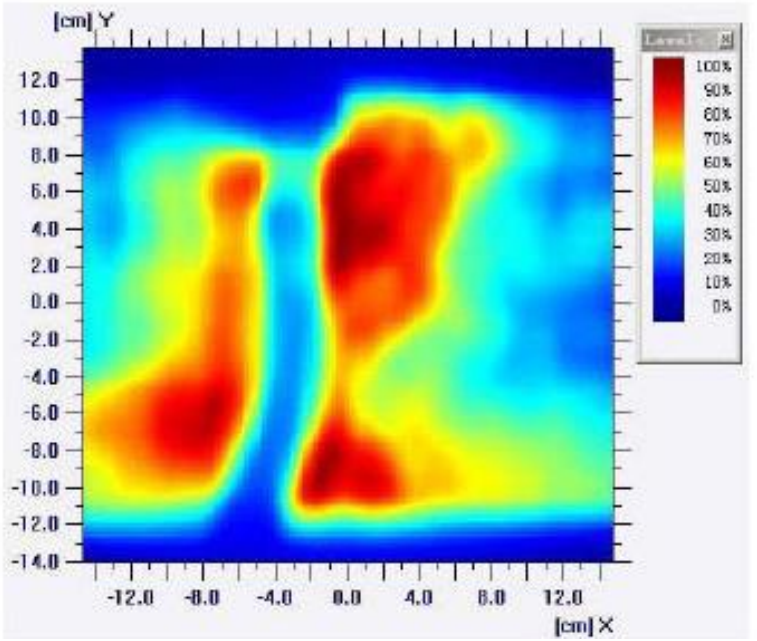
Friday afternoon at the radiotherapy department…

Dose measurement



TPS dose calculation



Not OK for treatment?

We need limits to make objective decisions!

From JörgenOlofsson (Dose Modeling and dose verification ESTRO COURSE)

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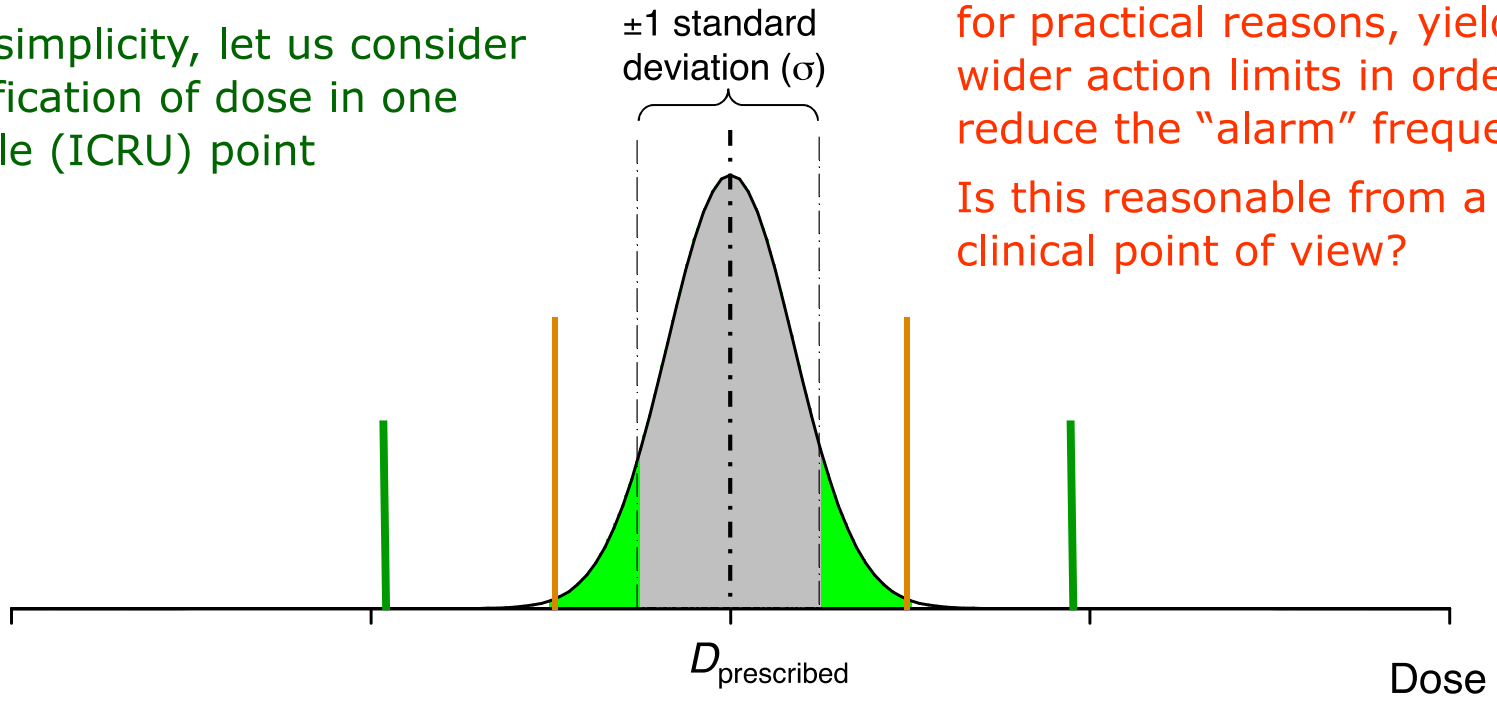
How are those limits set?

For simplicity, let us consider verification of dose in one single (ICRU) point



Hence, large uncertainties may, for practical reasons, yield wider action limits in order to reduce the "alarm" frequency.

Is this reasonable from a clinical point of view?

A reasonable (?) tolerance limit: ± 2σ

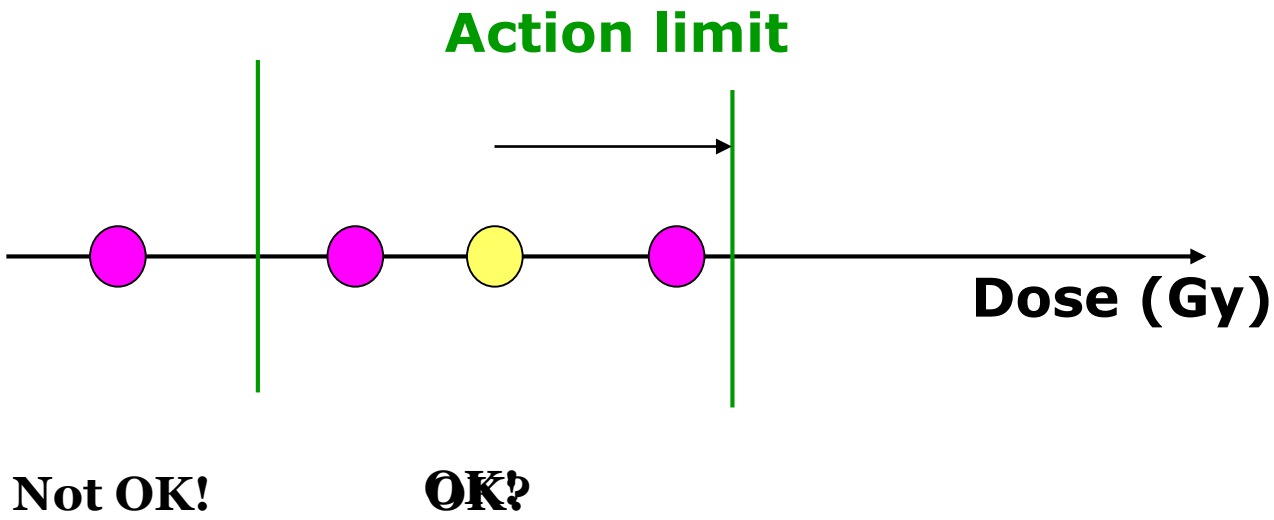
A reasonable (?) action limit: ± 4σ (= 2 × tolerance limit)

From JörgenOlofsson (Dose Modeling and dose verification ESTRO COURSE)

Action limits - Traditional philosophy

Prescribed dose (=TPS dose)

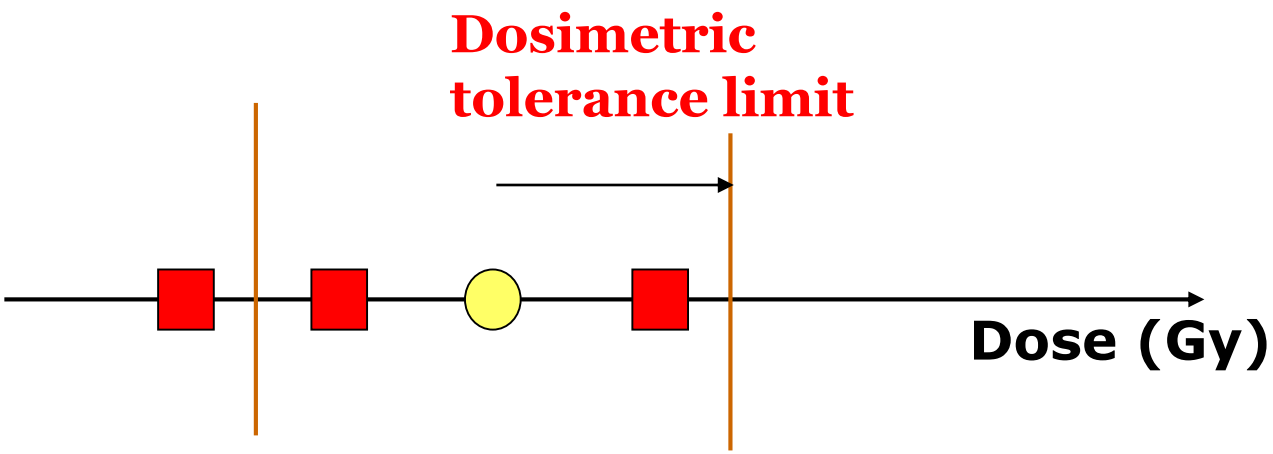
Independent dose calculation/measurement



Reality

Prescribed dose (=TPS dose)

True dose (=Actually delivered dose)



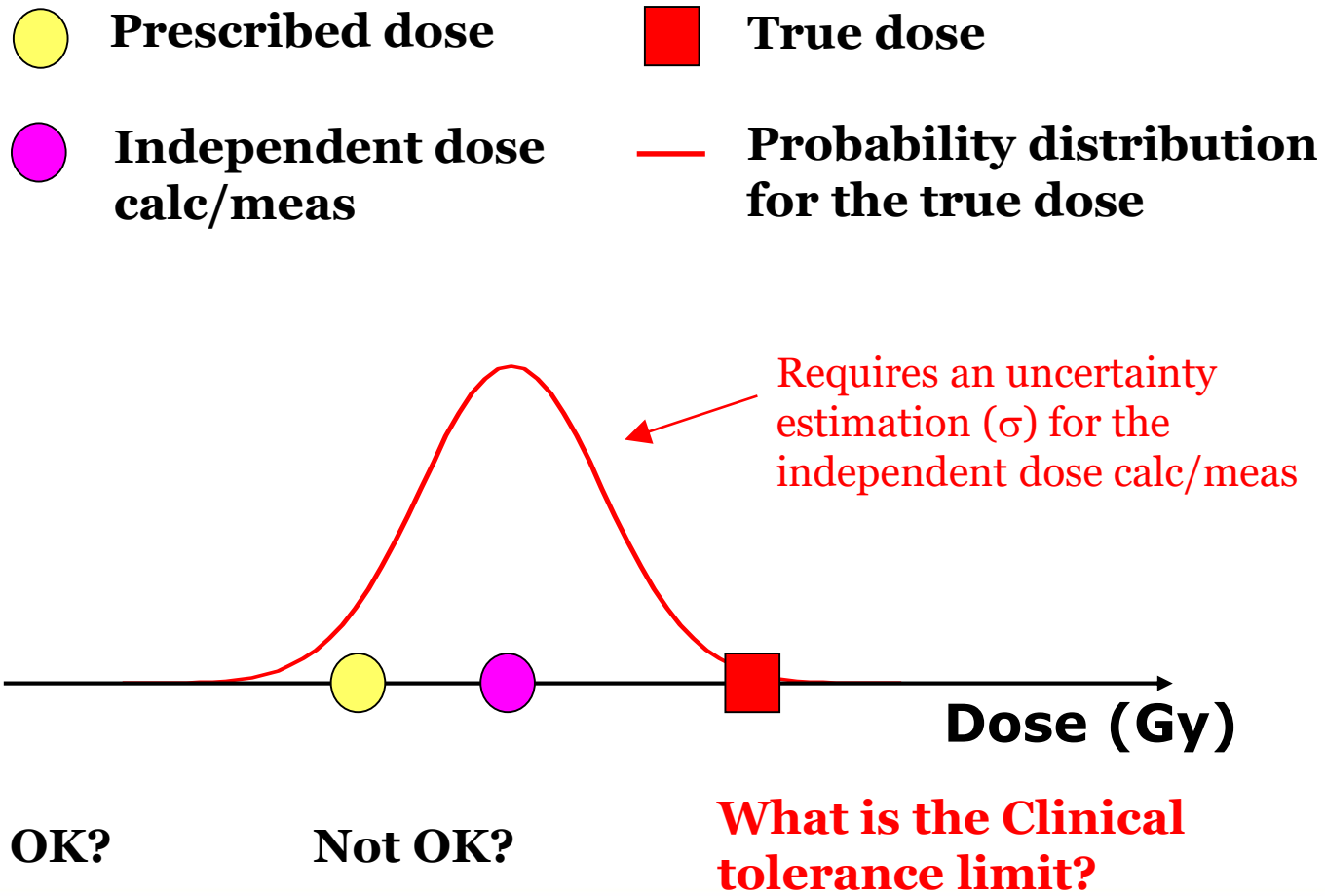
Not OK!

OK?

Do we know the True dose?

From JörgenOlofsson (Dose Modeling and dose verification ESTRO COURSE)

Action limits - Proposed philosophy



From JörgenOlofsson (Dose Modeling and dose verification ESTRO COURSE)

How to set the Clinical tolerance limit (TL_{Δ})?

- Clinical tolerance limits or specifications should be based on clinical experience.
- Clinical experience can be summarized through statistical analysis of the outcome of a particular treatment for a particular tumor disease.
- Examples:
  - Local tumor control as a function of dose.
  - Fraction of survivors after five years as a function of dose.
- At the same time, normal tissue complications must be taken into account.

From JörgenOlofsson (Dose Modeling and dose verification ESTRO COURSE)

How to set the Clinical tolerance limit (TL_{Δ})?

Minimum acceptable cure rate

Maximum acceptable complication rate

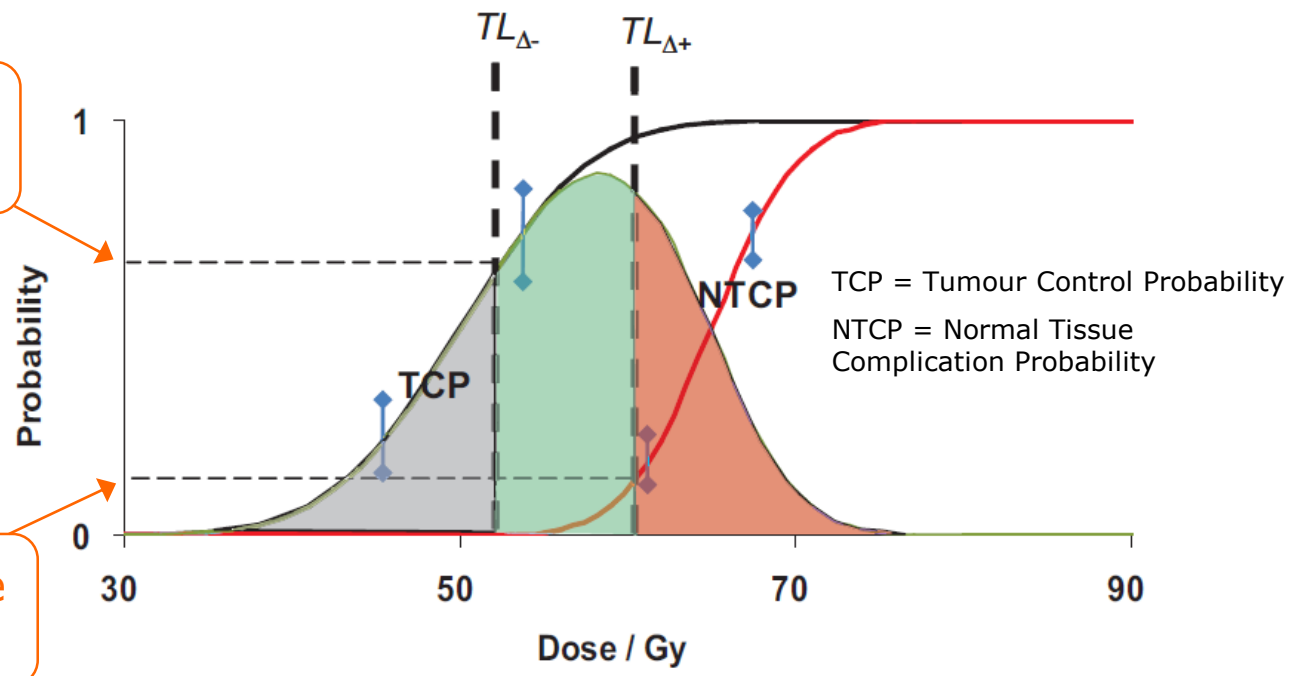
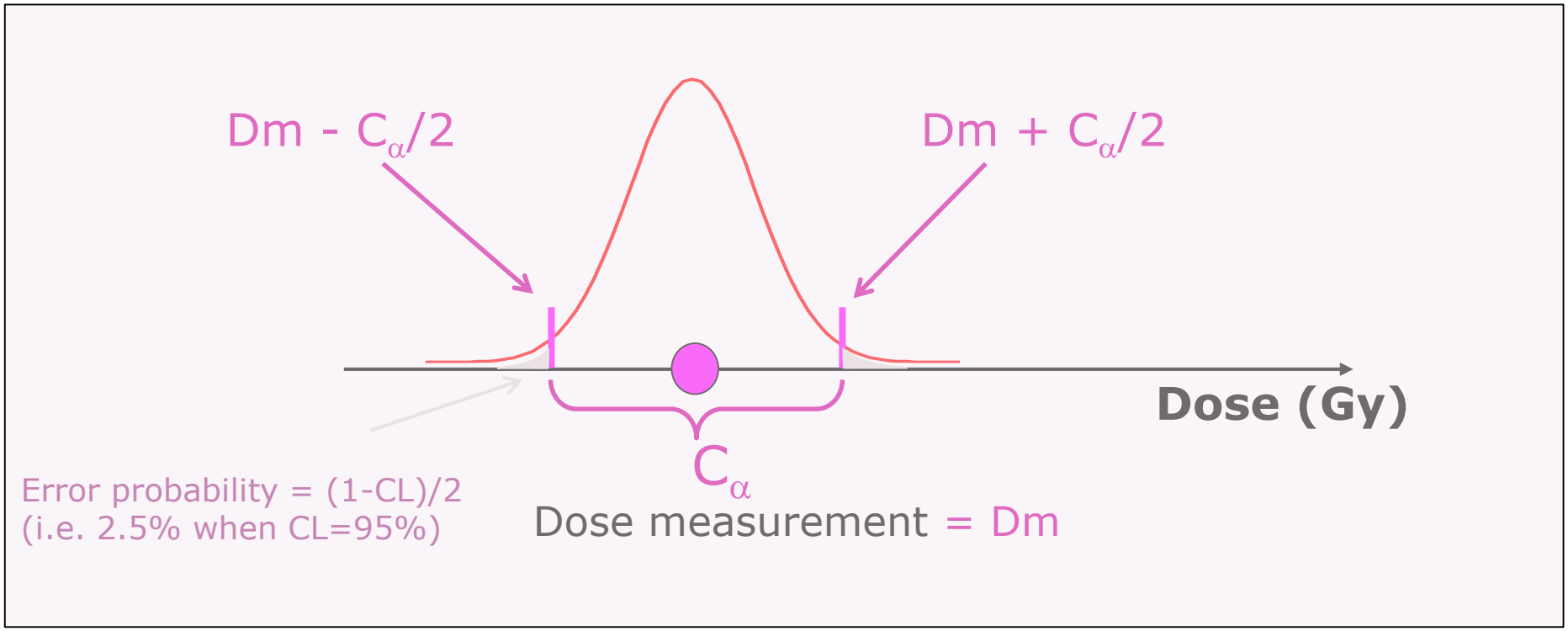


Figure 3.2 Illustration of the procedure to obtain dosimetric tolerance limits from TCP and NTCP data. $TL_{\Delta-}$ is set to a minimum acceptable cure rate and $TL_{\Delta+}$ to a maximum acceptable complication rate.

Action limits - Proposed philosophy

Step 1: Determine the uncertainty (σ) for the dose measurement, yielding the probability distribution for the true dose.



Step 2: Set a confidence level CL for the true dose, e.g. CL =95%, and determine the corresponding dose interval C_α.

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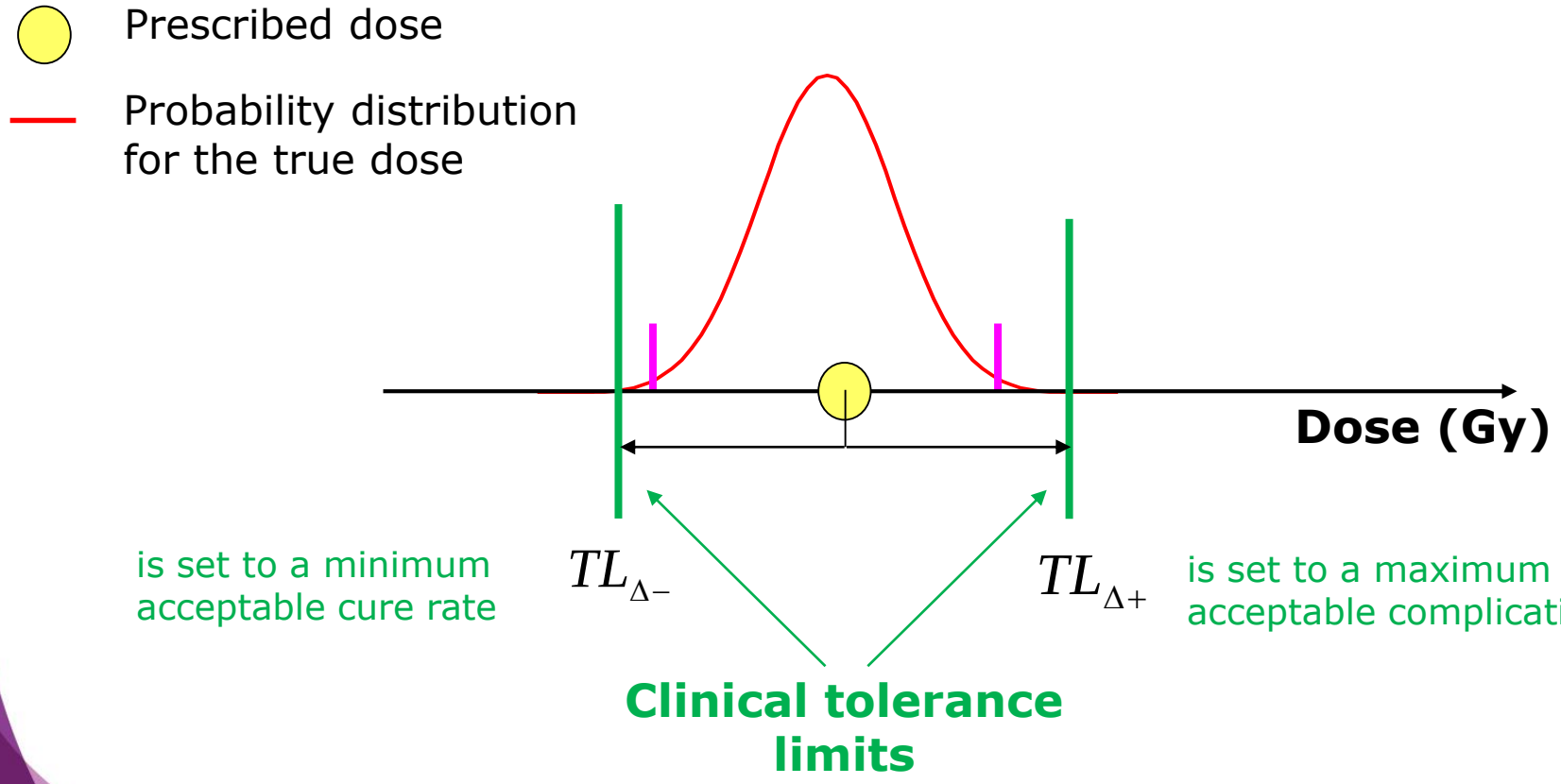
Action limits - Proposed philosophy

Step 3: Adjust the true dose probability distribution such that the dose limits IDC-$C_\alpha/2$ and IDC+$C_\alpha/2$ coincide with the clinical tolerance limits.



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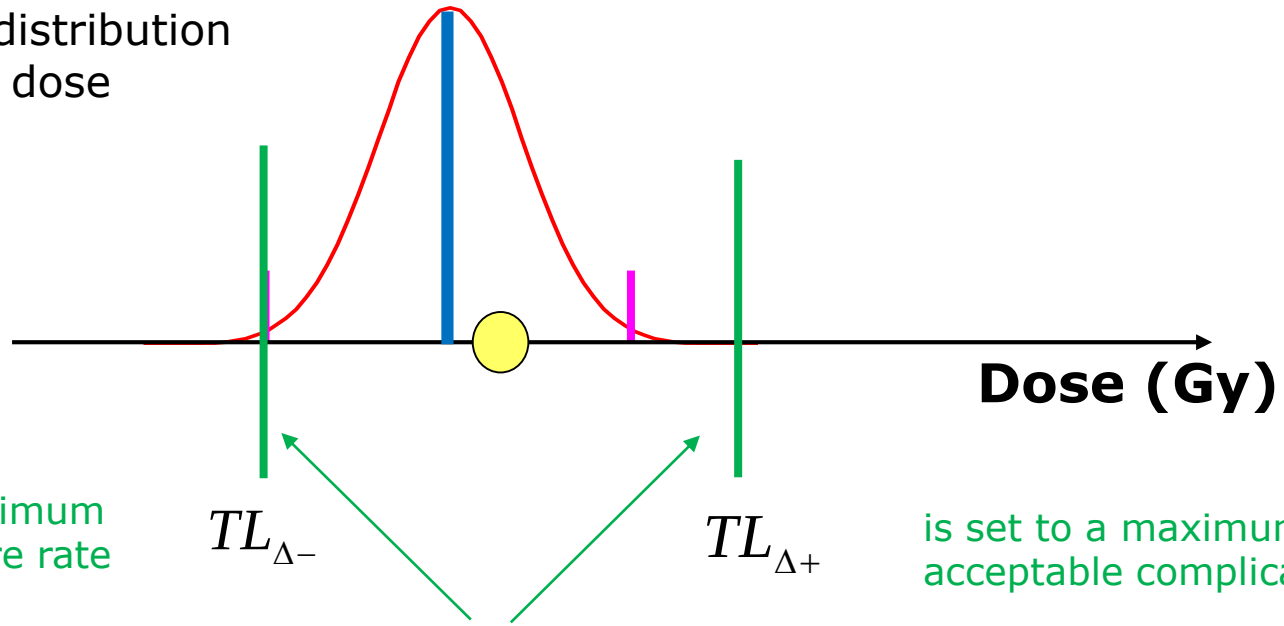
Action limits - Proposed philosophy

Step 4: Define the center of the true dose probability distribution as the lower and upper **action limit**, respectively.

Prescribed dose

Probability distribution for the true dose



is set to a minimum acceptable cure rate

is set to a maximum acceptable complication rate

Clinical tolerance limits

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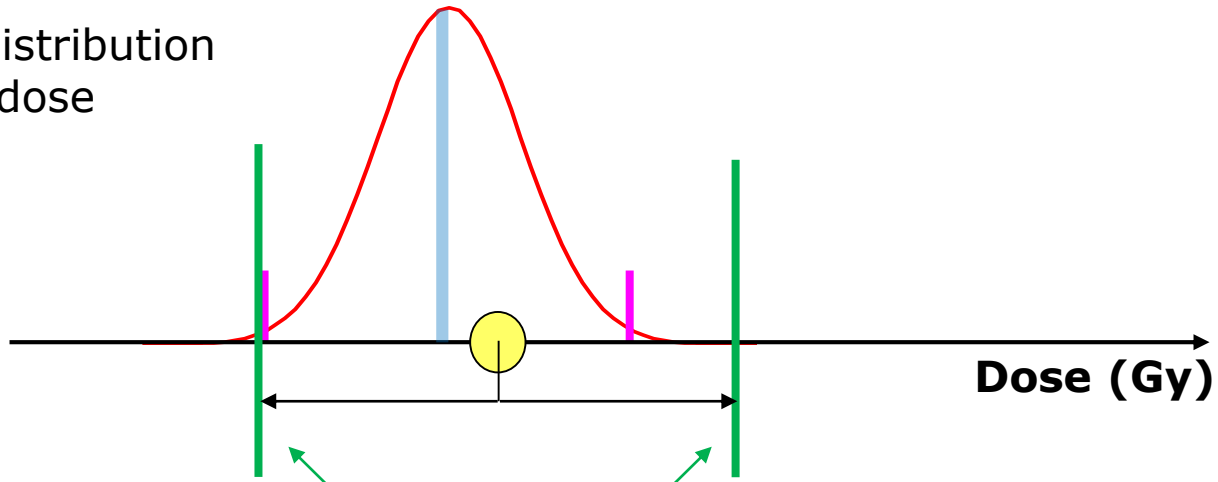
Action limits - Proposed philosophy

Step 3: Adjust the true dose probability distribution such that the dose limits IDC-$C_\alpha/2$ and IDC+$C_\alpha/2$ coincide with the clinical tolerance limits.

Prescribed dose

Probability distribution for the true dose



is set to a minimum acceptable cure rate

is set to a maximum acceptable complication rate

Clinical tolerance limits

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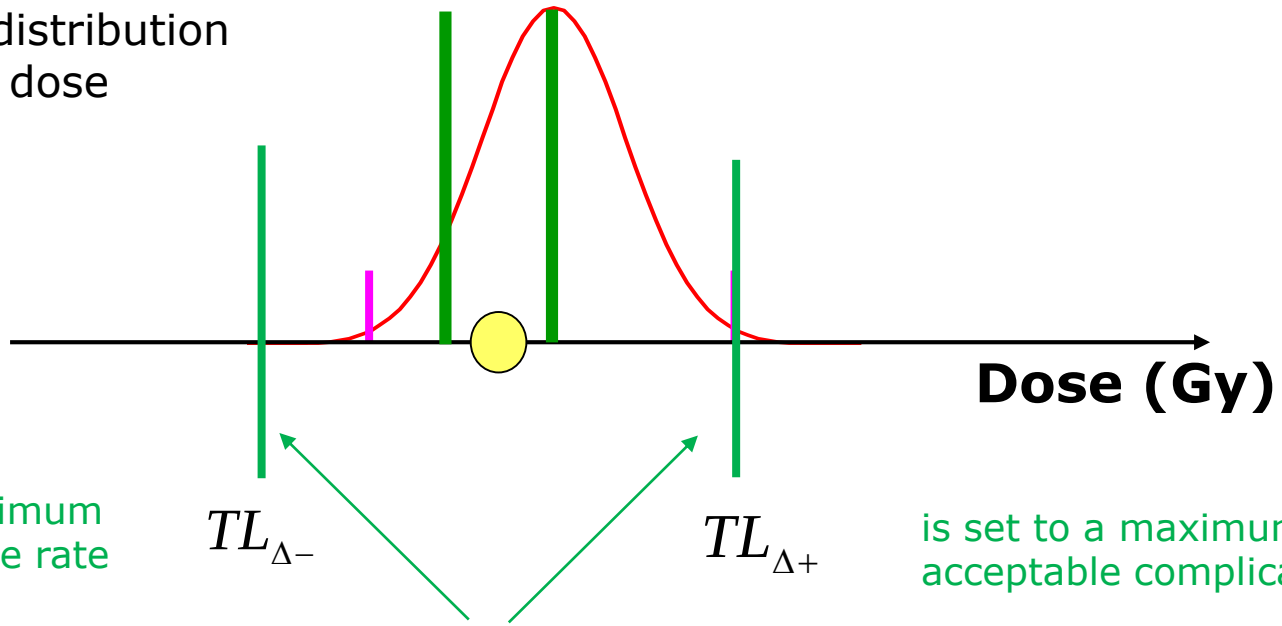
Action limits - Proposed philosophy

Step 4: Define the center of the true dose probability distribution as the lower and upper **action limit** respectively.

Prescribed dose

Probability distribution for the true dose



is set to a minimum acceptable cure rate

is set to a maximum acceptable complication rate

Clinical tolerance limits

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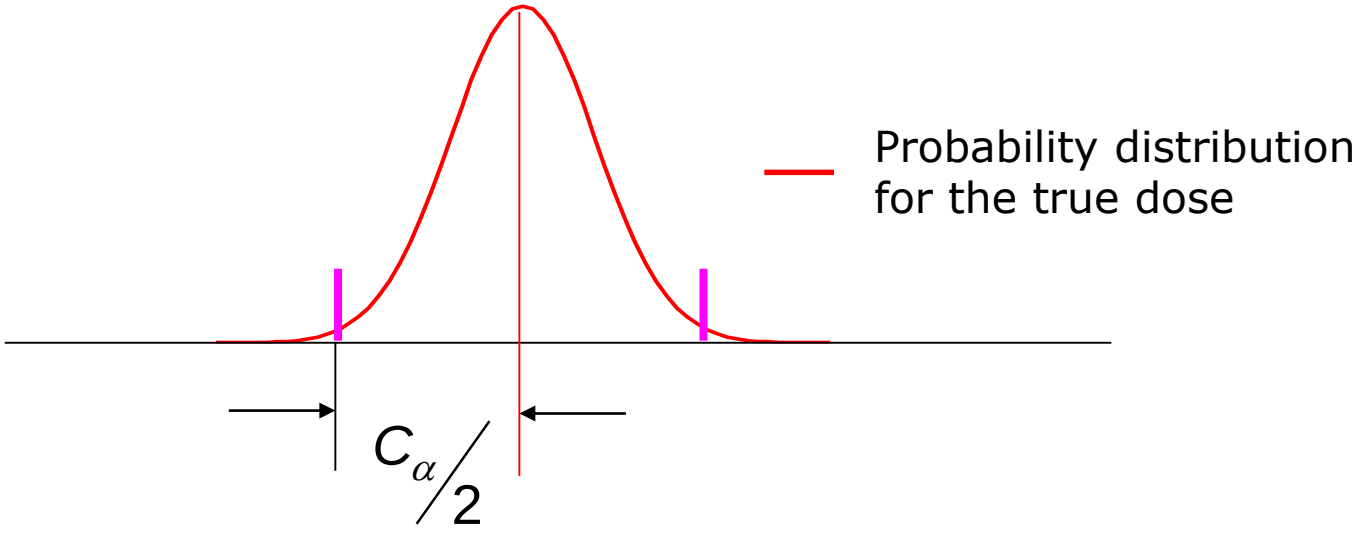
Action limits - Proposed philosophy

Hence, the action limits should be calculated as

Clinical tolerance=specification

Measurement uncertainty

$$\Delta L_{\pm} = TL_{\pm} \pm \frac{C_{\alpha}}{2}$$



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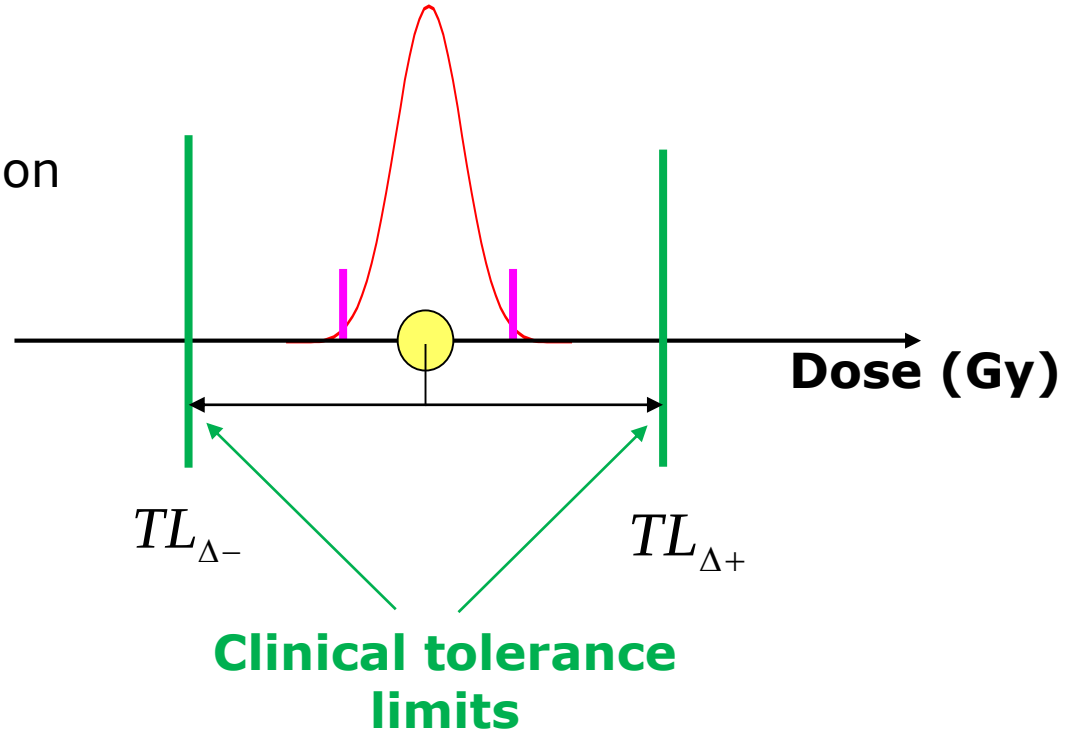
Example with small uncertainty:

Prescribed dose

Probability distribution for the true dose



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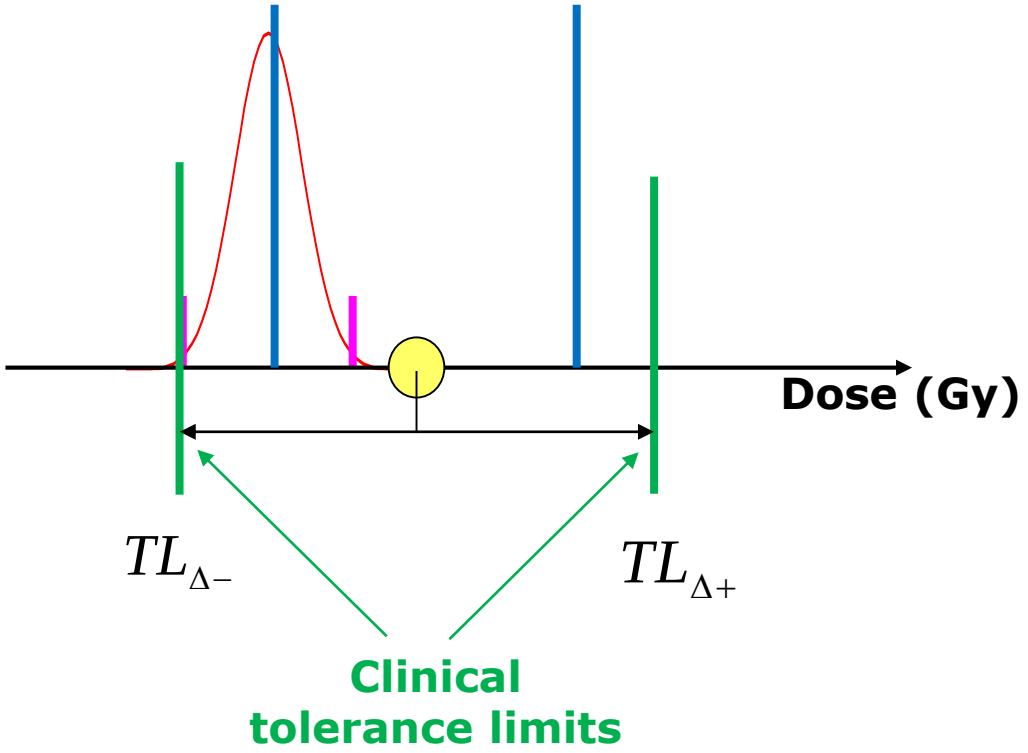
Example with small uncertainty:

Prescribed dose

Probability distribution for the true dose

Action limits smaller than tolerance limits



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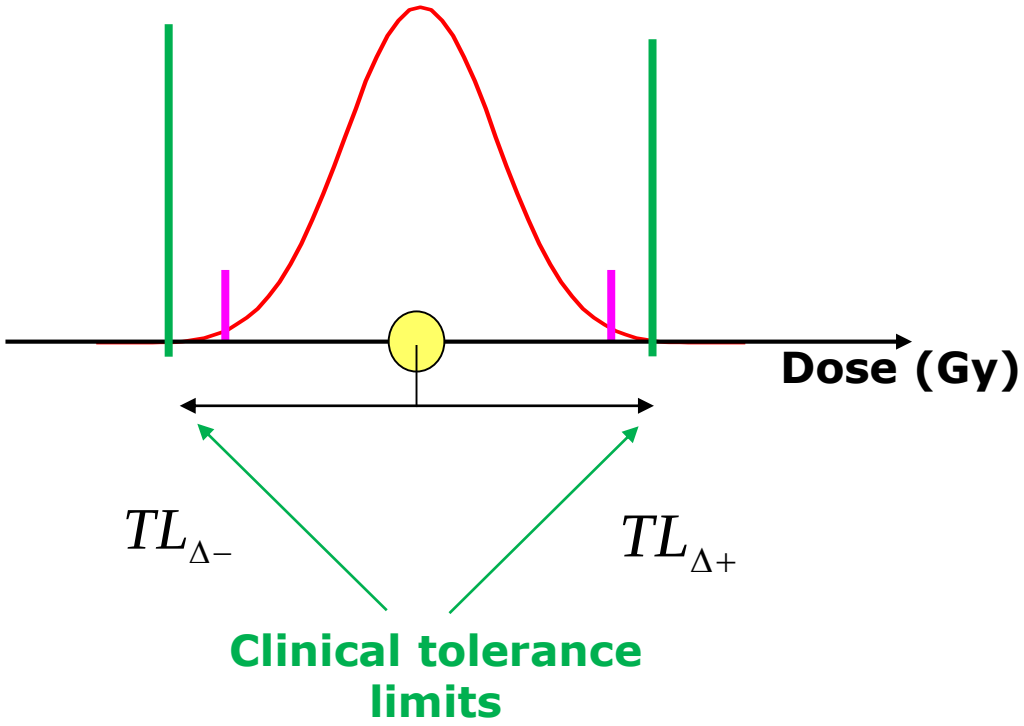
Example with large uncertainty:

Prescribed dose

Probability distribution for the true dose



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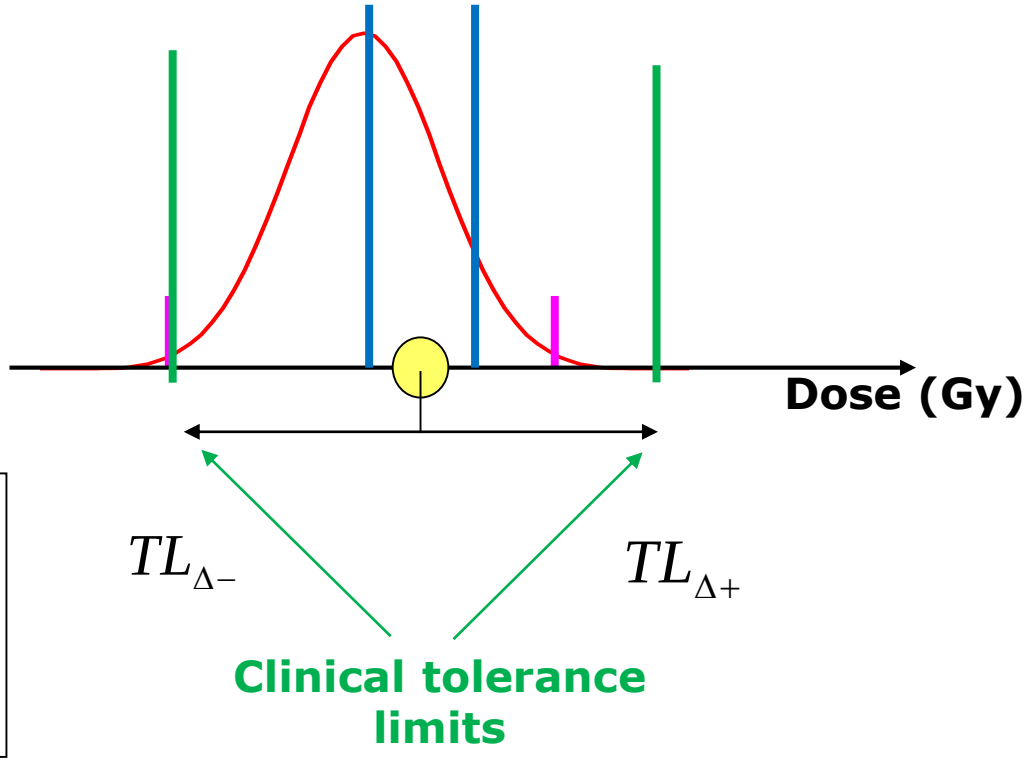
Example with large uncertainty:

Prescribed dose

Probability distribution for the true dose



Action limits go to zero when dose measurement uncertainty increases

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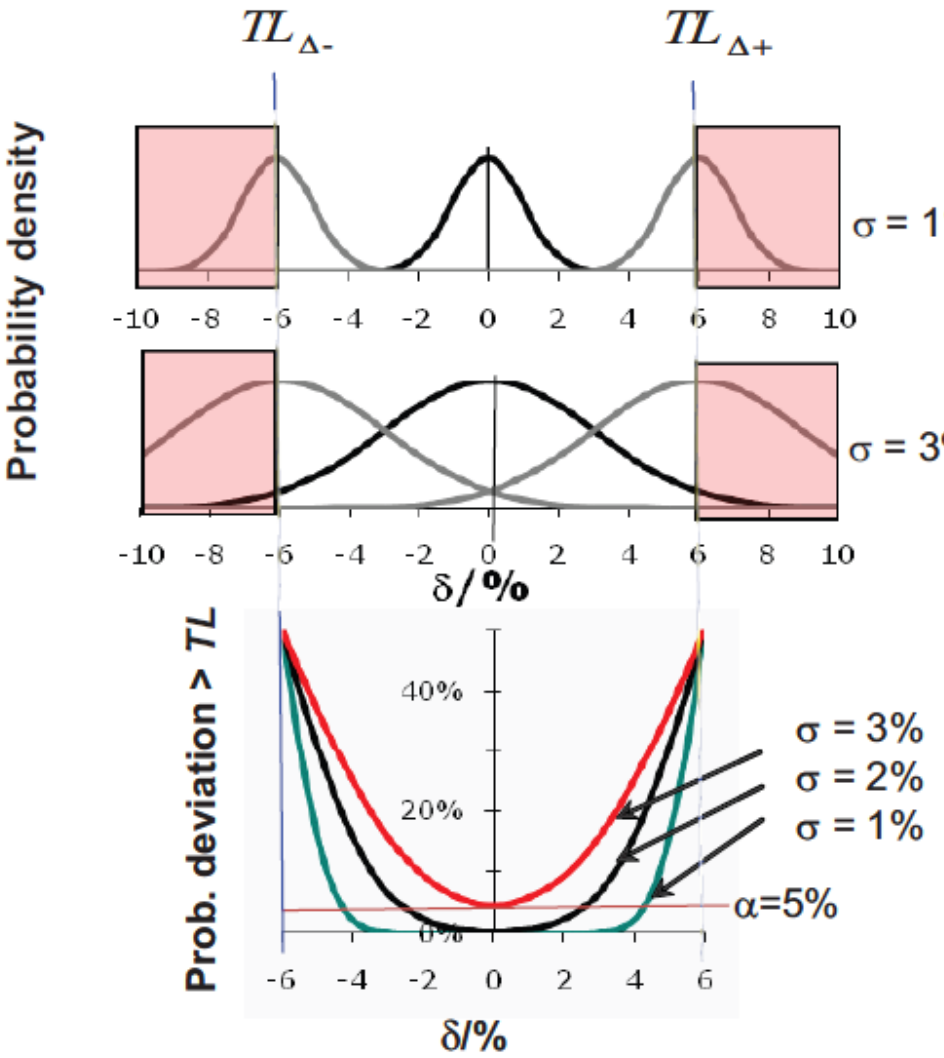
Relations between TL_{Δ}, $AL_{\pm}$, σ and α



AL_+= 6-2=4

AL_+= 6-6=0

$$\Delta L_{\pm} = TL_{\pm} \pm \frac{C_{\alpha}}{2}$$

Dosimetric tolerance set to ± 6%

Different measurements standard deviations (σ)

What is the Action level (δ) if I set the confidence level in 95% (α=5%)?

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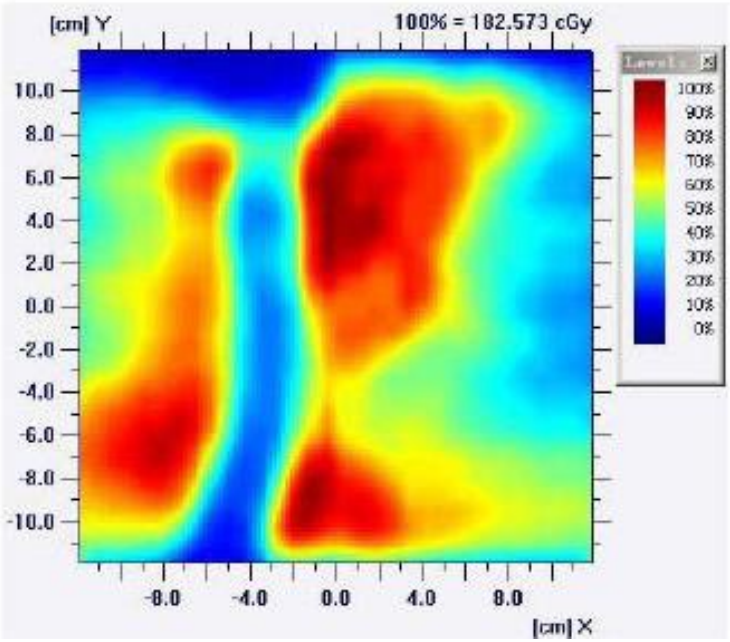
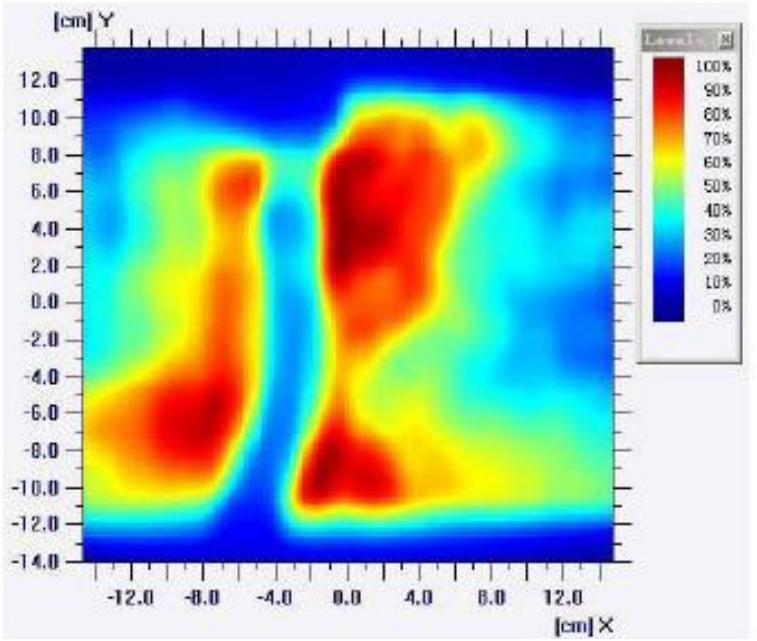
Friday afternoon at the radiotherapy department…

Dose measurement



TPS dose calculation



Not OK for treatment?

We need limits to make objective decisions!

From JörgenOlofsson (Dose Modeling and dose verification ESTRO COURSE)

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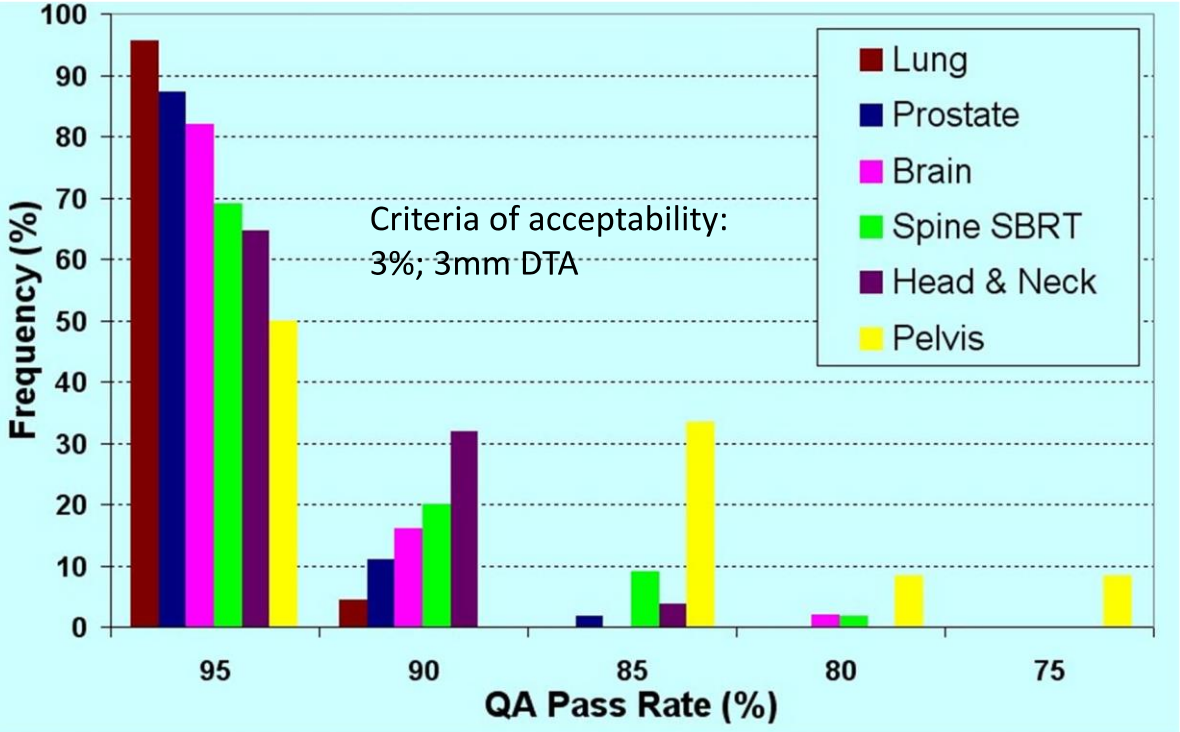
IMRT; Does it make sense to have different action limits for different sites?



Higher failure rates for more complex delivery

Data from Florida University

IMRT; Does it make sense to have different action limits for different sites?

The uncertainty in the measurement: The same

The clinical tolerance limits: The same???

YES

The action levels should be the SAME

Same gamma settings (3%-3mm)

IMRT; Does it make sense to have different action limits for different treatment units?

The uncertainty in the measurement: The same

The clinical tolerance limits: The same???

YES

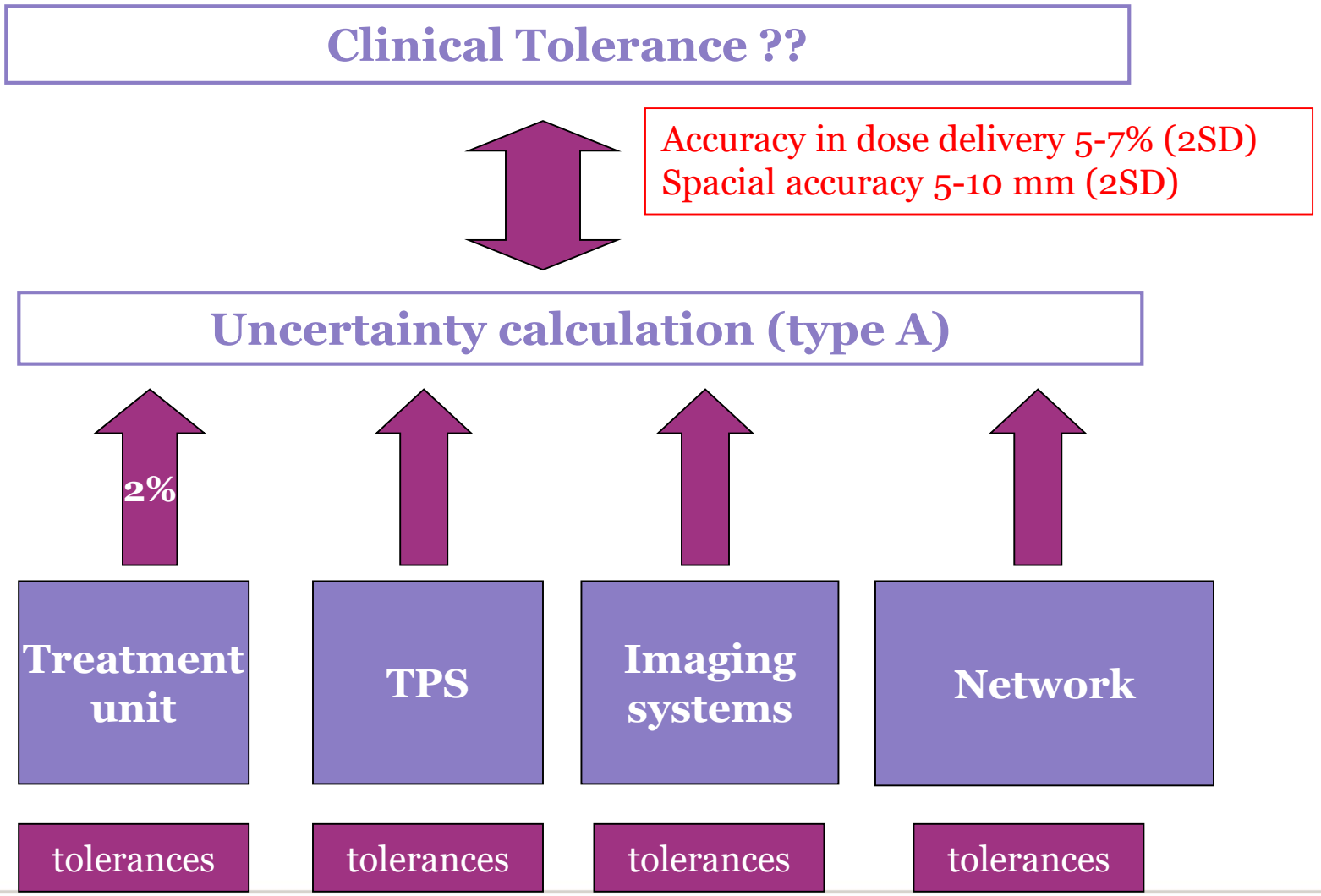
The action levels should be the SAME

Same gamma settings (3%-3mm)

We need to know what is the uncertainty of our measurements

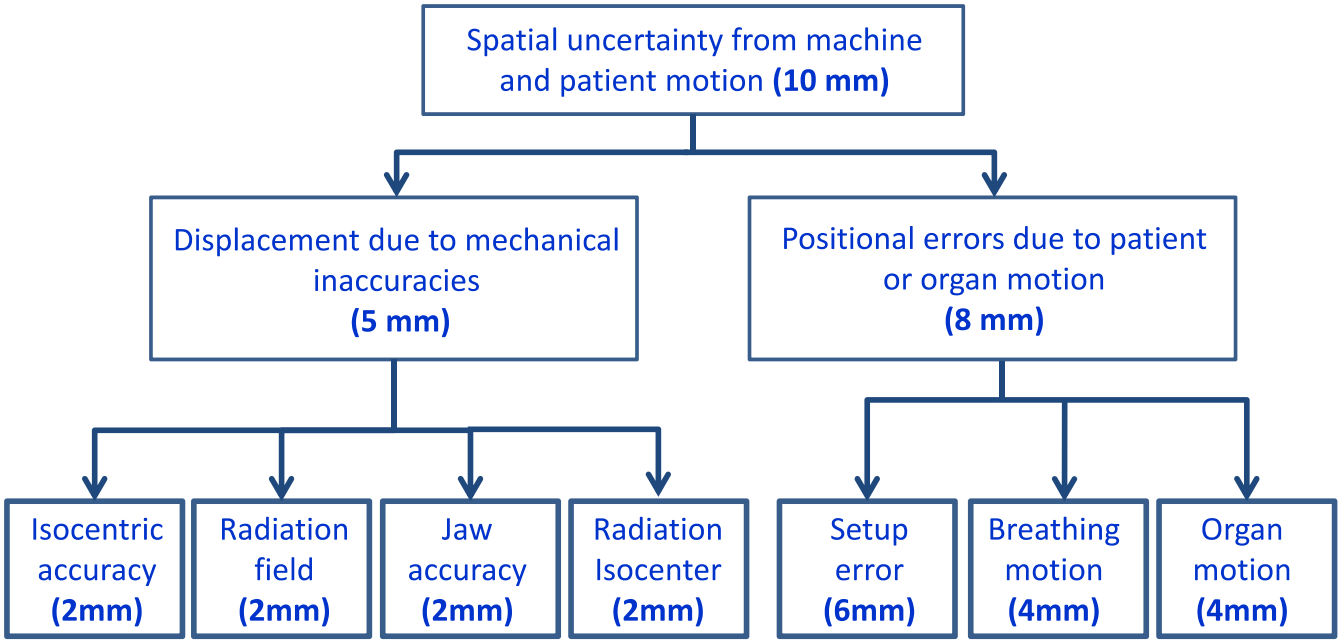
"QA documents specify acceptable tolerance levels for individual parameters WITHOUT considering the cumulative effect on the uncertainty in the dose delivered to a specified volume in a patient" AAPM (1984)

Uncertainty propagation is difficult and considered by some to be scientifically unsound because we are dealing with the combined effect type A and type B uncertainties

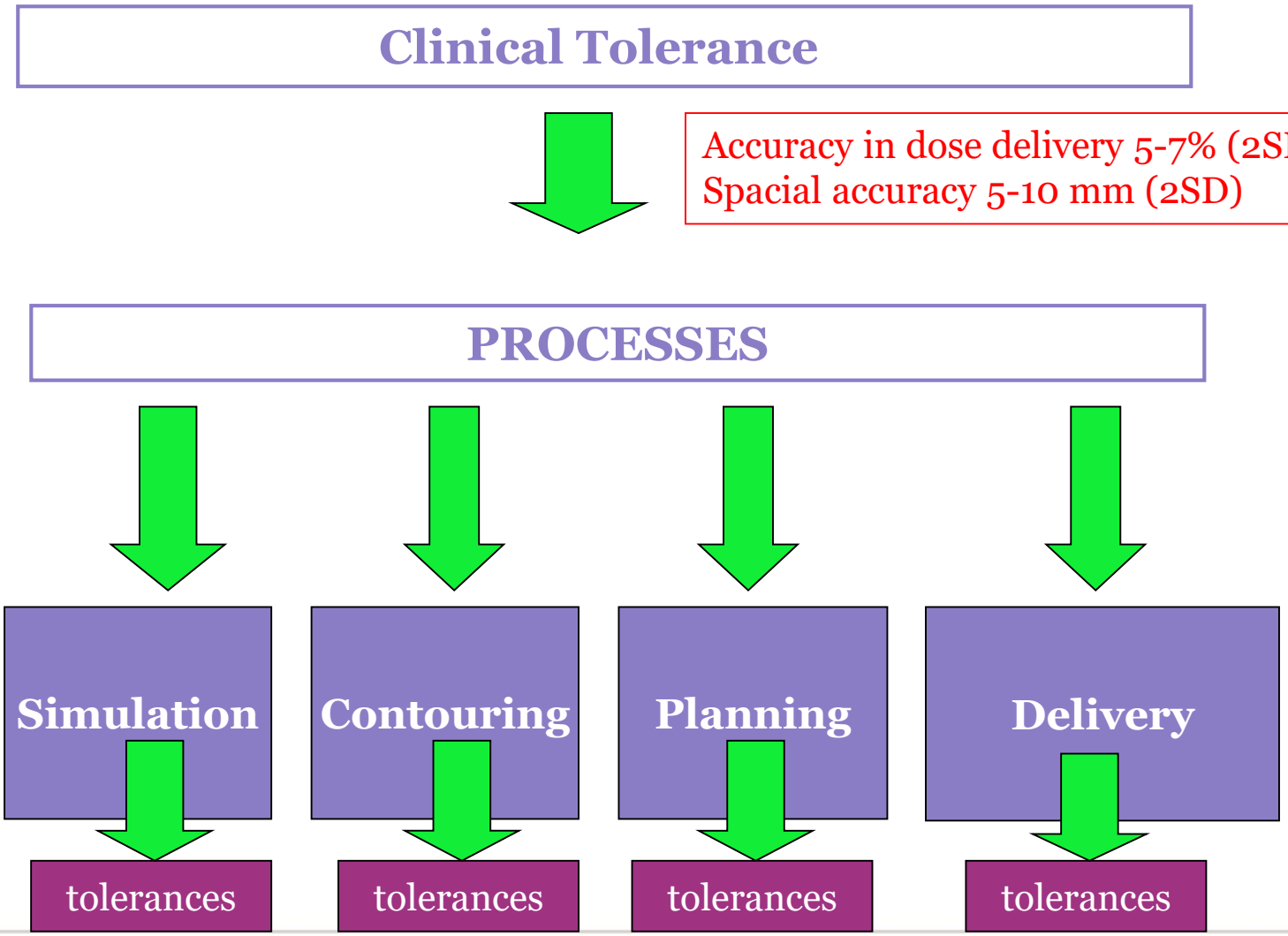

Clinical Tolerance ??
Accuracy in dose delivery 5-7% (2SD)
Spacial accuracy 5-10 mm (2SD)
Uncertainty calculation (type A)
2%
Treatment unit
TPS
Imaging systems
Network
tolerances
tolerances
tolerances
tolerances

Spatial Uncertainties

(95% confidence level)



AAPM Report #13


Clinical Tolerance
Accuracy in dose delivery 5-7% (2SD)
Spacial accuracy 5-10 mm (2SD)
PROCESSES
Simulation
Contouring
Planning
Delivery
tolerances
tolerances
tolerances
tolerances

Event driven tolerance limits

Missed or late report of a serious adverse event (SAE)

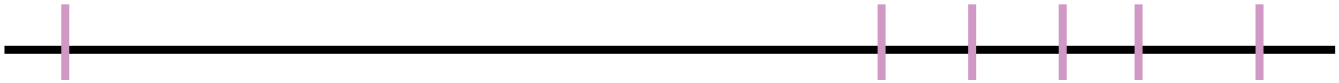
CAUTION, BE AWARE AND INFORM

TRIGGER A MITIGATION PLAN OR STOP

Event driven tolerance limits

Occurence of an unwanted situation

Recurrence of an unwanted situation



Randomisation error

CAUTION, BE AWARE AND INFORM

TRIGGER A MITIGATION PLAN OR STOP

Event driven tolerance limits

Treatment should be administered in 45 Days (5 days per week)

Machine breakdown
Treatment interruption

Inform

TRIGGER A MIGATION STRATEGY

Event driven tolerance limits

Treatment should be administered in 45 Days (5 days per week)

Machine breakdown Treatment interruption

Inform

Deliver two fractions next day (6h between both fractions)

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Event driven tolerance limits

Treatment should be administered in 45 Days (5 days per week)

Machine breakdown Treatment interruption

Machine breakdown Treatment interruption

Inform

Adjust the dose per fraction to deliver 66 Gy if the dose per fraction is lower than 3 Gy

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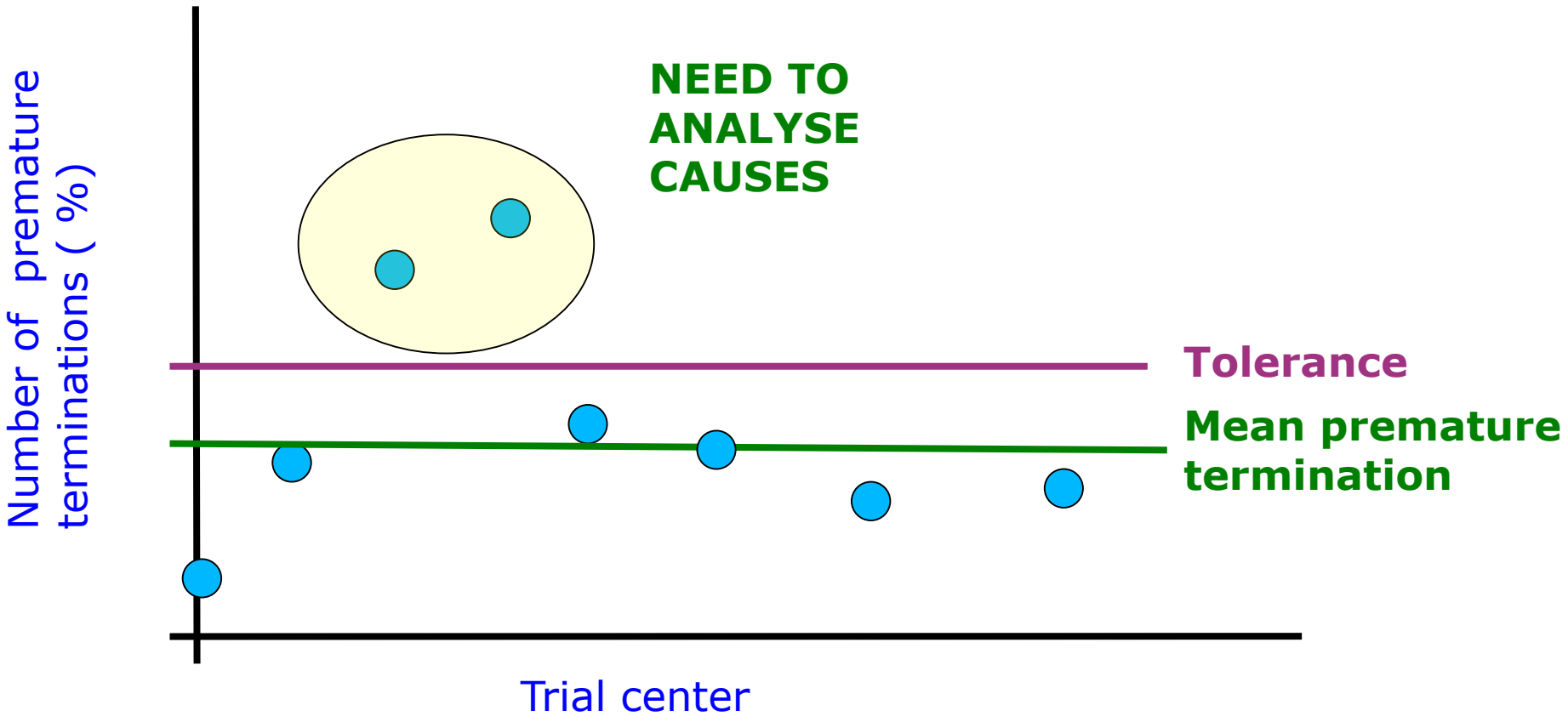
Important to control the premature terminations



DEVIATIONS FROM PROCESSES: protocol perfomance

Example: clinical trial

EFC 5512: RT QA documentation an Operation Resource Manual (QART)

Definitions of significant deviations in protocol performance

Dose delivered:

Treated Volume	PTV1	PTV2	PTV3	GTV
Protocol requirement	50 Gy	70Gy	60Gy	70Gy
Deviation definition	<44 Gy to any part of PTV1	<66.5 Gy Or D10>70 Gy	D90<57 Gy	<66.5Gy to any part of GTV
Tolerance	Lower limit -6 Gy	Upper and lower limit	Lower limit	Lower limit

Dose per fraction 2 Gy. If other re-scale doses to Biological Equivalent doses

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Conclusion

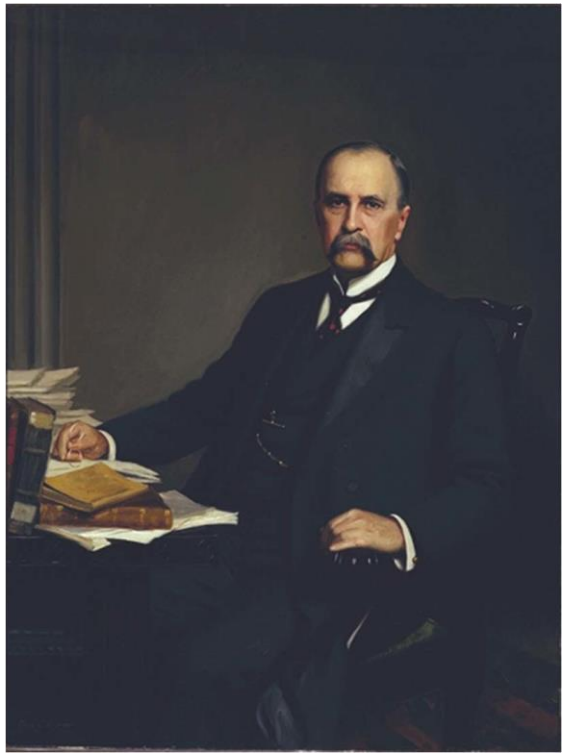
Be critical when setting **value driven** tolerance and action limits

- The action limit must be set according to clinical tolerances and measurement uncertainty
- If your measuring equipment has large uncertainties it may not be suitable for QC

Event driven tolerance and action limits

- must also be set according to clinical consequences and ability to mitigate the consequences

“Medicine is a science of uncertainty and an art of probability”



Sir William Osler (1849-1919)
A Canadian Physician,
The Father of Modern Medicine

References

H. Jin, J. Palta, T Suh and S. Kim. A generalized *a priori* dose uncertainty model of IMRT delivery. Med. Phys. 35, 982 (2008)

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M. Goitein, Calculation of the uncertainty in the dose delivered during radiation therapy. Med. Phys. 12(5) (1985)

Lujan et al. A method for incorporating organ motion due to breathing into 3D dose calculations. Med. Phys. 26 (5) (1999)

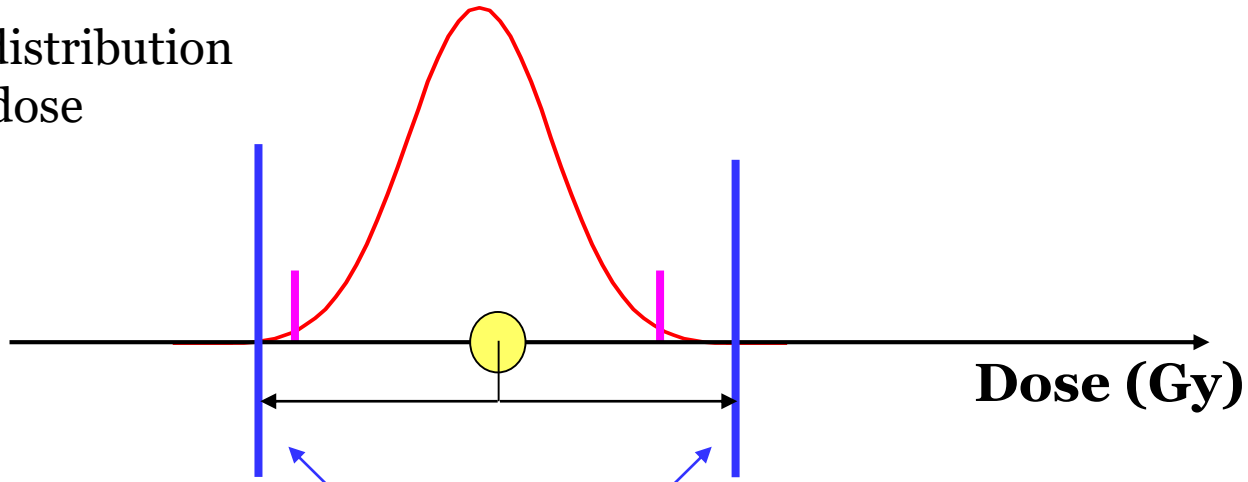
G.K Svensson et al. AAPM Report 13. Physical aspects of Quality Assurance in Radiotherapy. (1994)

Action limits - Proposed philosophy

Step 3: Adjust the true dose probability distribution such that the dose limits IDC-$C_\alpha/2$ and IDC+$C_\alpha/2$ coincide with the clinical tolerance limits.

Prescribed dose

Probability distribution for the true dose



is set to a minimum acceptable cure rate

is set to a maximum acceptable complication rate

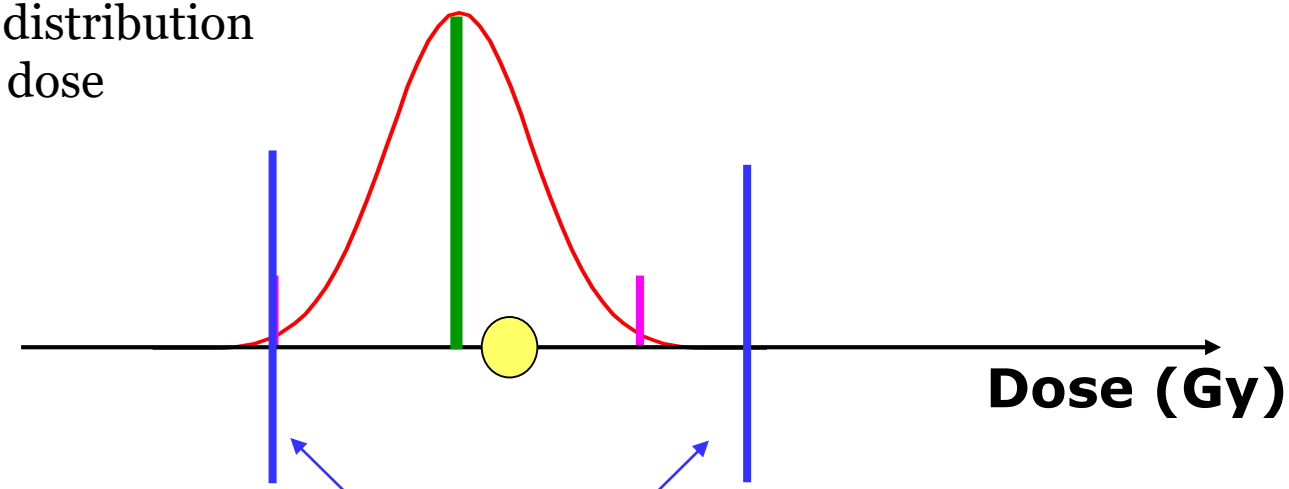
Clinical tolerance limits

Action limits - Proposed philosophy

Step 4: Define the center of the true dose probability distribution as the lower and upper **action limit**, respectively.

Prescribed dose

Probability distribution for the true dose



is set to a minimum acceptable cure rate

is set to a maximum acceptable complication rate

Clinical tolerance limits

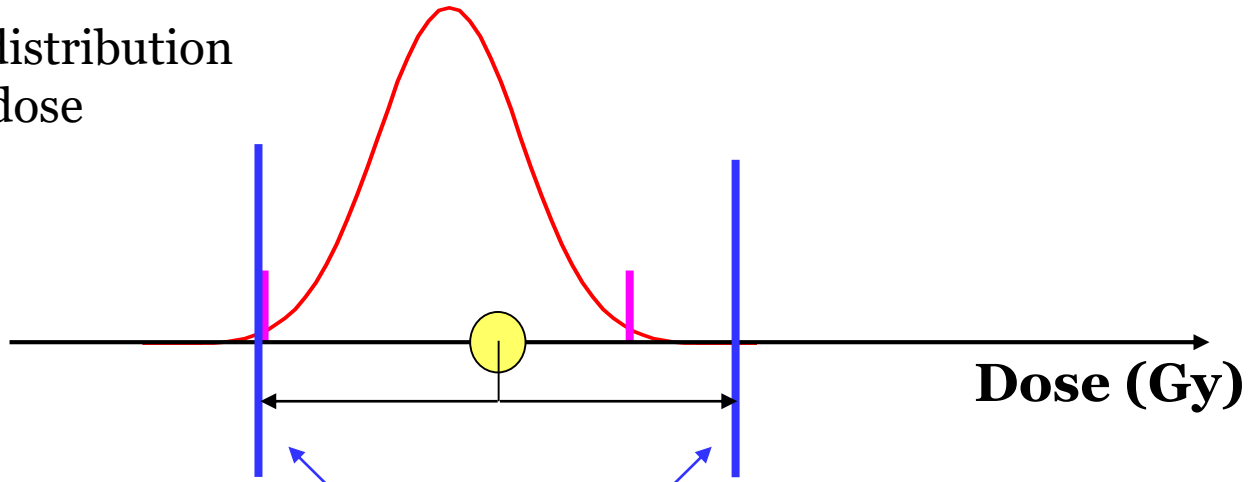
From JörgenOlofsson (Dose Modeling and dose verification ESTRO COURSE)

Action limits - Proposed philosophy

Step 3: Adjust the true dose probability distribution such that the dose limits IDC-$C_\alpha/2$ and IDC+$C_\alpha/2$ coincide with the clinical tolerance limits.

Prescribed dose

Probability distribution for the true dose



is set to a minimum acceptable cure rate

is set to a maximum acceptable complication rate

Clinical tolerance limits

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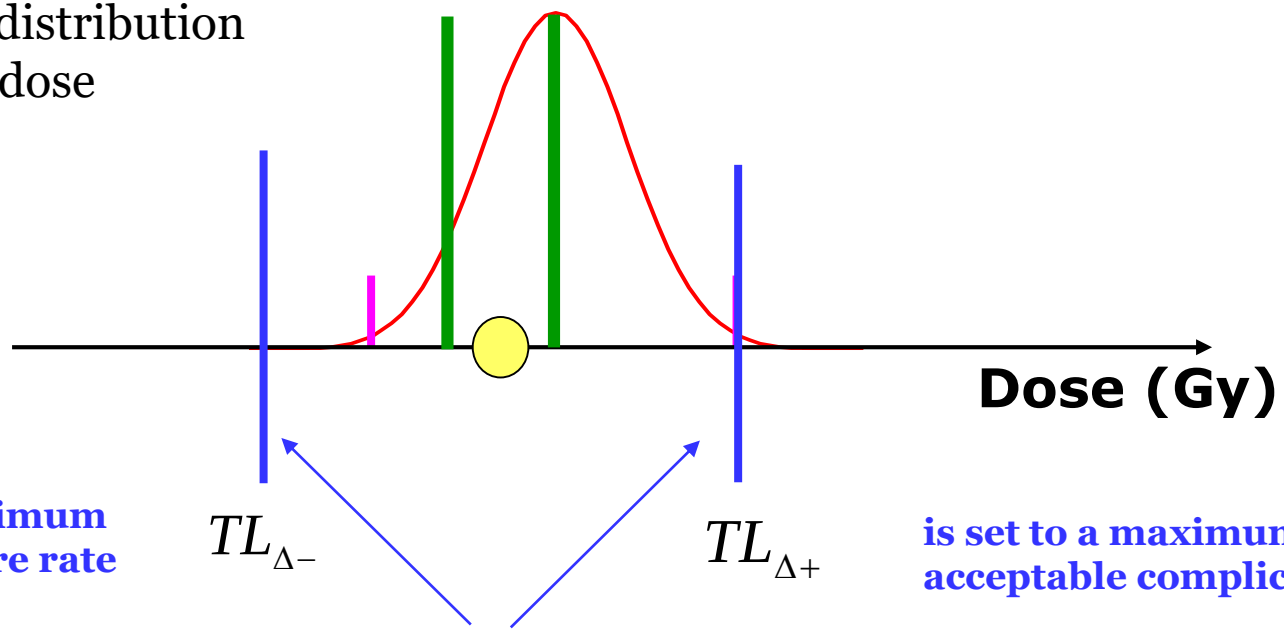
Prescribed dose

Probability distribution for the true dose



is set to a minimum acceptable cure rate

is set to a maximum acceptable complication rate

Clinical tolerance limits

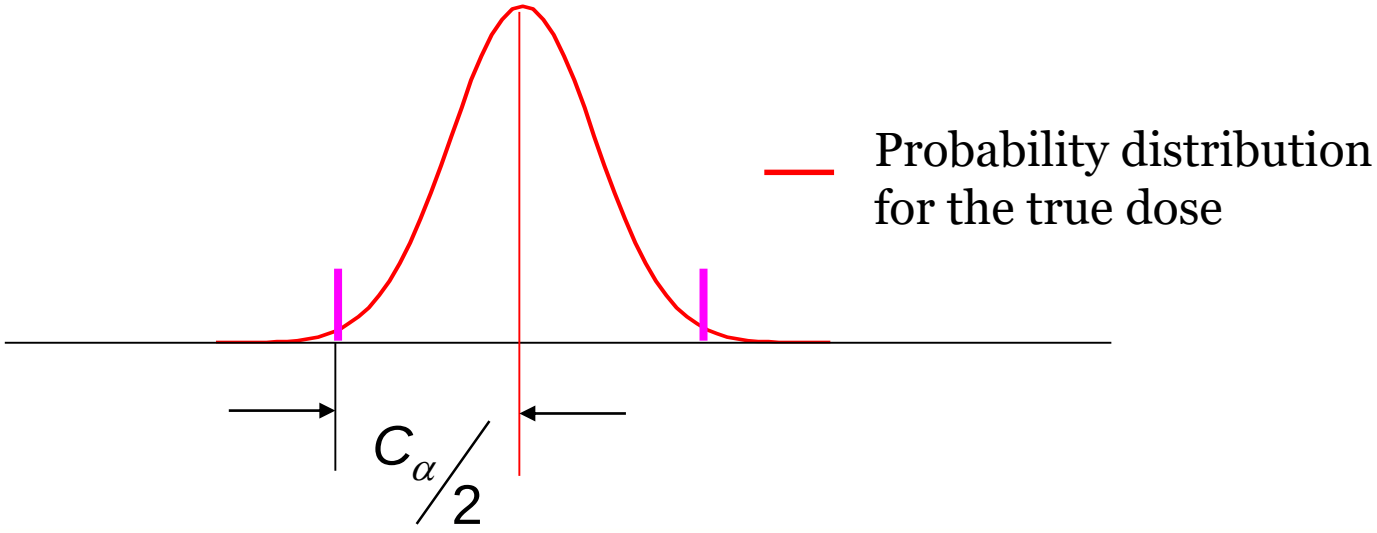
Action limits - Proposed philosophy

Hence, the action limits should be calculated as

Clinical tolerance=specification

Measurement uncertainty

$$\Delta L_{\pm} = TL_{\pm} \pm \frac{C_{\alpha}}{2}$$



From JörgenOlofsson (Dose Modeling and dose verification ESTRO COURSE)

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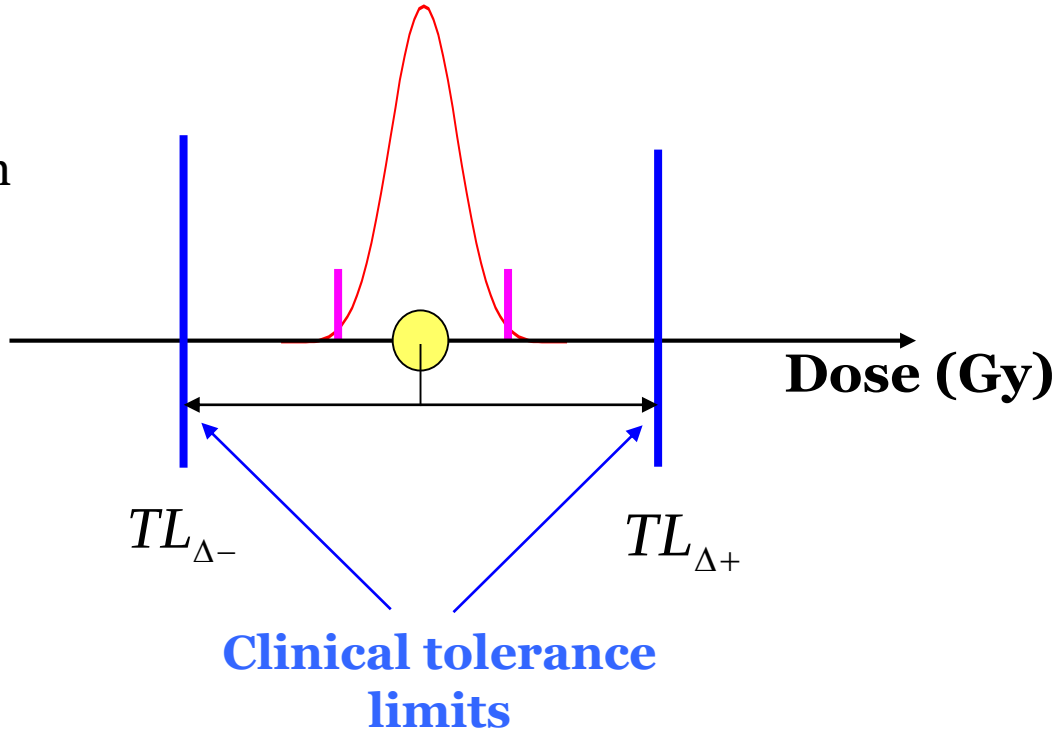
How does the uncertainty (σ) influence the action limits?

Example with small uncertainty:

Prescribed dose

Probability distribution for the true dose



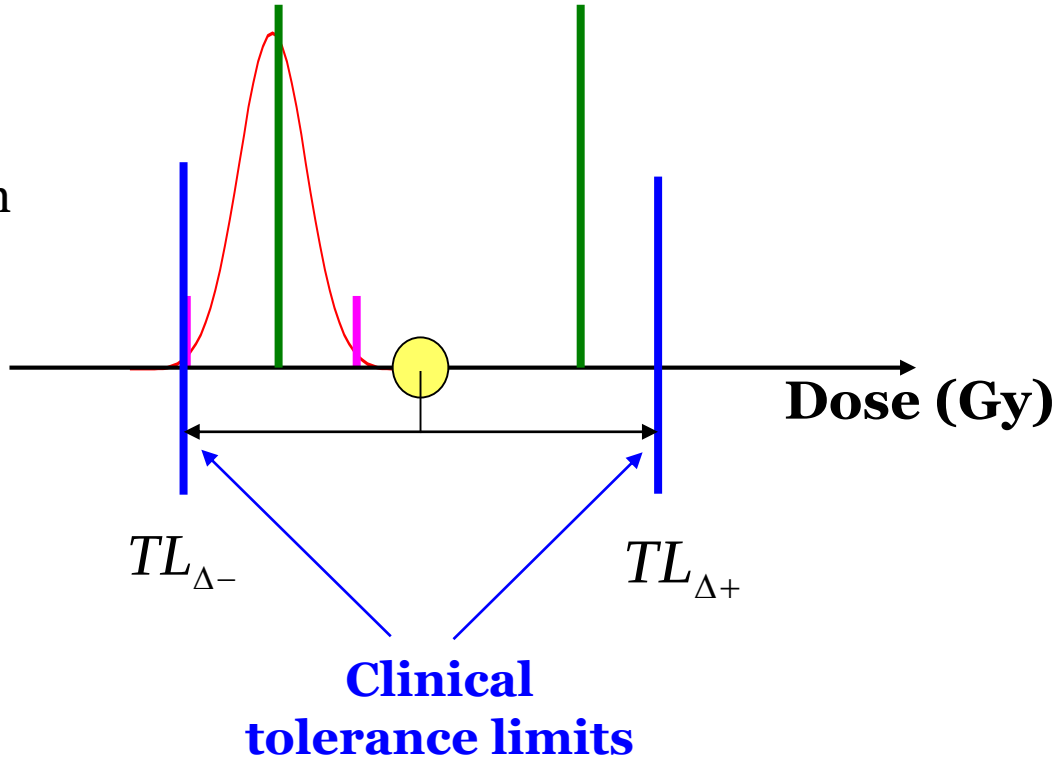
From JörgenOlofsson (Dose Modeling and dose verification ESTRO COURSE)

How does the uncertainty (σ) influence the action limits?

Example with small uncertainty:

Prescribed dose

Probability distribution for the true dose



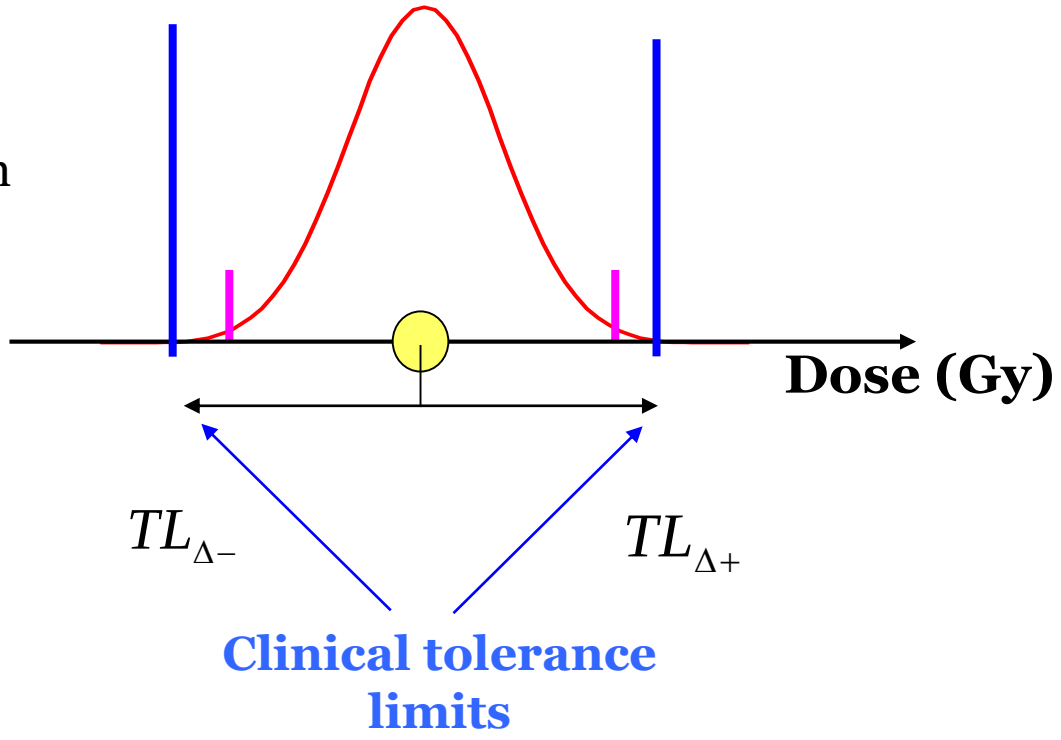
Action limits smaller than tolerance limits

How does the uncertainty (σ) influence the action limits?

Example with large uncertainty:

Prescribed dose

Probability distribution for the true dose



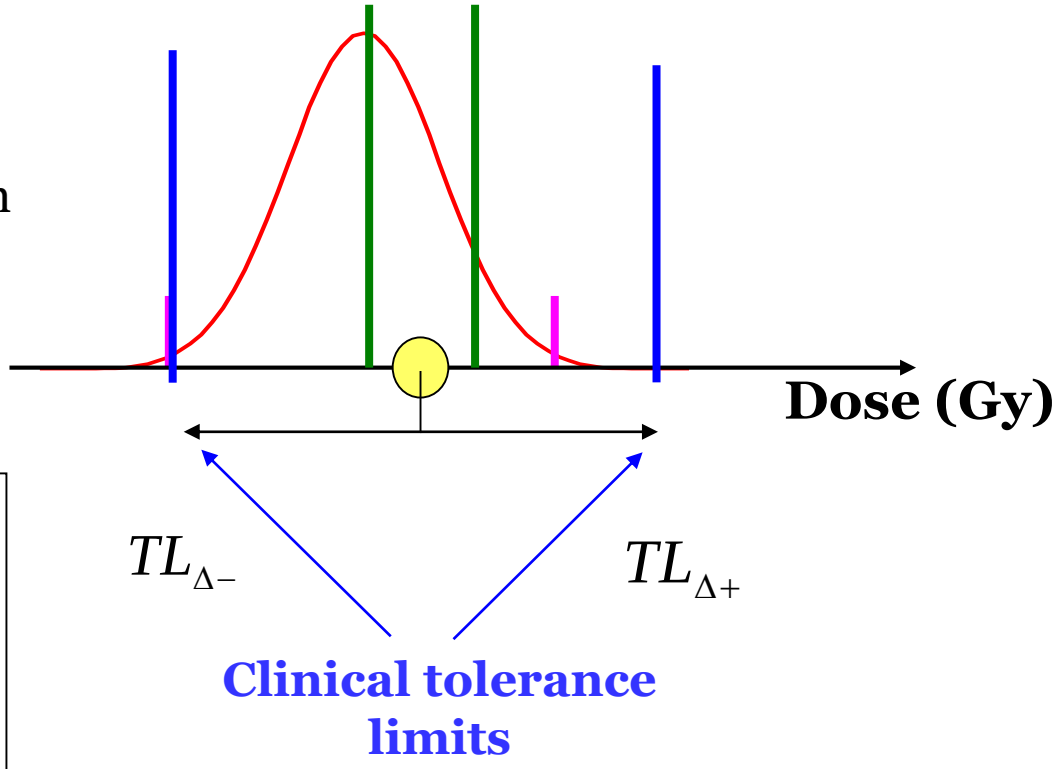
From JörgenOlofsson (Dose Modeling and dose verification ESTRO COURSE)

How does the uncertainty (σ) influence the action limits?

Example with large uncertainty:

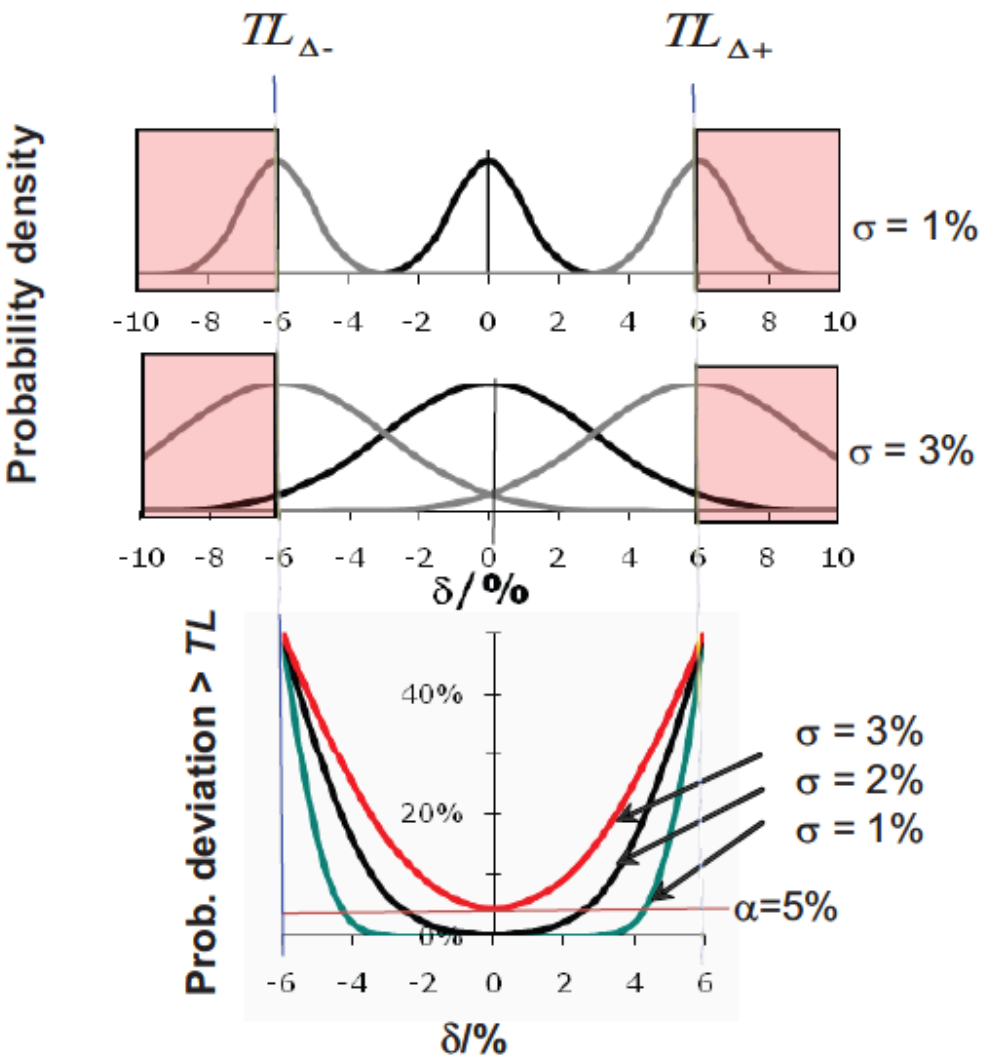
Prescribed dose

Probability distribution for the true dose



Action limits go to zero when dose measurement uncertainty increases

Relations between TL_Δ, AL_Δ, σ and α



Dosimetric tolerance set to ± 6%

Different measurements standard deviations (σ)

What is the Action level (δ) if I set the confidence level in 95% (α=5%)?

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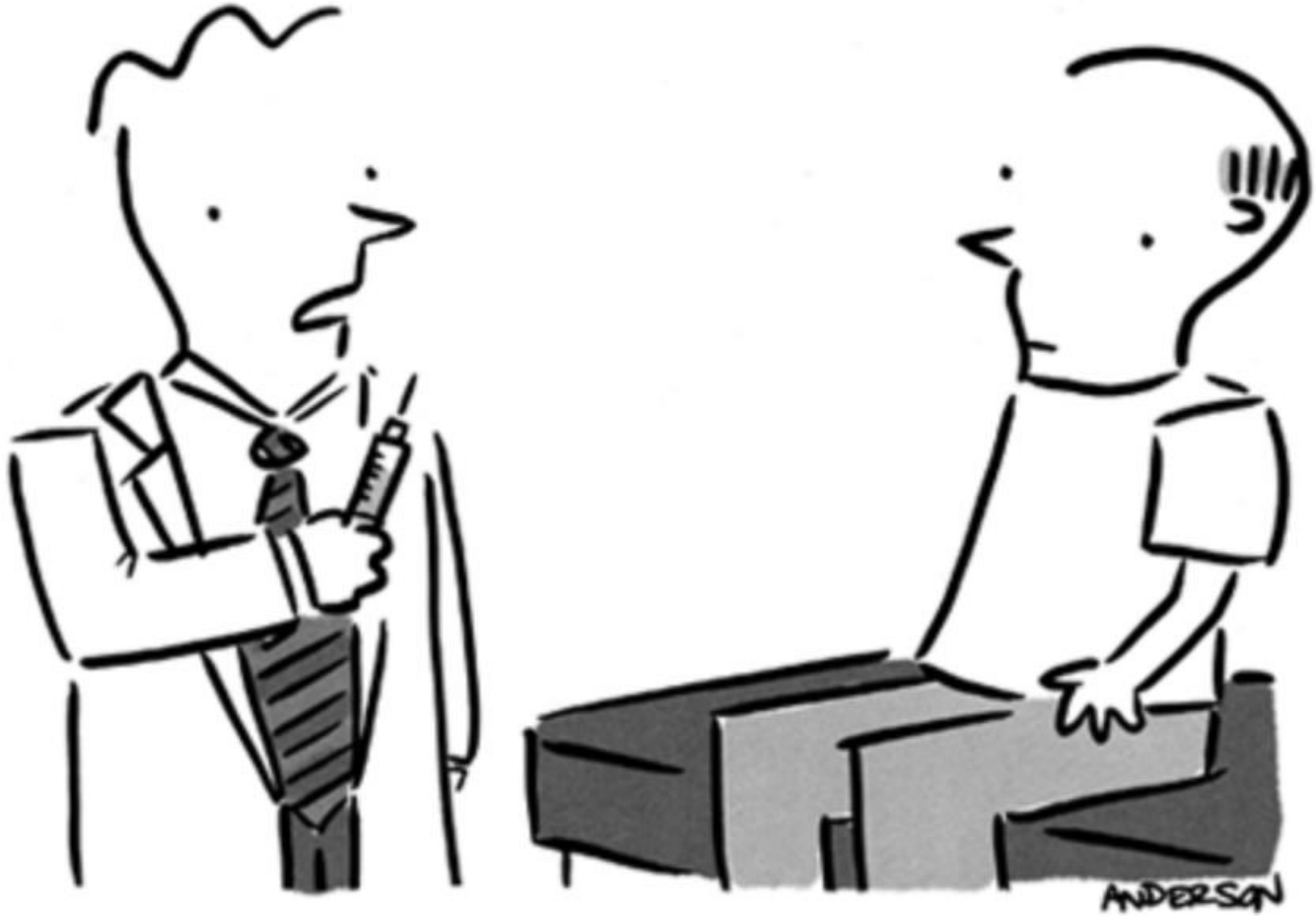
How to balance different endpoints?

Coen Hurkmans



"You'll feel a little pinch, then another pinch, and then a few more because I'm pretty bad at this."

Learning objectives

After this talk, you should be able to:

- Define different population perspectives on Quality
- Name different quality indicators for each perspective
- Start a structured discussion on which Quality indicators you want to introduce / update in your hospital

Which population perspectives are there?

- Patient
- Clinical (high quality decision making)
- Management (high quality performance)
- General public

	Organisation	outcome
Patient	Consumer Quality Index	Patient reported outcome
Clinician	Minimum Quality Regulations	Registries

Management / general public

Clinician

Clinician / researchers?

Clinician / management

Example perspective used in Holland

Which population perspectives are there?

- Patient
- Clinical (high quality decision making)
- Management (high quality performance)
- General public

	Organisation	outcome
Patient	Consumer Quality Index	Patient reported outcome
Clinician	Minimum Quality Regulations	Registries

Example perspective used in Holland

Disclaimer:

-This is NOT the only possible categorisation.

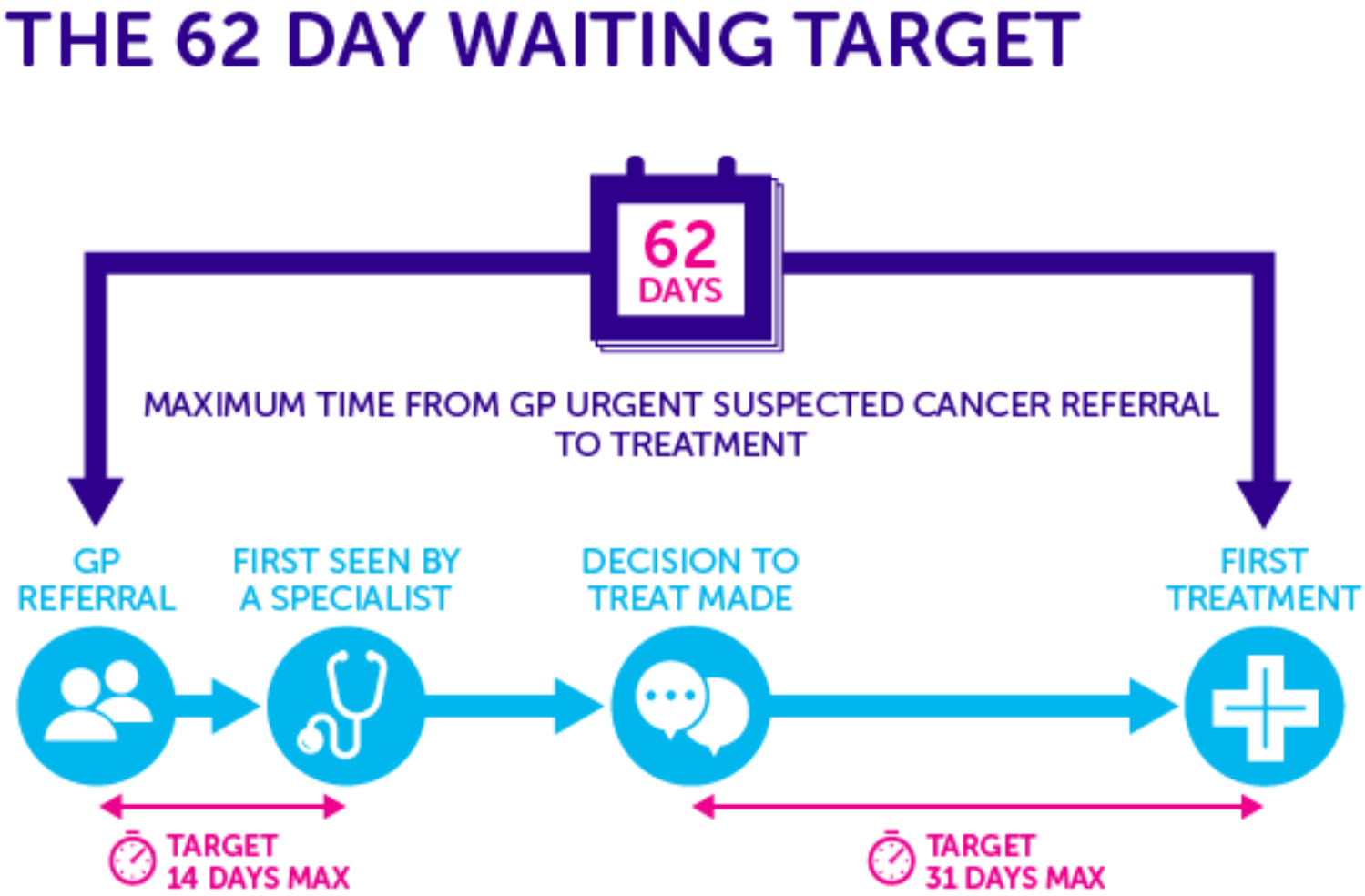
-Topics addressed often have MULTIPLE perspectives

-I just want to make it a bit less chaotic….

Patient perspective

- Access to the best care
  - From first line to specialised care
  - Multidisciplinary oncology approach with one case holder
- Patient satisfaction
  - Friendlyness of staff
  - Proper information, both clinically as practically
  - Hospital environment
- Treatment outcome….

Patient perspective: access times



catharina ziekenhuis

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Patient perspective: access times

catharina ziekenhuis

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Patient perspective: patient surveys

- The patients prefers to have one dedicated radiation oncologist. How… incorporate nurse practitioners and/or radoncs in training?
- Personal attention by the RTTs is appreciated. How to … dedicated personel and flexibility?
- Patient information is sometimes too g… …d info in folder and on our website.
- Information on possible s… …etter with introduction of “after RT” letter. Introduction…
- A sidewal… …coming by public transport.
- O… …places.

Do patients have a choice?

Clinical perspective

Levels of evidence

Ia - Evidence from Meta-analysis of Randomized Controlled Trials

Ib - Evidence from at least one Randomized Controlled Trial

IIa - Evidence from at least one well designed controlled trial which is not randomized

IIb - Evidence from at least one well designed experimental trial

III - Evidence from case, correlation, and comparative studies.

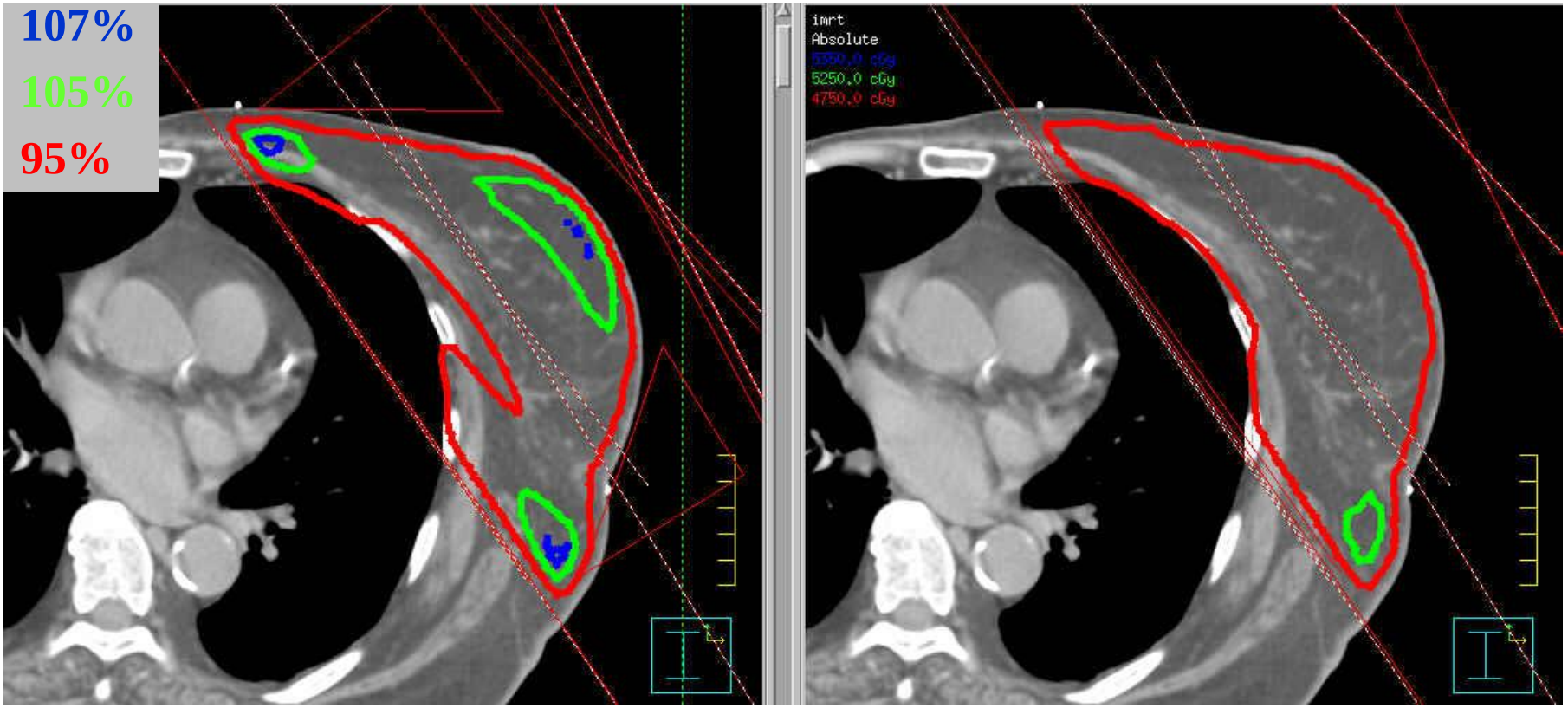
IV - Evidence from a panel of experts

Clinical perspective

- Have a system in place to periodically update your medical protocol – based on new evidence
  - Indication
  - Dose fractionation
  - Targets and OARs

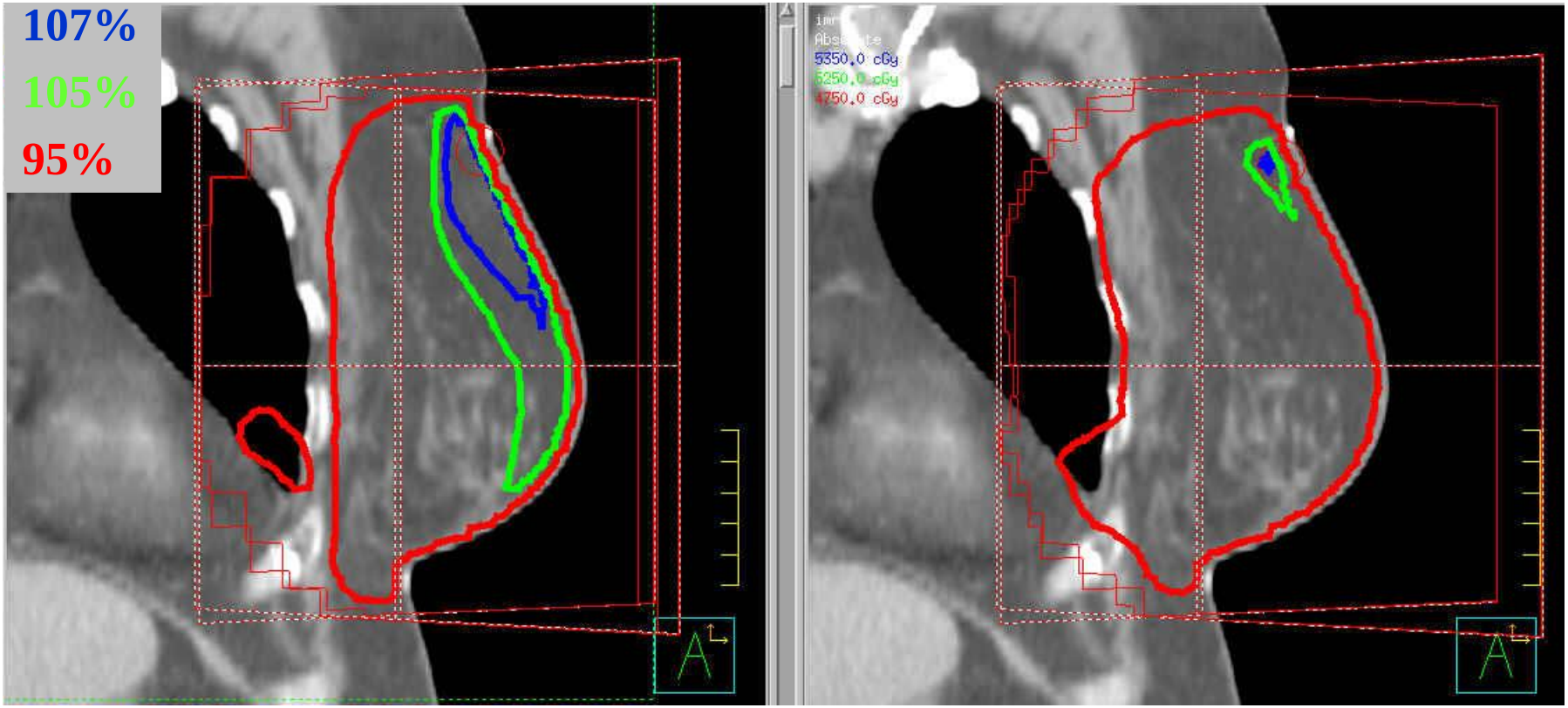
- Technical issues:
  - Which technique?
  - Optimization of the plan

Breast: Wedges vs IMRT



Wedges IMRT

Breast: Wedges vs IMRT



Wedges IMRT

WBH IMRT vs control group: level III

172 patients, CT plan, 25x1.8Gy+8x2 Gy phot.

2D with wedges vs 3D IMRT

Toxicity	IMRT (%)	Wedges (%)	*p*
Acute grade ≥2			
Dermatitis	41	85	<0.001
Breast edema	1	28	<0.001
Pain	8	8	0.78
Hyperpigmentation	5	50	<0.001
Chronic grade ≥2			
Hyperpigmentation	7	17	0.06
Breast edema	1	25	<0.001
Fat necrosis	0	1	0.46
Induration/fibrosis	0	6	0.11
Good/excellent cosmesis	99	97	0.60

Harsolia *et al.*
IJROBP 68-5 (2007)

Royal Marsden phase III randomised trial: level I-b?

240 patients, single contour plan, 25x2 Gy+5x2Gy elec.

2D with wedges vs 3D IMRT with wedges

Reduced late effects

- change in breast appearance from 58% to 40%
- Reduction of induration

Donovan *et al.* R&O 82 (2007)

	Year 5 assessment		*P*-value
	Standard 2D	IMRT 3D	
Centre of the breast	37/117 (32%)	25/118 (21%)	0.02
Pectoral fold	34/118 (29%)	26/119 (22%)	0.006
Inframammary fold	28/116 (24%)	20/117 (17%)	0.009
Boost site	70/114 (61%)	43/115 (37%)	<0.001

Canadian phase III multicentre trial: level I-b

331 patients, CT plan, 25x2Gy+8x2 Gy elec.

3D with wedges vs 3D IMRT

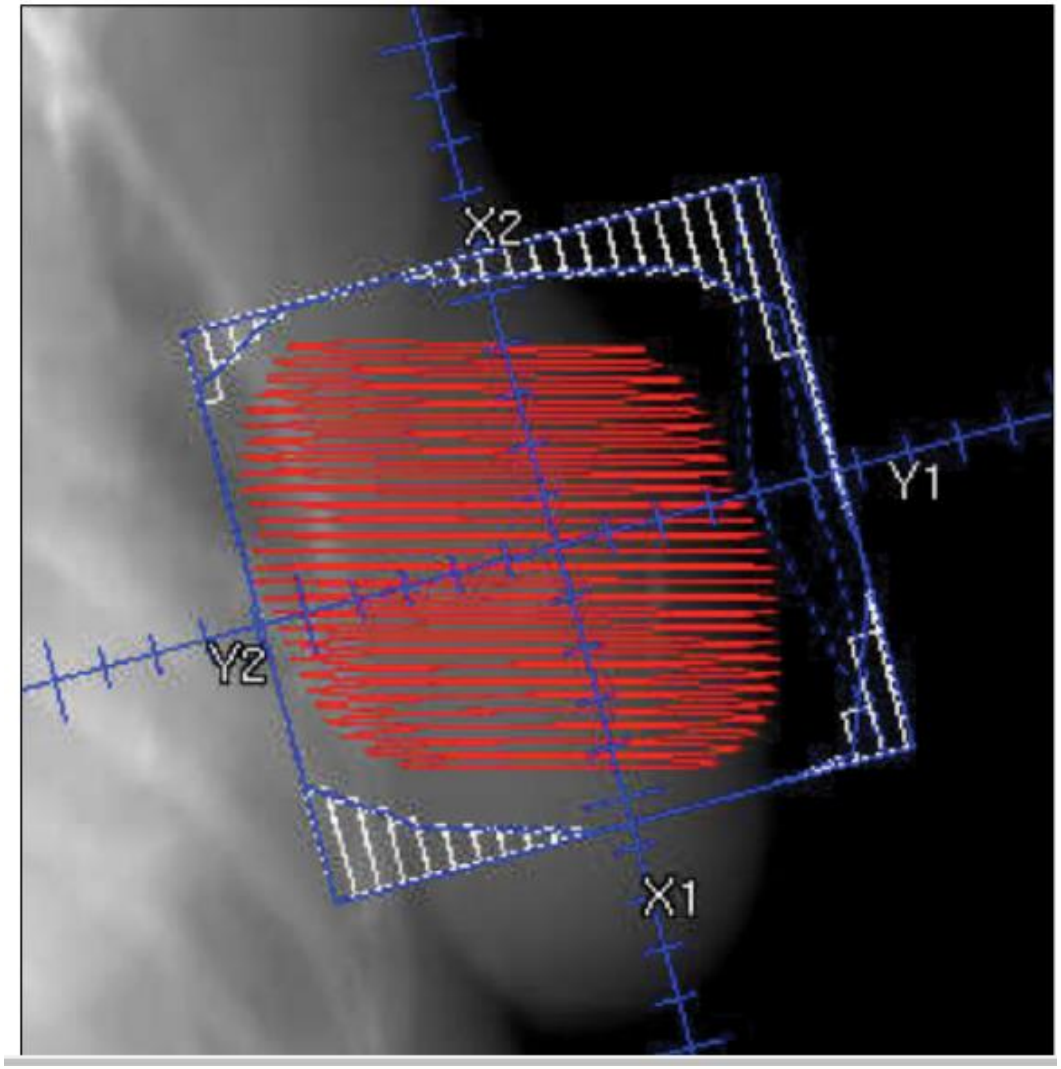
Reduced acute effects

Pignol *et al.* JCO 26-13 (2008)

			P
Skin toxicity grade 3-4 (NCI CTC 2.0)	27.1	36.7	.06
Moist desquamation, all breast	31.2	47.8	.002
Moist desquamation, inframammary crease	26.5	43.5	.001
Pain grade 2-4 (NCI CTC 2.0)	23.5	25.5	.68

Factor	Odds Ratio	95% CI	P
BIMRT technique	0.418	0.232 to 0.753	.0034
Breast size (per 100 cm^3)	1.236	1.157 to 1.321	< .0001

Import low trial: randomised phase III trial



Low risk breast cancer

2018 patients, CT plan,

40 Gy in 15 fractions vs

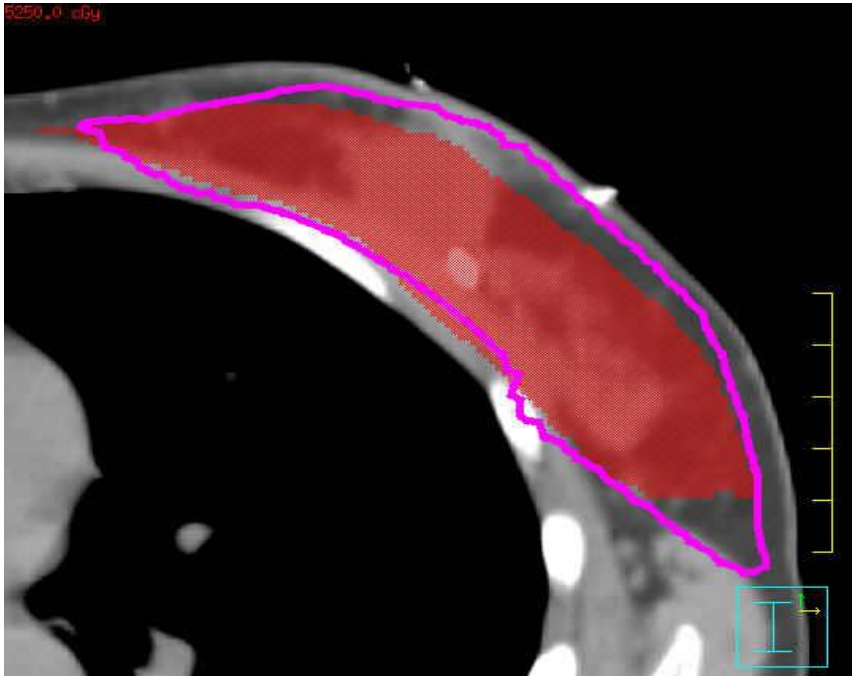
36 Gy in 15 fractions with 40 Gy to the partial breast vs

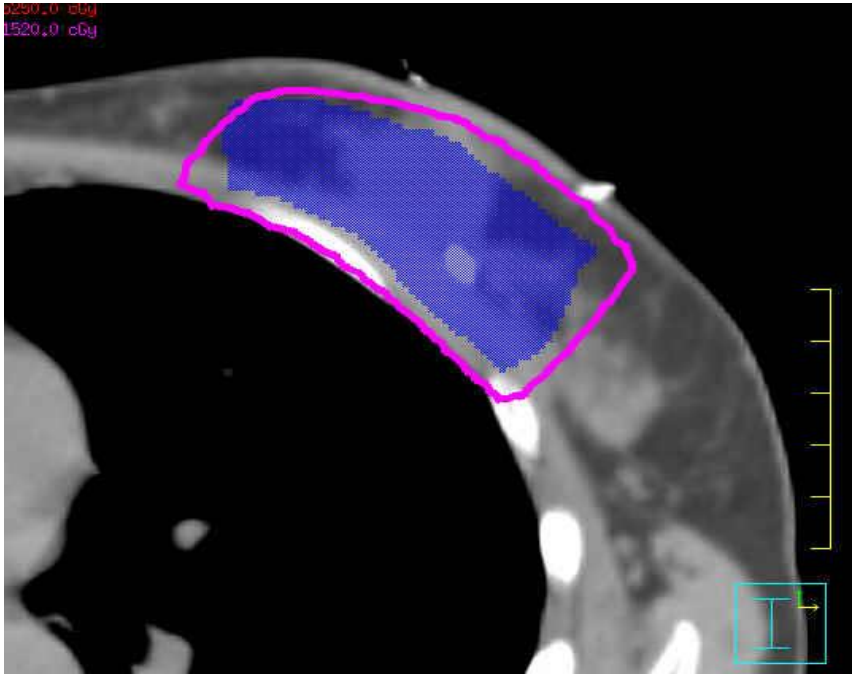
40 Gy to partial breast

5-year results:

Non-inferiority of partial breast RT with similar or reduced toxicity.

Including the boost: Sequential planning





Breast plan

Boost plan

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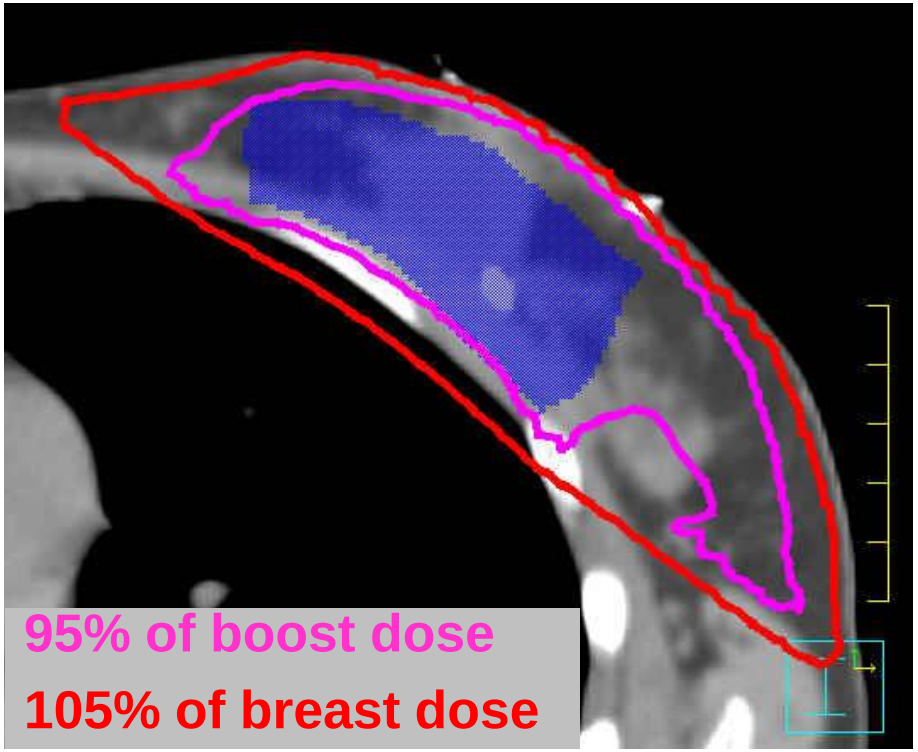
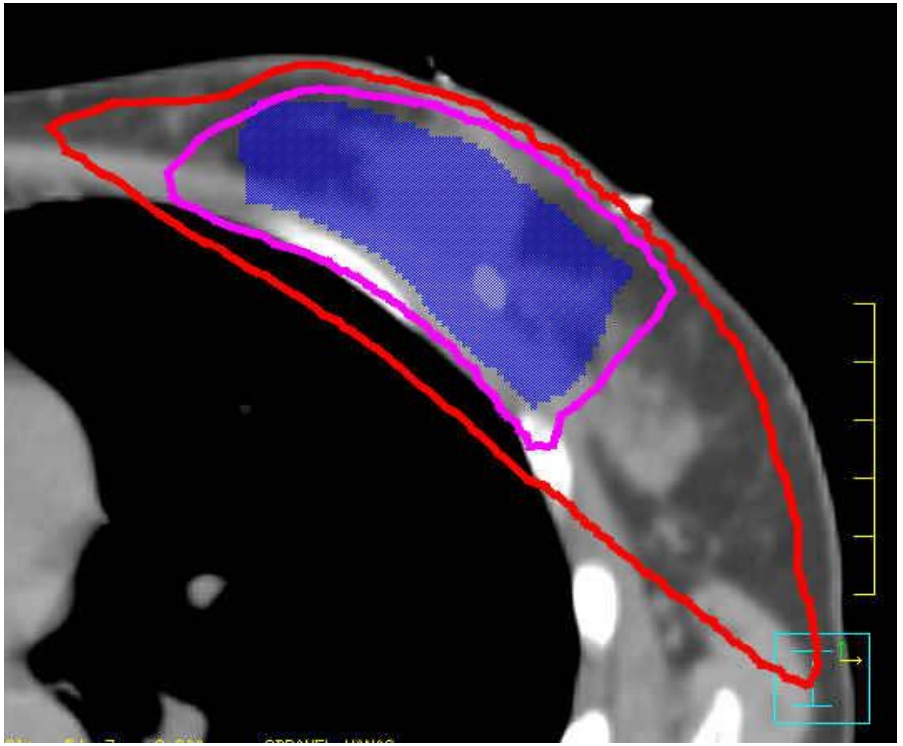
Boost: Sequential vs SIB: level 4?

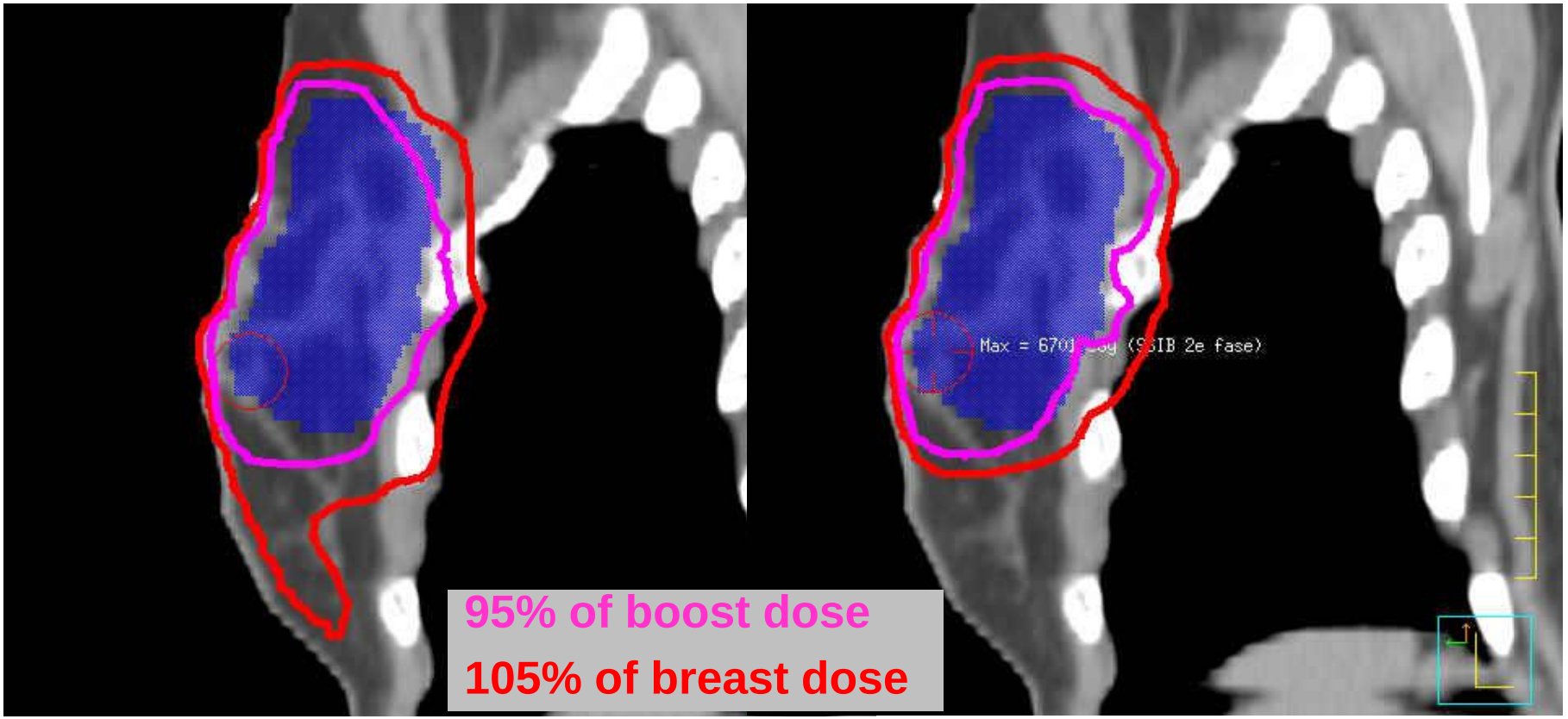


Sequential plan



Simultaneous Integrated Boost

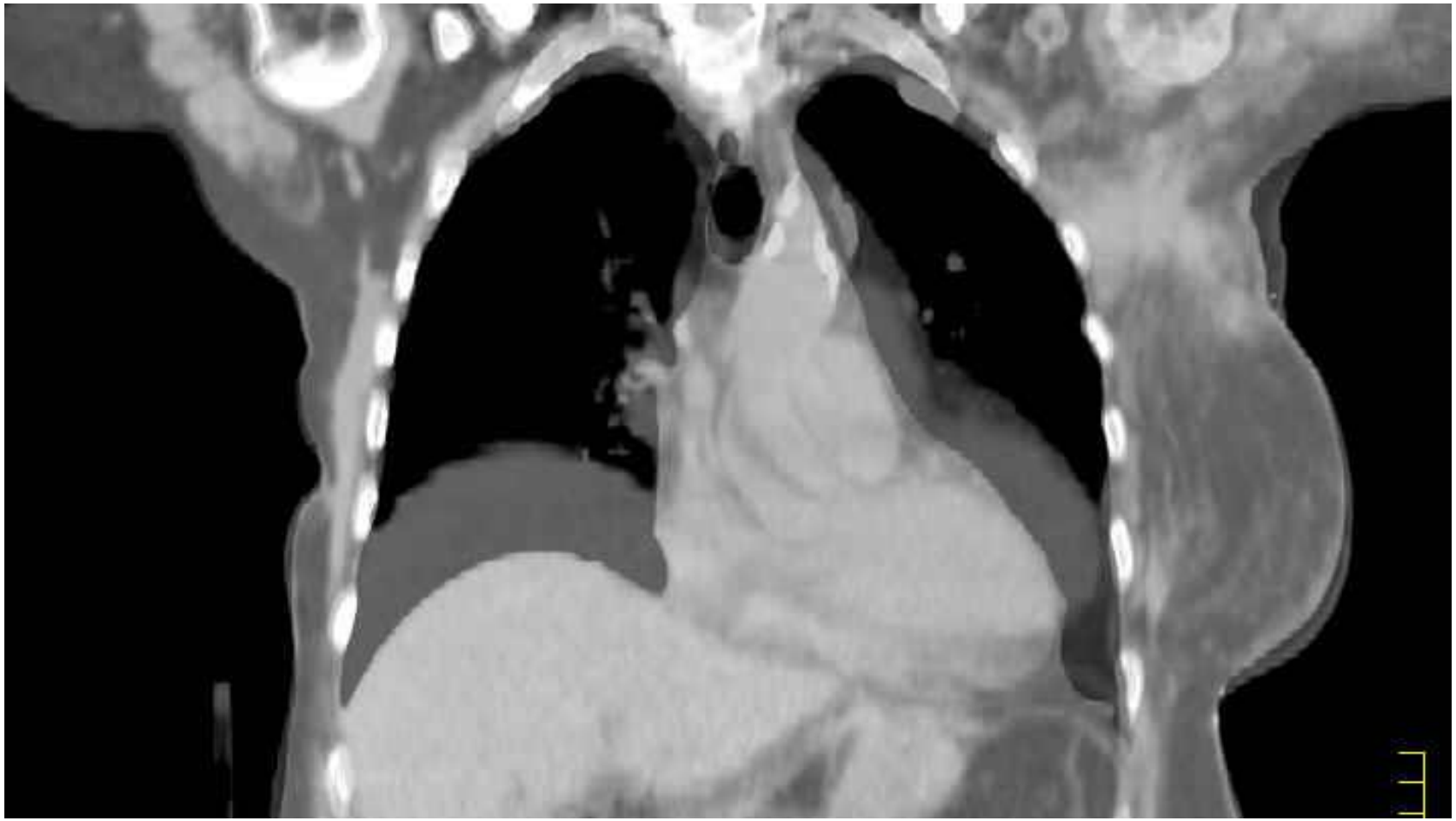
Boost: Sequential vs SIB: level 4?



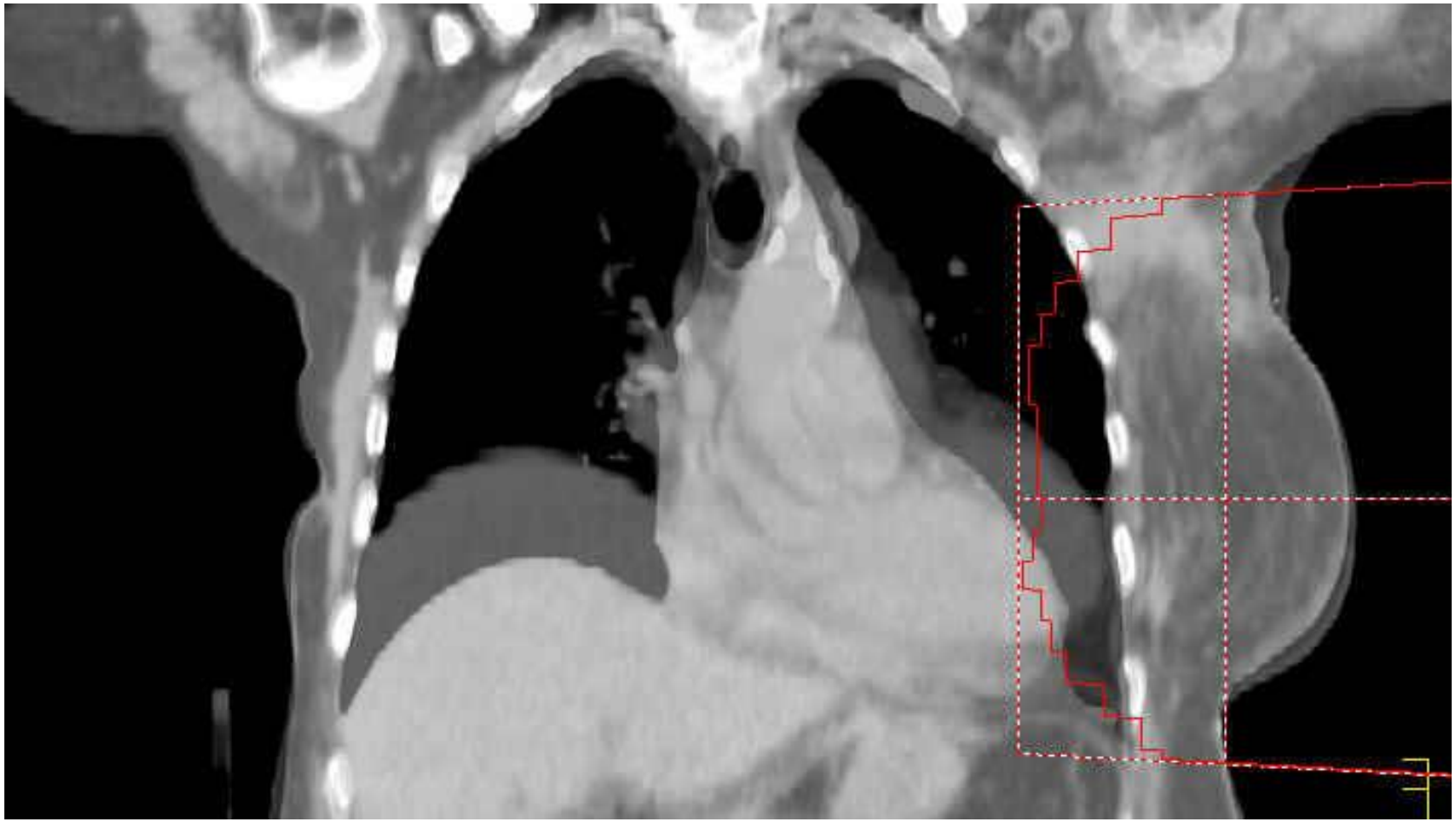
Sequential plan

Simultaneous Integrated Boost

Breathhold: Heart sparing: level 4?

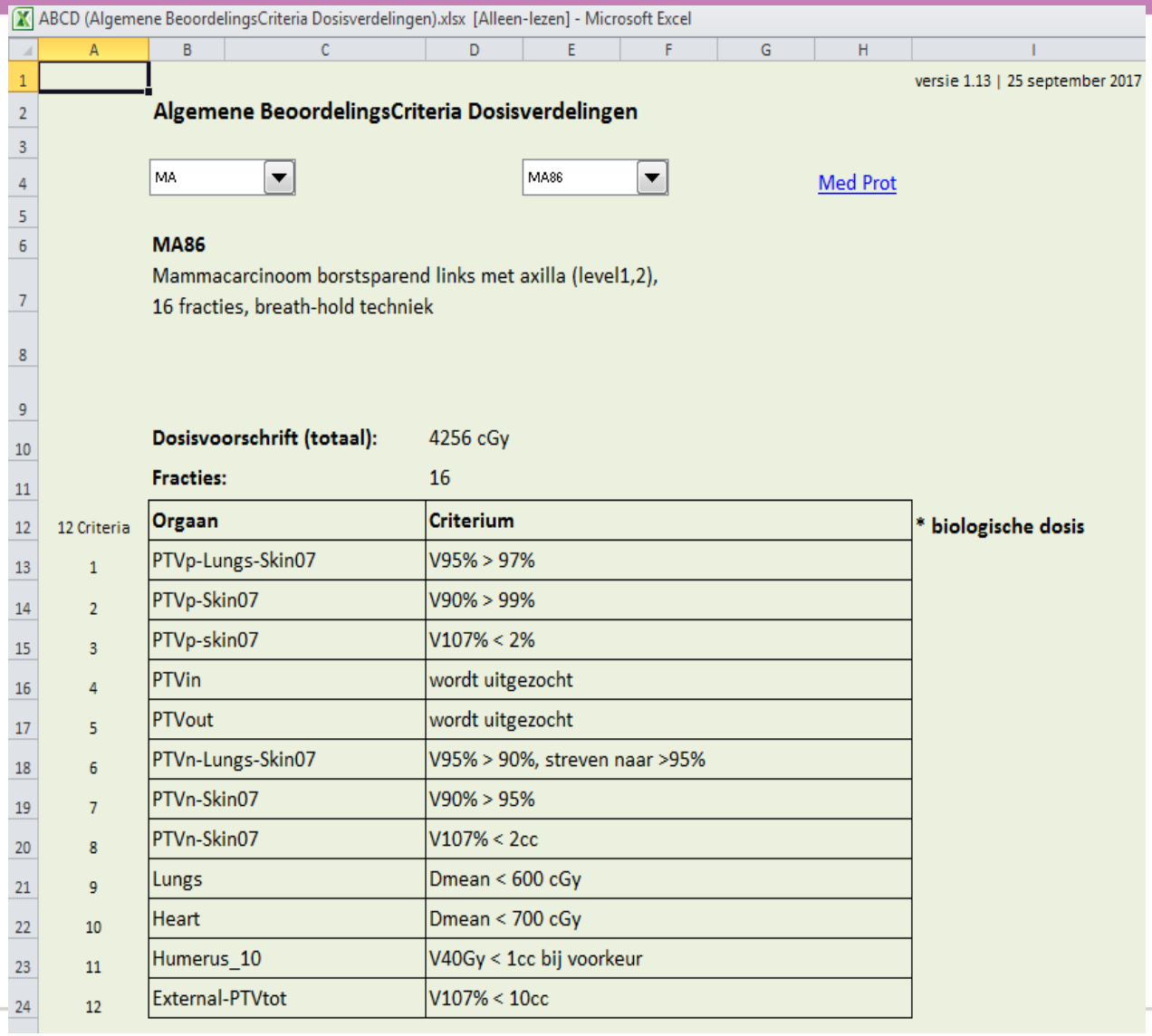


Breathhold: Heart sparing: level 4?



Rectangular fields vs Conformal fields

Clinical perspective: optimizing a treatment plan



ABCD (Algemene BeoordelingsCriteria Dosisverdelingen).xlsx [Alleen-lezen] - Microsoft Excel

versie 1.13 | 25 september 2017

Algemene BeoordelingsCriteria Dosisverdelingen

MA | MA86 | Med Prot

MA86

Mammacarcinoom borstsparend links met axilla (level1,2),
16 fracties, breath-hold techniek

Dosisvoorschrift (totaal): 4256 cGy

Fracties: 16

12 Criteria	Orgaan	Criterium
1	PTVp-Lungs-Skin07	V95% > 97%
2	PTVp-Skin07	V90% > 99%
3	PTVp-skin07	V107% < 2%
4	PTVin	wordt uitgezocht
5	PTVout	wordt uitgezocht
6	PTVn-Lungs-Skin07	V95% > 90%, streven naar >95%
7	PTVn-Skin07	V90% > 95%
8	PTVn-Skin07	V107% < 2cc
9	Lungs	Dmean < 600 cGy
10	Heart	Dmean < 700 cGy
11	Humerus_10	V40Gy < 1cc bij voorkeur
12	External-PTVtot	V107% < 10cc

*** biologische dosis**

- For each indication.
- Set goals based on planning studies + own tests

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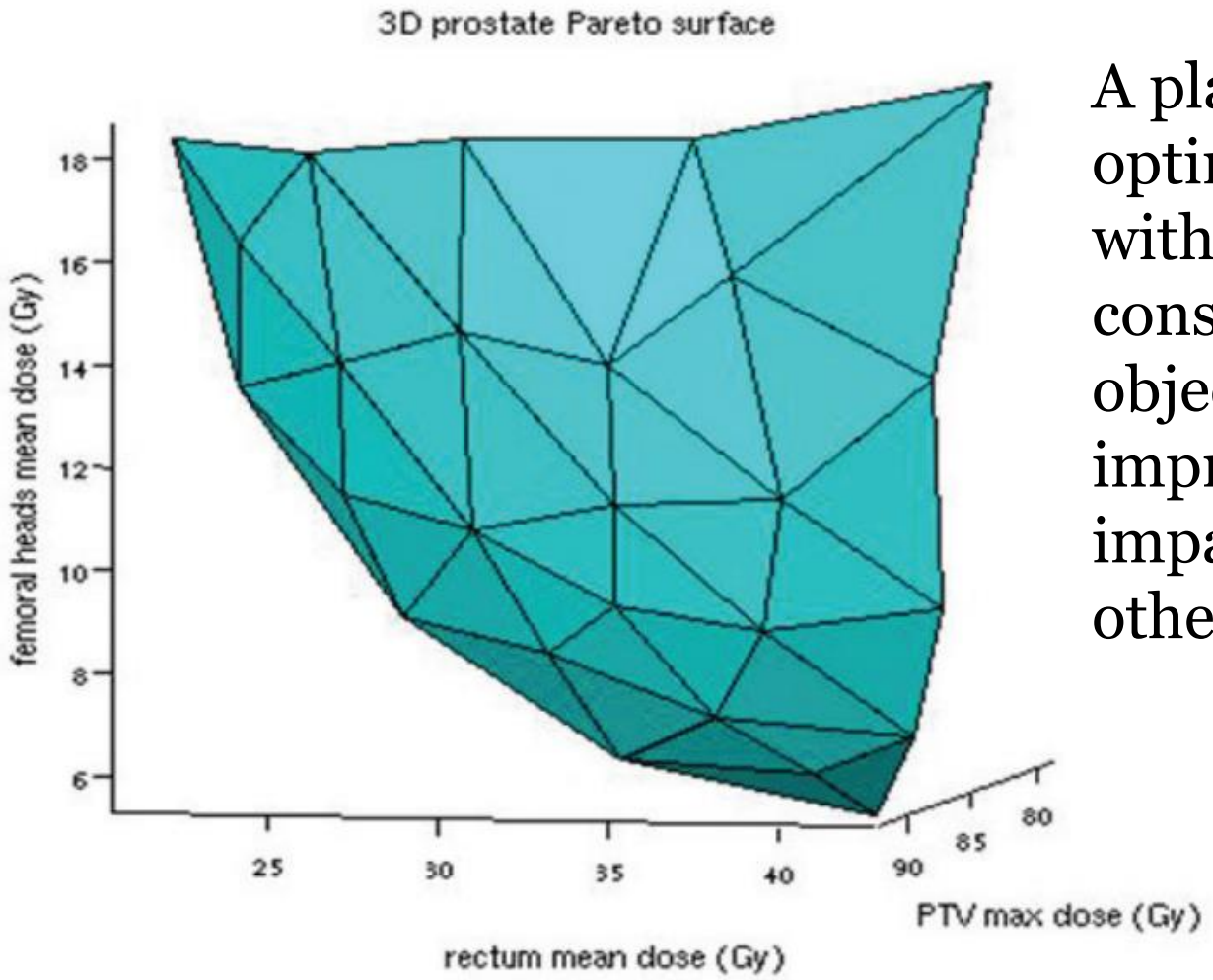
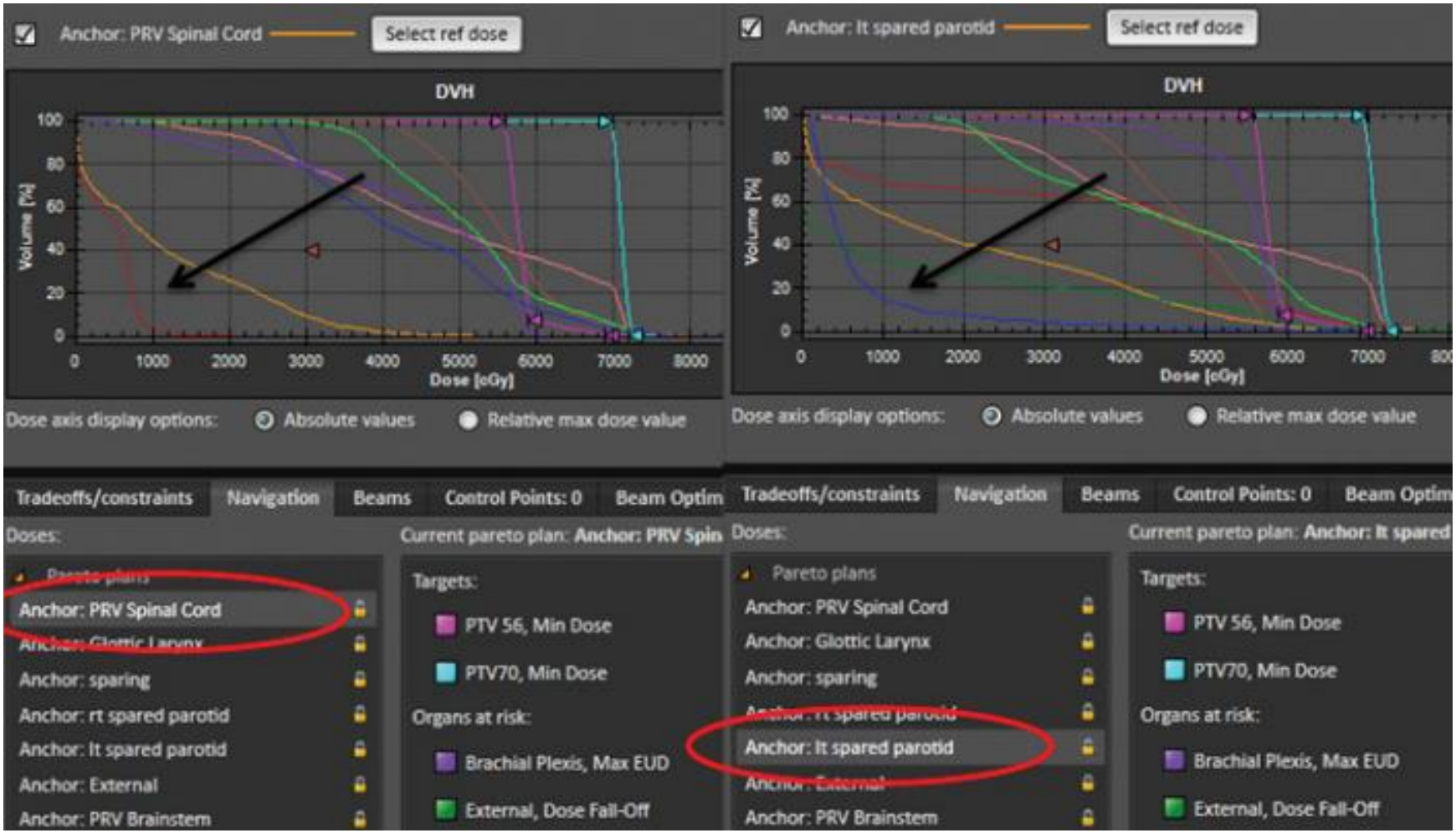
Clinical perspective: Pareto optimisation



A plan is Pareto optimal if it is feasible with respect to all constraints and no objective can be improved without impairing at least one other.

Clinical perspective: Pareto optimisation



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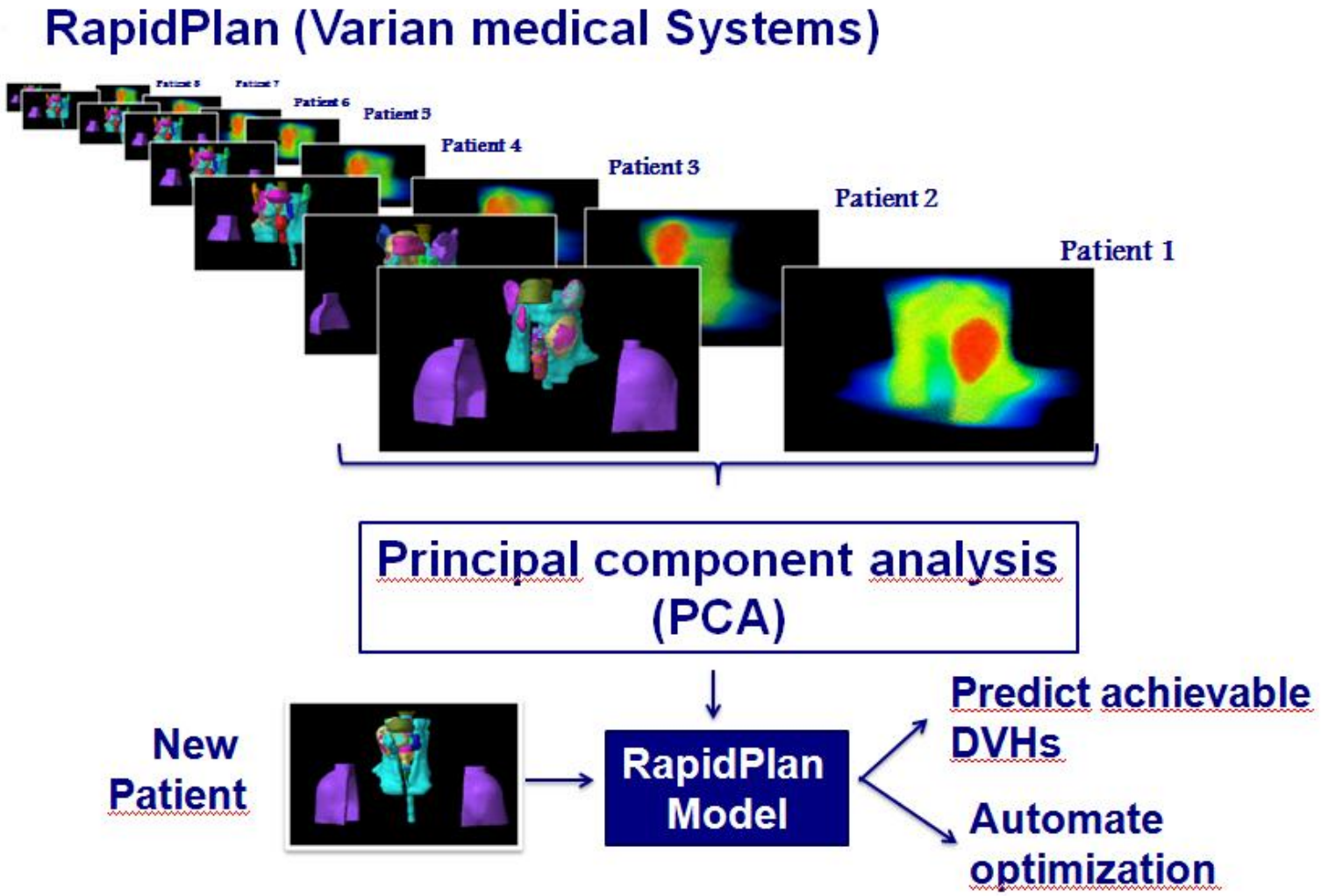
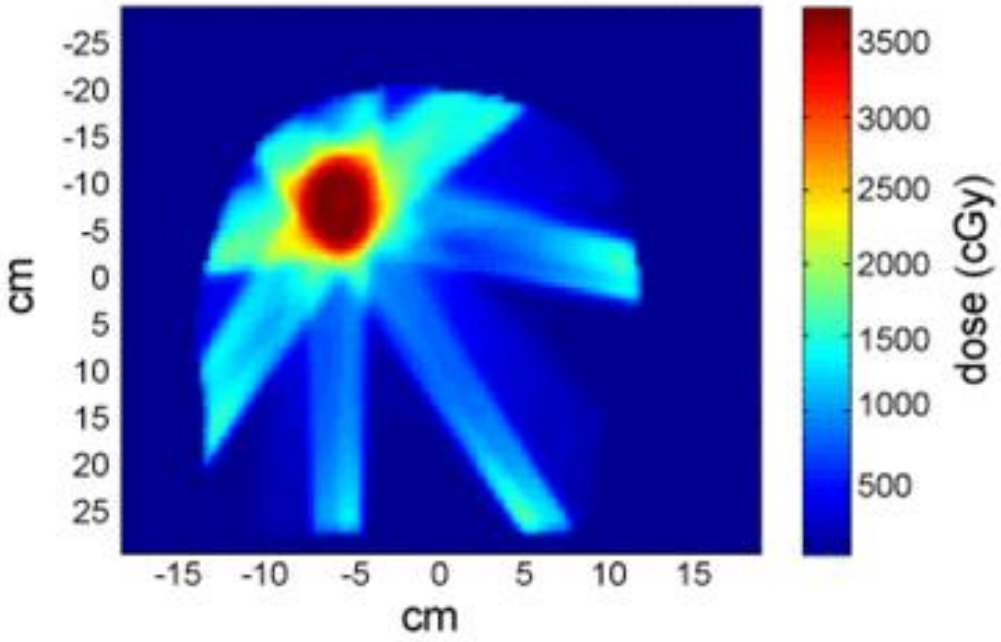
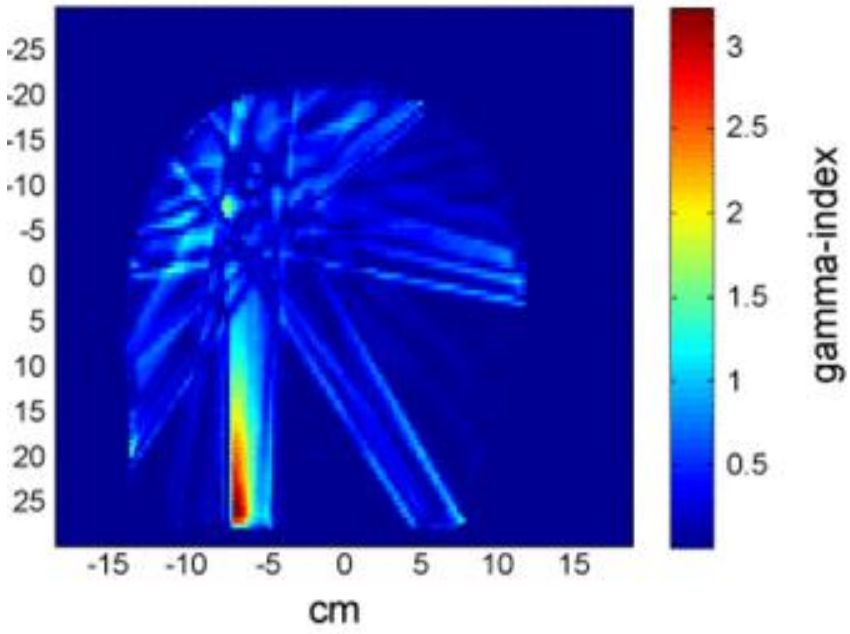
Clinical perspective: Individual optimization



Courtesy Tol - VUmc

Clinical perspective: SPC applied to patient QA

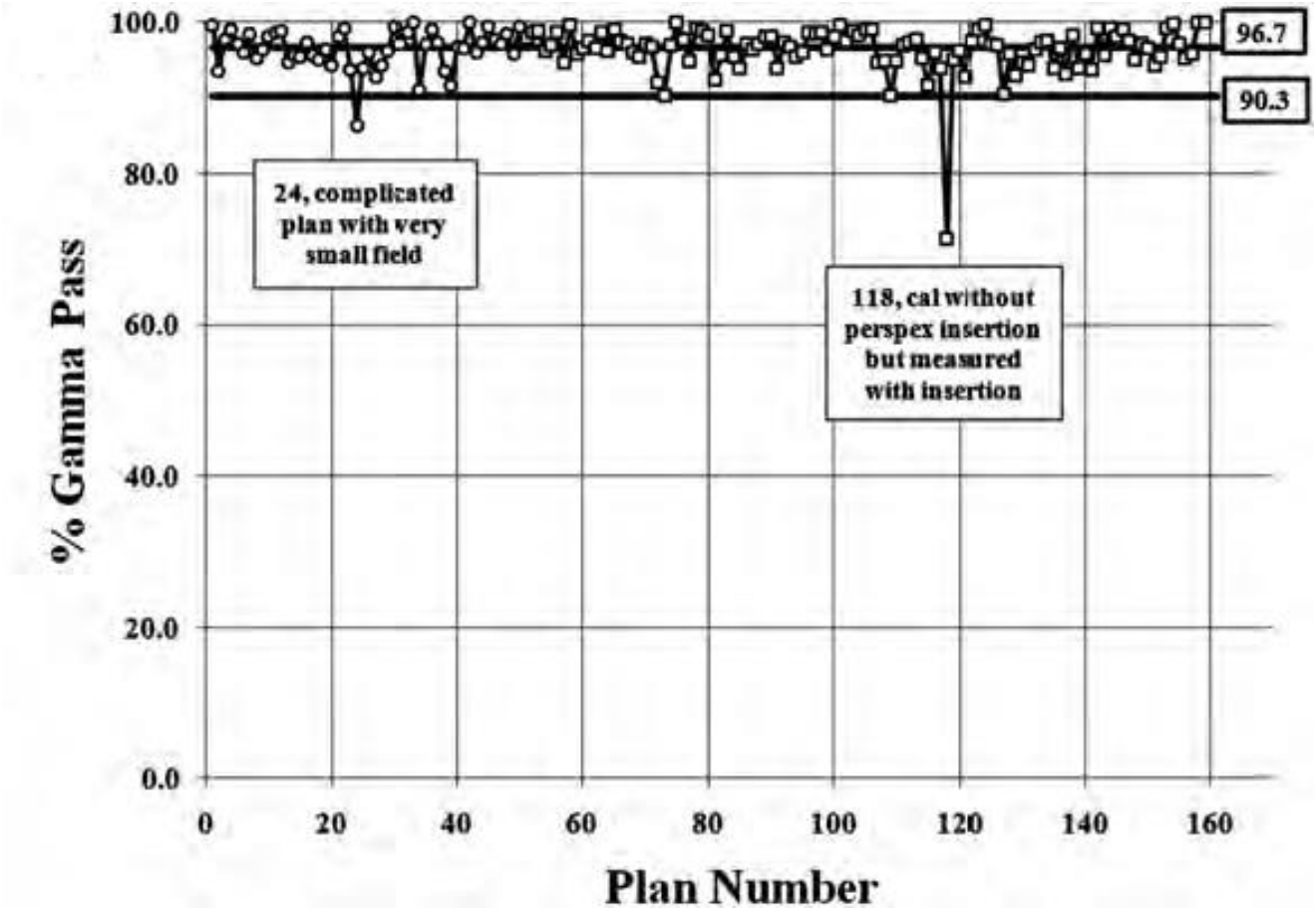




Measurements often mandatory

Gamma pass rate: almost all measurements pass…

Clinical perspective: SPC applied to patient QA



center line

lower control limit

"SPC can potentially be applied to patient-specific QA"

Sanghangthum T *et al.* J Radiat Res. 2013

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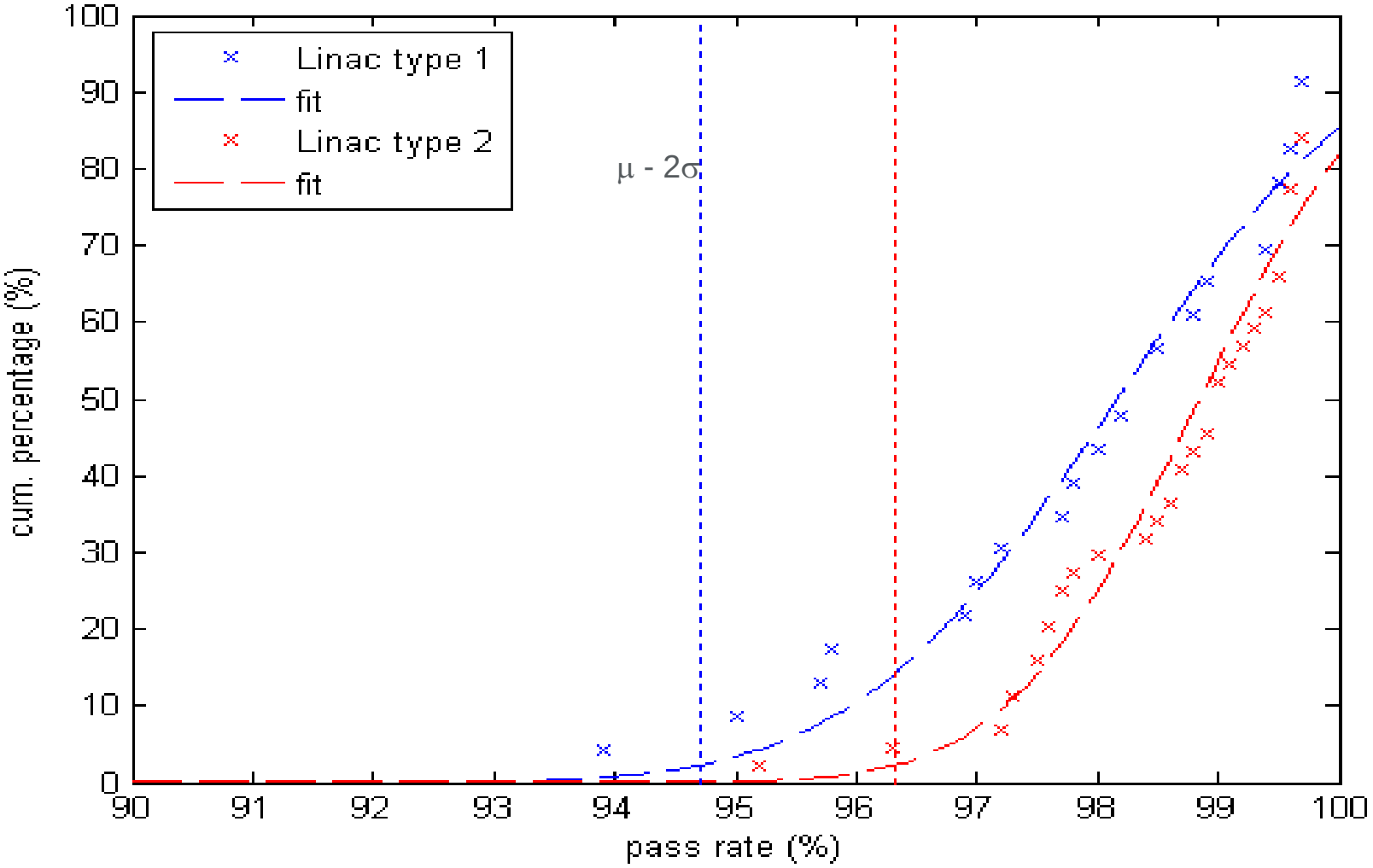
Example:

Differences between linac types (VMAT of lung tumors)



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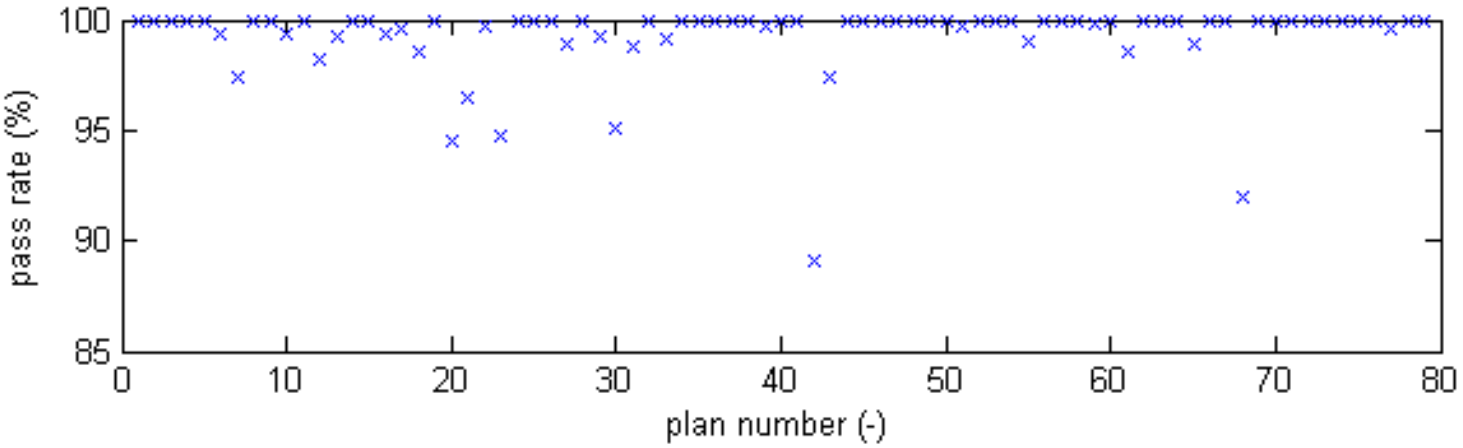
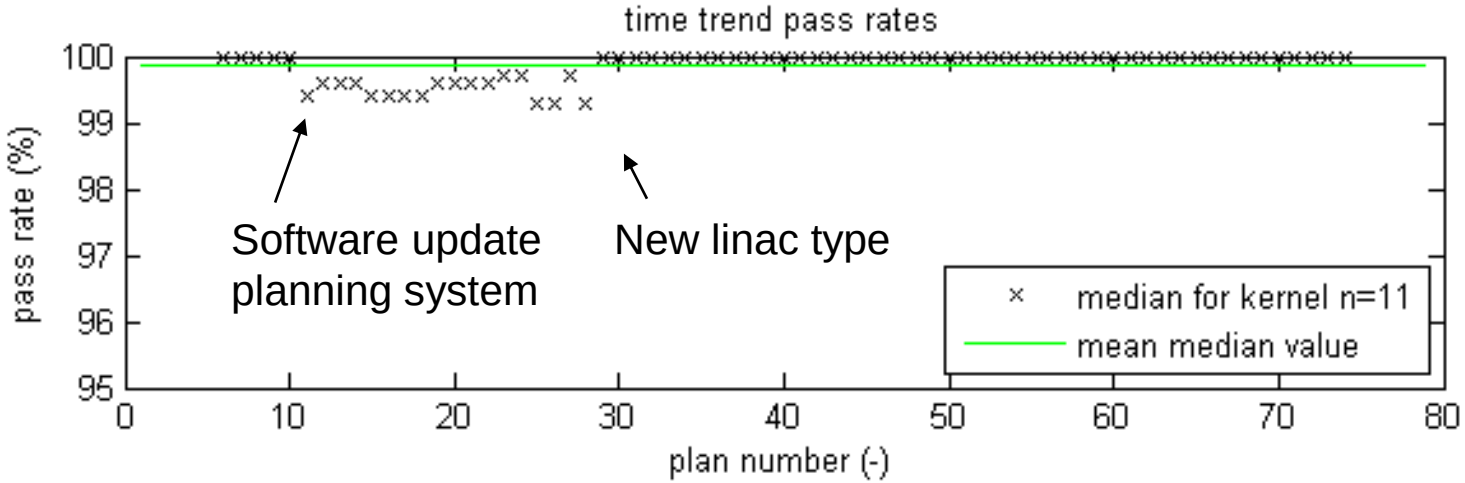
Example:
Time trend analysis (VMAT of brain tumors)





Discussion on practical value of SPC

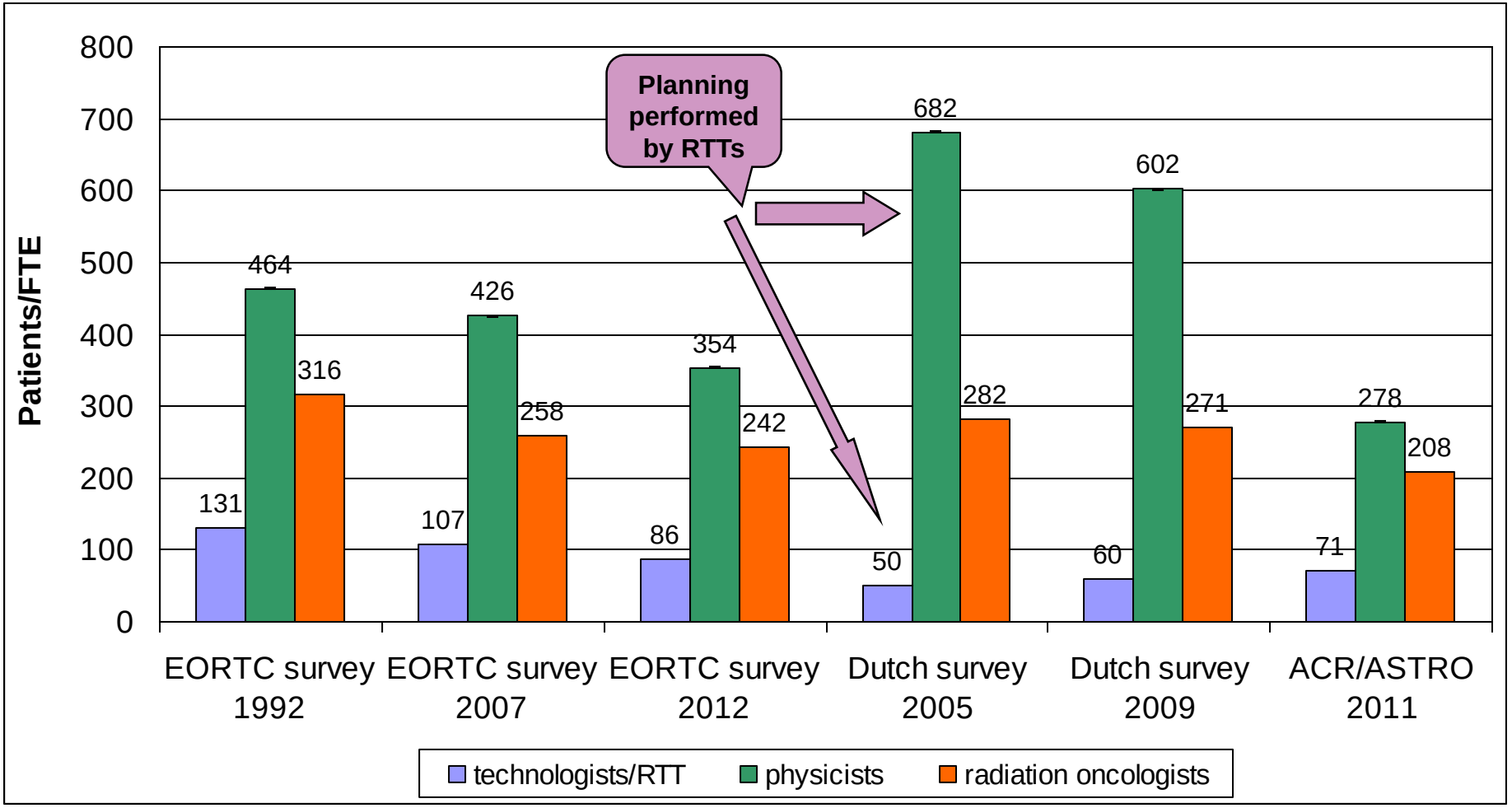
- SPC can be used for patient-specific QA

- It might trigger changes in performance due to, e.g.:
  - altered treatment protocols
  - change in patient population
  - performance change of linac
  - software/hardware updates of:
    - Planning system
    - Linac
    - QA system

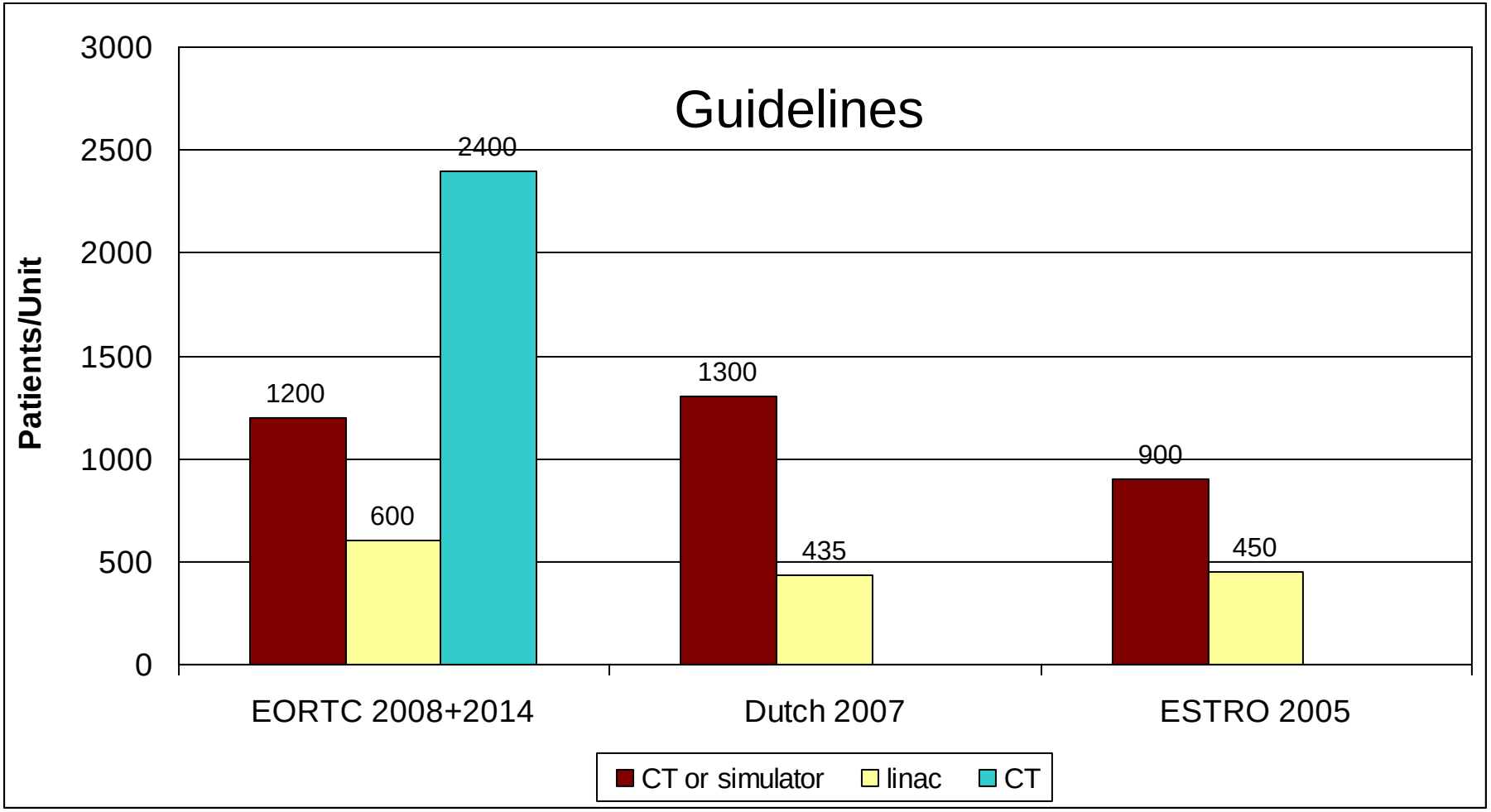
Management perspective

- Efficiency
  - Staff
  - Equipment
- Regulations
  - Laws on e.g., Radiation protection
  - QA certification systems (e.g., ISO)
- Guidelines
  - From professional organisations (ESTRO, IAEA, national RT society)

Management perspective: staff efficiency



Management perspective: equipment efficiency



Guidelines

Contents lists available at ScienceDirect

Radiotherapy and Oncology

journal homepage: www.thegreenjournal.com

Original article

ESTRO ACROP consensus guideline on implementation and practice of stereotactic body radiotherapy for peripherally located early stage non-small cell lung cancer

Matthias Guckenberger [a,*], Nicolaus Andratschke [b], Karin Dieckmann [c], Mischa S. Hoogeman [d], Morten Hoyer [e], Coen Hurkmans [f], Stephanie Lang [b], Eric Lartigau [g], Alejandra Méndez Romero [d], Suresh Senan [h], Dirk Verellen [i]

Medical Physics
The International Journal of Medical Physics Research and Practice

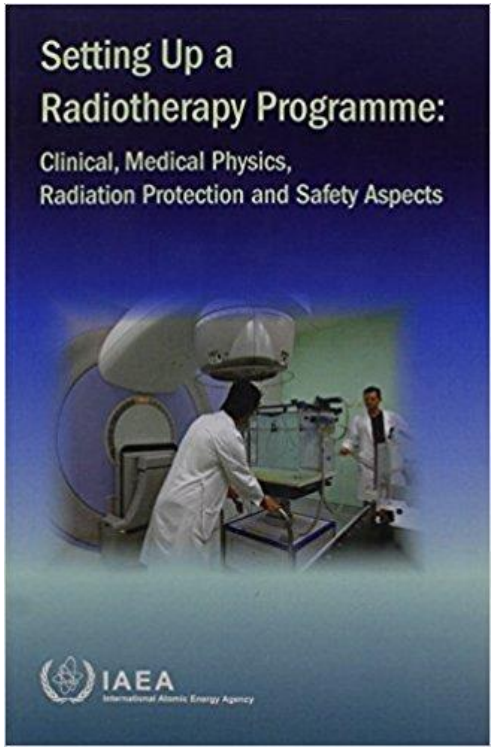
Explore this journal >

Task group report

Task Group 142 report: Quality assurance of medical accelerators[a)]

Eric E. Klein, Joseph Hanley, John Bayouth, Fang-Fang Yin, William Simon, Sean Dresser, Christopher Serago, Francisco Aguirre, Lijun Ma, Bijan Arjomandy, Chihray Liu, Carlos Sandin, Todd Holmes

View issue TOC
Volume 36, Issue 9Part1
September 2009
Pages 4197–4212



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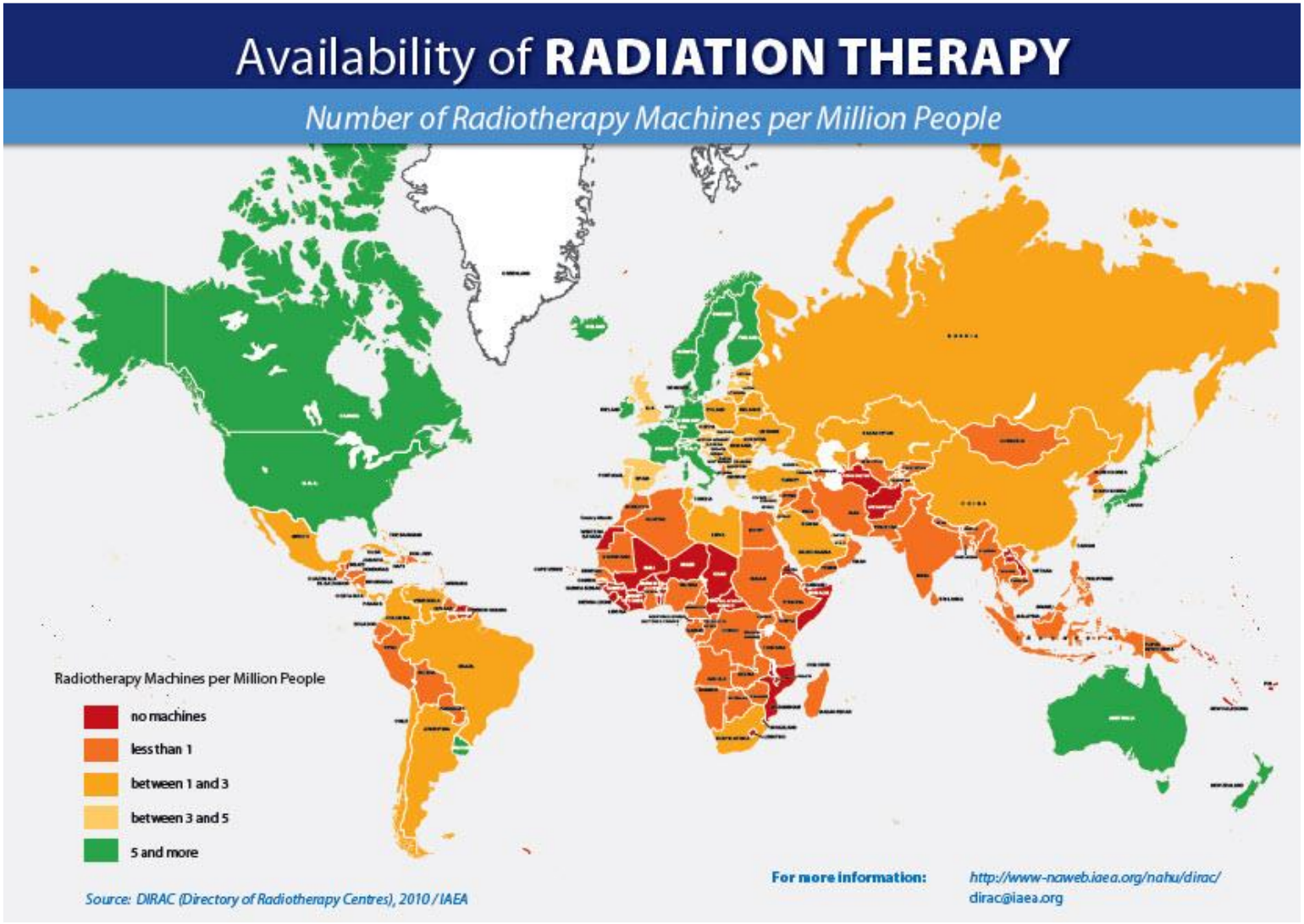

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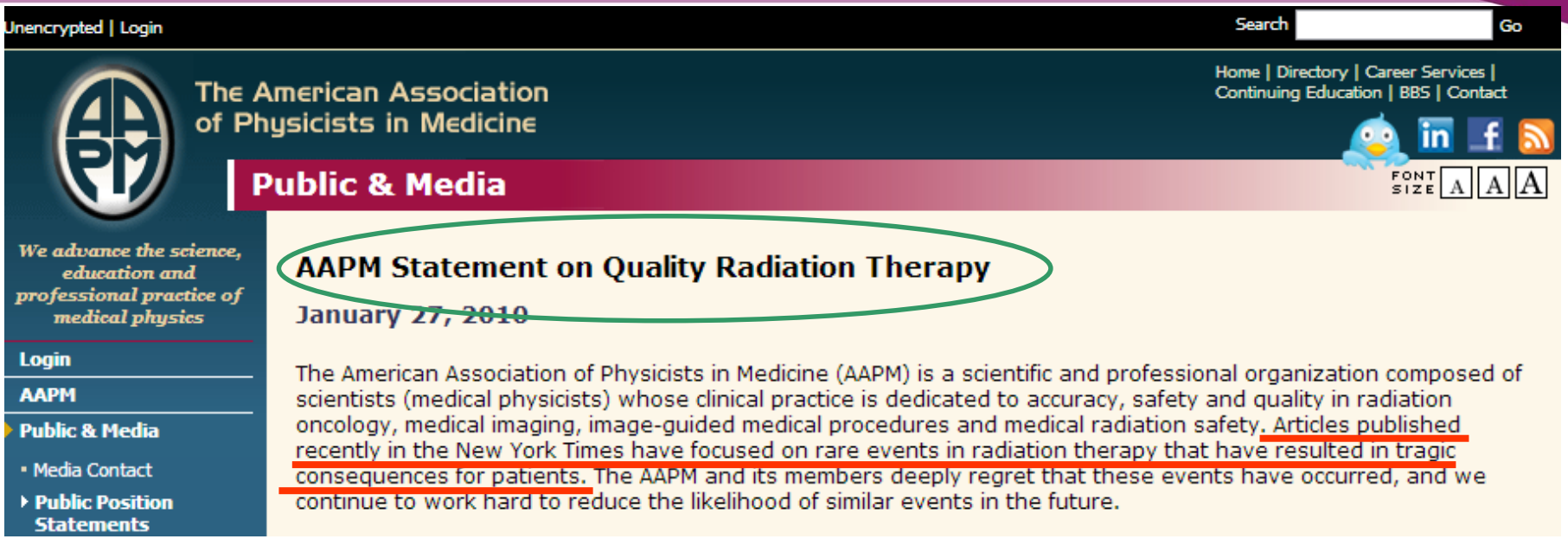
General public?



"Articles published recently in the New York Times have focused on rare events in radiation therapy that have resulted in tragic consequences for patients."

Conclusions

- Quality is subjective and depends on your perspective
- Quality indicators for each perspective are abundant and everybody in the department can contribute to it.
- You can be in the lead to start structured discussions on Quality in your hospital!

Further reading

- www-pub.iaea.org/MTCD/.../PDF/Pub1297_web.pdf (Quatro)
- Pawlicki and Mundt, Quality in Radiation oncology, Med. Phys. 34 (5), 2007
- Tripartite Radiation Oncology Practice Standards, http://www.ranzcr.edu.au/quality-a-safety/radiation-oncology/tripartite-radiation-oncology-practice-standards
- ESTRO booklet 4, practical guidelines for the implementation of a Quality system in RT, 1998
- Guidelines from IAEA, AAPM, ESTRO-ACROP, national guidelines etc.

Staffing levels in radiation oncology: Practical Comparative Exercise

ESTRO Teaching Course
"Quality Assessment and Improvement"

Brussels – October 2017

Yolande Lievens, MD, PhD
Department of Radiation Oncology, Ghent University Hospital, Belgium

ESTRO School

Aim of the exercise

- To document the generally accepted staffing levels in various world regions
  - Radiation Oncologists
  - Medical Physicists
  - RTTs
- To document on which recommendations they are based
- To evaluate the impact of independent variables

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11 groups have been defined

Based on geographical spread + Gross National Income

- Group 1: Belgium (n=9)
- Group 2: France, UK + Canada (n=6)
- Group 3: Northern EU (n=6)
- Group 4: Spain + Malta (n=10)
- Group 5: Greece + Turkey (n=6)
- Group 6: Baltic states + Slovenia (n=5)
- Group 7: Montenegro + Bosnia-Herzegovina (n=7)
- Group 8: South-Eastern Europe (+ Belarus) (n=8)
- Group 9: (European) Russia (n=9)
- Group 10: APAC + Latin America + Bahamas (n=9)

How to perform the exercise?

- Different scenario's are described (see next & handouts)

- Describe per scenario
  - Which numbers of personnel would be advocated/accepted in your country/ies
  - Which changes you would expect with changes in complexity/fractionation

  Please define one response per group, if needed indicate a range

  Please mention if specific considerations apply for other professional groups (e.g. dosimetrists,,…?), for multiple shifts, for annual leaves…

- Define on which (inter)national recommendations your answer is based

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Scenario 1 = base case scenario

Assume a department is delivering **1000 EBRT treatments** on annual basis.

About two thirds of the patients are treated with curative intent, the others with palliative intent.

The equipment consists of **2 linear accelerators**, both equipped with MLC and EPID, and a CT-simulator.

IMRT nor SBRT have been implemented in the department.`

- How many radiation oncologists would you advocate?

  2 >2-3 >3-4 >4-5 >5, specify don't know
- How many medical physicists would you advocate?

  2 >2-3 >3-4 >4-5 >5, specify don't know
- How many RTTs would you advocate?

  6 >6-8 >8-10 >10-15 >15, specify don't know

Please define possible numbers for other personnel categories

Please define on which recommendations your answer is based

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Scenario 2

How would your staffing change if the department would deliver **2000 EBRT treatments** , and would operate 4 linear accelerators (MLC and EPID) and 1 CT simulator?

The number of personnel would double/more than double/less than double/stay the same

- radiation oncologists
- medical physicists
- RTTs

Please define possible impact on other personnel categories

Please define on which recommendations your answer is based

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Scenario 3

How would your staffing change compared to base case if the department decided to purchase an **additional linear accelerator**?

This decision would require the same/higher/lower number of:

- radiation oncologists
- medical physicists
- RTTs

Please define possible impact on other personnel categories

Please define on which recommendations your answer is based

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Scenario 4

How would your staffing change compared to base case if the department decided to **introduce IMRT and SBRT**, and therefore invest in CBCT on the 2 linear accelerators?

This decision would require the same/higher/lower number of:

- radiation oncologists
- medical physicists
- RTTs

Please define possible impact on other personnel categories

Please define on which recommendations your answer is based

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Scenario 5

How would your staffing change following an evolution towards more **hypofractionated schedules**?

This decision would require the same/higher/lower number of:

- radiation oncologists
- medical physicists
- RTTs

Please define possible impact on other personnel categories

Please define on which recommendations your answer is based

Good luck!

Institut de Cancérologie de Lorraine

Alexis Vautrin

Ensemble, construisons l'avenir

PRACTICAL EXERCISE

The use of Statistical Process Control (SPC) to monitor processes

Karine HERLEVIN-GERARD, Physicist PhD

- Institut de Cancérologie de Lorraine (ICL), Nancy (France) -

ESTRO School

Aim of the practical exercise

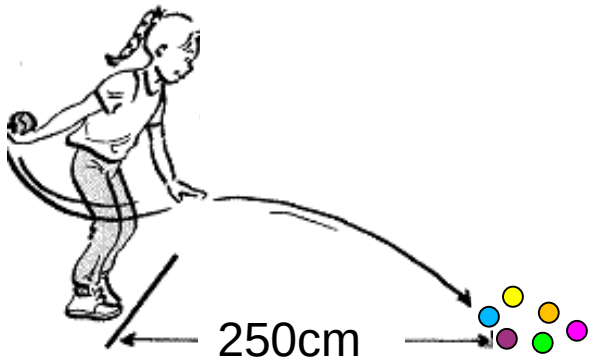
To make you lead a SPC analysis (step by step) through a practical example.

OUTLINE

Radiotherapy: To deliver the right dose at the right place

SPC practical exercise: To throw balloons (⇔ beams delivering dose) at the right distance.

STUDY:
Monitoring a process of balloons' throws with SPC.



→ You will be the actors of this study.

→ You will collect your own set of data and analyze it with SPC.

Use the Excel spreadsheet

LEARNING OBJECTIVES

✓ To understand the **basics of SPC** and be able to apply it in the management of your department, for any processes.

✓ To build and interpret **control charts** for a practical example.

✓ To calculate and interpret **performance indicators** for a practical example.

WORK TO DO

You have to set up **SPC tools** to improve the quality of the process of balloons' throws ⇒ to satisfy the customer.

Proceed step by step…

D M A I C S

Introducing a SPC analysis: DMAICS method*

* From a Six sigma approach

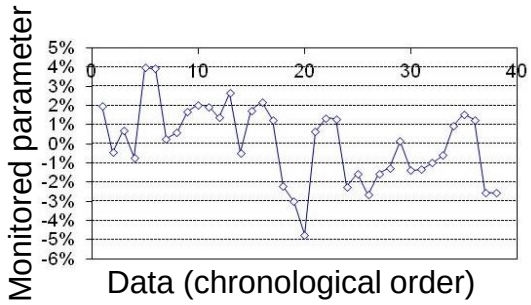
DEFINE

Choice of relevant quality indicators to monitor

MEASURE

1. Verification of the measurement system 's **capability**
2. Characterization of the data distribution
3. Observation of the process

Building a control chart without limits



ANALYZE

Calculation of the process **performance** indicators
Choice of control charts and calculation of control limits

ANALYZE

Searching the **sources of variability**
(Ishikawa)

CONTROL

Process monitoring using control charts
Detection of special causes
Is the process 'under control'?

IMPROVE

Reduction of variability
(5 WHY, Design of Experiments)

STANDARDIZE

Optimization of the process, maintain the gain
Reduction of the frequency of controls?

CONTINUOUS IMPROVIEMENT

DEFINE

What to measure?

Customer's requirements:

The balloons have to reach a target distance of **250cm ± 30cm.**

High accuracy
High precision

Choice of relevant **indicators**, **target** and **specifications**.

Indicator	Measure	Process Target	Specification limits
What do you want to assess in your process?	*How can you measure this indicator? Be precise.*	*Customer's requirements*	

What to measure?

Customer's requirements:

The balloons have to reach a target distance of **250cm ± 30cm.**

High accuracy
High precision

Choice of relevant **indicators**, **target** and **specifications**.

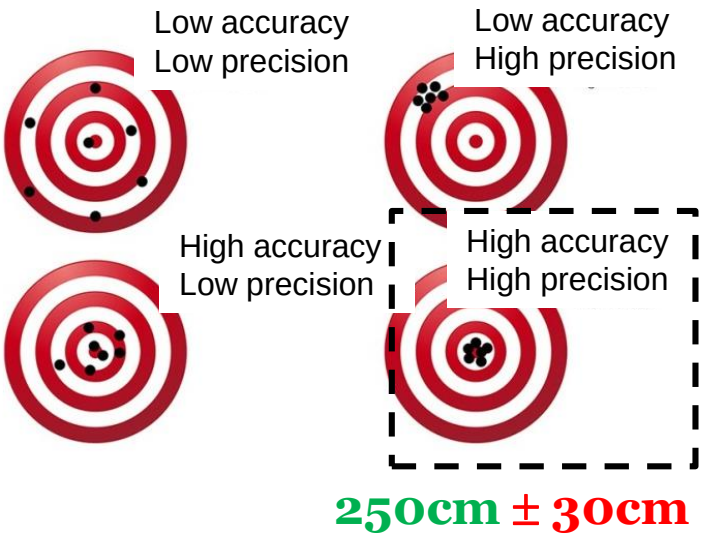
Indicator	Measure	Process Target	Specification limits
Accuracy and precision of the balloons' throws	Distance between the starting line and the 1st rebound of the balloon	**250cm**	LSL: 220cm USL: 280cm

MEASURE

Collection of the data and verification of the capability of the measurement system

STEP 1: COLLECT YOUR OWN SET OF DATA

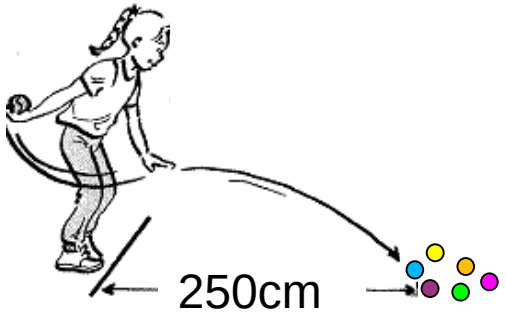
Take time to define your measurement protocol so that your balloons' throws can meet the customer 's requirements.



→ Do **50 throws** in the same conditions: same operator, same ball (10 samples of 5 throws).

→ **Do 4 new series of throws:**

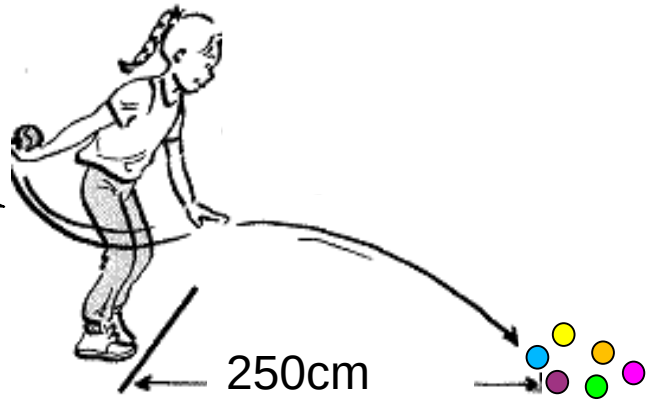
- 1st: **same protocol** than the 50 first throws
  (do 5 samples of 5 throws)
- 2nd: same operator, **other hand**
  (do 5 samples of 5 throws)
- 3rd: same operator **eyes closed**
  (do 5 samples of 5 throws)
- 4th: **change** the **operator**
  (do 5 samples of 5 throws)



Collection of the data and verification of the capability of the measurement system

STEP 1: COLLECT YOUR OWN SET OF DATA

Time to play
~ 20 minutes



Fulfill the Excel spreadsheet

Date	Operator	Sample #	1st throw	2nd throw	3rd throw	4th throw	5th throw	Comments
03/10/2017		1						
03/10/2017		2						
03/10/2017		3						
03/10/2017		4						

Collection of the data and verification of the capability of the measurement system

VERIFICATION OF THE MEASUREMENT SYSTEM

- Let's suppose the measuring tapes have been calibrated ⇒ the measurement capability indicator (Cpc) must be very high (> 4)

Cpc > 4

N° faisceau	Opérateur 1				Opérateur 2			
	1ère mesure Δ(%)	2ème mesure Δ(%)	$\overline{X}$	R	1ère mesure Δ(%)	2ème mesure Δ(%)	$\overline{X}$	R
1	-0,59%	-0,39%	-0,49%	0,20%	-0,76%	-0,44%	-0,60%	0,32%
2	-0,21%	-0,13%	-0,17%	0,08%	-0,44%	-0,34%	-0,39%	0,10%
3	-0,17%	-0,19%	-0,18%	0,02%	-0,70%	-0,47%	-0,59%	0,23%
4	-1,19%	-1,09%	-1,14%	0,10%	-1,19%	-0,99%	-1,09%	0,20%
5	-0,24%	-0,40%	-0,32%	0,16%	-0,36%	-0,59%	-0,48%	0,22%
6	0,17%	0,20%	0,19%	0,03%	-0,03%	-0,26%	-0,14%	0,23%
7	-0,67%	-0,77%	-0,72%	0,10%	-0,85%	-0,81%	-0,83%	0,04%
8	-0,91%	-0,66%	-0,78%	0,24%	-1,09%	-1,07%	-1,08%	0,02%
9	-1,35%	-1,25%	-1,30%	0,10%	-1,39%	-1,43%	-1,41%	0,04%
10	-0,44%	-0,24%	-0,34%	0,21%	-0,75%	-0,71%	-0,73%	0,04%

We can use the results of the measuring tape to perform a SPC analysis.

ANALYZE

Characterization of the data distribution

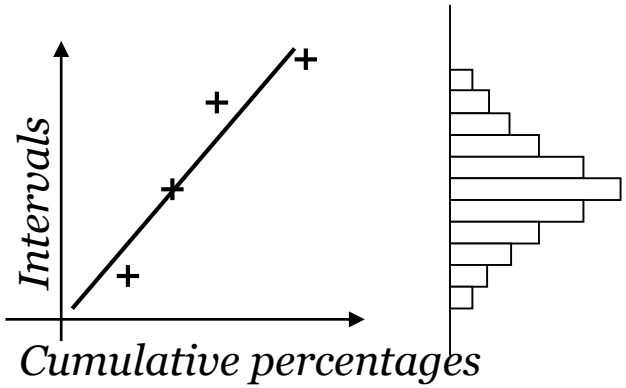
Use the Excel spreadsheet

STEP 2: BUILD AN HISTOGRAM OF YOUR DATA

- Understand the shape of your data distribution. Was it expected?

STEP 3: PERFORM A STATISTICAL TEST TO VERIFY THE NORMALITY OF YOUR DATA

- Graphical method: Henry line proposed



✓ Aligned points?
⇒ Yes: Hypothesis of a normal distribution

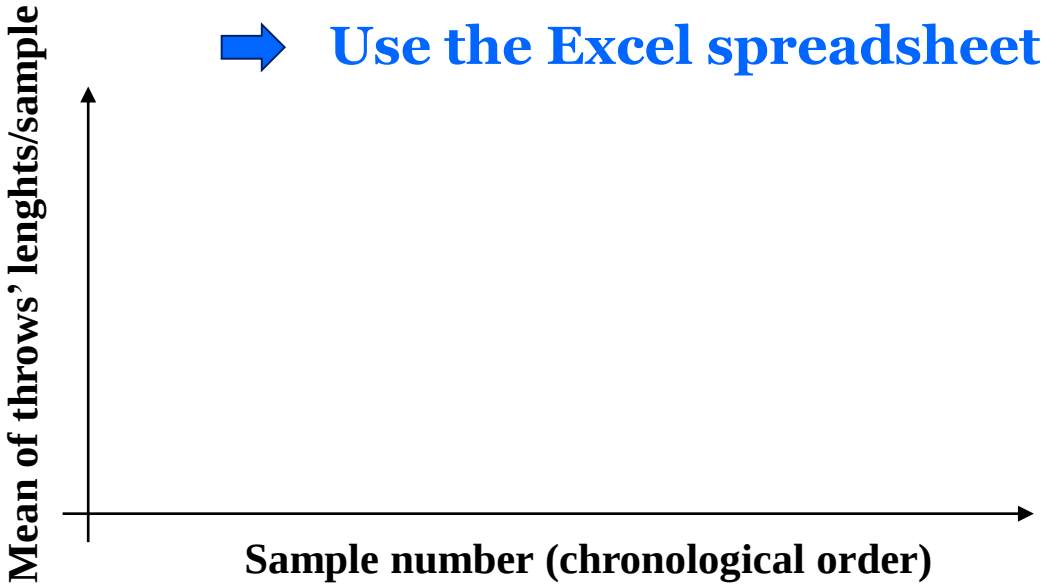
Control chart without limits

STEP 4: OBSERVE THE PROCESS: BUILD A FIRST CONTROL CHART WITHOUT ANY CONTROL LIMITS (INDIVIDUAL VALUE CONTROL CHART).

- Monitored parameter: mean of throws' lengths per sample.

Date	Operator	Sample #	1st throw	2nd throw	3rd throw	4th throw	5th throw	Comments	Sample mean
03/10/2017		1							#DIV/0!
03/10/2017		2							#DIV/0!
03/10/2017		3							#DIV/0!

Use the Excel spreadsheet



Control chart without limits

STEP 4 (NEXT): ANALYSE THE CONTROL CHART

- **General overview** of the results
- Are the results close to the customer's target?
- Anything specific?
- …

Capability indicators

STEP 5. CALCULATE THE CAPABILITY INDICATORS (SHORT TERM CAPABILITY) AND INTERPRETE THE RESULTS

⇒ Have a look at the % of data out of the specifications

Analyse of the throws	Mean	σ_{v-1} (Stand dev)	Number of data		Pp	Ppk	Ppm	% out of specifications
Samples 1 to 10	#DIV/0!	#DIV/0!	0		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!

➡ **Use the Excel spreadsheet** ⬅

	Pp	Ppk	Ppm	% out of specifications	Interpretation
Samples 1 to 10					**Pp:** *dispersion?* **Ppk:** *+ LSL and LSL ?* **Ppm:** *+ target ?*

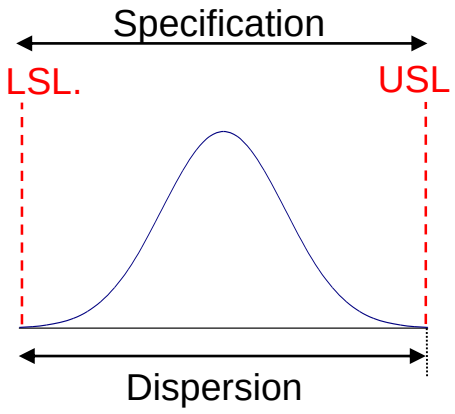
Performance indicators : Calculation of Pp, Ppk and Ppm

Related to the specifications

Pp

Dispersion

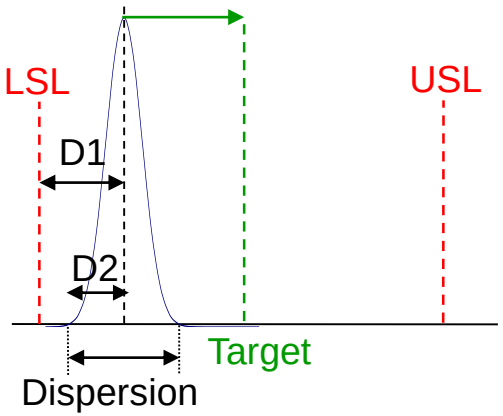
$$Pp = \frac{Specification}{6\sigma}$$



Ppk

Dispersion + position

$$Ppk = \frac{D1}{D2} = \frac{Min\{(USL - \overline{X}); (\overline{X} - LSL)\}}{3\sigma}$$

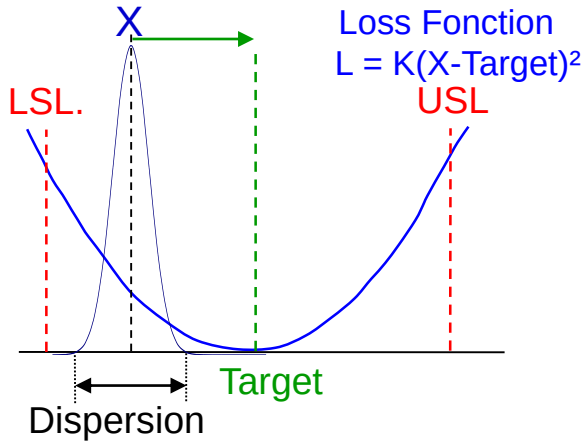


Related to the target

Ppm

$$Ppm = \frac{Specification\ Interval}{6\sqrt{\sigma^2 + (\overline{X} - target)^2}}$$

$$Ppm = \frac{Pp}{\sqrt{1 + 9(Pp - Ppk)^2}}$$



Target and specifications concern each throw (not a sample of *n* throws)

=> to calculate the performance indicators: **use σ of the individual throws' results**.

Capability indicators

STEP 5. COMPARISON OF THE CAPABILITY INDICATORS BETWEEN THE DIFFERENT TEAMS

	Pp	Ppk	Ppm	% out of spec.	Interpretation
Team 1					
Team 2					
Team 3					
Team 4					
Team 5					
Team 6					
Team 7					

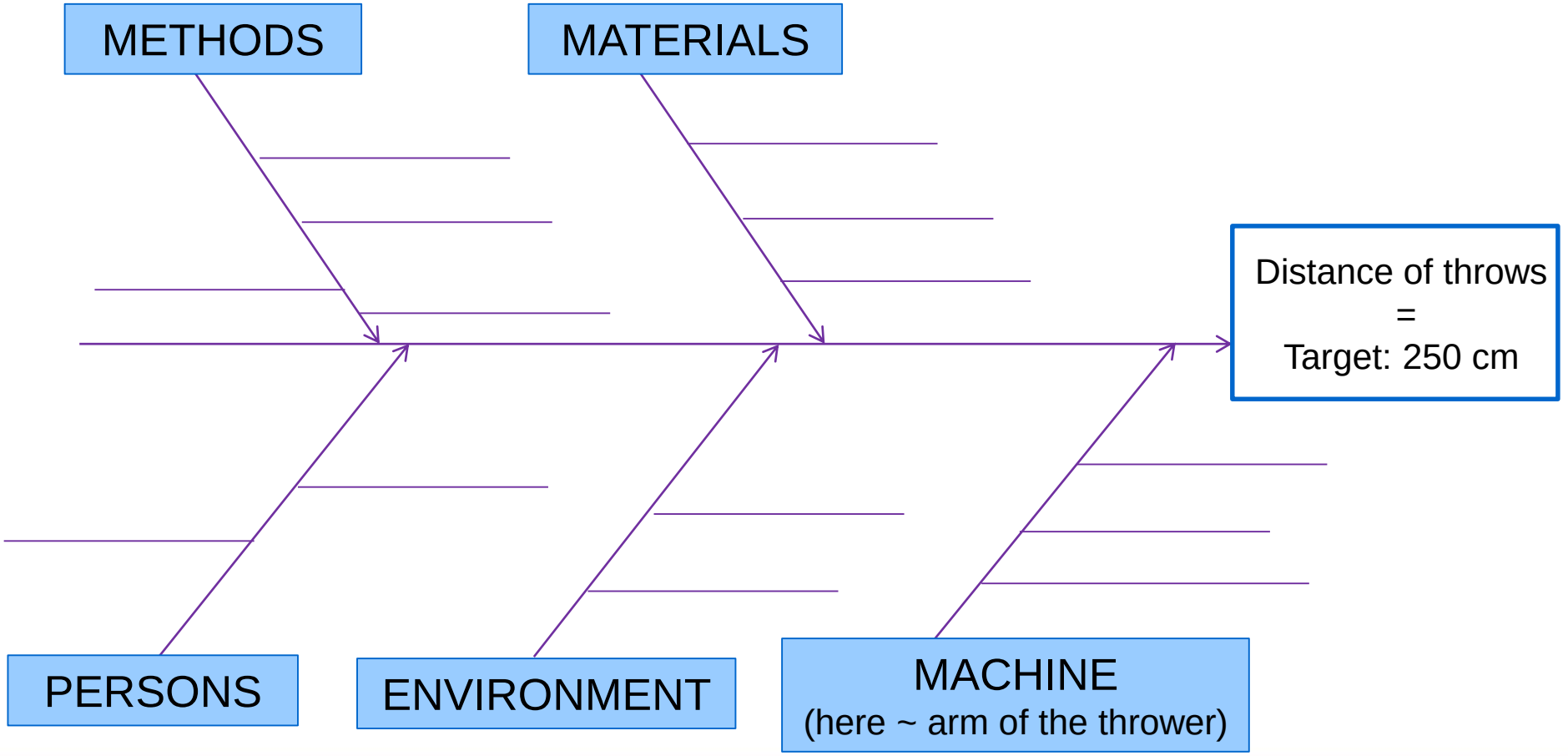
= **COMMUN LANGUAGE to compare the quality of a process.**

= **CAPABLE?**

- If **yes,** you can use these results to calculate and **set** the control limits
- If **no**, search for the sources of variability, improve the capability before setting the limits.

Search for the sources of variability

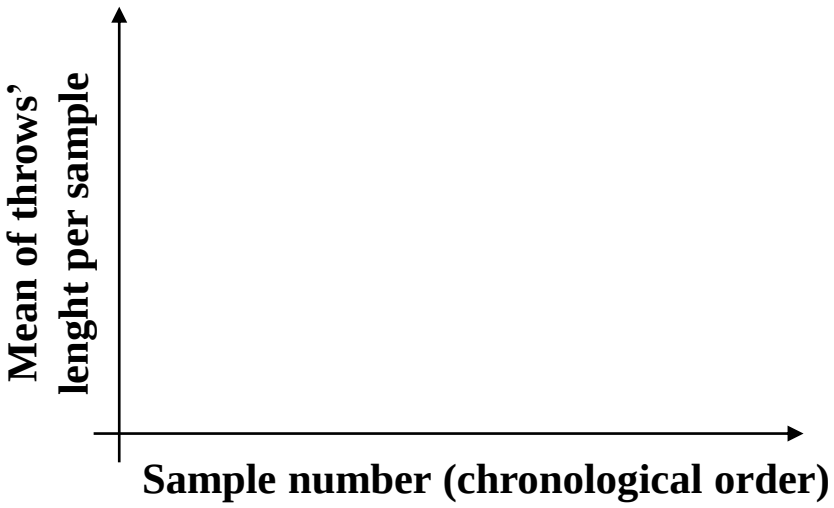
Example of tool: Ishikawa diagram



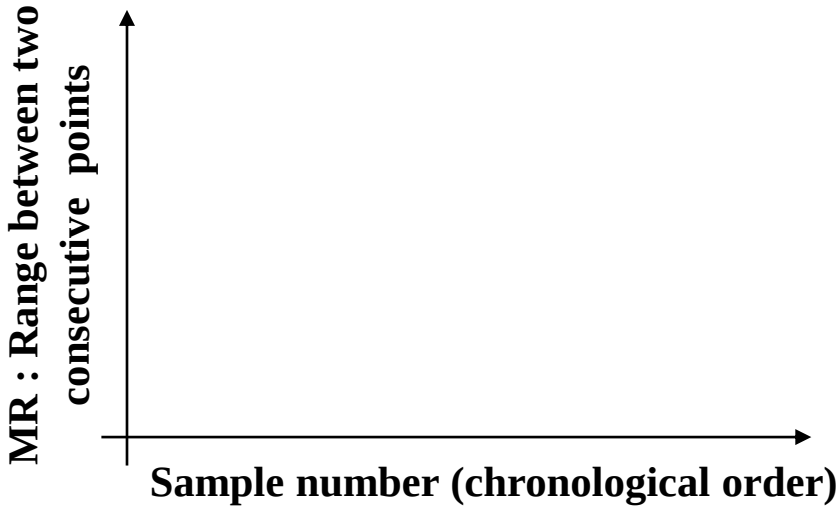
Control charts: Calculation of control limits

STEP 6. CALCULATE THE CONTROL LIMITS FOR THE I-MR CHART

I : **I**ndividual value control chart



MR : **M**oving **R**ange control chart



Excel spreadsheet:

	Nb of data (Means/sample)	Xbar=Mean of Means/sample	Rbar=Mean of MR	σ=Rbar/d2
Data used to calculate the control charts' limits = Samples 1 to 10 :	0	#DIV/0!	#DIV/0!	#DIV/0!

Control charts: Calculation of control limits

1. Individual value control chart

$$LCL_X = \bar{X} - 3\sigma_X = \bar{X} - 3\frac{\bar{R}}{d_2} = \bar{X} - A_4.\bar{R}$$

$$Center\ line = Target = \bar{X}$$

$$UCL_X = \bar{X} + 3\sigma_X = \bar{X} + 3\frac{\bar{R}}{d_2} = \bar{X} + A_4.\bar{R}$$

- d_2 and A_4 are constants (see tables)

2. Moving range control chart

$$LCL_R = \bar{R} - 3\sigma_R = \bar{R} - 3 \cdot d_3 \cdot \frac{\bar{R}}{d_2} = D_3\bar{R}$$

$$Center\ line = Target = \bar{R}$$

$$UCL_R = \bar{R} + 3\sigma_R = \bar{R} + 3 \cdot d_3 \cdot \frac{\bar{R}}{d_2} = D_4\bar{R}$$

- d_3, D_3,and D_4 are constants (see tables)

Control chart: Calculation of control limits

Tables of constants to calculate control limits

Estimation of Standard deviation σ		
n	d_2	d_3
2	1,128	0,853
3	1,693	0,888
4	2,059	0,880
5	2,326	0,864
6	2,534	0,848
7	2,704	0,833
8	2,847	0,820
9	2,970	0,808
10	3,078	0,797
11	3,173	0,787
12	3,258	0,778
13	3,336	0,770
14	3,407	0,762
15	3,472	0,755
20	3,735	0,729

Constants used for control charts' limits calculation			
n	A_4	D_3	D_4
2	2,659	-	3,267
3	1,772	-	2,574
4	1,457	-	2,282
5	1,290	-	2,114
6	1,184	-	2,004
7	1,109	0,076	1,924
8	1,054	0,136	1,864
9	1,010	0,184	1,816
10	0,975	0,223	1,777
11	0,946	0,256	1,744
12	0,921	0,283	1,717
13	0,899	0,307	1,693
14	0,881	0,328	1,672
15	0,864	0,347	1,653
20	0,803	0,415	1,585

n = number of data used to calculate the moving-range

Control charts: Calculation of control limits

STEP 6 (NEXT): INTERPRETATION OF THE CONTROL CHARTS

- Verify that the process is stable over time in position and in dispersion (no change, no adjustment during this period).
  ⇒ ∅ **special causes in the data used to calculate the limits**.

- Do you detect points out of the limits? Are they **outliers?** Are they due to the **α risk**? ⇒ Decide if you prefer removing them to recalculate narrower limits ⇒ better quality.

- **Set your limits. They will be used to monitor next results (samples 11 to 30) and to detect any potential special cause.**

Samples 11 to 30: Calculation of the capability indicators

STEP 7: CALCULATE THE CAPABILITY INDICATORS FOR SAMPLES 11 TO 30

- **For samples 11 to 15** *(same protocol than 1 to 10)*
- **For samples 16 to 20** *(same operator, **other hand**)*
- **For samples 21 to 25** *(same operator, **eyes closed**)*
- **For samples 26 to 30** *(**new operator**)*
- **For samples 1 to 30** (long term capability, including variability of the 5 'M ').

Analyse of the throws	Mean	σ_{v-1} (Stand dev)	Number of data		Pp	Ppk	Ppm	% out of specifications	INTERPRETATION
Samples 1 to 10	#DIV/0!	#DIV/0!	0		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	
Samples 11 to 15 *(same protocol than 1 to 10)*	#DIV/0!	#DIV/0!	0		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	
Samples 16 to 20 *(same operator, other hand)*	#DIV/0!	#DIV/0!	0		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	
Samples 21 to 25 *(same operator, eyes closed)*	#DIV/0!	#DIV/0!	0		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	
Samples 26 to 30 (new operator)	#DIV/0!	#DIV/0!	0		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	
Samples 1 to 30	#DIV/0!	#DIV/0!	0		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	

Samples 11 to 30: Interpretation of the capability indicators

STEP 7 (NEXT): TRY TO INTERPRET YOUR CAPABILITY RESULTS

	Pp	Ppk	Ppm	% out of spec.	Interpretation
Samples 1 to 10					**Pp:** *dispersion?* **Ppk:** *+ LSL and LSL ?* **Ppm:** *+ target ?*
Samples 11 to 15					**Pp:** **Ppk:** **Ppm:**
Samples 16 to 20					**Pp:** **Ppk:** **Ppm:**
Samples 21 to 25					**Pp:** **Ppk:** **Ppm:**
Samples 26 to 30					**Pp:** **Ppk:** **Ppm:**
Samples 1 to 30					**Pp:** **Ppk:** **Ppm:**

Samples 11 to 30: Analysis of the updated control charts

STEP 8: ANALYSE THE UPDATED CONTROL CHARTS (INCLUDING SAMPLES FROM 11 TO 30)

- Are all the points within the limits on both charts? Which proportion is within or outside?

- Do you detect special causes? (out of the limits or trends)

  - ❑ **If yes**:
    - Has something changed in the process?
    - Can you remove those special causes and make the process back to a stable situation?
    - Check your capability indicators.

  - ❑ **If no**:
    - Analyze the capability indicators.
    - Good time for improvement.

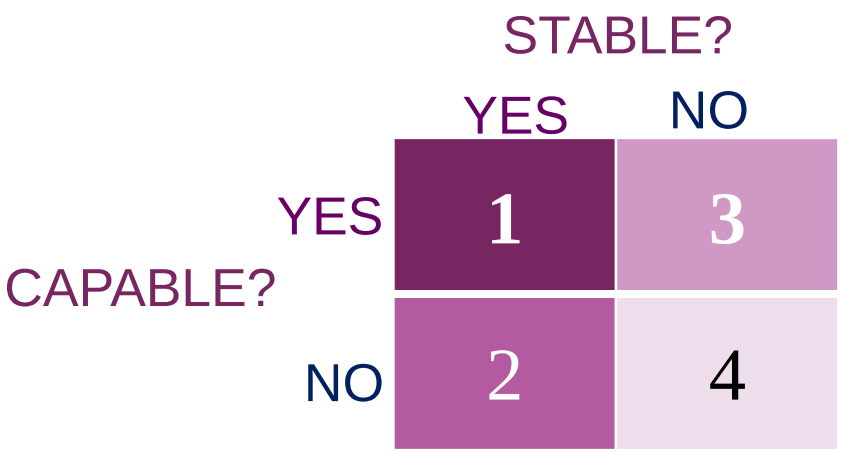
Measurable and **continuous** improvement of quality

Global analysis of the process: capability indicators and control charts

STEP 9: ANALYSE THE PROCESS IN TERMS OF CAPABILITY AND STABILITY TOGETHER

Excel spreadsheet:

	CAPABILITY/PERFORMANCE INDICATORS					CONTROL CHARTS	STATE OF THE PROCESS	SUGGESTIONS FOR QUALITY IMPROVEMENT? (see the Ishikawa diagram)
Analyse of the throws	**Pp**	**Ppk**	**Ppm**	**% out of specifications**	**INTERPRETATION**	**STABLE?**		
Samples 1 to 10	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	0	* I: * MR:		
Samples 11 to 15 *(same protocol than 1 to 10)*	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	0	* I: * MR:		



GUIDE: 4 possible states of a process:

1. Comfortable situation

- ❑ 100% of products conform to specifications
- ❑ Not a constant situation
- ❑ Good time to improve the process

CAPABLE? \ STABLE?	YES	NO
YES	1	3
NO	2	4

2. Limit case

- ❑ Improve the process to go in 1
- ❑ Decrease dispersion or recenter the process on the target, or reconsider the definition of spec. limits

3. Process close to chaos

- ❑ 100% of products conforms to spec. but probably for a short period of time
- ❑ Unstable process where everything could happen.
- ❑ Find the special causes, eliminate them and stabilize the process to go in 1 or 2.

First : STABILIZE the process ⇐

and then

Make it CAPABLE ⇑

4. Chaotic/disordered situation

- ❑ Make large improvements to stabilize the process

Methodology of Lean Thinking in Radiotherapy

Marjolein van Os

Radiation Technologist,

Erasmus MC, Rotterdam, NL

Quality Assessment & Improvement

Brussels, 2-5 October 2017

Erasmus MC University Medical Center Rotterdam Cancer Institute

ESTRO School

Learning Objectives

- To explain the basis of Lean Methodology
- To describe the term Kaizen
- To identify the 8 ways of Waste
- To apply Lean Process Optimization in Radiotherapy
- To describe the value of multi-professional approach in Process Optimization

Outline

- Background of Lean; origin Toyota / Japan
- Lean tools: Six Sigma, 5-S, Muda, Kaizen, Gemba Walk
- Application of Lean in Health Care
    - Optimizing Processes (part I)
    - Quality Improvement (part II)
- Optimizing the process for prostate cancer patients:
    - Gemba Walk
    - Value Stream Mapping
    - Ideal state, Future state
    - Multi-professional approach in implementation
- Discussion

Lean Thinking: Background

Lean is NOT a goal in itself, it is a methodology

Lean is NOT a science, merely a practical approach

Lean can be applied in any environment

Lean principle:

*Maximize **customer value** while minimizing waste*

-Simply, lean means creating more value for customers with fewer resources.

The ultimate goal is to provide perfect value to the customer through a perfect value creation process that has zero waste.

Lean Thinking: Origin

Toyota Production System: “Just in time” (JIT) production

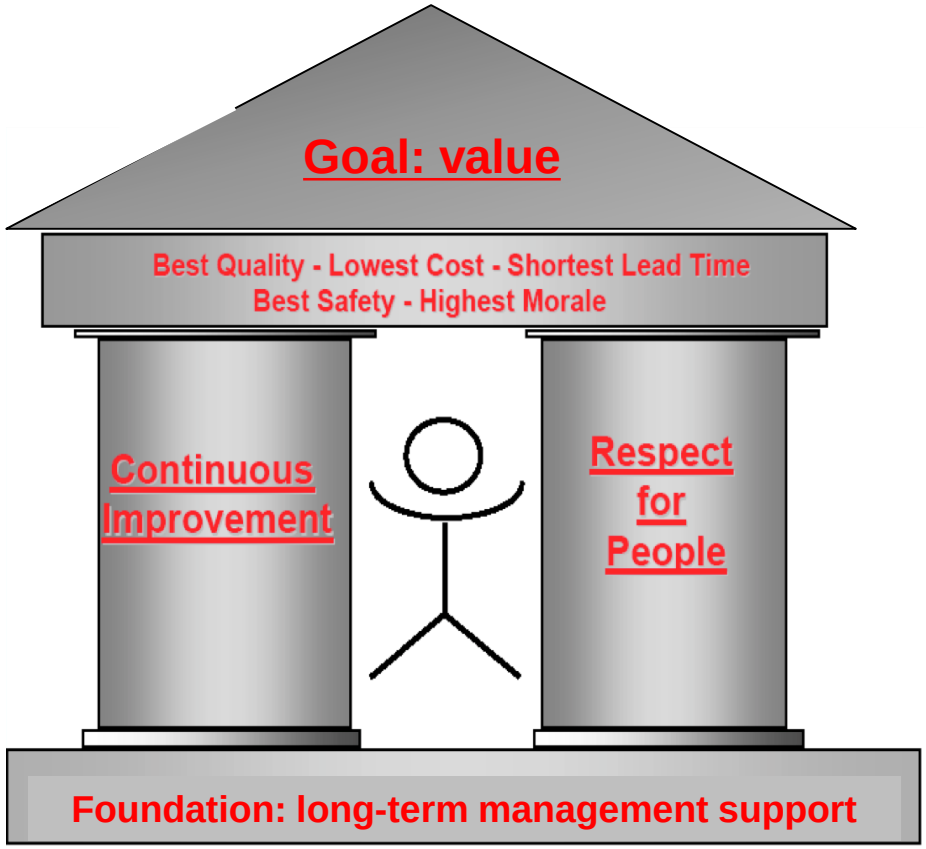
Add value for the customer, eliminate waste

‘Produce what you need,
in the amount you need,
by the time you need it‘

Taiichi Ohno,

Workplace management (2007)

House of Lean:

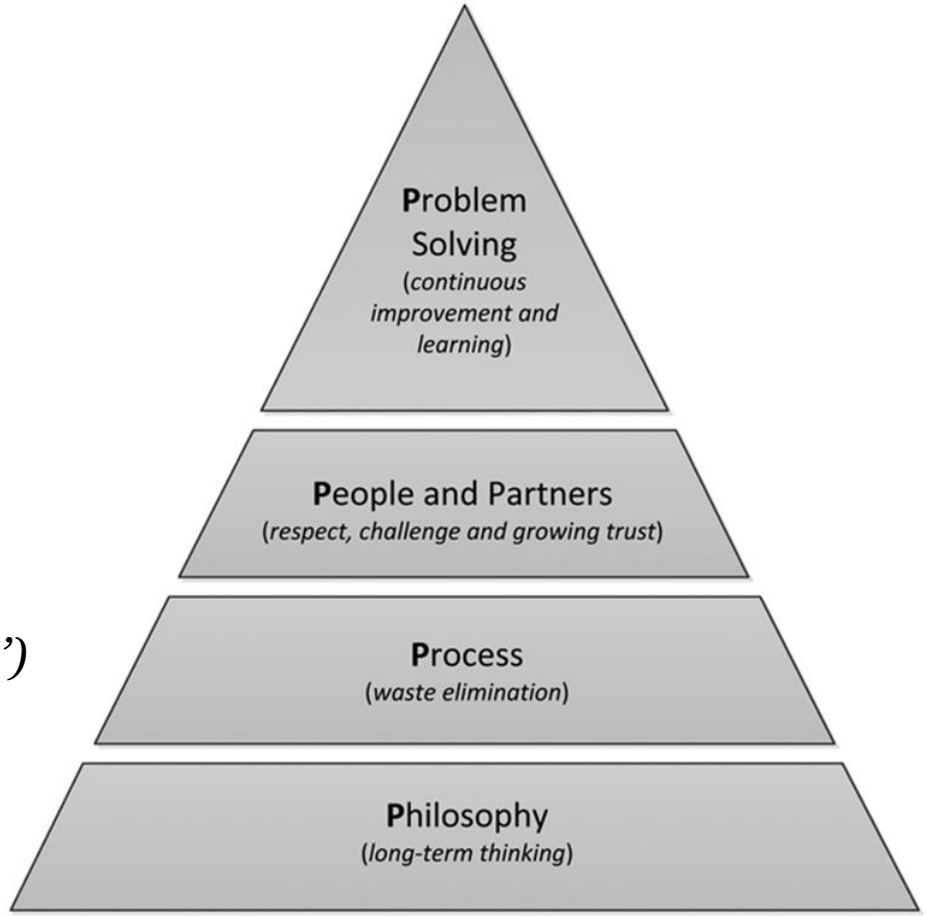


Lean Thinking: Origin

The Toyota Way (4P):

('...but to tell the truth
there is another part to this
and that is 'at lower cost'.
But that part is not written down.')

Taiichi Ohno, Workplace management (2007)



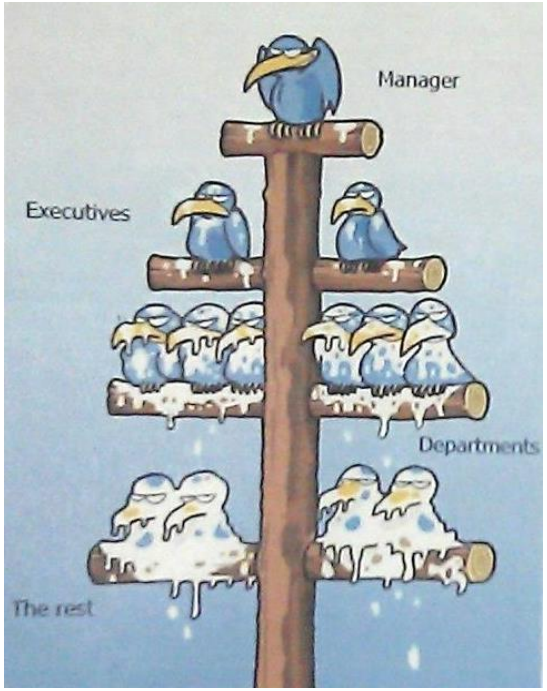
Source: Adapted from Liker (2004)

Lean Thinking: Origin

Important values for success:

- Long term management support
- Respect for people

Shitty management:



when the top level guys look down, they see only shit
when the bottom level guys look up, they see only assholes

Lean Thinking: Origin

Important values for success:

Work together, bottom up:

From Toyota:
"We get brilliant results from average people managing brilliant processes. Our competitors often get average or worse results from brilliant people managing broken processes".

Multi professional approach:

"…. However, when undertaken on their own in this way, they create islands of excellence which, if they are not linked together, make little difference to the bottom line."

Dan Jones, Beginners guide to Lean

Six Sigma

- Six Sigma literally stands for an error rate of 0,00034%, implemented by Motorola (1986) to improve production results by reducing variation.
- Grown into a structured improvement methodology in itself, with trained experts (belts)
- Optimizing processes by reducing variation, the error rate and cost;
  - In industry/production processes endpoints are merely financial
  - In healthcare applied in process improvement at operating rooms: less errors, more efficient use of OR's.

6σ

Program	Six Sigma	Lean thinking
Theory	Reduce variation	Remove waste
Application guidelines	1. Define. 2. Measure. 3. Analyze. 4. Improve. 5. Control.	1. Identify value. 2. Identify value stream. 3. Flow. 4. Pull. 5. Perfection.
Focus	Problem focused	Flow focused

Dave Nave,
How to compare Six Sigma, Lean, and Theory of Constraints

5-S

5-S is original Japanese, in most languages also translated into 5 x S

(*just not in French..*)

- Seiri (整理) : Sort
- Seiton (整頓) : Straighten
- Seisō (清掃) : Shine
- Seiketsu (清潔) : Standardise
- Shitsuke (躾) : Sustain

To apply to your working environment

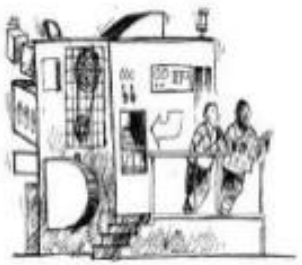
Muda

Muda = waste, from customer's perspective.

8 ways of waste, together making the word DOWNTIME;

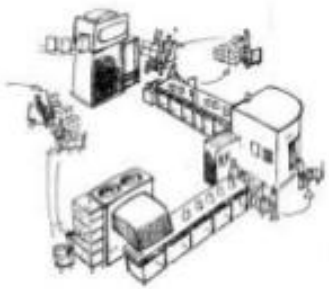
Defects

Overproduction



Waiting

Non-used talent



Transport

Inventory

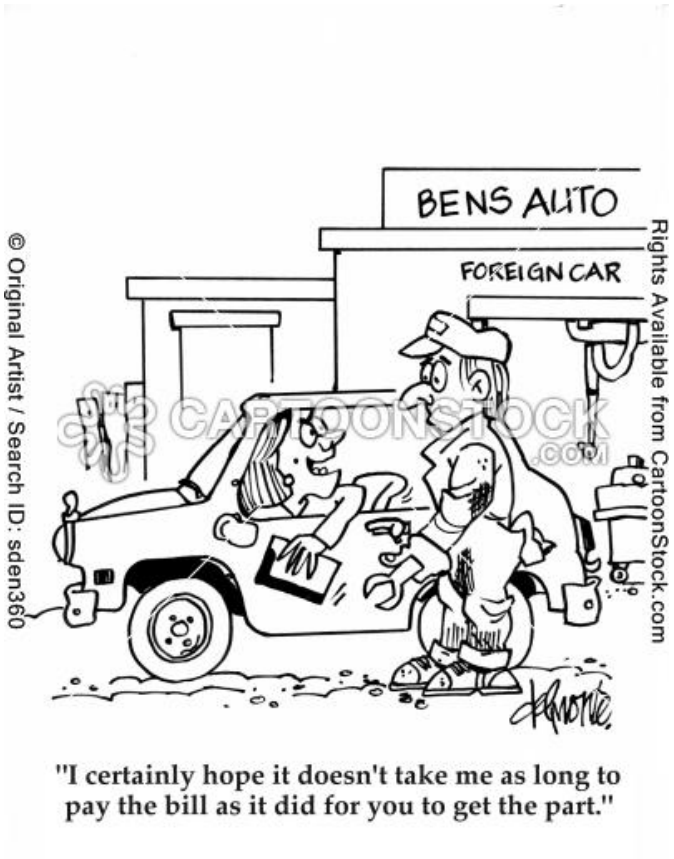
Motion

Excess processing

Identifying Muda (example)

When your car needs repair…

- **D**: You want it back working properly
- **O**: You want only replaced what needed to be
- **W**: You want it back as soon as possible
- **N:** Creative and cheap solutions are welcome
- **T:** You want the garage to be near
- **I**: You don't need 4 spare tires
- **M**: It may be delivered @ home
- **E**: Extra checks..



.. Would you be willing to pay for that?

Kaizen

Kaizen is a methodology for improvement: “good change”

5 steps model of Womack & Jones:

5: Aim for perfection through Continuous Improvement

1: Define value of product or service from customer’s perspective

2: Identify and visualize the valuestream and eliminate waste

3: Create continuous flow

4: Establish Pull

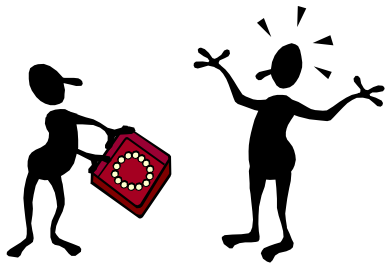
Womack & Jones, Lean Thinking

Kaizen; Gemba Walk

5 steps model of Womack & Jones

1. Define value;
   Specify value from the standpoint of the end customer

   Would the customer be willing to pay for this..?



2. Identify the Valuestream;
   Perform a Gemba Walk (Gemba = “The actual place”)

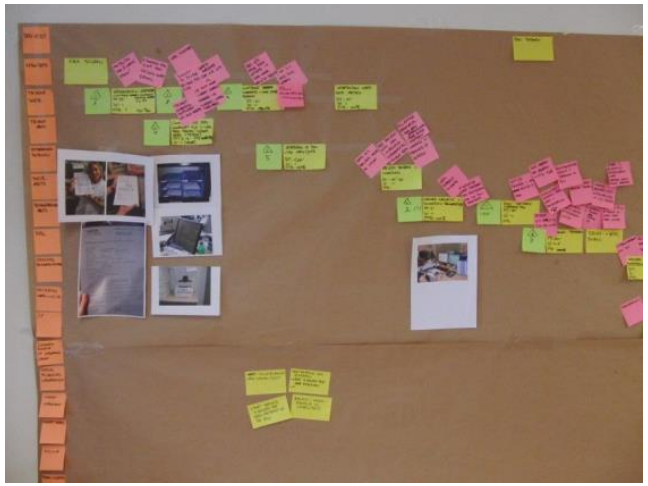
   Visit each activity within the process, interview the experts; experience the process.
   Focus on added value / waste

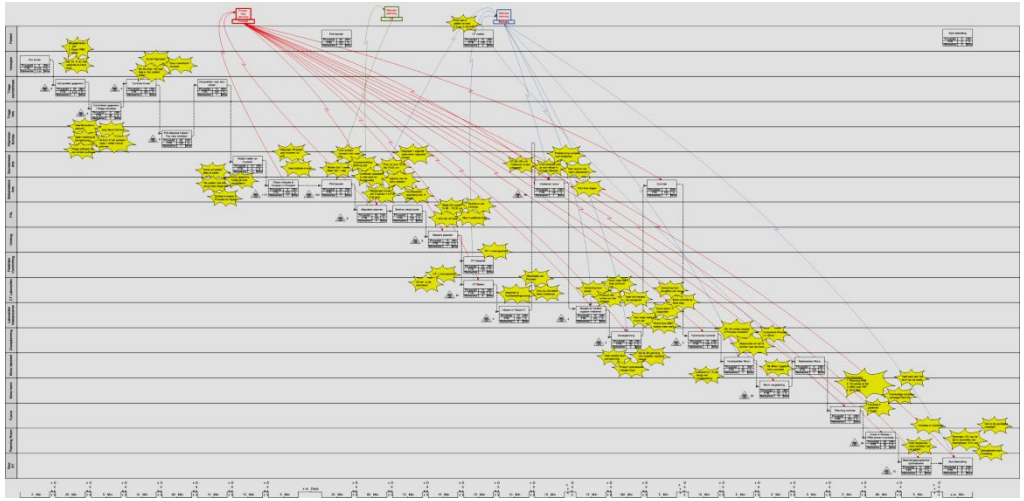
Kaizen; Value Stream Map

5 steps model of Womack & Jones

2. Visualize each step of the process in a Value Stream Map;
   Sequence the activities, each handling station is a “swimming lane”

   Identify value / waste / bottlenecks
   Eliminate whenever possible those steps that do not create value



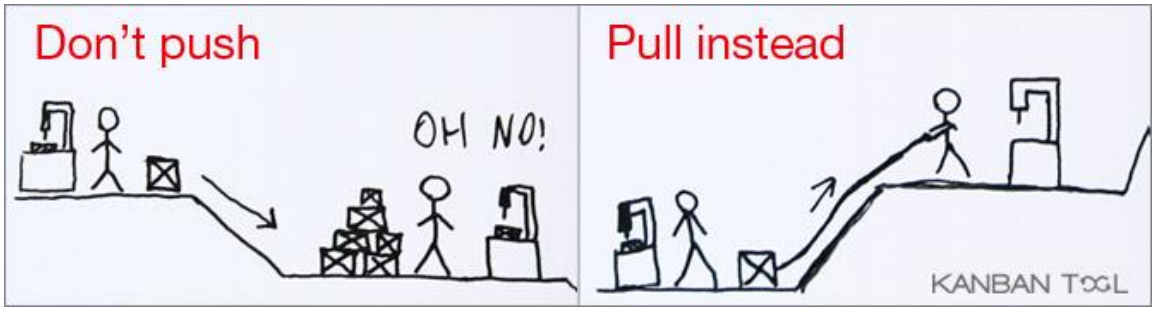


Kaizen; Flow

5 steps model of Womack & Jones

3. Create flow in the process;
   Make the value-creating steps occur in tight sequence
   so the process will flow smoothly

4. Drive process by “pull” rather than “push”;
   Let customers pull value from the next upstream activity



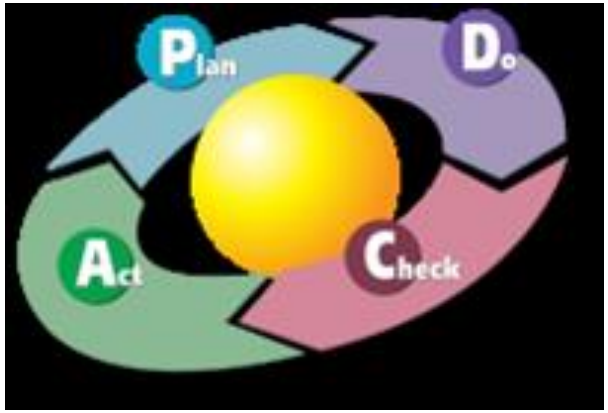
Kaizen; PDCA

5 steps model of Womack & Jones

5. Seek perfection;
   Begin the process again and continue it until a state of perfection is reached

Continuous improvement (part II); Circle of Deming

Plan
Do
Check
Adjust

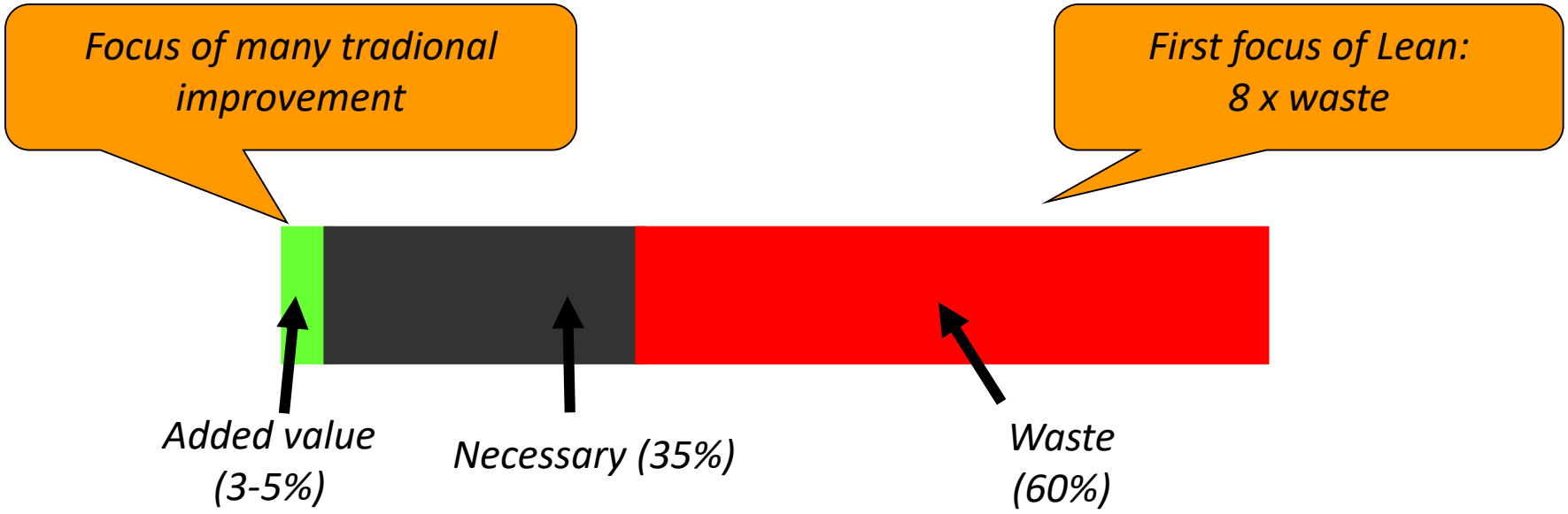


Lean in healthcare

The parallel:

Also built of processes

Need for improvement



Lean in healthcare

The translation:
Add value for the patient while minimizing waste;

I. Improve the process of patient treatment (part I)
II. Lean as method for (continuous) Quality Improvement (part II)

Lean process improvement in healthcare:

Focusses on adding value for the patient

Saves processing time

Gives more stable workflow / less frustration

Lean adopted in Erasmus MC

Aim: process improvement in Radiotherapy

- Decrease waiting time for the patient
- Less errors / less re-processing / less frustration
- Identify and eliminate waste
- Create flow, more pull (rather than push)

Visit to Akzo Nobel

Better properly stolen, than badly invented…
(very bad translation of Dutch saying)

Akzo Nobel is known for it's successful application of Lean Management.

On February 15, 2011 the majority of Radiotherapy Erasmus MC visited Akzo Nobel Sassenheim (NL)

Aim: (to steal)
How to apply Lean Thinking

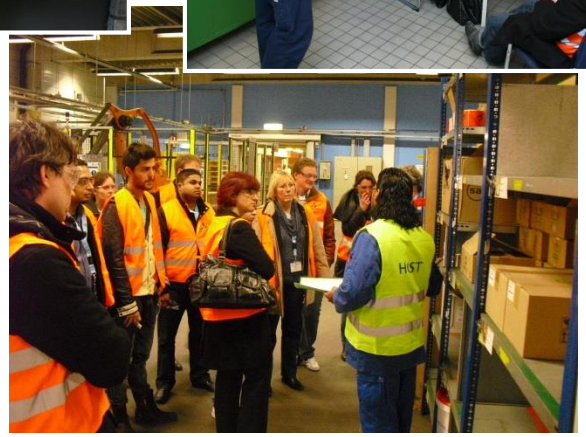
AkzoNobel
Tomorrow's Answers Today

Visit to Akzo Nobel

Messages taken home:

- Lean Improvements “bottom up” (experts themselves involved)
- Multi professional approach in implementing
- Daily short briefing at all levels to check on the process

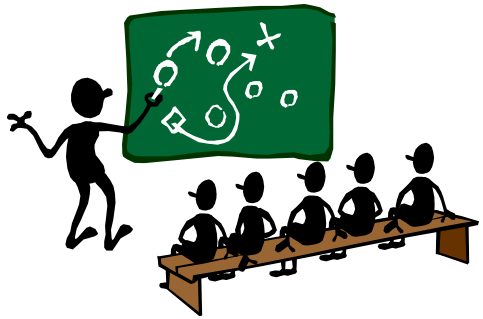
AkzoNobel
Tomorrow's Answers Today



Applying Lean to Radiotherapy

Intended method / lessons learned:

- Multi professional approach
- Inspection of each involved station; Gemba walk
- Analysis of the process: Value Stream Mapping
- Focus on added value / waste
- Ideal state / plan future state
- Multidisciplinary implementation
- Evaluation and adjustments



Pilot in RT-process of prostate patients

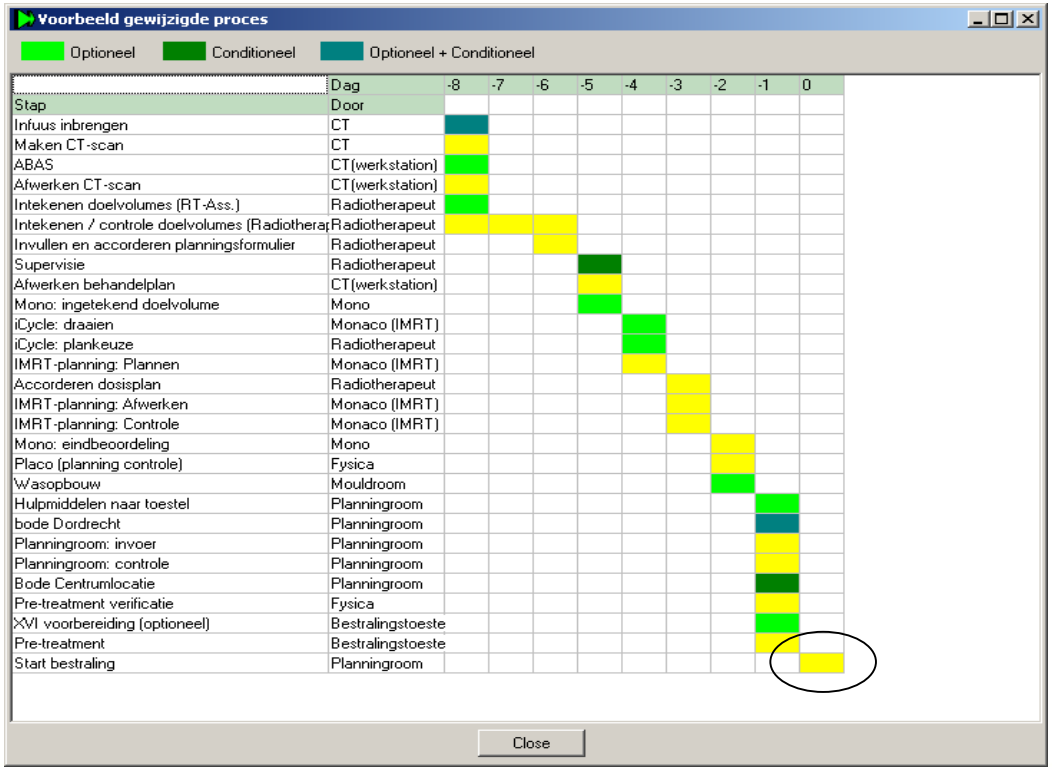
Background:

- Long process time (referral - first treatment)
- Many patients (350/year)
- Fairly straight forward process (Markers yes/no, no other dependencies)
- Many involved professionals motivated to introduce Lean into their processes

RT-process for prostate cancer patients

Step 1: defining value:

- Less waiting time before start of treatment
- No last-minute delay in start treatment



	Dag	-8	-7	-6	-5	-4	-3	-2	-1	0
Stap	Door									
Infuus inbrengen	CT									
Maken CT-scan	CT									
ABAS	CT(werkstation)									
Afwerken CT-scan	CT(werkstation)									
Intekenen doelvolumes (RT-Ass.)	Radiotherapeut									
Intekenen / controle doelvolumes (Radiotherap	Radiotherapeut									
Invullen en accorderen planningsformulier	Radiotherapeut									
Supervisie	Radiotherapeut									
Afwerken behandelplan	CT(werkstation)									
Mono: ingetekend doelvolume	Mono									
iCycle: draaien	Monaco (IMRT)									
iCycle: plankeuze	Radiotherapeut									
IMRT-planning: Plannen	Monaco (IMRT)									
Accorderen dosisplan	Radiotherapeut									
IMRT-planning: Afwerken	Monaco (IMRT)									
IMRT-planning: Controle	Monaco (IMRT)									
Mono: eindbeoordeling	Mono									
Placo (planning controle)	Fysica									
Wasopbouw	Mouldroom									
Hulpmiddelen naar toestel	Planningroom									
bode Dordrecht	Planningroom									
Planningroom: invoer	Planningroom									
Planningroom: controle	Planningroom									
Bode Centrumlocatie	Planningroom									
Pre-treatment verificatie	Fysica									
XVI voorbereiding (optioneel)	Bestralingstoeste									
Pre-treatment	Bestralingstoeste									
Start bestraling	Planningroom									

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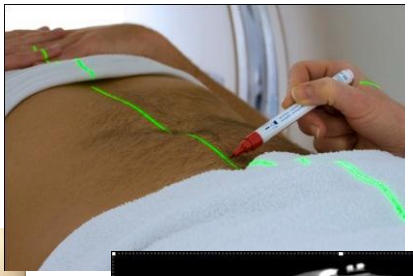
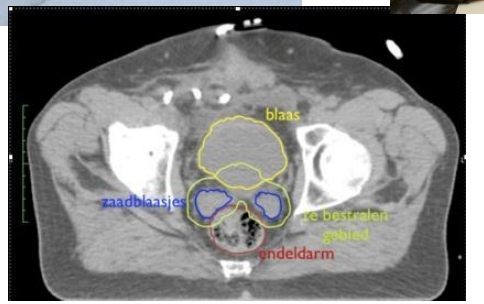
Optimizing the process

Step 2: Describing the complete process

Referral

Intake Radiation Oncologist





Preparation

Treatment

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Gemba walk

Visit to each activity within the process, “shadowing”

Gemba walk

Interview each expert, focus on added value / waste:

- What is your task
- How long does it take you / should it take, why?
- How many incoming / outgoing / waiting (stack)?
- Who is your supplier and your customer?
- First Time Right percentage? If not FTR >> why?
- Consequences / risks?
- Any frustrations / other issues?

"You're going to stitch me up in this interview aren't you?"

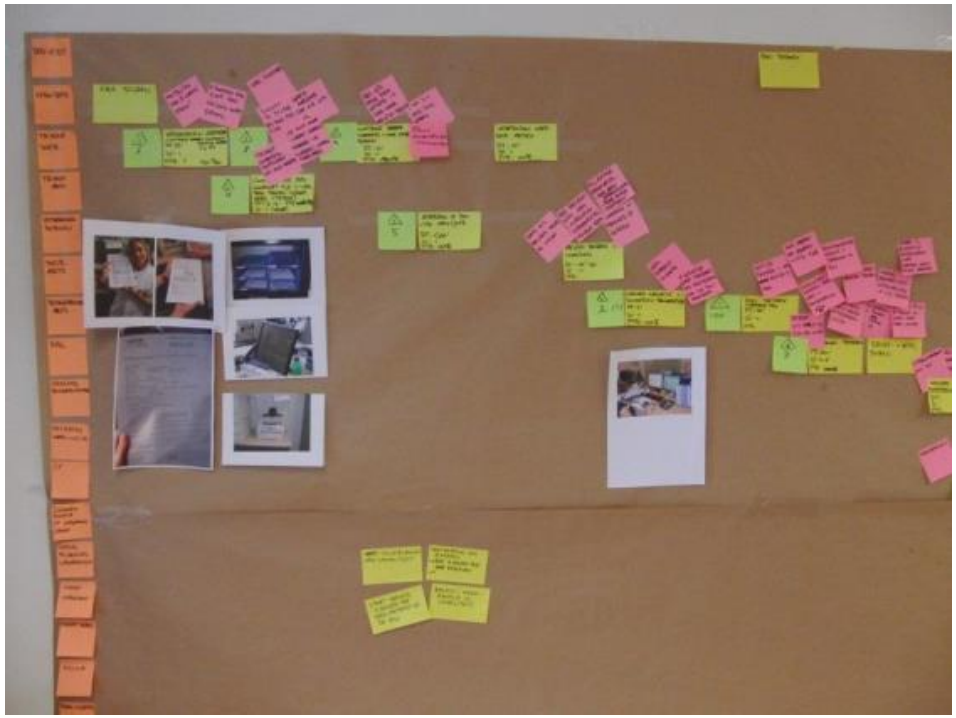
Analysis of the process

"Brown paper": map the valuestream after Gemba Walk

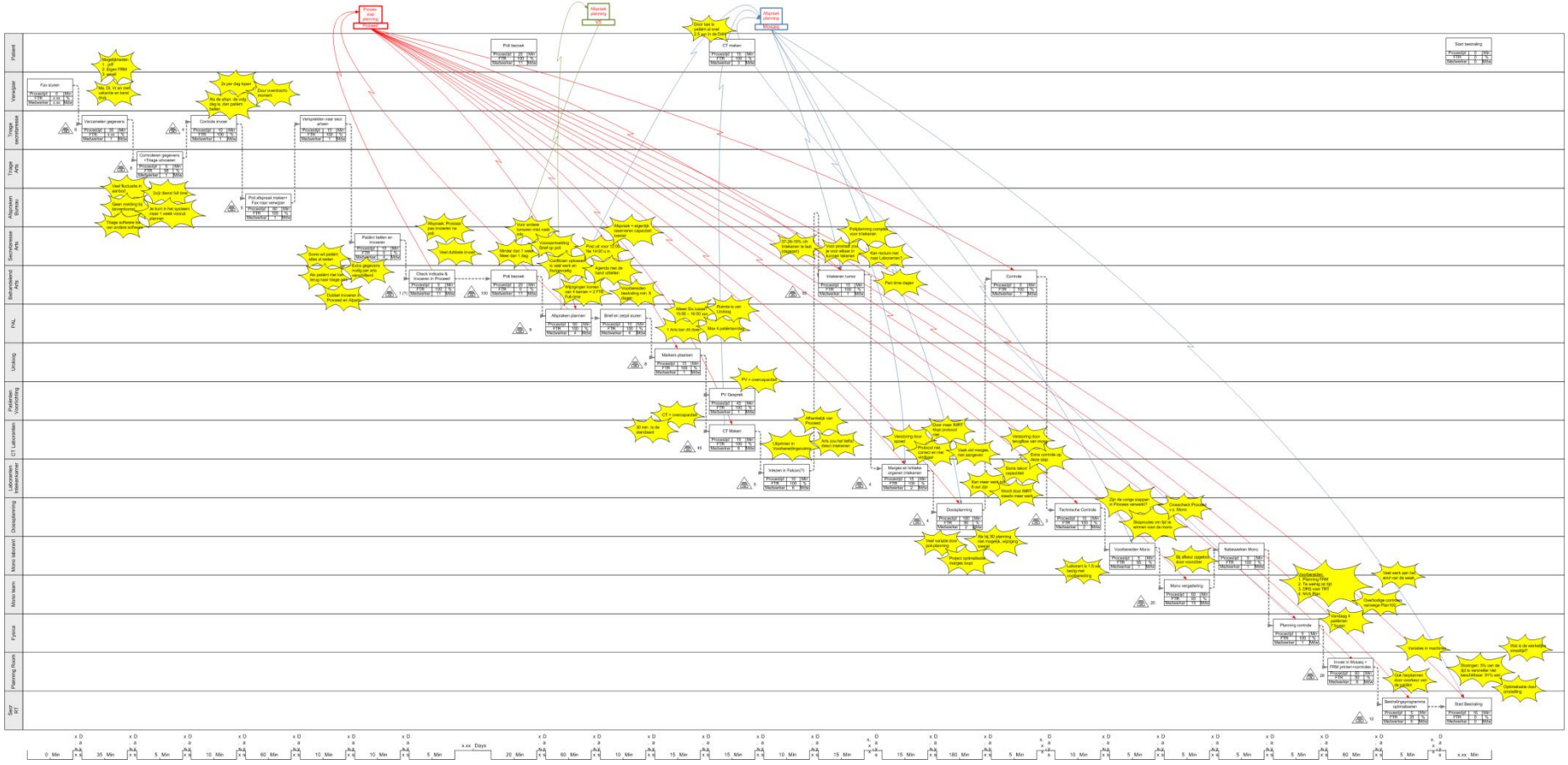
- Sequence each activity within the process (yellow notes)
- Note all issues / frustrations (pink notes)
- Mark the time needed

Our experiences:

- Many activities going back and forth, taking days
- Many issues/frustrations at start and end of preparation
- FTR for last step in preparation is only 50%!!



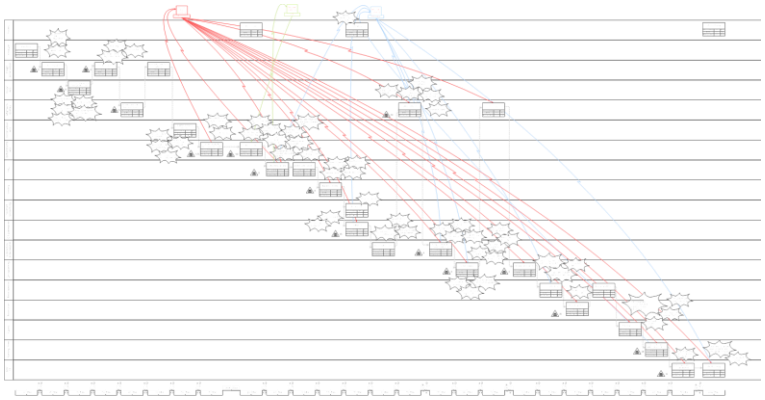
Value Stream Map (VSM)



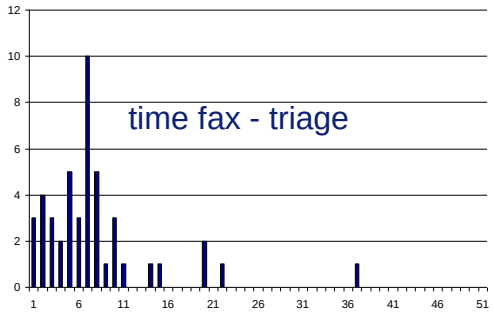
Current state

Analysis of process

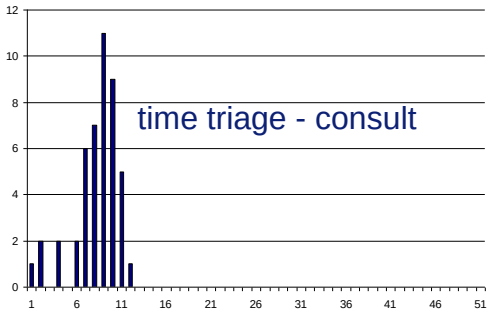
- Mean processing time = 36 days
- 18 stations / swimming lanes
- 26 process steps
- 67 issues
- 10-11 hrs adding value
- 13 days necessary (due to marker implantation)



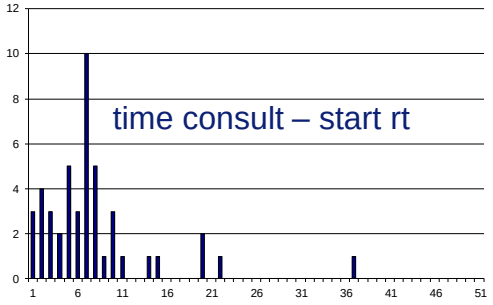
patients june – august 2011 (excl “prostaatcentrum”)



median 6



median 8



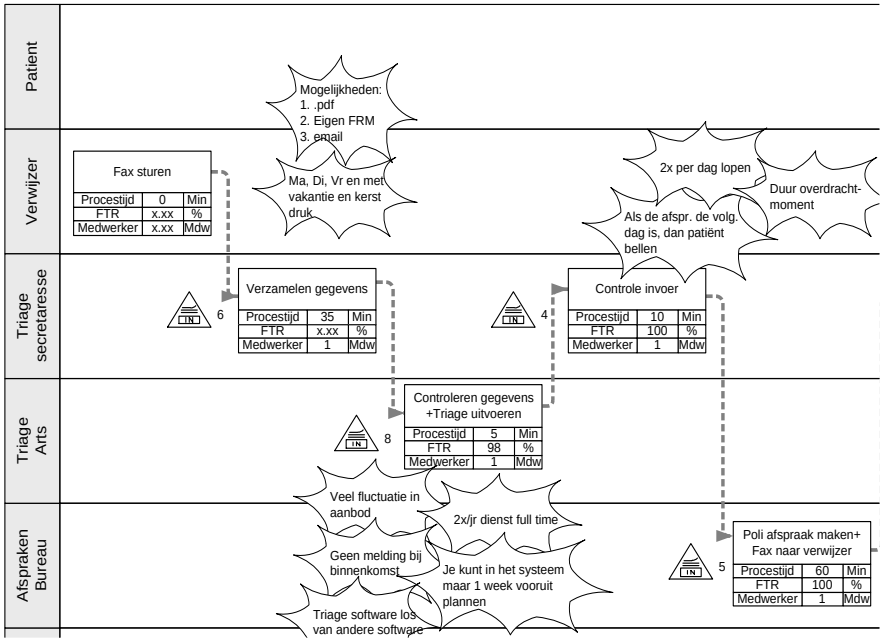
median 18

Identifying waste (I)

1. Patient admission (referral – intake RO)
   - Incomplete data
   - Many activities / 4 SL
   - Waiting (wasting) time
   - Actions not adding value

<u>Wastes</u>:

Defects (data not complete)
Waiting (for availibility next SL)
Transport (of case between SL)
Motion (inefficient order)
Excess processing (many checks)



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Identifying waste (II)

2. Patient preparation process (CT – 1st treatment)
   - Many actions, many swimming lanes, many disciplines
   - Waiting between stations (SL's)
   - Availability next station
   - Facilities (implantation 1x pw, timing RO-meeting)
   - FTR end preparation 50%!!
   - Fixed starting date, so PUSH in (re-)processing the preparation

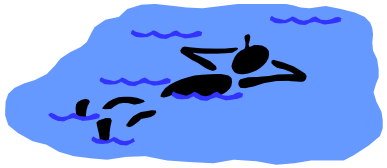
Wastes:

Defects (data not complete)
Waiting (for availibility next SL)
Inventory / no flow (markers once a week)
Motion (between different Swimming Lanes)
Excess processing (checks)

Ideal state

Imagine…

- Referral through website
- (No acceptation of patient unless) all required data received
- Standard implantation of markers at birth…
- No other patients, plenty of time
- All experts available at all time
- All equipment available, no downtime
  (base stability)
- …

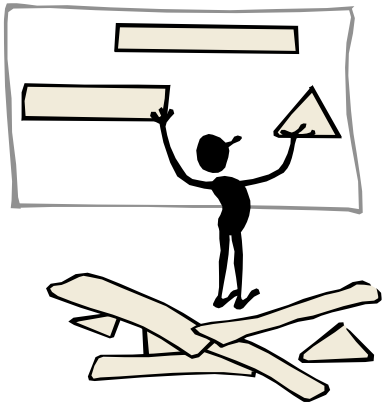


Future state

More realistic, mind the Circle of Influence;

1. Optimize admisson procedure, clear requirements
   Inform referring specialists

2. Rearrange preparation process, CT- first treatment
   Call in patient no sooner than plan approved by RO-team
   Create pull



Plan

How?

Who does what by when?

Who is problem owner

What do we aim for

What if..? –consequences / risks

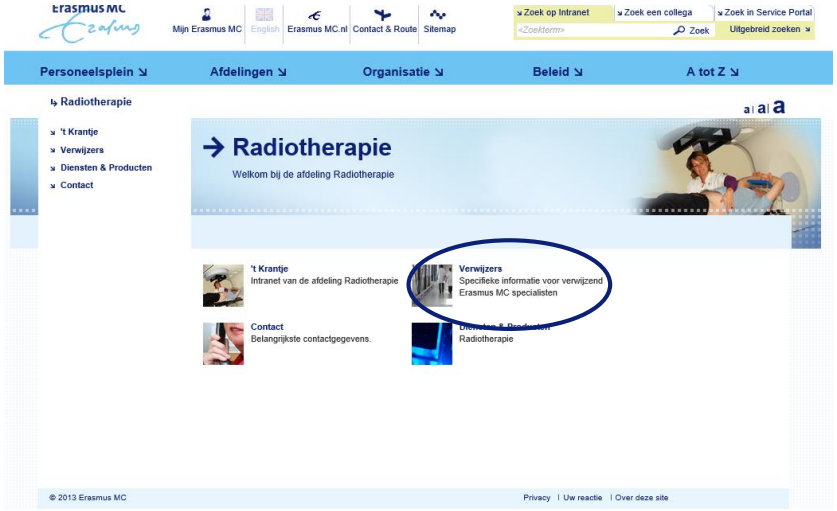
Communication plan (inform/involve all others!)

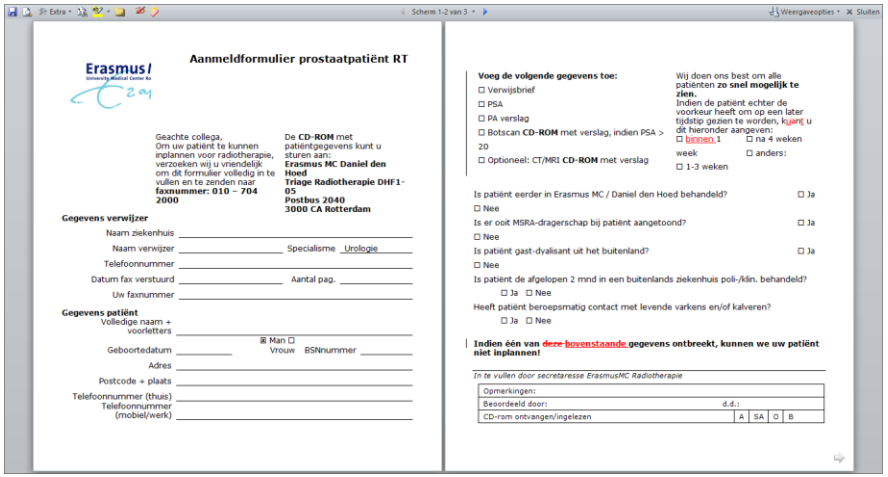
Multi -professional approach!

"...However, when undertaken on their own in this way, they create islands of excellence which, if they are not linked together, make little difference to the bottom line."

Actions

1. Admission;
   changes introduced by RO and administration:
   - Letter to referring specialists (required data)
   - Website adjusted
   - New admission form
   - Secretary authorized to give out patient number and plan intake herself





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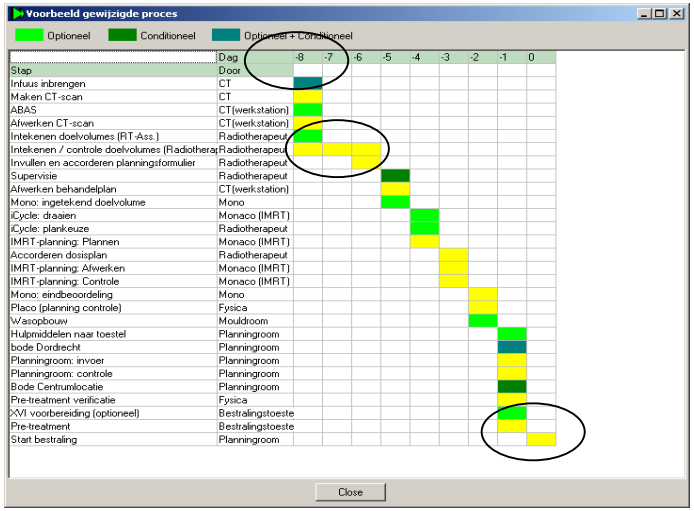
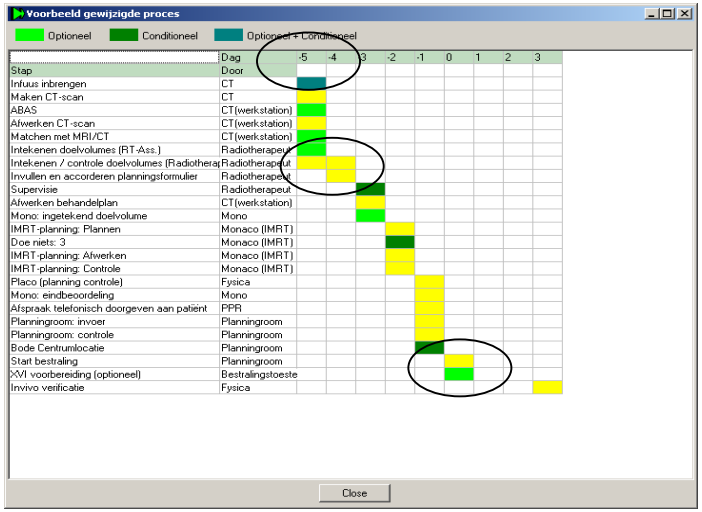
Actions

2. Process CT – start treatment;
   changes introduced by RO, RTT, Physicists, administration and logistics
   - Flow in delineation (Technologist / Rad. Onc. including margin)
   - No RO needed after dose planning: clear constraints
   - Plan approval after review meeting by RO's chairperson
   - IT: data transfer for RO-meeting during night (when marked)
   - Call in patient <u>AFTER</u> plan approval





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Results

Lean Process Optimization:

- Decrease Overall Time (fax – start treatment) from 36 → 26 days, including marker implantation
  - Admission from 6 > 2 days
  - Preparation from 8 > 5 days
- 100% patients with marker implantation included; 3x/week
- Final preparation FTR 70% >> less frustration, less re-processing
- No push, more flow
- No delay in start treatment for patient

Results

Lean Process Optimization, changes in organization:

- Awareness and enthusiasm in participants
- Learned to identify Muda
- Learned to involve all the experts
- Learned to let Patient Value prevale before own agenda
- Create a new process and dare to experiment
- Evaluate and adjust (Continuous Improvement)
- Daily meeting at all levels to check on the processes ("*scrum*")

Lessons learned

Do it together, multidisciplinary and bottom up:

- No *'shitty management'*!

Keep the Lean spirit alive, it's a long term process;

- Show results and celebrate success
- Ambassadors of Lean are needed
- Management has to support and encourage staff

Lean can become a waste in itself

- Apply it with a purpose
  and focus on patient value

Other leanprojects in Erasmus MC

Process Optimization for Breast and Lung cancer patients

New process for palliative patients / all-in-one-day *("palliatiepoli")*

Process optimization for triage for all patients

Current challenge: balancing all patients, processes and quality:

- Relocation of the hospital with all its patients and processes
- New equipment and systems
- Finding new base stability, then optimization

In conclusion / take home

- Lean Thinking is very much “common sense”,
  a practical approach to Quality Improvement
- Focus on minimizing waste / adding value
- Invest time and resources for multi-professional Process optimization,
  sustain by Continuous Improvement
- FUP’s (Frequently Used Processes) give most benefit of Process optimization
- It takes time and continuous effort

Lean Thinking has value in any environment!

Application of Lean Thinking in Radiotherapy Quality Improvement

Marjolein van Os

Radiation Technologist,

Erasmus MC, Rotterdam, NL

Quality Assessment & Improvement

Brussels, 2-5 October 2017

Erasmus MC University Medical Center Rotterdam Cancer Institute

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Learning Objectives

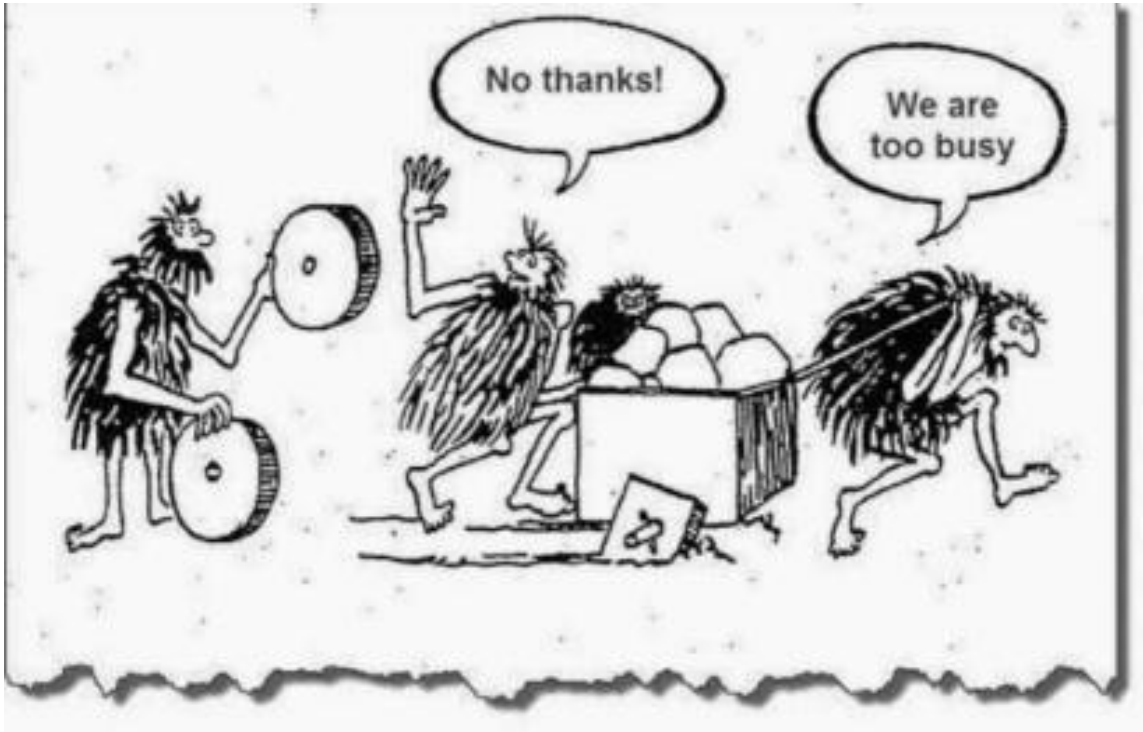
- To describe the methodology of Continuous Improvement
- To explain the term PDCA
- To apply 2 different methods of problem analysis
- To link the outcome of an Incident Registration System to Lean Continuous Improvement in Radiotherapy
- To describe the value of multi-professional approach in Continuous Improvement

Outline

- Application of Lean in Healthcare
  - Process Optimization (part I)
  - Quality Improvement (part II);
    Continuous Improvement; Kaizen, PDCA
- Methods for Continuous Improvement:
  - 5-S, Fishbone / Ishikawa Diagram, 5 x why,
    Work breakdown sheet
  - Examples from RT practice
- Link to Incident Registration System
  - Reporting System Erasmus MC
  - To Quality Improvement using Lean methodology
- Discussion

Basis for Continuous Improvement

Awareness of what is to be improved, thinking in possibilities



"You don't have to be sick to get better"

Basis for Continuous Improvement

In radiotherapy:

Daily meeting at all levels, each discipline, to check on the processes ("*scrum*")

- flow: in/out/waiting/production on scheme?
- defects / adjustments
- bottlenecks, assigned to problem owner

- 10 / 15 minutes
- Bottom up (check by experts themselves)
- Multi-professional approach, no islands of excellence

Kaizen

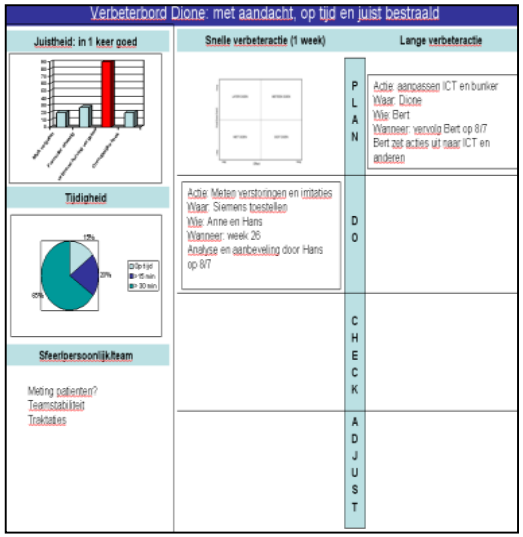
Kaizen = “Good Change”; (Continuous) Improvement

Kaizen board to guide daily meeting (format developed by experts)

Aim:
1. Visualise and check the process
2. Identify bottlenecks and assign them to a problem owner
3. Check and adjust

Kai 改 Change

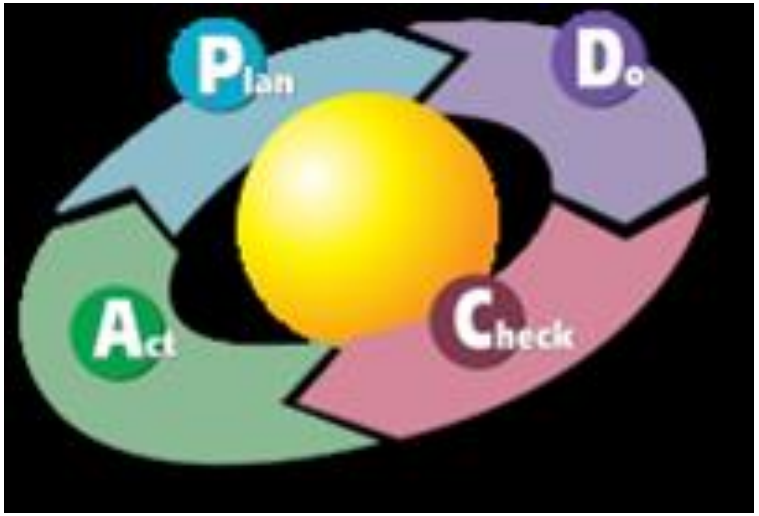
Zen 善 Good



PDCA

PDCA / Circle of Deming:

- Plan
- Do
- Check
- Act / Adjust



Remember Process Optimization,
5 steps model of Womack & Jones:

Aim for perfection through continuous improvement

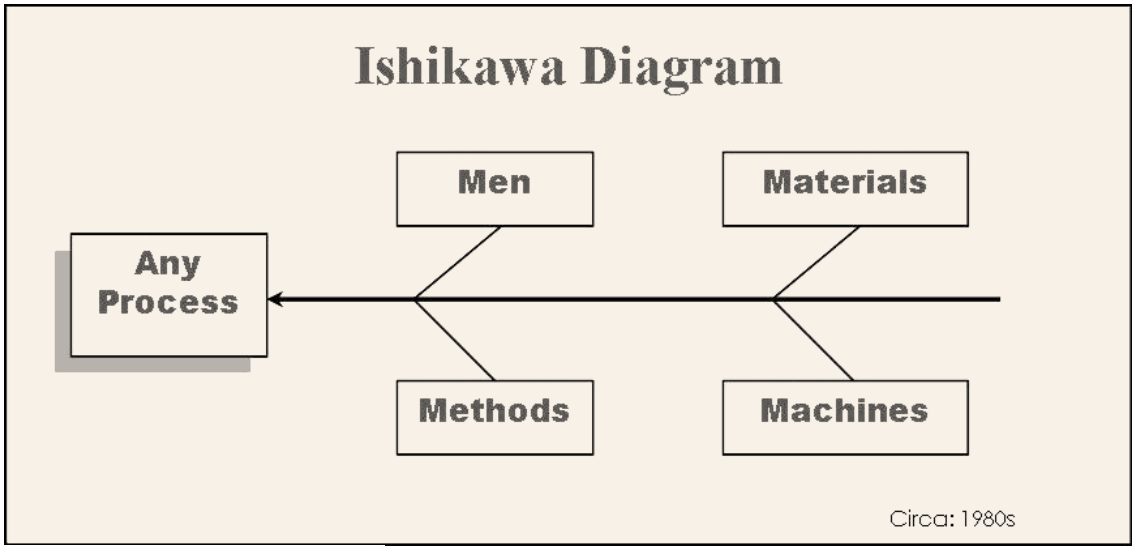
Focus on added value for the patient!

Base stability

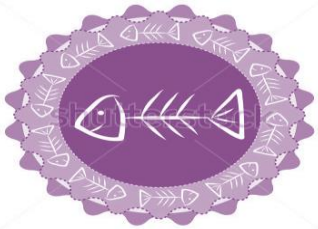
No Continuous Improvement without base stability of the process elements:

(Process Optimization, part I)

4M: **M**an
Material
Method
Machine

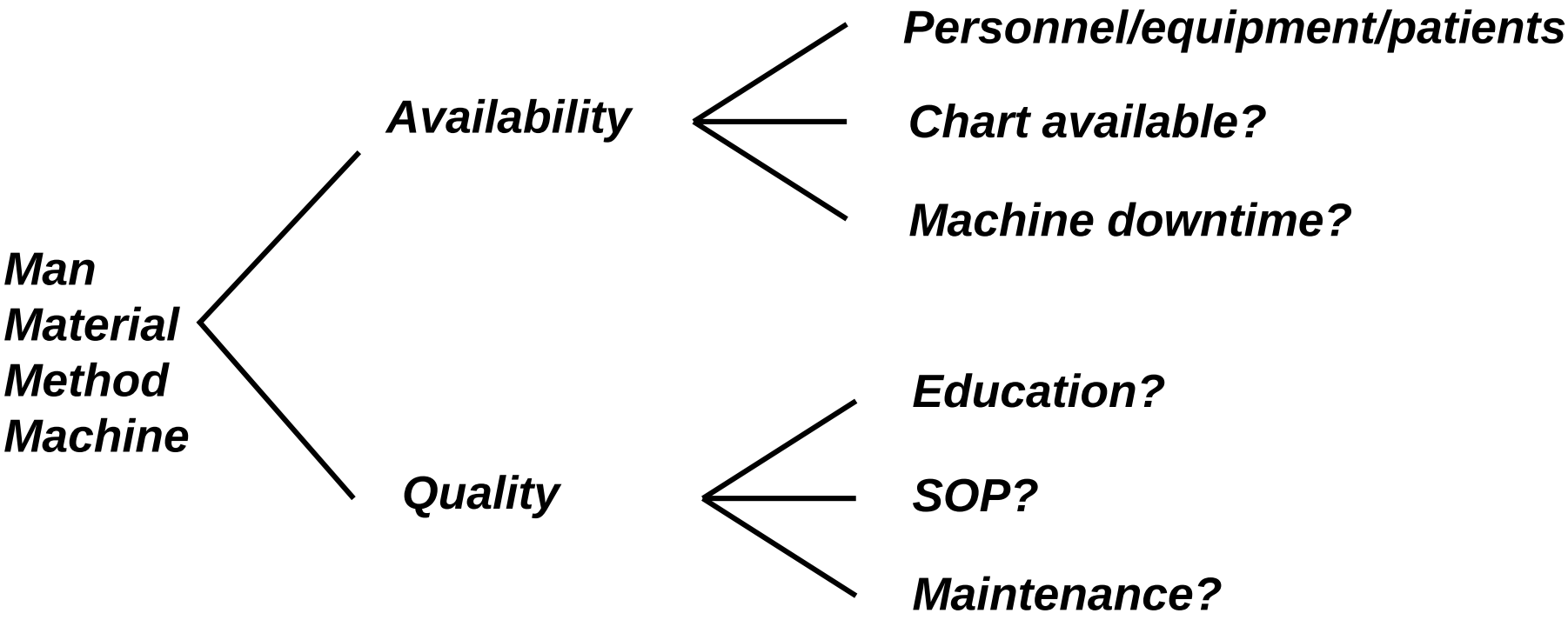


Ishikawa or
Fishbone Diagram



Base stability

In radiotherapy:



Standard method

- Standard tact, time, order, flow;
  everyone working according to same methodology
- Visualisation of work flow and procedures
  distinguish right from wrong
- 5-S

5-S

5-S = Sort, Straighten, Shine, Standardise and Sustain

To apply to working environment,

visualisation / picto's is helpful to sustain

- Seiri (整理)
- Seiton (整頓)
- Seisō (清掃)
- Seiketsu (清潔)
- Shitsuke (躾)

5-S in Radiotherapy

Example of 5-S in Radiotherapy department:

Linac with mostly H&N –patients / many thermoplast masks:
always searching for right mask.

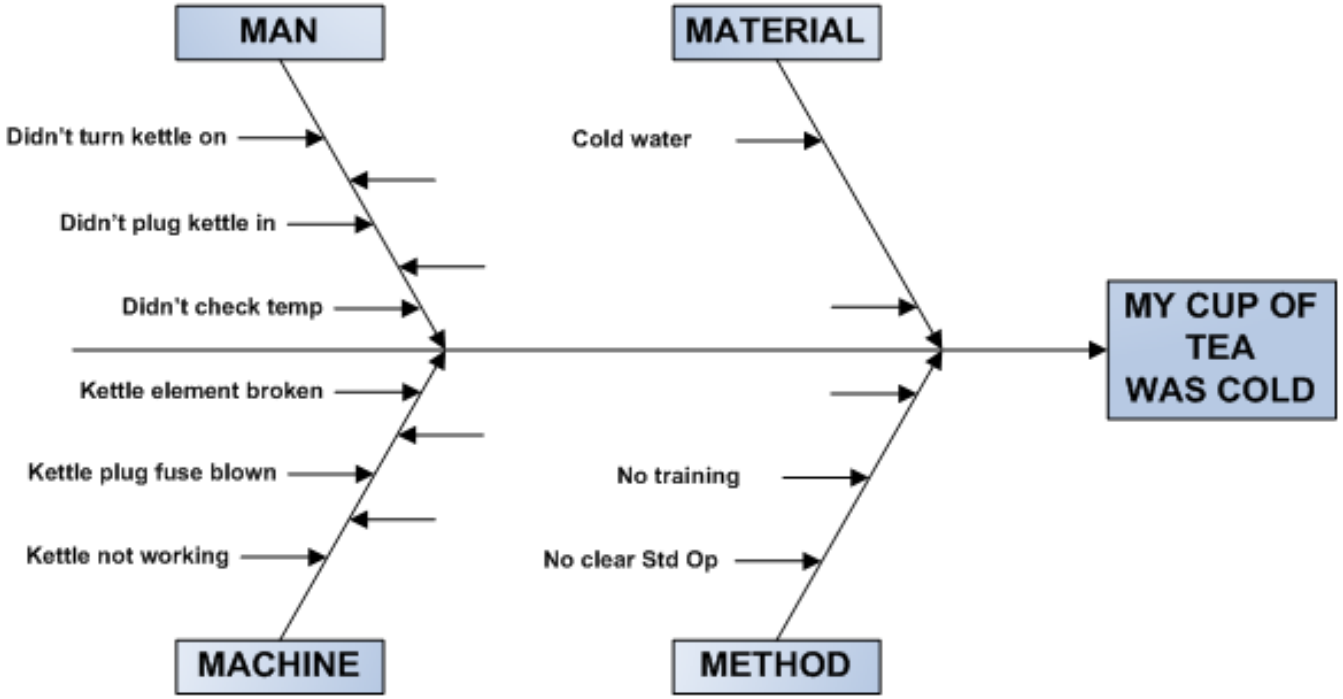
⇨ Sort, straighten and standardize with coordinates (also on patient chart)

Added value for the patient: confidence of right treatment, more adequate (faster)

Fishbone analysis

Method for problem analysis: Fishbone or Ishikawa diagram
To analyse potential causes of a problem

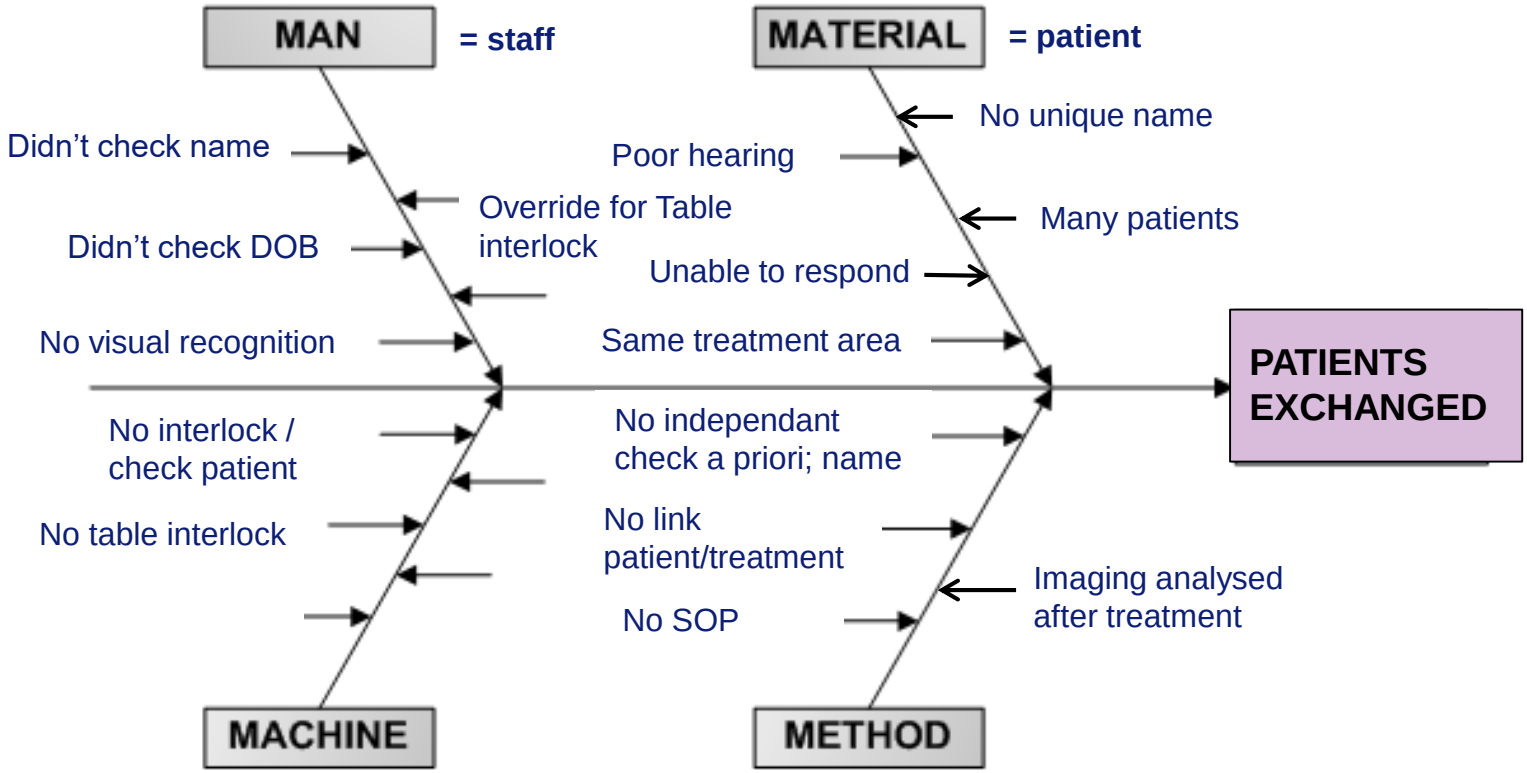
Malfunction in Man / Machine / Material / Method, causing overall effect



Fishbone analysis in Radiotherapy

Example: patient switched with another patient, wrong treatment administered

Value for the patient: right treatment, patient safety!!

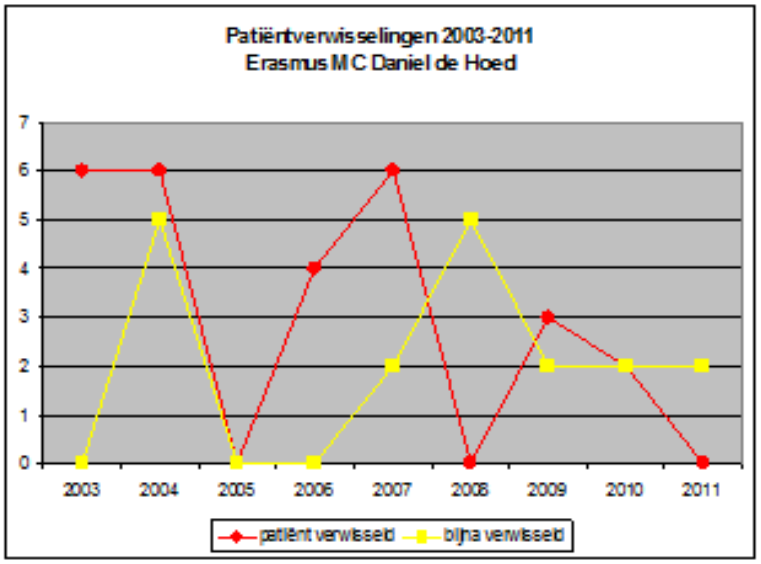


Patient exchange linked to Lean

Patient exchange:

In 2011 we used the Lean method for quality improvement at this point

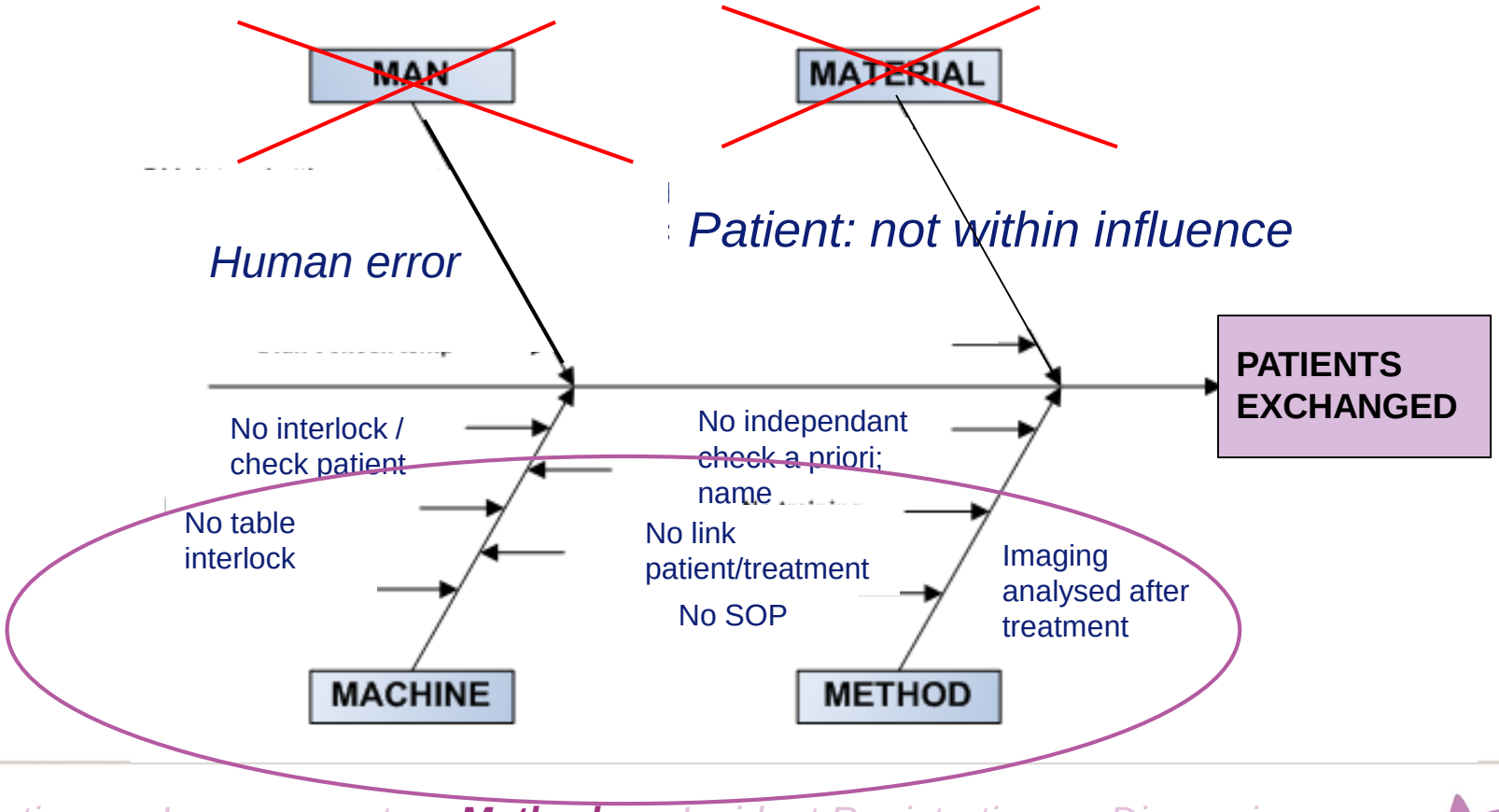
Aim: zero, never ever again!



Fishbone analysis

Possible solution should be sought in Machine and/or Method:

Man is never 100% safe, Material is not within circle of influence

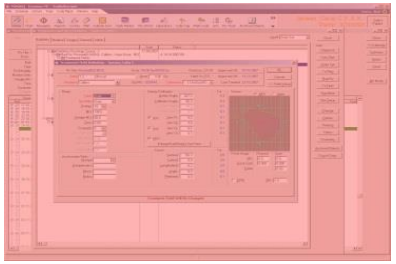


Possible solution

PLAN: Possible solution in Machine, IT:

- Link treatment to patient ID-card

Figuur 3



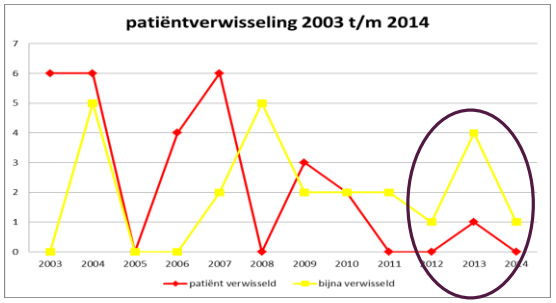
DO: Patient scans ID-card at entry

- Patient is queued in V&R-system
- Treatment is released in V&R after 2nd scan at Linac

PDCA-cycle

CHECK: Result is not yet satisfying:

- Patients in bed don't bring their card
- Patient forgets his/her card
- Scanner often fails



> Management decided to end this "solution"

ADJUST: Next solution in Method:

- Stopping rules applied (as SOP)
> check DOB, and other topics
- Involve (instruct) patients
- Both visualized!

CHECK: Since 2014 4 near-incidents, no more patient exchanges.

5 x why analysis (I)

5 x why checklist:

1. Define the problem;
   what, how, who..?
2. Collect information;
   is it real, for how long, what are consequences? (don't jump to it)
3. Identify possible root-causes;
   what steps caused the problem? What circumstances?
4. Identify real root-cause;
   use 5 x why

5 x why analysis (II)

5 x why checklist:

5. Think of a solution and recommendations;
    - How to implement
    - Appoint a problem owner
    - Identify consequences / risks
    - Communicate
6. Implementation;
    - Just start doing it!
7. Check/adjust
    - Measure after implementation whether the problem indeed has been solved
    - If necessary go through 5 x why checklist again. And again…

5 x why in Jamaican traffic

1. Define the problem:
   - On Jamaica many biker-hit-by-car accidents
   Value for the customer: to survive on a bike
2. Collect information: how many times, under what circumstances?
3. Possible root causes: dark, drunk, no separate cycle path, no lights

→ 5 x why:

1. why were drivers drunk >> drank rhum
2. why they drink rhum >> it's legal to drink and drive
3. why is it legal to drink and drive?? >> no problem man!
4. why no problem >> only accidents in the evening
5. why accidents in the evening >> dark, no lights, no separate cycle path and.. More rhum

- *So, no more cycling after 18.00 hrs*!!

5 x why in Radiotherapy

1. Problem:
   First Time Right for start treatment is low resulting in increased workload and delay for the patient
2. Information: in 30% still adjustments in treatment plan just before start treatment
3. Possible causes: extended disease, no plan approval, other imaging protocol, or just LATE;

→ 5 x why:

1. why late adjustments >> checkpoints late in relation to start
2. why checkpoints late >> no flow, push into the process,
3. why push, no pull >> fixed startdate
4. why fixed startdate >> to have an endpoint
5. why? >> to be in time for the patient

-Now are we??

5 x why, possible solution

Value for the patient: Just in time, no delay

Possible solution:

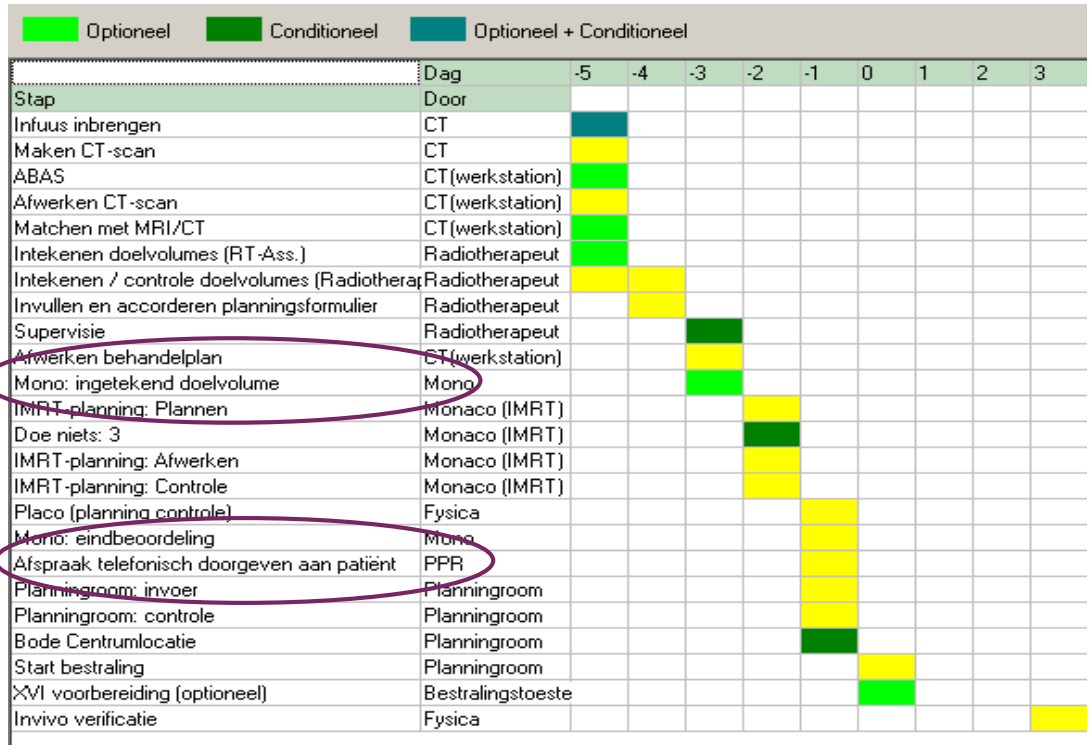
- Advance the checkpoint for treatment approval (patient meeting)
- Pull, no fixed start date for patient: call in *after* plan approval
- Consequence / risk:
  - might be close call for patient (- 1 day)
  - no endpoint, more processing time (which is waste)
  - each discipline has to conform (and NOT give the 1st appointment)

- To be implemented (tested) in prostate process optimization

5 x why, solution implemented

"Pull" implemented in prostate process optimization work flow

(IT-solution to manage work flow, communication plan for all disciplines)



	Dag	-5	-4	-3	-2	-1	0	1	2	3
Stap	Door									
Infuus inbrengen	CT									
Maken CT-scan	CT									
ABAS	CT(werkstation)									
Afwerken CT-scan	CT(werkstation)									
Matchen met MRI/CT	CT(werkstation)									
Intekenen doelvolumes (RT-Ass.)	Radiotherapeut									
Intekenen / controle doelvolumes (Radiothera	Radiotherapeut									
Invullen en accorderen planningsformulier	Radiotherapeut									
Supervisie	Radiotherapeut									
Afwerken behandelplan	CT(werkstation)									
Mono: ingetekend doelvolume	Mono									
IMRT-planning: Plannen	Monaco (IMRT)									
Doe niets: 3	Monaco (IMRT)									
IMRT-planning: Afwerken	Monaco (IMRT)									
IMRT-planning: Controle	Monaco (IMRT)									
Placo (planning controle)	Fysica									
Mono: eindbeoordeling	Mono									
Afspraak telefonisch doorgeven aan patiënt	PPR									
Planningroom: invoer	Planningroom									
Planningroom: controle	Planningroom									
Bode Centrumlocatie	Planningroom									
Start bestraling	Planningroom									
XVI voorbereiding (optioneel)	Bestralingstoeste									
Invivo verificatie	Fysica									

5 x why, solution measured

Possible solution:

Pull, no fixed start date for patient: call in after plan approval

Checked in 10 patients:

Patients are ok;

- CT informs patient about start treatment after approx. 1,5 week
- Patient is aware of short notice

More processing time due to no endpoint is an issue though

- Needs time and awareness
- Workload is decreased!

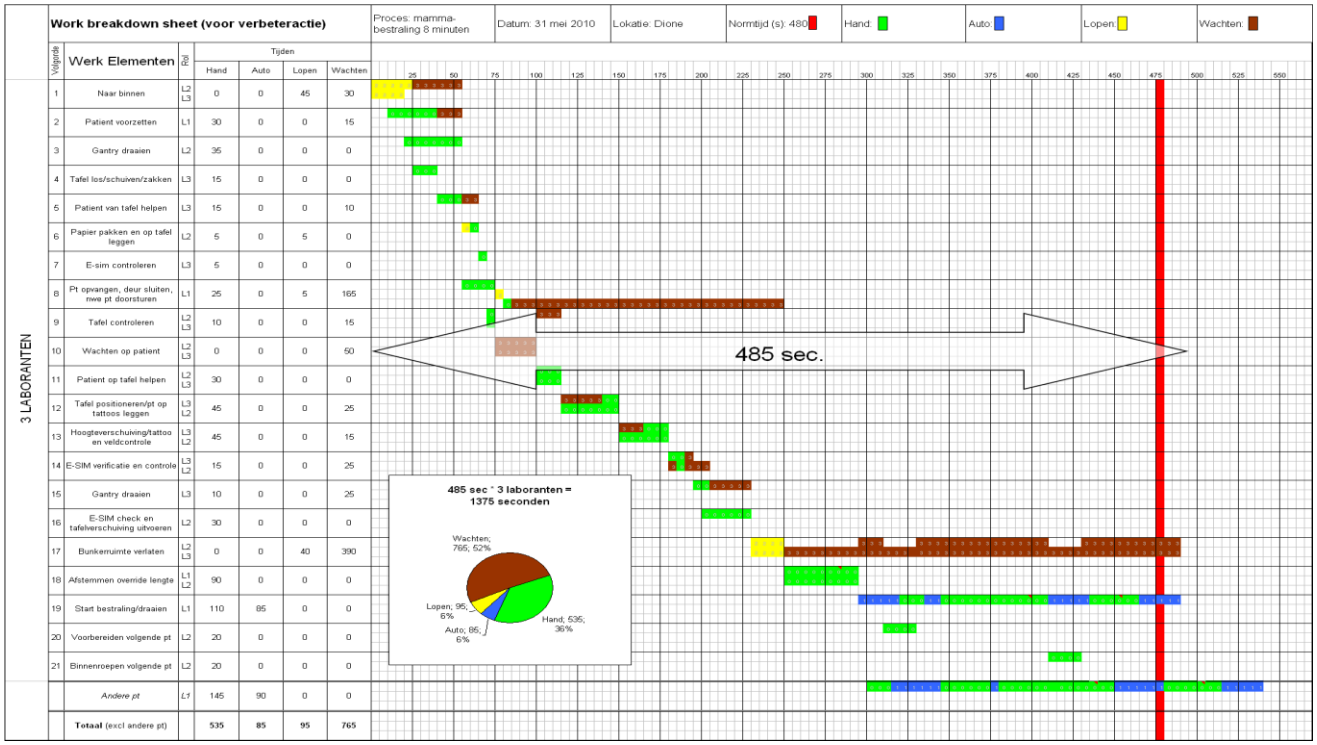
Multi-disciplinary approach works (most of the time..)

⇨ Now implemented in more patient groups, but still in PDCA

Work Breakdown Sheet

To analyse all sequenced activities within process
(no swimming lanes, just detailed timing)
Focus on added value / waste!

- Example: patient treatment at Linac, timeslot 8 min



Work breakdown sheet (voor verbeteractie)

Proces: mamma-bestraling 8 minuten | Datum: 31 mei 2010 | Lokatie: Dione | Normtijd (s): 480 | Hand: | Auto: | Lopen: | Wachten:

3 LABORANTEN

Volgorde	Werk Elementen	Pos	Tijden Hand	Auto	Lopen	Wachten
1	Naar binnen	L2 L3	0	0	45	30
2	Patient voorzetten	L1	30	0	0	15
3	Gantry draaien	L2	35	0	0	0
4	Tafel los/schuiven/zakken	L3	15	0	0	0
5	Patient van tafel helpen	L3	15	0	0	10
6	Papier pakken en op tafel leggen	L2	5	0	5	0
7	E-sim controleren	L3	5	0	0	0
8	Pt opvangen, deur sluiten, nwe pt doorsturen	L1	25	0	5	165
9	Tafel controleren	L2 L3	10	0	0	15
10	Wachten op patient	L2 L3	0	0	0	50
11	Patient op tafel helpen	L2 L3	30	0	0	0
12	Tafel positioneren/pt op tattoos leggen	L3 L2	45	0	0	25
13	Hoogteverschuiving/tattoo en veldcontrole	L3 L2	45	0	0	15
14	E-SIM verificatie en controle	L3 L2	15	0	0	25
15	Gantry draaien	L3	10	0	0	25
16	E-SIM check en tafelverschuiving uitvoeren	L2	30	0	0	0
17	Bunkerruimte verlaten	L2 L3	0	0	40	390
18	Afstemmen overide lengte	L1 L2	90	0	0	0
19	Start bestraling/draaien	L1	110	85	0	0
20	Voorbereiden volgende pt	L2	20	0	0	0
21	Binnenroepen volgende pt	L2	20	0	0	0
	Andere pt	*L1*	145	90	0	0
	Totaal (excl andere pt)		**535**	**85**	**95**	**765**

485 sec.

485 sec * 3 laboranten = 1375 seconden

Wachten; 765; 52%
Hand; 535; 36%
Auto; 85; 6%
Lopen; 95; 6%

Work Breakdown Sheet

Helped to rearrange tasks to reduce from 4 > 3 RTT's / Linac

Efficient use of time, place and responsibility:

- All administration banned from treatment room
- definition of a left- and right hand side of the patient with separate and ordered activities for RTT 1, 2 and 3.

Work Breakdown Sheet

Risk:

Breaking down too much, making the proces too tight, too much focus on numbers and timelines.
Result was the patient being pushed through the treatment proces, no time to talk to the patient.

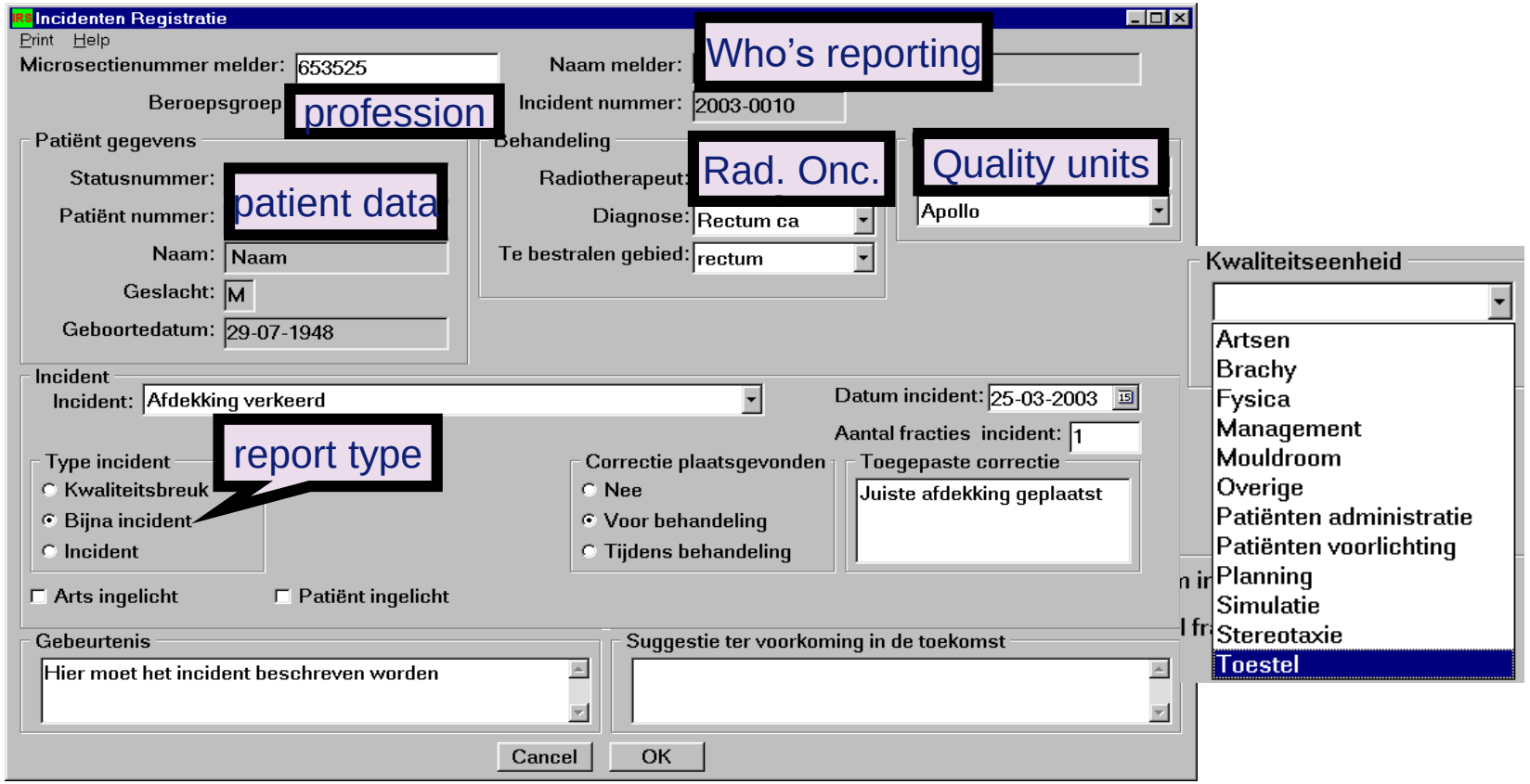
Lesson learned:

Beware not to get TOO lean, focus on added value

Incident Registration in Radiotherapy

Type of error	Moment of discovery	Consequence
Quality breach	Regular checkpoint Next activity, before start treatment	Corrected before treatment Patient not involved No harm
Near miss	Coincidence, before start treatment	Corrected before treatment Patient not involved No harm
Incident	During or after treatment	Patient involved Harm yes / no

Digital system for Radiotherapy



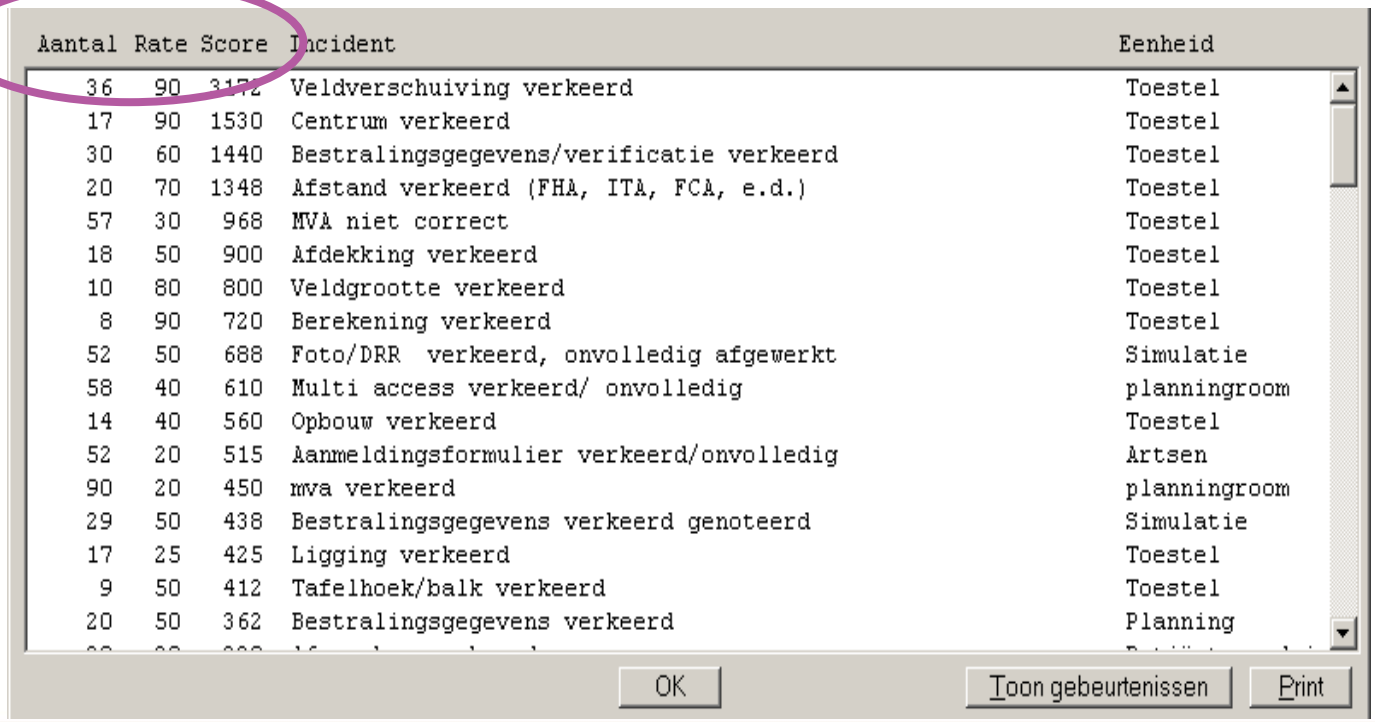
All reports monitored by overall Quality Manager Radiotherapy

Scoring of incidents

Score function:

Risk Score = Frequency x Risk rate

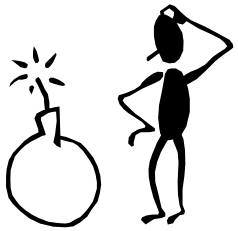
(Quality breaches count for ¼ of risk rate in total risk-score)



Aantal	Rate	Score	Incident	Eenheid
36	90	3172	Veldverschuiving verkeerd	Toestel
17	90	1530	Centrum verkeerd	Toestel
30	60	1440	Bestralingsgegevens/verificatie verkeerd	Toestel
20	70	1348	Afstand verkeerd (FHA, ITA, FCA, e.d.)	Toestel
57	30	968	MVA niet correct	Toestel
18	50	900	Afdekking verkeerd	Toestel
10	80	800	Veldgrootte verkeerd	Toestel
8	90	720	Berekening verkeerd	Toestel
52	50	688	Foto/DRR verkeerd, onvolledig afgewerkt	Simulatie
58	40	610	Multi access verkeerd/ onvolledig	planningroom
14	40	560	Opbouw verkeerd	Toestel
52	20	515	Aanmeldingsformulier verkeerd/onvolledig	Artsen
90	20	450	mva verkeerd	planningroom
29	50	438	Bestralingsgegevens verkeerd genoteerd	Simulatie
17	25	425	Ligging verkeerd	Toestel
9	50	412	Tafelhoek/balk verkeerd	Toestel
20	50	362	Bestralingsgegevens verkeerd	Planning

OK | Toon gebeurtenissen | Print

Criteria for immediate action



- Event with total risk score of > 300
- Event frequency >50
- If Quality Committee decides so
  (fe. score is below action level, but occurence is worrying)

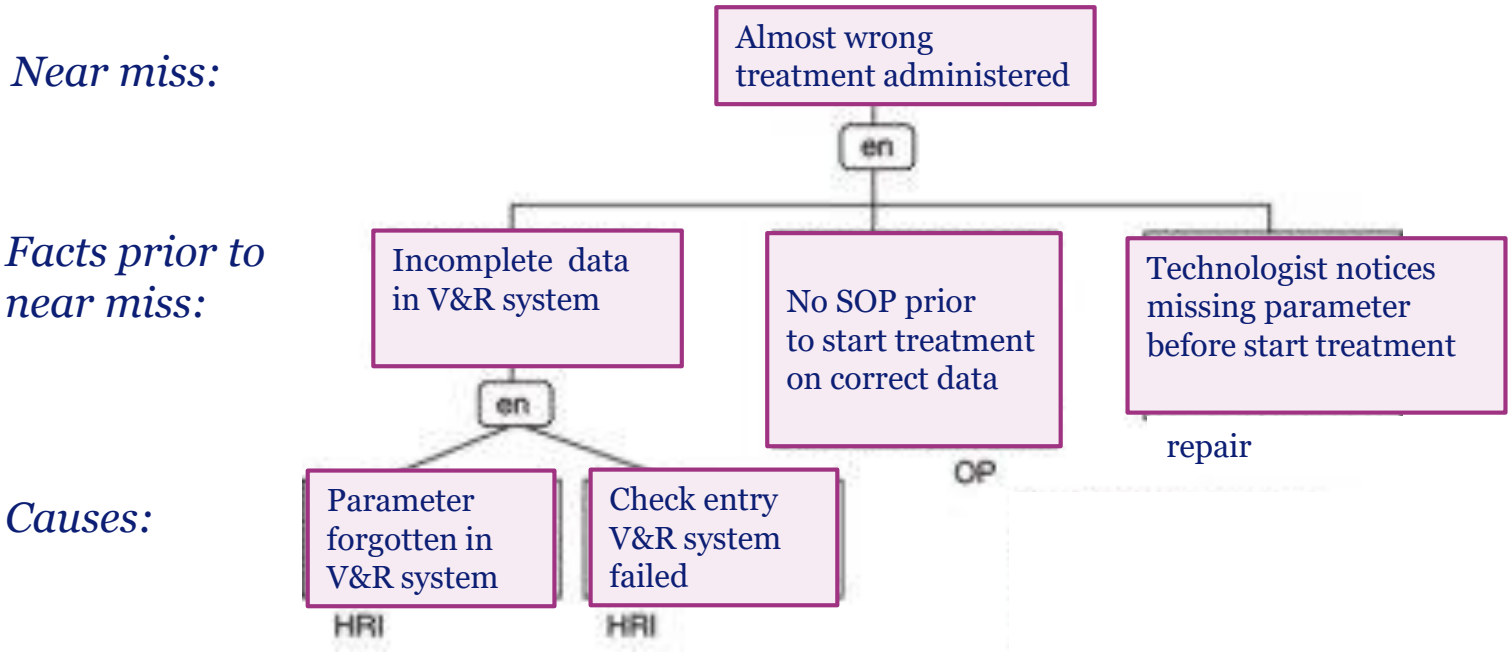
Actions came top-down: Actions for improvement, escalated to manager

- often invented from behind desks
- who is going to do what?
- no multi-professional implementation
  (although Quality Committee is multi-professional)
- yet well analysed (Prisma)

To Incident Quality System

Renamed: Incident Registration System (IRS) > Incident Quality System (IQS)
- Not just reporting, also Prisma analysis and actions to improve quality

Prisma analysis of near-miss:



Causes classified in T=technical, HR= human, O=organizational

Link between IQS and Lean

Current procedure:

IQS-committee / Prisma analysis; action is required

- Problem is defined, info collected, root-cause identified (5xwhy checklist!)

Collaboration with quality experts per team/discipline, regular meetings;
- working together towards continuous improvement,
- bottom up, experts themselves involved
- multi-professional implementation of solution

- Think of solution, make an implementation plan en start doing it
- Measure results; check and adjust

IQS linked to Lean (II)

Incident: no / wrong shift applied for treatment

- Patient is setup on reference points, then shift has to be applied according to planning and/or imaging protocol
- High score, high frequency:

Aantal	Rate	Score	Incident
36	90	3172	Veldverschuiving verkeerd
17	90	1530	Centrum verkeerd
20	70	1348	Afstand verkeerd (FHA, ITA, FCA, e.d.)
57	30	968	MVA niet correct
18	50	900	Afdekking verkeerd

> Prisma analysis / fishbone: Machine or Method

IQS linked to Lean

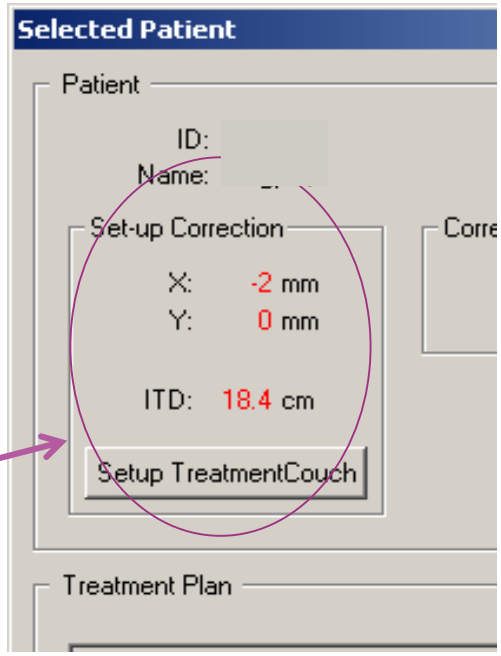
Mixed Prisma / fishbone analysis:

- *Man:*
  Unreliable!
- *Material* (patient):
  Tried marking the (new) isocenter >> extra marking/tattoos give more confusion, especially in small shift
- *Method:*
  Tried orange form on charts of patient with shift >> today is common use SOP reduced “no shift applied”, wrong shift remains.
- *Machine:*
  Shift entered in treatment couch control (TCSA, Theraview®)

Multi-disciplinary decision:
RO, physicists, RTT’s, management and industry involved.

Possible solution

Possible solution in Machine, IT again:
- Shift automatically transferred to treatment couch



1) Shift imported in imaging system (TNT®)
   - shift both from planning system / imaging protocol
2) Setup imaging system concurrent with V&R-system
   - linked to patient ID/treatment
3) Activate TCSA in imaging system
4) In treatment room:
   After patient setup on reference point, activate couch for applying shift

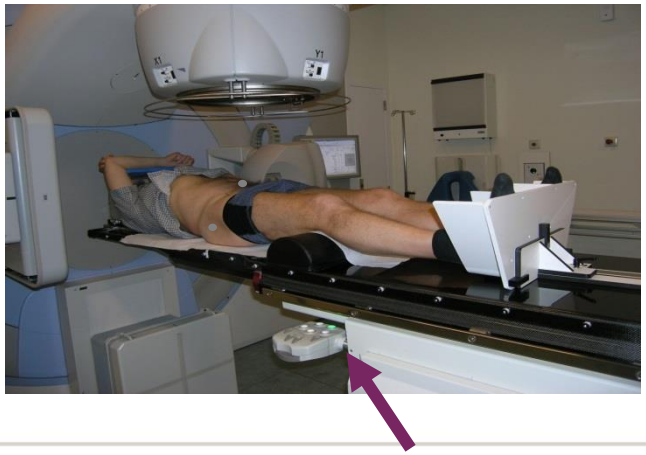
Tested on 2 (Elekta) linacs, with TCSA already implemented for online corrections

Result of solution

Very satisfying:

- No wrong shifts applied (no wrong size or direction)
- Occasionally forgotten, but mainly when TCSA is out of order

- >> TCSA mounted on Varian and Siemens Linacs as well
- Also in SOP (stopping rules) to check if couch shift was executed



Results of Lean Continuous Improvement

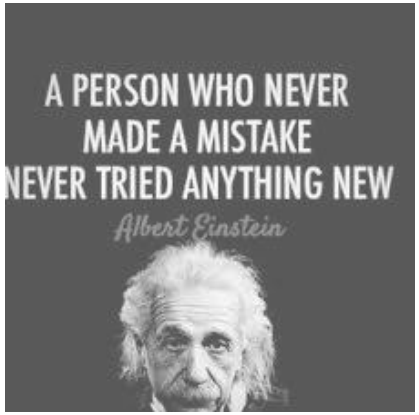
- Involvement of experts themselves, taking responsibility for improving quality
- Successful projects:

  - daily meeting at all levels
  - 5-S in treatment rooms
  - linked to IQS: execution of patient shift to (new) isocentre
  - all kinds of (small) initiatives according to PDCA;
    currently working on patient appointments

- Work in progress:
  - share the Lean-methodology; connect the *islands of excellence*.
  - in general: finding a system for Continuous Improvement

Lessons learned

- Awareness of possibilities for quality improvement
- Multi-professional approach to quality improvement,
  no islands of excellence
- Lean Continuous Improvement is NOT the solution to everything:
  - it gives methods for problem analysis, but so does Prisma
  - it gives opportunity for “trial and error”; do, check AND adjust,
    it does NOT give the perfect solution at once
  - it is Quality Improvement driven by men,
    thereby dependent on motivation



- How to solve the discrepancy between SOP and “personalised medicine”
  in patient treatment

In conclusion / take home

- Lean Continuous Improvement involves all levels in Quality Improvement and requires time, effort and motivation from all experts
- It focusses on patient value and minimizing waste
- It provides in problem analysis and PDCA-cycles at all levels
- Linked to the outcome of a reporting system it makes 1+1=3
- Beware of your circle of influence in improving quality, do it together, multi-professionally to break barriers and achieve more

The role of quality audits in quality assessment and management

Prof. Philippe MAINGON

GHU La Pitié Salpêtrière – Charles Foix

Sorbonne Université

Paris

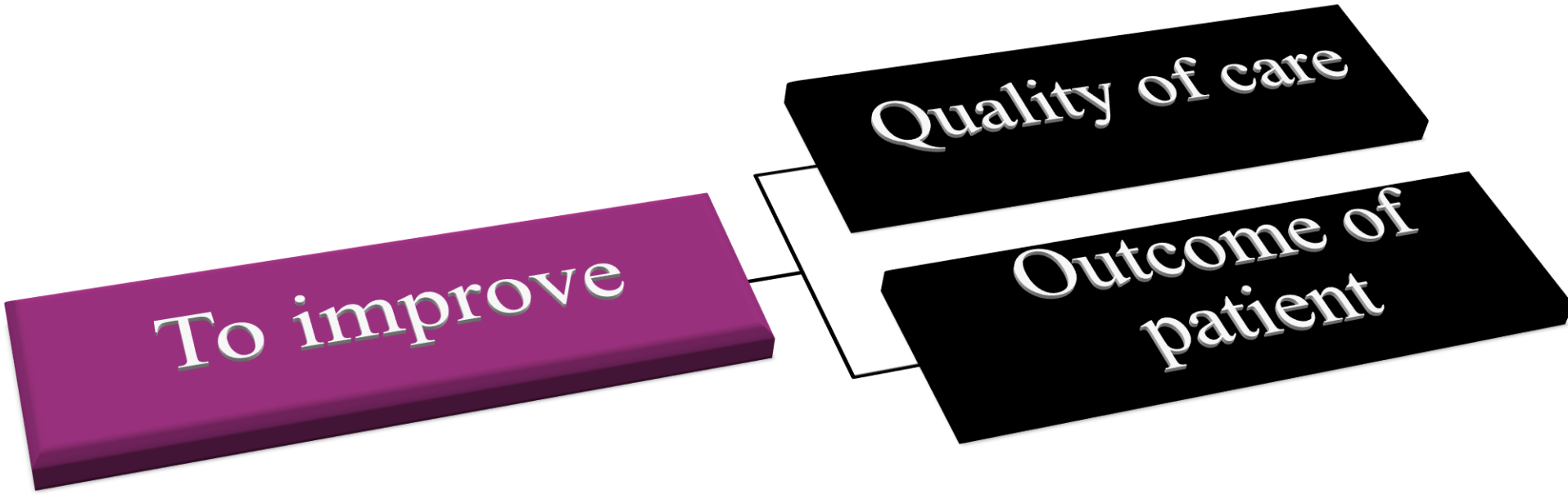
Objectives

- To include the process in all departments
- To distinguish internal audit and external audit
- To know the audited components
- To be informed about QUATRO audit processes
- To discover some added values provided by quality audits

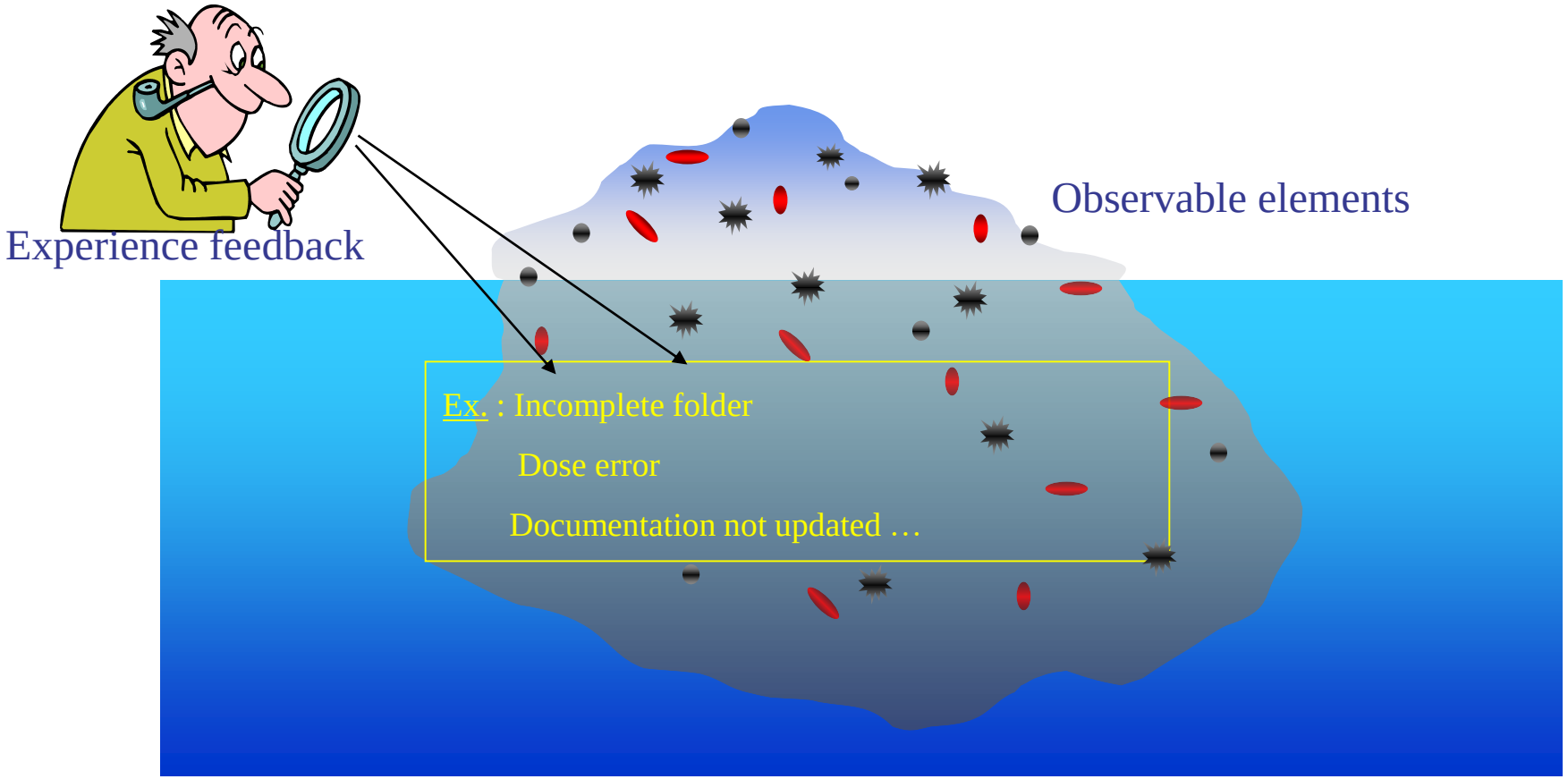
The RT process: radiotherapy is a *treatment* of cancer

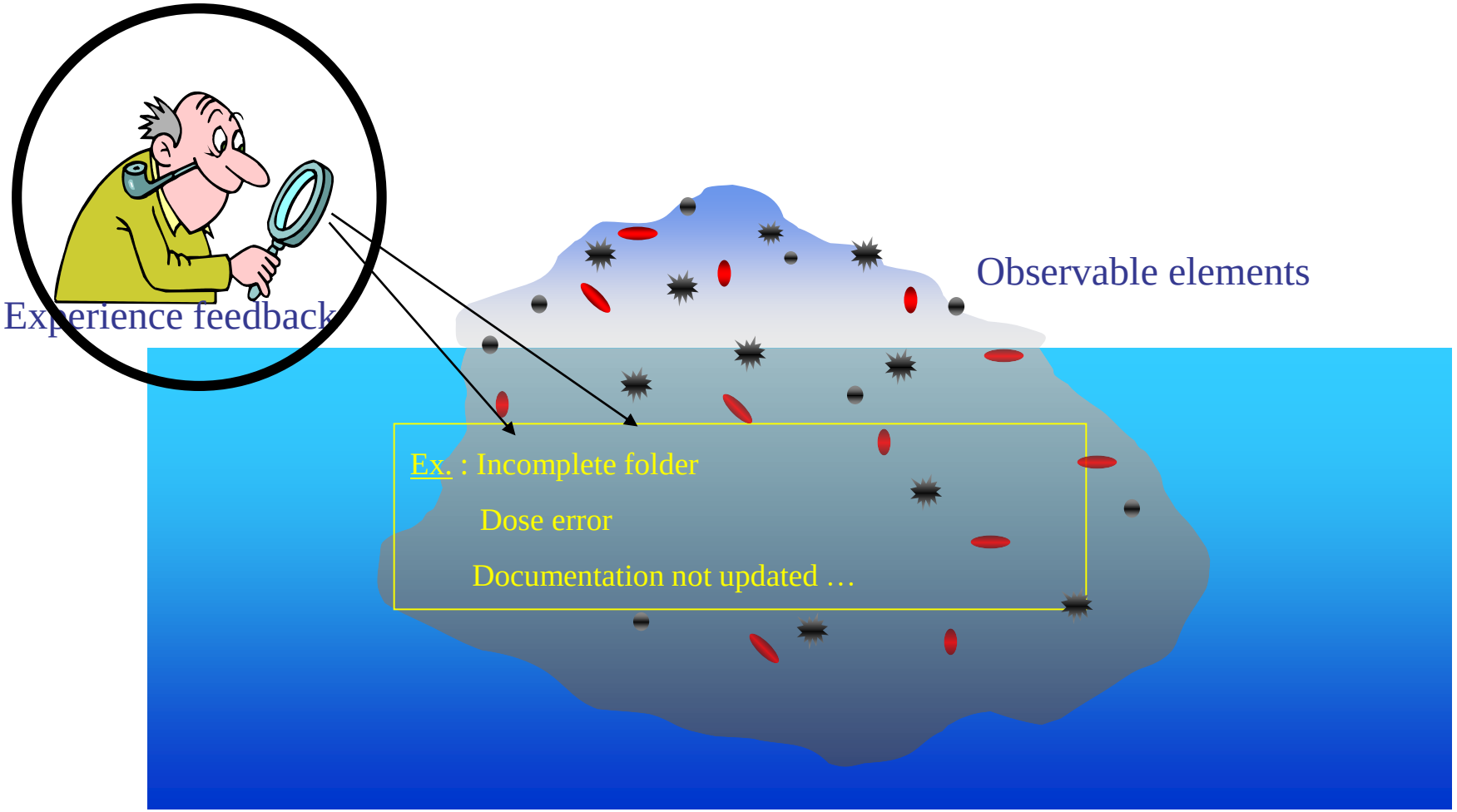
Radiotherapy applies *lethal* doses that are only tolerated because of a strict framework of application.

Aim of clinical audit



Article 6.4 of Council Directive 97/43/ EURATOM


Experience feedback
Observable elements
Ex. : Incomplete folder
Dose error
Documentation not updated …


Experience feedback
Observable elements
Ex. : Incomplete folder
Dose error
Documentation not updated …

Experience feedback

Ex. : Incomplete folder

Dose error

Documentation not updated …

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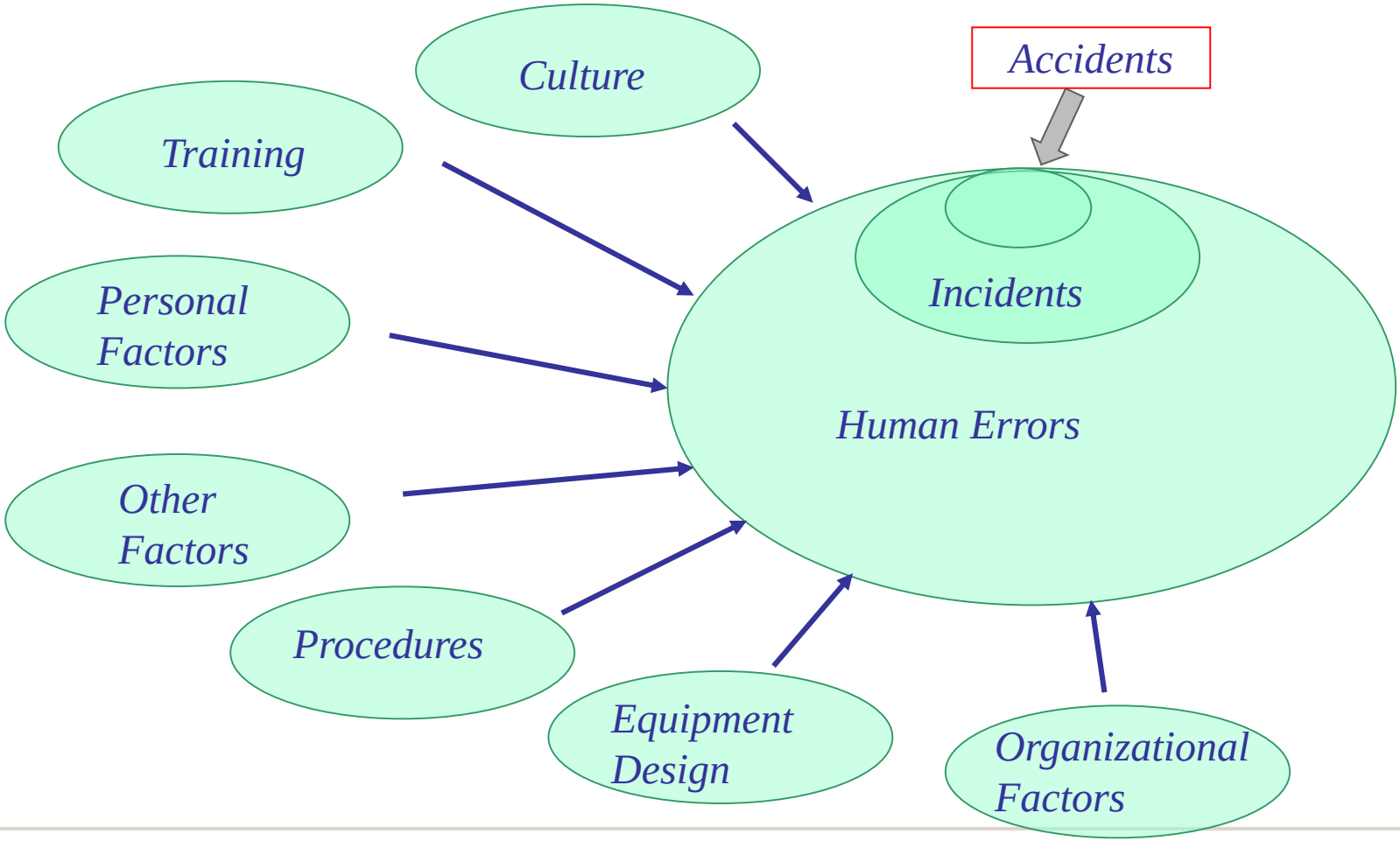
Contributing factors to human error education / training



BSS appendix II.23

"Quality assurance programmes for medical exposures shall include:

…

and

(e) as far as possible, regular and independent **quality audit reviews** of the quality assurance programme for radiotherapy procedures"

Internal versus external audits

An internal audit is us checking on us

For evaluating how well our QM program is performing

For providing the essential feedback to shape and prioritize changes

External audits have the advantages of being perceived as more authoritative

May be problematic

- With a political agenda ‘we need to clean the house’
- Inadequate respect of local circumstances
- Just done poorly …

A Comprehensive QA Program

typically comprises

- Quality Assurance Committee
- Policies and Procedures Manual
- Quality Assurance team
- Quality audit
- Resources

QA Committee Membership

- Must represent the many disciplines within the department
- Should be chaired by the Head of Department
- As a minimum must include a medical doctor, a physicist, a radiotherapy technologist and an engineer responsible for service and maintenance
- Must be appointed and supported by senior management
- Must have sufficient depth of experience to understand the implications of the process
- Must have the authority and access to the resources to instigate and carry out the QA process

Quality Assurance Committee

- Should ‘represent’ the department
- Should be ‘visible’ AND accessible to staff
- Oversees the entire Quality Assurance program
- Writes policies to ensure the quality of patient care
- Assists staff in tailoring the program to meet the needs of the Department (using published reports as a guide)
- Monitor and audit the program to ensure that each component is being performed and documented

QA Team

Includes all disciplines

- Well defined responsibility and reporting structure
- Each member of the team must
  - Know his/her responsibility
  - Be trained to perform them
  - Know what actions are to be taken should a test or action be outside the preset “action levels”

QA Committee review

- Where “Action Levels” have been exceeded
- Where set procedures have been discovered to be faulty
- After a review, recommendations must be formulated in writing for improving the QA program
- When errors are discovered the fault often lies in the process rather than in the action of individuals

- The Committee must meet at established intervals and retain for audit purposes the minutes of its meetings, actions recommended and the results attained.

In short, there is a QA program for the QA Committee

Policies and Procedures Manual

This manual contains clear and concise statements of all the policies and procedures carried out in the Department

- Reviewed (typically) yearly
- Updated as procedures change

Policies and Procedures Manual

As a minimum, sections should exist for

- Administrative procedures
- Clinical procedures
- Treatment procedures
- Physics procedures
- Radiation safety

Policies and Procedures Manual

- It must be “signed off” by the Head of Department and appropriate section heads
- It is important that all staff have “ownership” to the manual - it should reflect the opinions of all and be agreed to by all
- A list of all copies of the Manual and their locations must be kept to ensure that each copy is updated

In the beginning……EORTC Setting the Standard

Workshop of the EORTC Radiotherapy Group on QA in trials (1987): that the group should establish a centralised QA program:

- Site visits to all participating centres
- Mailed dosimetric measurements
- Review of radiotherapy treatment records for individual patients

In the beginning……EORTC Setting the Standard

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- Site visits to all participating centres
- Mailed dosimetric m
- Re treatment records for ind patients

Do we do what we say we do ?

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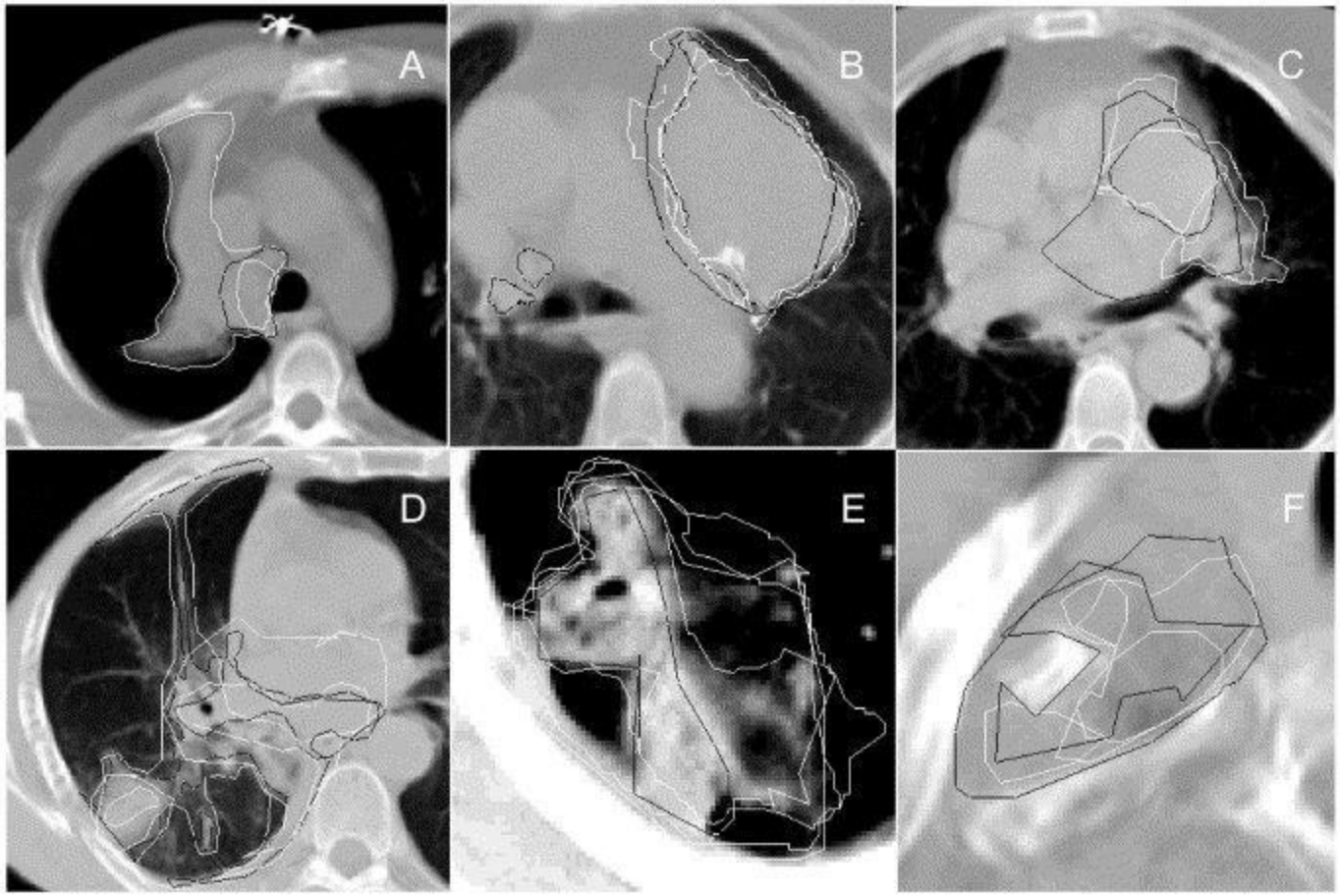
Uncertainty in target volume delineation



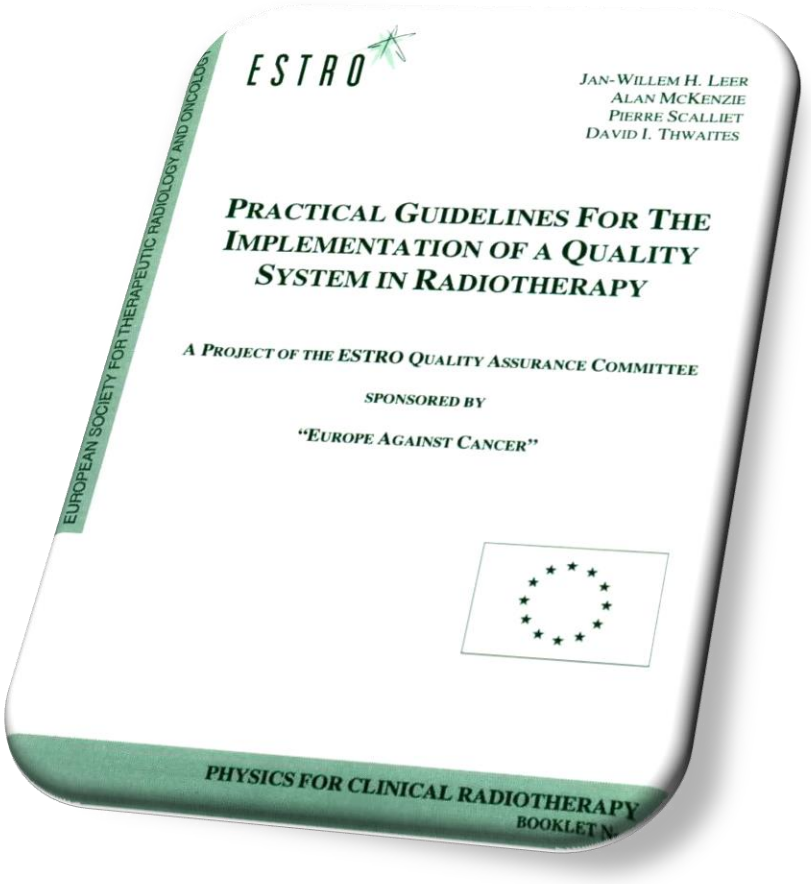
ESTRO 1995

Is based on ISO 9000 requirements.

Has been adapted in several countries, particularely UK, The Netherlands, France…

Has become a requirement in EU countries.

Last chapter: audit.



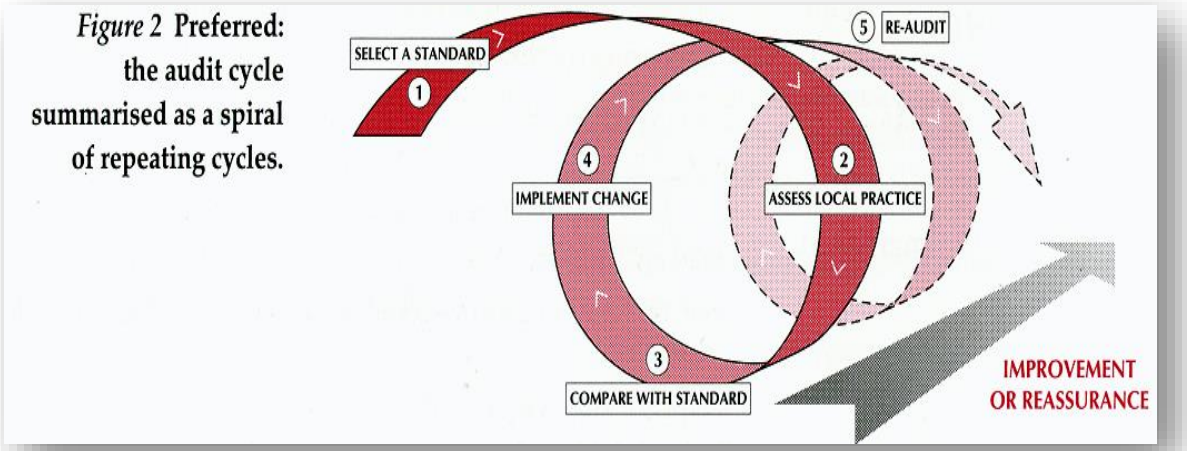
AUDIT: DEFINITIONS

- Necessary part of a comprehensive quality assurance programme
- Independant external evaluation, assessment and peer review
- The interpretation of audit is made against appropriate criteria of good clinical radiotherapy practice (quality standard)

QUATRO

Comprehensive audit of radiotherapy practice: a tool for quality improvement (by IAEA) – 1999-2000

Quality Assurance Team For Radiation Oncology



IAEA
Atoms For Peace

Endorsed by EFOMP, ESTRO, UE

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What is a quality audit?

Quality audit is the process of systematic examination of a quality system by an audit team.

- It is a *process*.
- It is *systematic* (a tool for continuous improvement).
- The presence of a *quality system* is a prerequisite

The process

Observation of practice and concordance
between protocols and practice
is the major component of a clinical audit.
Therefore not too much time is devoted to paperwork (≠ ISO).

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PURPOSE

- For support in their application to become an accredited training centre for a region,
- To receive assistance to improve clinical practice,
- To strengthen their quality assurance (QA) program,
- To receive assistance to ensure that the requirements for patient protection are met,
- To serve as guidance for further departmental development,
- To solicit funding from national authorities or other funding bodies including the IAEA,

NOT designed for :

- Regulatory purpose
- Investigation of accidents or reportable medical events
- Assessment for entry into cooperative clinical research studies

Prerequisites

Comprehensive audit in radiotherapy **is voluntary.** The request originates from the department to be audited, **approved** by the administration, **endorsed** by the head of the department.

The composition of the on-site visit team will depend on the scope, level and expected content of the audit visit, but will usually include as a minimum:

- A radiation oncologist,
- A radiotherapy physicist,
- A radiation therapist[3] (RTT).
- As appropriate, an engineer or other member with special competencies may be included.

The role of the institution

- Prepare data and relevant documentation to enable the auditors to complete evaluation according to the format of this document (Sections 3 – 7),
- Provide material for any requested dosimetry audit
- To identify and assure participation of individuals needed for the audit, although the audit team should be free to interview any staff member they deem appropriate,
- Provide treatment records requested by the audit team, although the audit team should be free to review any records.
- Provide clinical records outside the department relevant to the reviewed cases.
- Inform the entire department and hospital management of the audit and its time.

Aim of the department (by the head)

- Role of the department within the health care system,
- Relationship with neighbouring oncology services (if any),
- Relationship with other specialties within the hospital,
- Role in teaching - undergraduate/postgraduate,
- Role in research,
- Current objectives of the department (as they relate to quality, utilization of resources, institutional approach to patient care) and the documentation to support the objectives,
- Financial structure and source of funding (state, private, etc)
- Vision and future plans.

Premises

- **Location**, size and lay-out, rooms, physicists rooms …
- **Radiotherapy equipment**
  - Full inventory of linacs (number, age …), brachytherapy, IT, dosimetry, immobilisation devices, supporting equipements
- **Communication**
  - Across disciplines, horizontally, vertically …
- **Training programme**
- **Radioprotection** of patients, staff and general public
  - Committee, manual, certification …

Patient demographics

- Number of new (cancer or patients) cases per year (Appendices II and III); use information on new cases registered in cancer registry
- Types of cancer (primary sites and number),
- Stages of disease of the more common tumours,
- Source of information, e.g. cancer registry,
- Ratio of radical (curative) treatment (25 or more fractions) to moderately high dose palliative therapy (10 to 24 fractions) to palliative treatment (<10 fractions),
- Fraction of cancer patients (of the total number in the catchments area) who come for radiotherapy, where the statistical data are available,
- Socio-economic concerns that impact on treatment[6], (payment required by hospital from patients e.g. private, out-of-pocket, government funded (free for patients), co-payment).

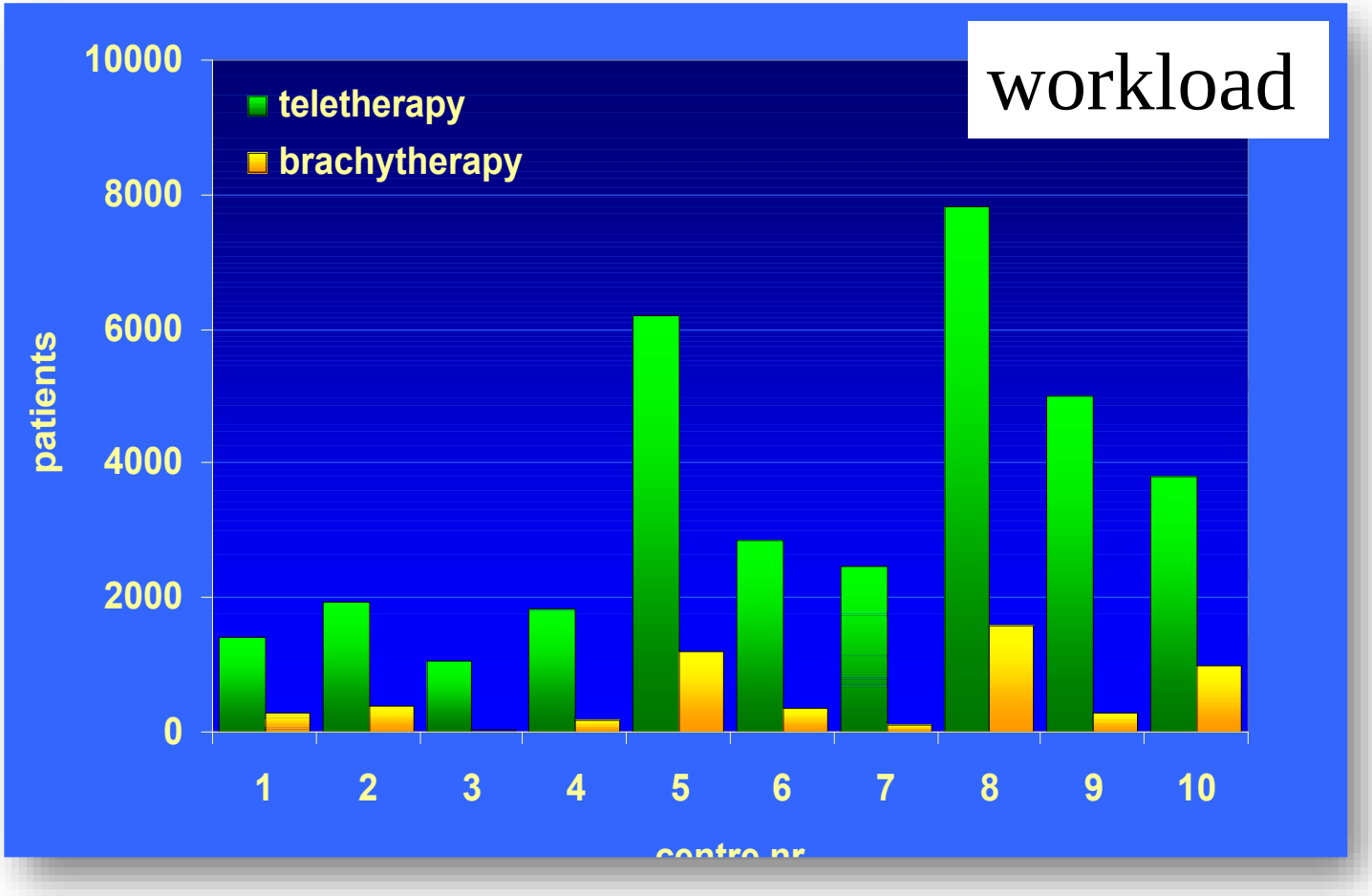
Workload

- Number of new cancer cases[7] or consultations of patients entering the department.

This annual figure can be much larger than the number of treatments with radiotherapy if the department integrates medical oncology and/or haematology.

- Number of new radiation therapy cases treated per annum in the department.
- Number of sessions/fractions[8] given monthly over a one-year period by each teletherapy machine (T),
- Number of applications given annually by each brachytherapy machine (B)[9],
- Annual total of CT scans performed for planning purposes,
- Annual total of simulations performed,
- Annual number of treatment plans generated by computer treatment planning,
- Relative proportion of simple, intermediate and complex treatments each machine delivers,
- Average treatment time on each machine.

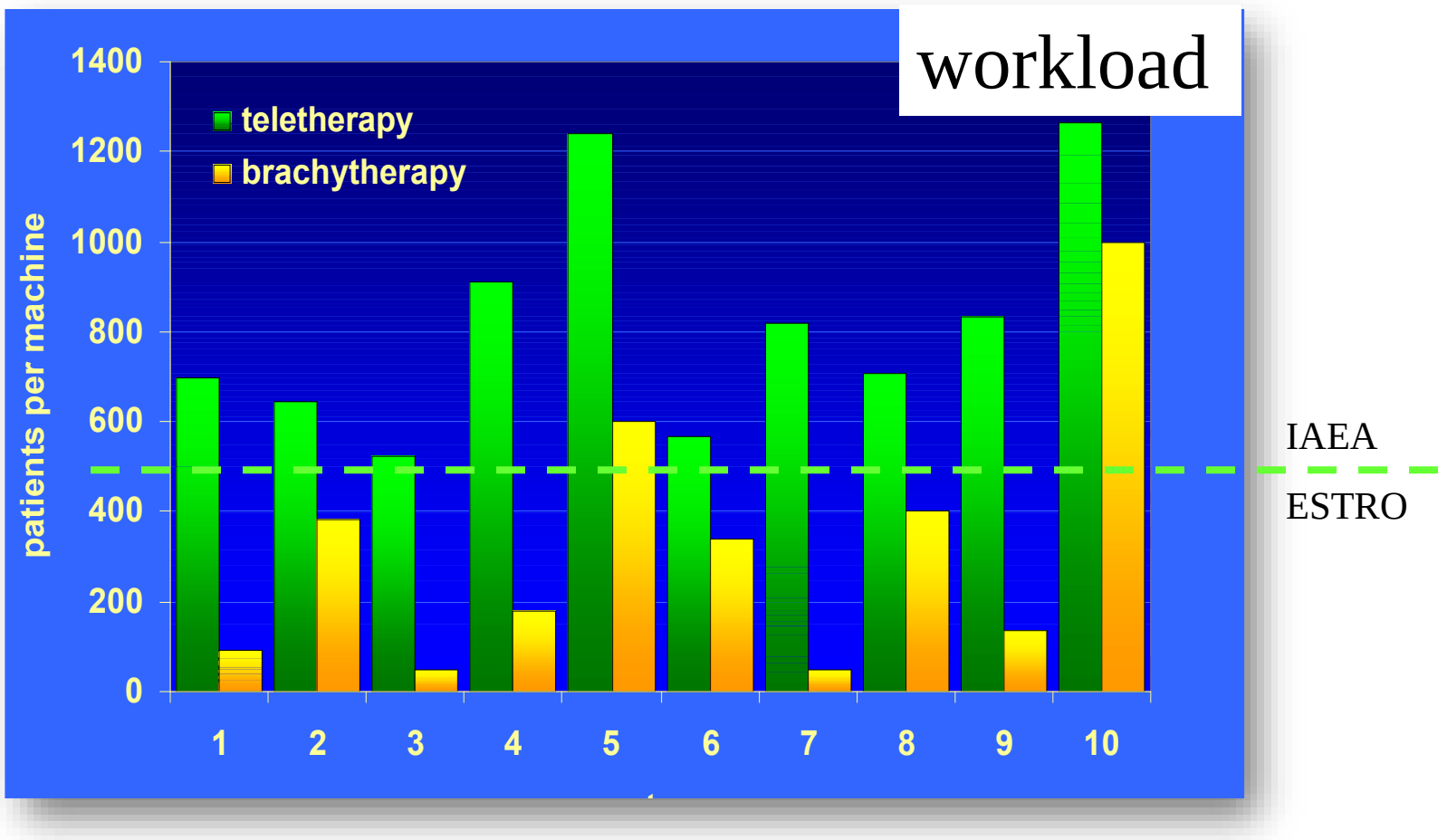
Audited centres profile (1)



Number of cancer patients treated in individual centres

Courtesy P. Scalliet

Audited centres profile (2)



Number of cancer patients treated per RT machine

Courtesy P. Scalliet

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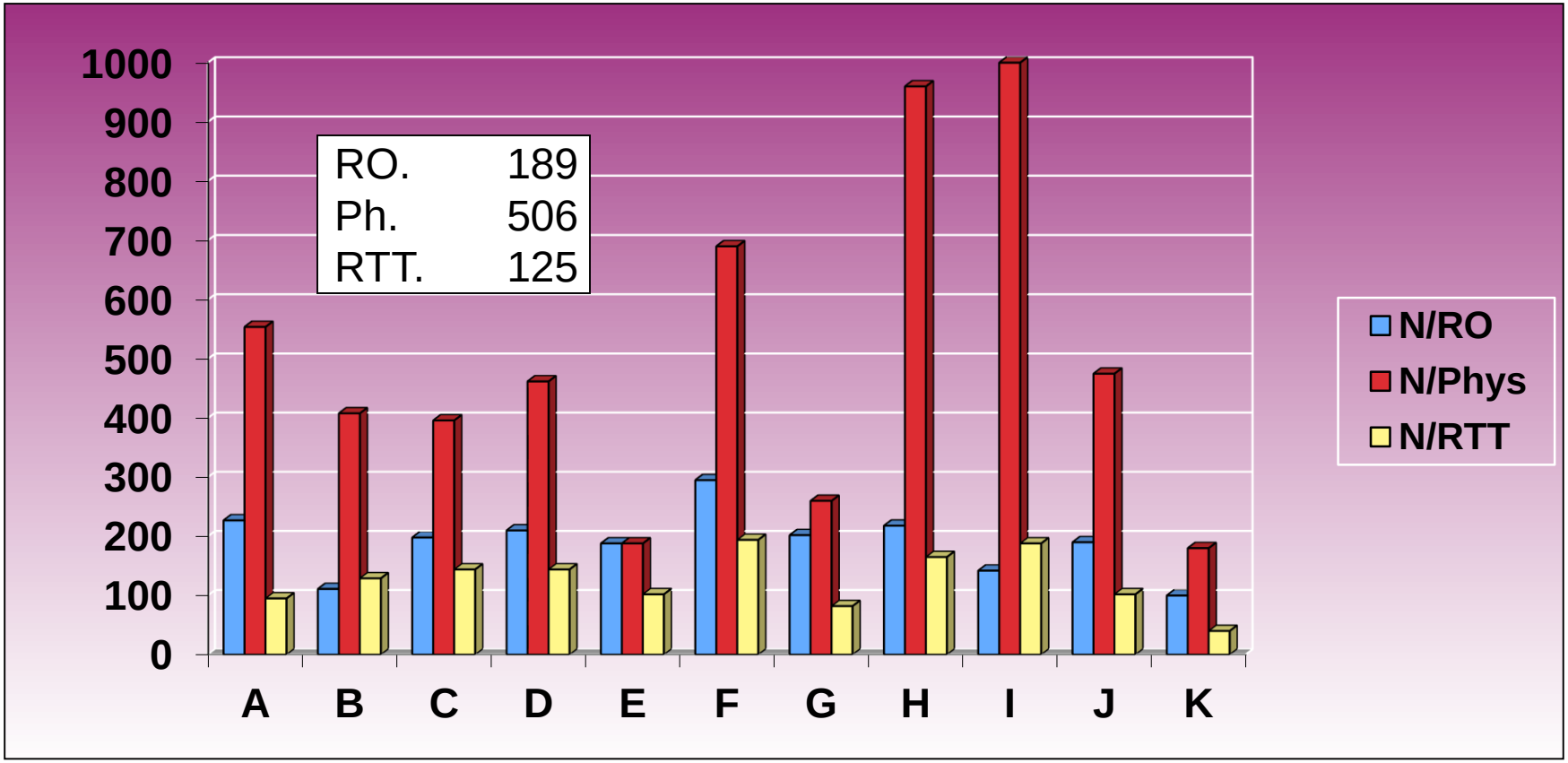
Workload staff EUR



Some RO do chemotherapy as well
Some staff work 6h shifts, other 8h…

Courtesy P. Scalliet

Structure of the radiotherapy department

- Number of radiation oncologists,
- Professional qualifications (degree, specialisation, accreditation, fellowships),
- Additional responsibilities (chemotherapy, nuclear medicine, other),
- Number of medical physicists in radiotherapy including medical physics experts,
- Professional qualifications (degree, specialisation, accreditation, fellowships),
- Additional responsibilities (e.g. diagnostics, radiation protection),
- Number of radiation therapists (RTT),
- Professional qualifications (degree, specialisation, accreditation, fellowships),
- Number of personnel assisting RTTs, e.g. nurses.

Departmental operation

- Treatment hours of the department,
- Days per week of operation,
- Are emergency radiation services provided after hours?
- Minimum number of RTTs for each item of equipment,
- Minimum number of radiation oncologists during treatment hours,
- Minimum number of physicists during treatment hours.

Quality management system

- Quality assurance committee,
- Quality manager (responsible for the programme),
- Frequency of quality review meetings, written minutes,
- Meetings to discuss introduction of new techniques
- Quality Control manuals,
- Directive of actions and triggers,
- QC procedures for each machine,
- QC records including calibrations,
- Documentation of response to out-of-tolerance checks,
- Quality audits (internal/external),
- Training of personnel in the use of equipment.

Indication and decision to treat

Items to be reviewed by the auditor	YES	NO	N/A
Are decisions to treat based upon meetings of multidisciplinary teams (tumour boards)?	☐	☐	☐
If yes, comment on meetings for:			
Every patient	☐	☐	☐
Specific tumours	☐	☐	☐
Frequency			
Meeting location (radiotherapy department, hospital)			
If no multidisciplinary team, who generally refers the patient to the radiotherapy department (general practitioner, specialist)?			
Is the decision to treat inappropriately affected by outside factors? (economical, other specialties, etc.)	☐	☐	☐
Overall comment on multidisciplinary practice			

Level of Scientific Evidence Underlying Recommendations Arising From the National Comprehensive Cancer Network Clinical Practice Guidelines

Thejaswi K. Poonacha and Ronald S. Go

Evidence and Consensus in 10 most common cancers with regard to recommendations for staging, initial and salvage treatment and surveillance.

1023 recommendations in 10 guidelines

- High level of evidence and consensus 6%
- Lower level with uniform consensus 83%
- Lower level without consensus 10%
- Any level of evidence with major disagreement 1%

JCO 2010;29:186-191

Data transfer from planning to delivery

Items to be reviewed by the auditor	YES	NO	N/A
Are simulation or virtual simulation images agreed prior to treatment course?	☐	☐	☐
Data transfer from planning to delivery			
Manual transfer	☐	☐	☐
Automatic transfer	☐	☐	☐
Record and verify system	☐	☐	☐
Is the data transfer double-checked?			
Frequency of checks			
Person in charge			
Comment (include QA, medical physics input)			

An Evaluation of Departmental Radiation Oncology Incident Reports: Anticipating a National Reporting System

Stephanie A. Terezakis, MD,* Kendra M. Harris, MD, MHS,* Eric Ford, PhD,*,† Jeff Michalski, MD,‡ Theodore DeWeese, MD,* Lakshmi Santanam, PhD,‡ Sasa Mutic, PhD,‡ and Hiram Gay, MD‡

Table 3 Most common events recorded in the incident reporting systems with potential clinical consequences

Incident type	Maximum severity	Error type	No. of incidents
Mismatch in Data Systems	4	Hu-S	38
Incorrectly Identified DRRs	4	Hu-S	30
Incorrect Shifts	4	Hu	27
Suboptimal Treatment Plan	4	Hu	25
Manual Data Entry Errors	4	Hu-S	24
Inadvertent Treatment Parameter Change	4	Hu-S	12

Abbreviations: Hu = human alone; Hu-S = human-software interaction.

IJROBP 2013;85:919-923

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Deviation in radiotherapy administration

Items to be reviewed by the auditor	YES	NO	N/A
What would be regarded and not regarded as an incident?			
Is the treating physician immediately notified of an incident?	☐	☐	☐
Is there a systematic reporting of incidents to a hospital committee?	☐	☐	☐
Is this verbal or written?	Verbal ☐	Written ☐	☐
How is a written report dealt with?			
Is a decision taken on the significance of the deviation?	☐	☐	☐
If so, is a significant deviation reported to regulatory authorities?	☐	☐	☐

Radiation physicist procedures

QA programme

- Quality Assurance Manual
- Acceptance procedures
- Commissioning procedures
- QC programme (tests, frequencies, responsible persons, action levels, actions)
  - warm-up procedure
  - geometry accuracy, couch and lasers
  - image quality (low and high contrast resolution etc)
  - data display, data transfer, data manipulation
  - accuracy and stability of CT numbers

Incident logbook

Repair and maintenance programme

- logbook
- frequency
- person in charge of repair
- procedure to accept repair

General condition of equipment and room

Radiation Therapy technologist procedures

Radiation oncology quality assurance committee

RTT representative	☐	☐
Process to review errors and near misses	☐	☐
RTTs procedure for the reporting of error	☐	☐
"No-blame" policy	☐	☐
Feedback mechanism	☐	☐
Mechanism for corrective action and RTT involvement	☐	☐
Mechanism for the implementation and monitoring of change	☐	☐

The RT process: radiotherapy is a *treatment* of cancer

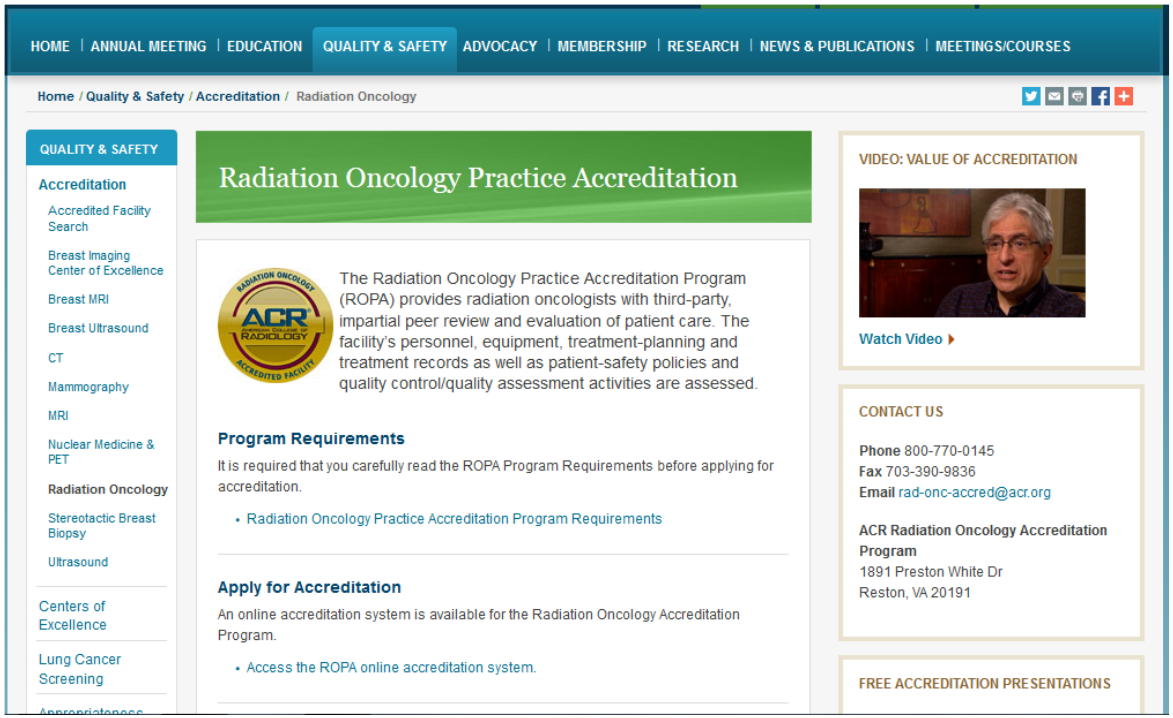
Results

The result is a report!

Structure of the report

- Objectives of the audit,
- A brief description of audit activities,
- Description of the facility (infrastructure, workload),
- Findings and results of the visit (includes checklist),
- Benchmarking if appropriate,
- Conclusions,
- Recommendations (to the institution, to the IAEA, to the government),
- Annexes.

ACR-ASTRO accreditation program



American College of Radiology: Radiation oncology accreditation program. Available at: http://www.acr.org/Quality-Safety/Accreditation/RO; Accessed September 23, 2012.

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Clinical Audits in Europe

- IN THE NETHERLANDS:
  - NVRO / NVKF = Evidence-based QA and treatment guidelines
  - Quality and training audits by independent committees
  - 2011-2012: National quality standards for radiotherapy departments and multi-disciplinary standards for cancer care
  - Quality of Patient care, functioning of the staff, strategic plan

- IN UK:
  - Audit culture since the 90ths
  - IPEM, Dosimetry, NCRI RT Trial QA group, National Physical Laboratory, UK SABR consortium

Clinical Audits in Europe

- In ITALY: Italian audit on dosimetry for SBRT

- In GERMANY:
  - QUIRO: project for assurance of quality and innovation in radiation therapy
  - Promotion of quality guided innovation
  - Web based documentation of all steps from planning to delivery

- In Switzerland, in France …

Conclusion of First 10 audits in Europe

A. The institution operates the radiotherapy services at the internationally accepted level: 2/10 centres

B. The audit team has identified areas for improvement, resolvable by the institution: 5/10 centres

C. There are underlying major problems that cannot be resolved without significant resources: 3/10 centres

B, C ☞ follow-up audits

QUATRO / IAEA clinical audits

Courtesy P. Scalliet

Trial Credentialing

Coen Hurkmans

QA RT Harmonisation in clinical trials

EORTC

catharina ziekenhuis

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Learning objectives

After this talk, one should be able to:

- Recognize various sorts of trial deviations
- Describe how trial deviations can impact trial outcome
- Recall the RTQA levels used for clinical trials
- Value the information collected by Facility Questionnaires
- Recognize the importance and diversity of Beam Output Audits

QA makes a trial stronger

Why is protocol compliance important in clinical trials?

Interpretation of results from study of clinical trials.

Reliability of results

Robusteness of results

Generalizability of results

Trial protocol ⟺ procedure / quality standard

Trial QA:pass/fail ⟺ quality indicators

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RTOG 00-22 MULTI-INSTITUTIONAL TRIAL OF ACCELERATED HYPOFRACTIONATED INTENSITY-MODULATED RADIATION THERAPY FOR EARLY-STAGE OROPHARYNGEAL CANCER

69 patients included

	n	%
Overall		
Minor variation	47	70
Major variation	6	9
Inevaluable	14	21
PTV66		
Minor variation	48	72
Major variation	5	7
Inevaluable	14	21
PTV60		
Not applicable	34	51
No variation	1	1
Minor variation	26	39
Major variation	1	1
Inevaluable	5	7
PTV54		
No variation	10	15
Minor variation	40	60
Major variation	3	4
Inevaluable	14	21
Parotid gland		
No variation	61	91
Minor variation	3	4
Inevaluable	3	4

Outcome	LR Failure *n*= (%)	*p*
Major Deviation (underdose)	**2/4 (50%)**	**0.04**
No Major Deviation	**3/49 (6.1%)**	

Eisbruch A et al. IJROBP 2010 Apr;76(5):1333-8.

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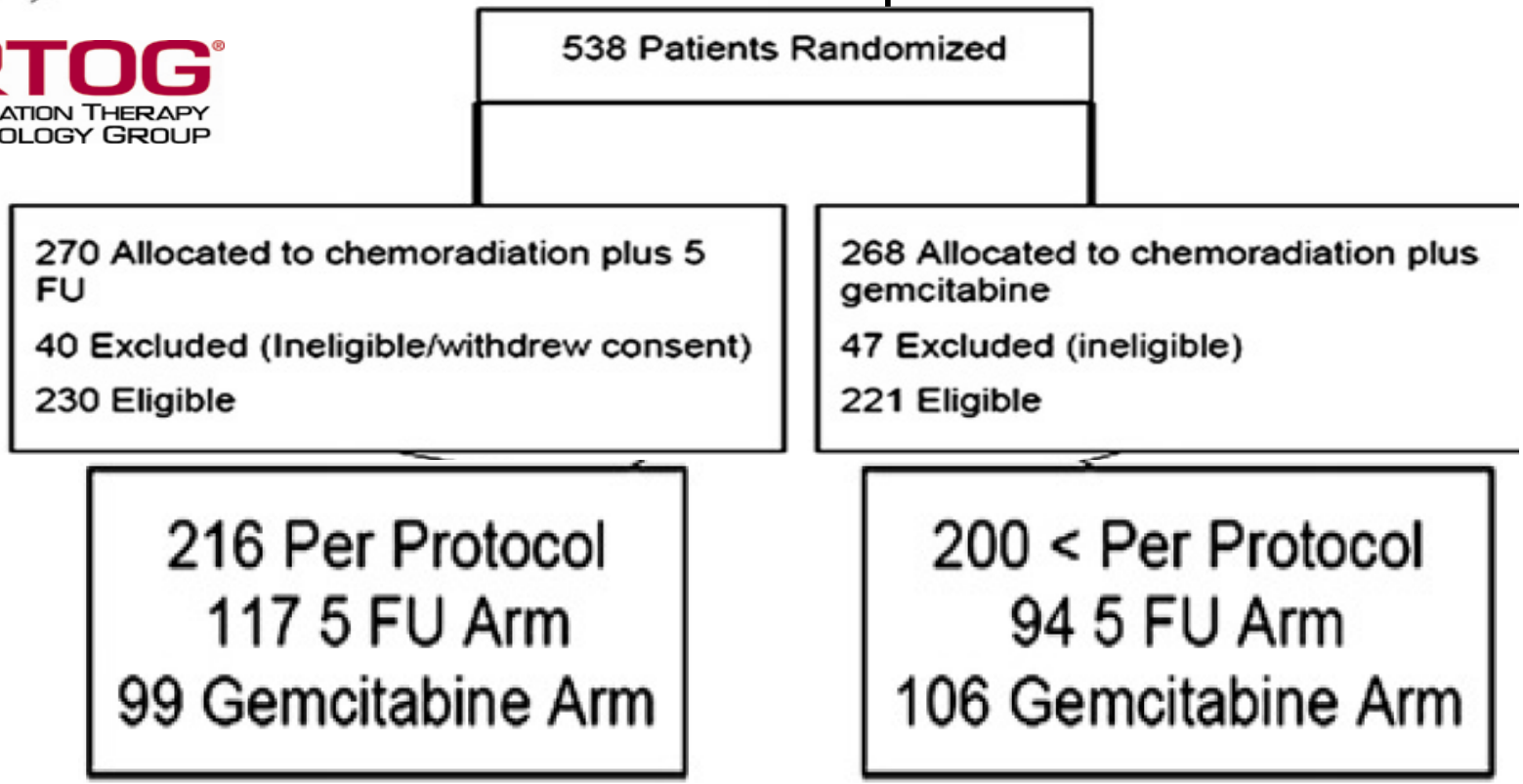
Phase III chemo 5FU vs. GEM after ChemoRT in resected pancreatic cancer

RTOG
RADIATION THERAPY ONCOLOGY GROUP



Abrams RA, et al. IJROBP 2012;82:809-16.

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Variation	Initial treatment or boost treatment	Frequency	
Field placement or size	Initial	140	70%
Dose administered	Initial	14	
Dose per fraction	Initial	6	
Elapsed treatment time	Initial	26	
Field placement or size	Boost	127	64%
Dose administered	Boost	12	
Dose per fraction	Boost	3	
Elapsed treatment time	Boost	14	

Abrams RA, et al. IJROBP 2012;82:809-16.

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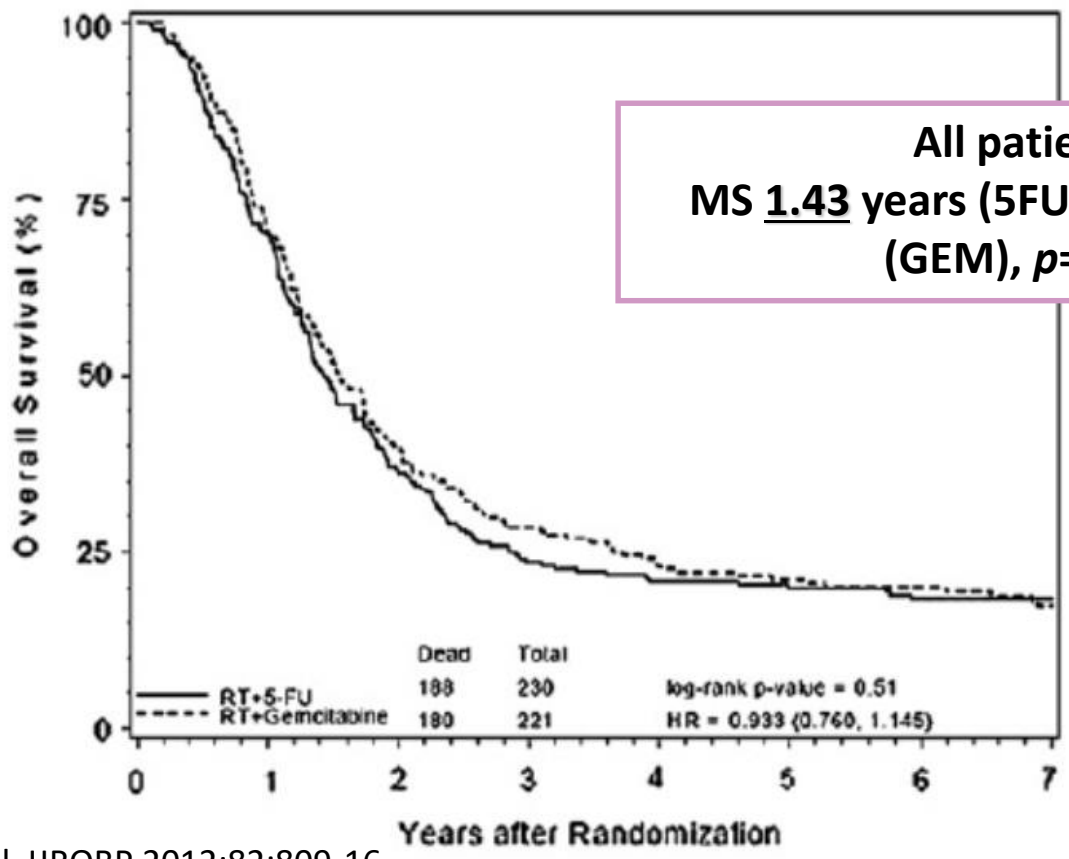
Do deviations from protocol-defined requirements have an impact on patient's outcome?



All patients
MS 1.43 years (5FU) *vs.* 1.55 years (GEM), *p*=0.51

Abrams RA, et al. IJROBP 2012;82:809-16.

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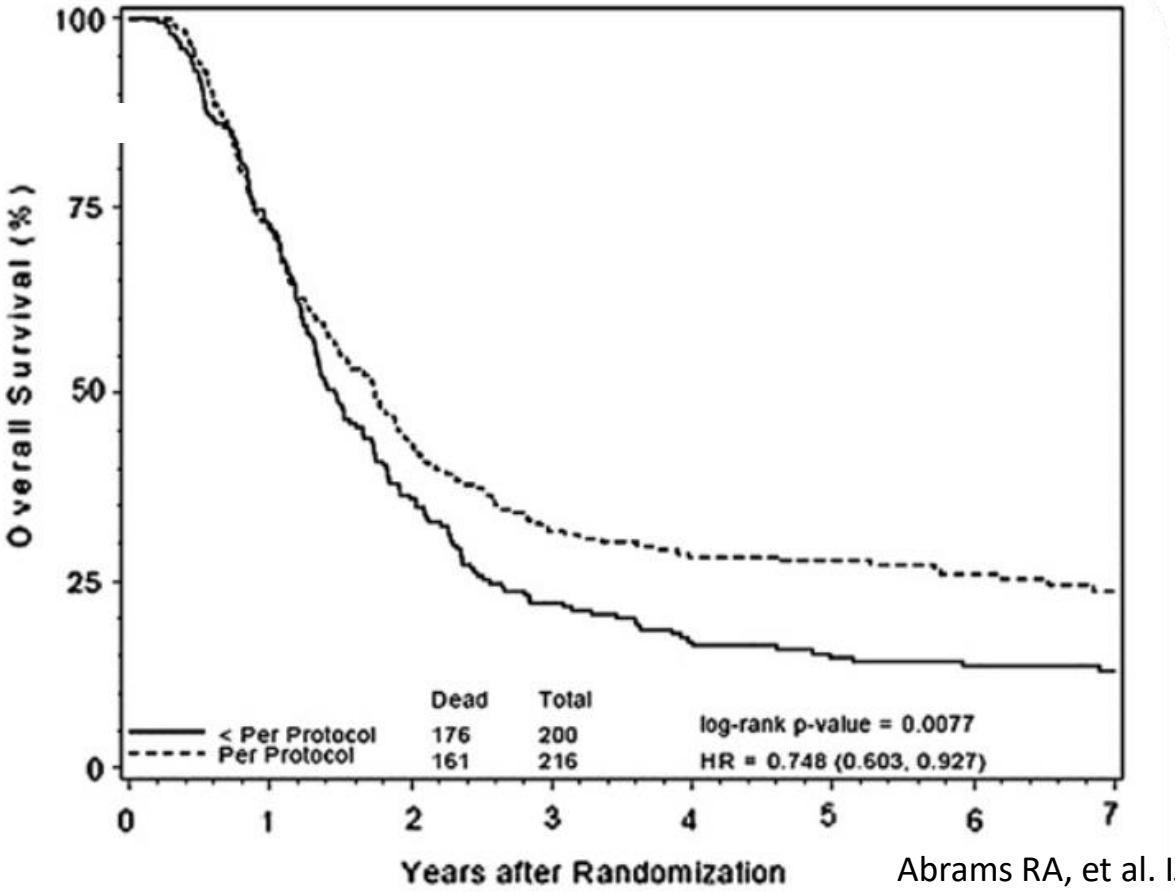
Median Survival 1.74 years (Per Protocol)
***vs.* 1.46 years (not Per Protocol), *p*=0.008**



Abrams RA, et al. IJROBP 2012;82:809-16.

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Multivariate analysis: Overall Survival

Adjustment variables	Comparison	Adjusted HR	*p* value[†]
Treatment	Gemcitabine vs. 5-FU	0.79 (0.62–0.99)	0.043
Nodal involvement	No vs. yes	1.47 (1.13–1.91)	0.0036
Tumor diameter	<3 vs. ≥3 cm	1.25 (0.98–1.59)	0.070
Surgical margin status	Negative	Reference level	–
	Positive	1.07 (0.82–1.40)	0.64
	Unknown	0.94 (0.69–1.27)	0.68
RT QA score	<PP vs. PP	0.75 (0.60–0.95)	0.016

Abrams RA, et al. IJROBP 2012;82:809-16.

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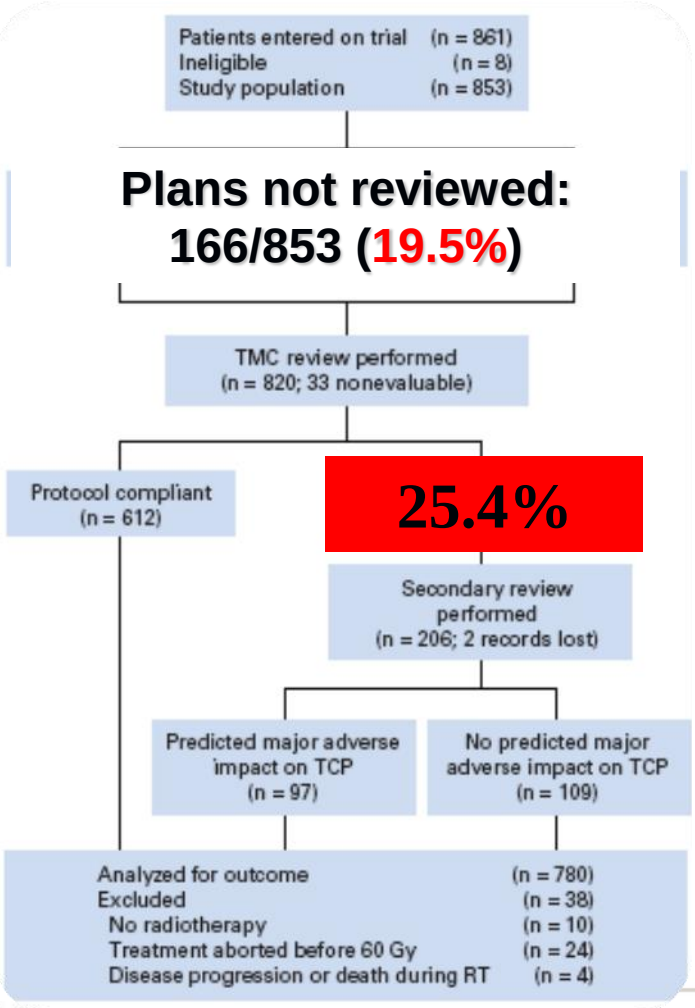
H&N phase III trial Tirapamazine N=861 patients



Peters LJ et al, JCO. 2010, 28(18):2996-3001.

QA makes a trial stronger

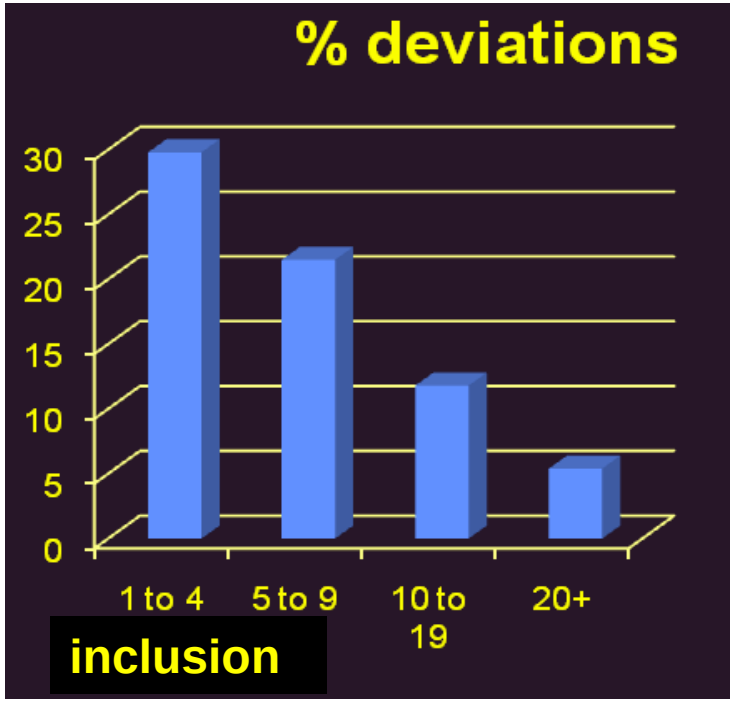
97 deviations with predicted major impact on TCP

Type of deviation	n
Incorrect Target definition	24
Dose distribution inadequate	41
Incorrect dose prescription	25
Prolonged treatment	7

Peters LJ et al, JCO. 2010, 28(18):2996-3001.

QA makes a trial stronger

Factor	No. of Patients	Number With Major Adverse Impact	%
Country			
Western Europe C	39	0	0.0
Oceania A	154	8	5.2
North America A	101	6	5.9
Eastern Europe A	48	5	10.4
South America A	54	6	11.1
Western Europe B	67	8	11.9
Western Europe E	25	3	12.0
Oceania B	16	2	12.5
Western Europe A	127	17	13.4
South America B	42	6	14.3
Eastern Europe B	28	4	14.3
North America B	63	10	15.9
Western Europe D	30	5	16.7
Western Europe F	6	2	33.3
Western Europe G	4	2	50.0
Eastern Europe C	14	13	92.9
Enrollment bracket			
1-4 (26 centers)	57	17	29.8
5-9 (22 centers)	130	28	21.5
10-19 (22 centers)	279	33	11.8
≥ 20 (11 centers)	352	19	5.4



Peters LJ et al, JCO. 2010, 28(18):2996-3001.

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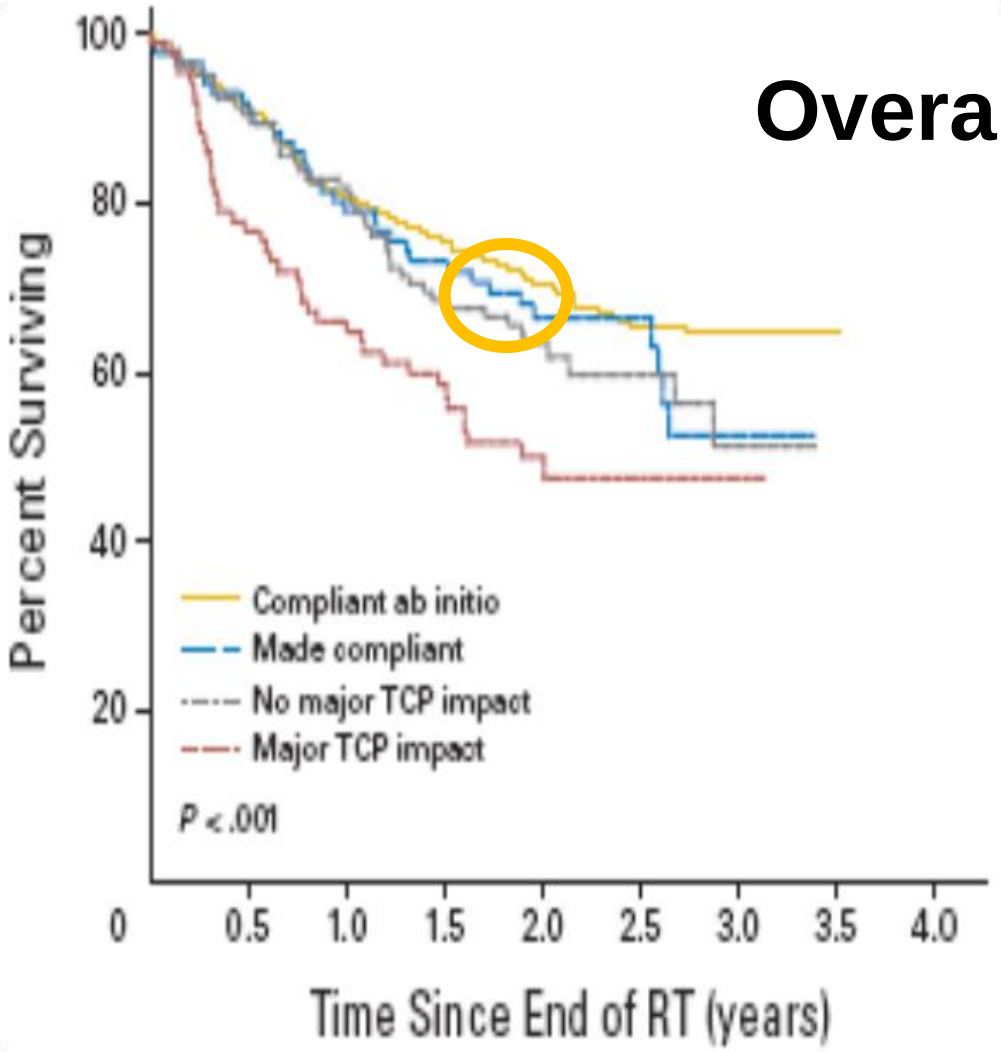

Peters LJ et al, JCO. 2010, 28(18):2996-3001.

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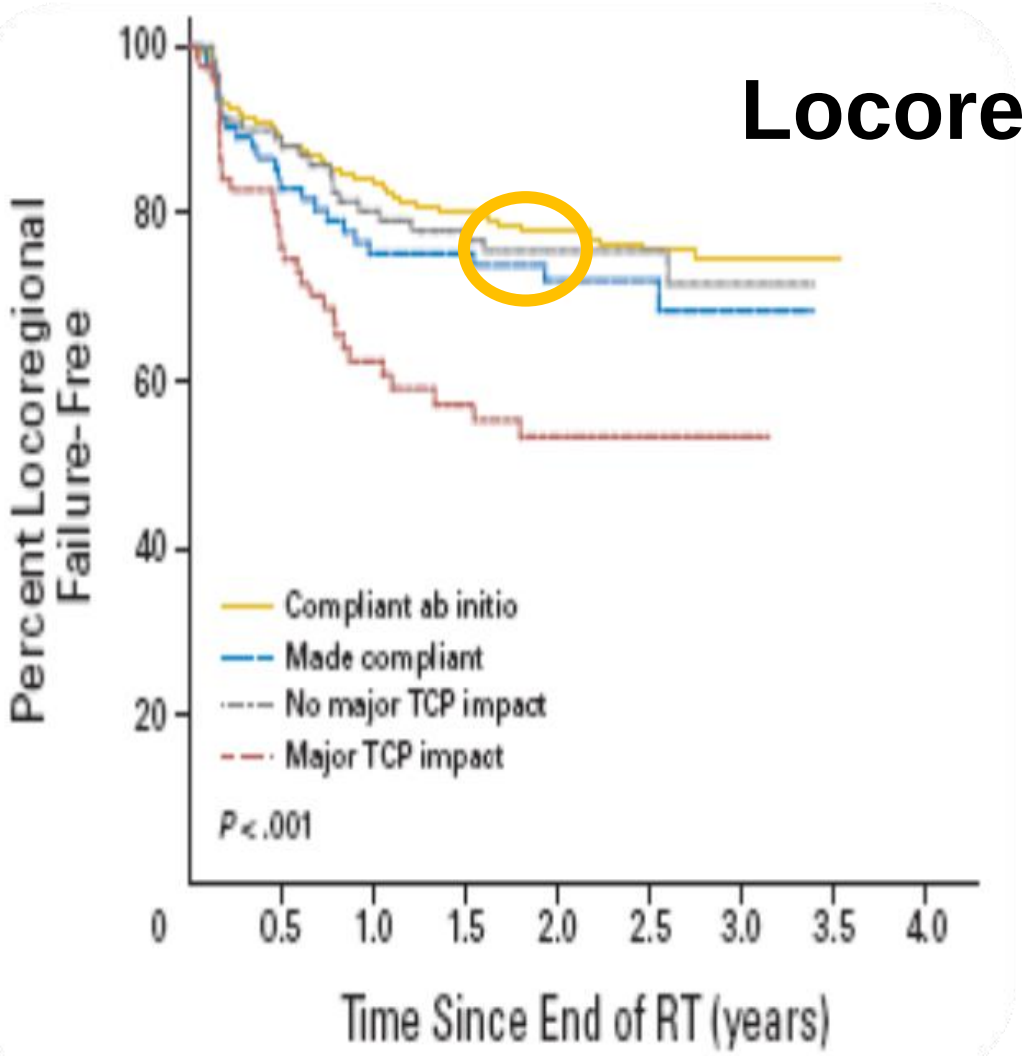

Peters LJ et al, JCO. 2010, 28(18):2996-3001.

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Multivariate analysis

Predictor		p
Major deviations		0.04 (OS) 0.01 (TTLRF)
Tumor site	Oropharynx/larynx vs. Oral cavity/hypopharynx	-
Hb level	< 13.5 g7dL vs. ≥ 13.5 g/dL	-

Peters LJ et al, JCO. 2010, 28(18):2996-3001.

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Study [ref]	Years of randomization	Major deviations (tumor)	Major deviations (normal tissues)
HD 4 [5] HD 7 [9]	1988–1993 1994–1998	• Excessive or incomplete tumor coverage by radiation • Total dose <90% or >110% of the prescribed dose • Dose administered too slowly • Technical deficiency	ND
HD 10-HD 11 [7]	1998–2002	• Deviation in the target volume delineation in a primary involved region • 90%-Isodose surface not encompassing the planning target volume • Total delivered dose of ±10% of the prescribed randomized dose • Overall treatment time exceeding the normal treatment time by 10%	ND
EORTC 20884 [2]	1989–2000	• Omission or partial irradiation of an originally involved region • 90% isodose-surface not covering the target volume	ND
RTOG 0411 [4]	2005–2006	• The inability to delineate gross tumor volume	• Contoured gross tumor volume >5 cm greater than the actual tumor size on the basis of diagnostic imaging • The use of block margins >5 cm
RTOG 9704 [1]	1998–2002	• Dose delivered not within ±10% of the prescribed dose	ND
RTOG 0022 [8]	2001–2005	• The prescription criteria for PTV66 are not met: 60 Gy isodose does not cover ⩾90% of PTV66. Also the 72.6 Gy isodose surface covers >25% of PTV66 • The prescription criteria for PTV60 and PTV54 are not met: 47-Gy isodose surface does not cover ⩾99% of PTV54 and the 54-Gy isodose surface does not cover ⩾90% PTV54. The 52-Gy isodose surface does not cover ⩾90% of PTV60 and the 72.6-Gy isodose covers >20% PTV54 and PTV60	• 60% of both parotid glands receive >30 Gy
TROG 0202 [15]	2002–2005	• Dose per fraction <2 Gy • Gross disease treated <66.6 Gy • D10% <66.5 Gy or >75 Gy (PTV)	• Dose Spinal cord >50 Gy • Volumes and doses to noninvolved normal tissues must not be excessive

Abbreviation: ND: not defined.

Weber D et al, Radiother Oncol. 2012 Oct;105(1):4-8.

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Study [ref]	Type of QA	Number of cases evaluated *n* (%)	Minor deviations *n* (%)	Major deviations *n* (%)	Technical issues with QA review *n* (%)	Impact on clinical outcome	*p* Value
HD 4 [5]	R	368 (98.0)	–	141 (37.5)*	8 (2.1)	7-year RFS with D: 72% *vs.* 7-year RFS with no D: 84%	0.004
EORTC 20884 [2]	R	135 (88.8)	–	63 (46.7)	46 (30.3)	5-year RFS with D: 90% *vs.* 5-year RFS without D: 84%	0.31
RTOG 0411 [4]	R	NS	–	13 (13.4)	NS	Grade GI ⩾ 3 toxicity with D:45%‡ *vs.* Grade GI ⩾ 3 toxicity without D:18%‡	0.05
RTOG 9704 [1]	R	416 (92.2)	–	200 (48.0)**	14/35 (40.0)†	mOS with D: 1.46 yo *vs.* mOS without D: 1.74 yo	0.008
RTOG 0022 [8]	R	67 (97.0)	47 (89.0)	6(11.0)	14/67 (21.0)	LRF with major D: 50% *vs.* LRF with no major D: 6%	0.04
TROG 0202 [15]	P & R††	687 (80.5)‡‡	–	97 (11.8)	33/820 (4.0)	OS with major D: 70% *vs.* OS without major D: 50%	<0.001

Weber D et al, Radiother Oncol. 2012 Oct;105(1):4-8.

QA makes a trial stronger

Factors affecting RTQA in clinical trials?

Phase III trials for which the patient accrual metric per center was significantly associated with radiotherapy protocol deviations.

Study [ref]	Type of tumor	Number of patients *n*=	Cutoff number patients per center/observed deviation	*p* value
HD 4 [5]	Hodgkin lymphoma	376	10	0.005
TROG 0202 [15]	Advanced H&N SCC	818	20	< 0.001

Abbreviations: H&N SCC: Head and Neck squamous cell carcinoma.

Weber D et al, Radiother Oncol. 2012 Oct;105(1):4-8.

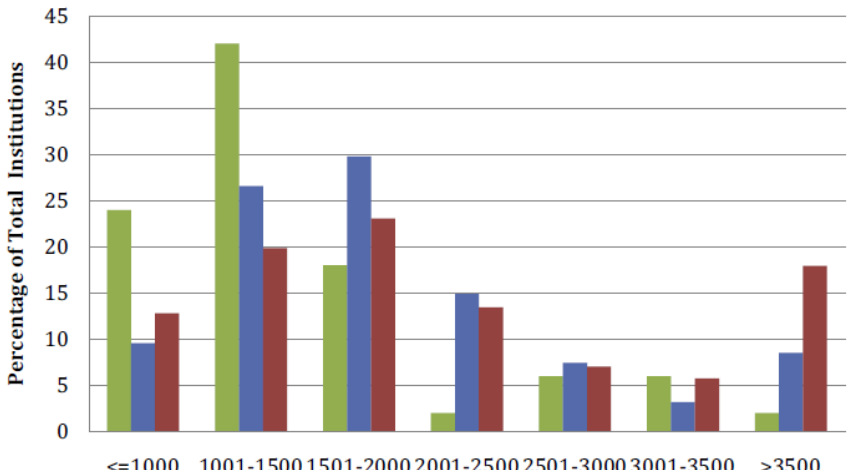
Levels of RTQA

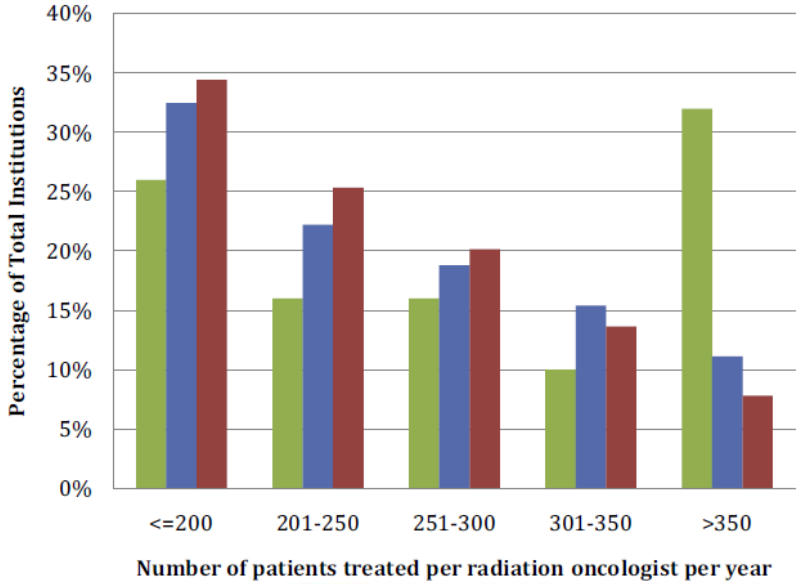
1. Facility Questionnaire (FQ)
   Beam output Audit (BOA)
2. Benchmark Case (BC)
3. Retrospective Individual Case Review (R-ICR)
4. Prospective Individual Case Review (P-ICR)
5. Complex Treatment Dosimetry Check
   Virtual Phantom Procedure

FQ: Why

- Contact Information
- Information on workload and equipment
  - Used to see if sites are potentially able to participate in a trial
  - Used to try to predict potential trial accrual
- Information on trial(s) participation and previous credentialing
  - Potential to predict ability to adhere to trial protocol

FQ: RT departments' improve





- Increasing number of patients and professionals
- Reduction number of patients per professional/machine per year

	Mean	Median
2013 (156 institutions)		
No. megavoltage units	5.3	4
No. patients per unit per year	468.6	450
No. patients per simulator/year	1622.9	1542
% inst. with dedicated CT	92	
% inst. with IMRT capability	94	
% inst. with SBRT capability	65	
2007 (98 institutions)		
No. megavoltage units	3.9	3
No. patients per unit per year	488.0	456
No. patients per simulator/year	1117.0	1038
% inst. with dedicated CT	86	
% inst. with IMRT capability	79	
% inst. with SBRT capability	54	

Grant W, Radiother Oncol. 2014; 112(3):376-380

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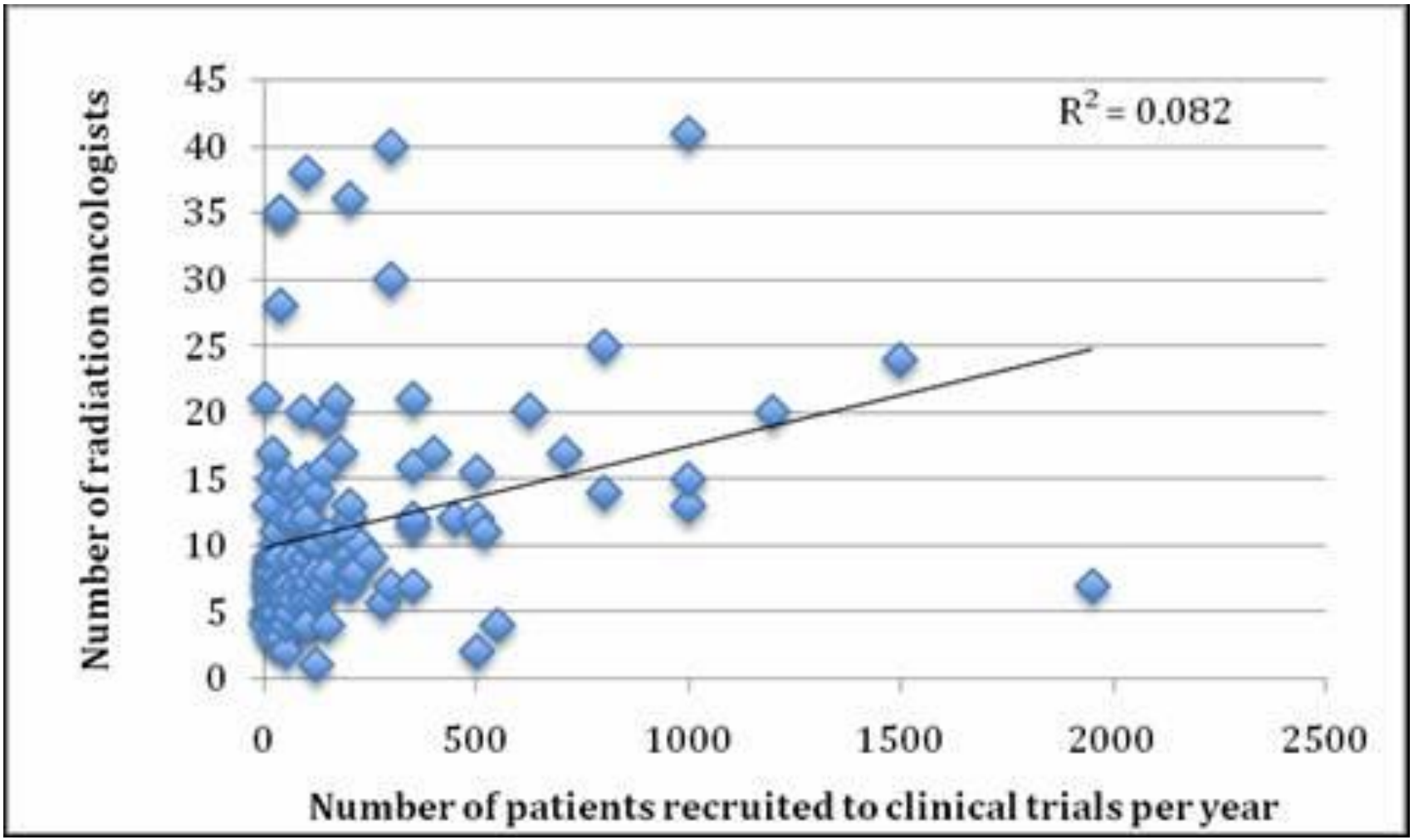
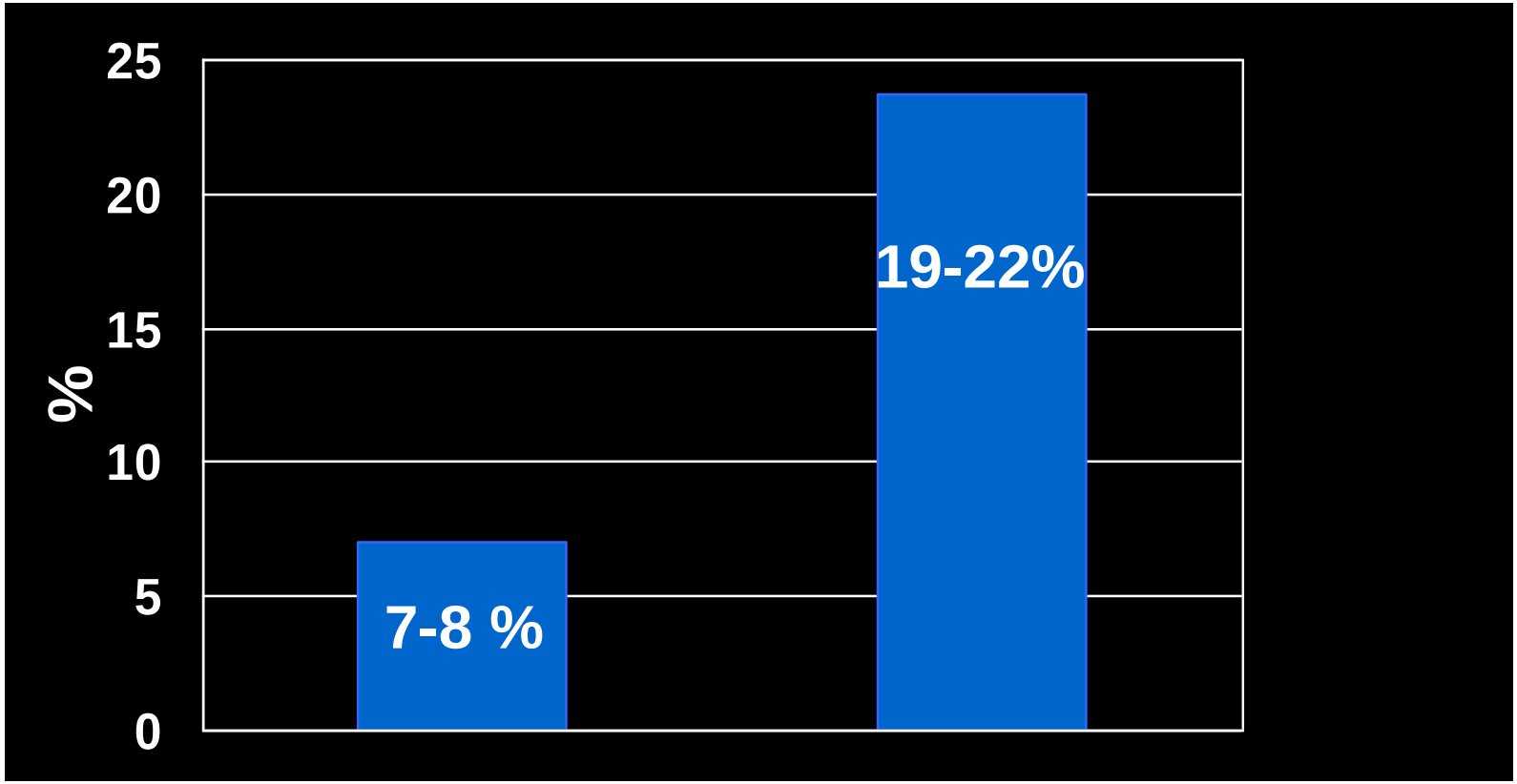
FQ


Number of radiation oncologists
45
40
35
30
25
20
15
10
5
0
$R^2 = 0.082$
0
500
1000
1500
2000
2500
Number of patients recruited to clinical trials per year

Beam Output Audit (BOA)

Clinical effect in 10% of beams with lowest and highest output



114 beams in 35 institutions

Bentzen, EJC, 36: 615, 2000

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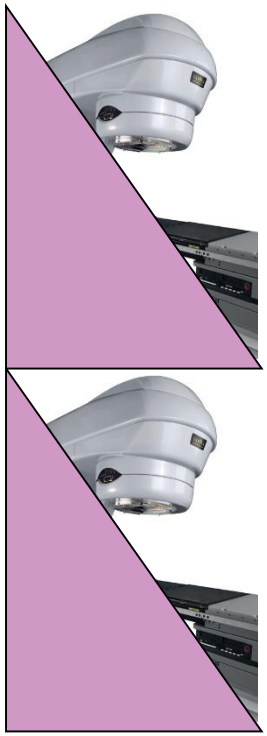
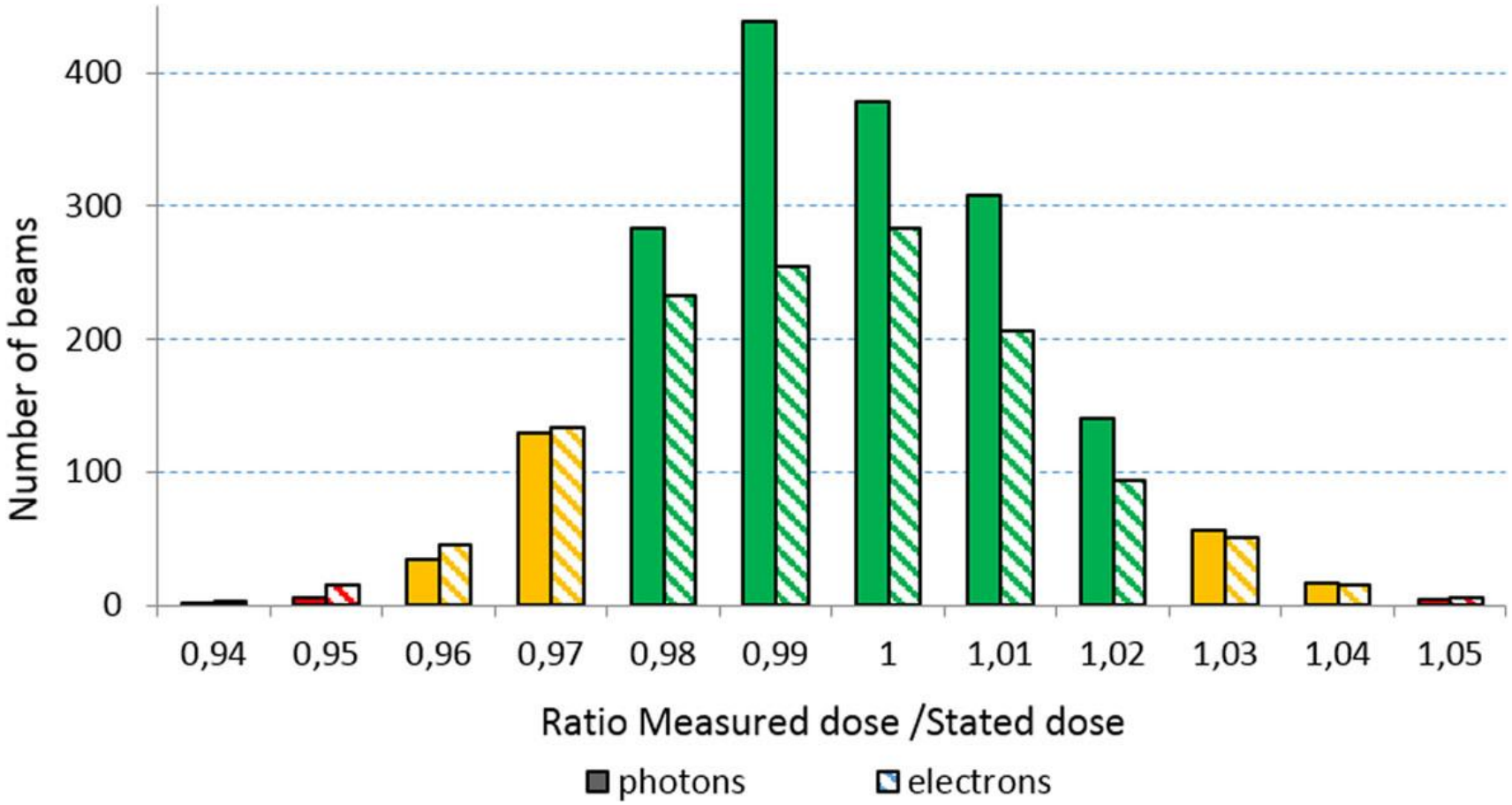
BOA – minimum requirements

BOA – minimum requirements



BOA – minimum requirements



Hurkmans et al, RadOnc, 2016

Conclusions

- Data stemming from prospective clinical trials shows that non-adherence to protocol-specified RTQA requirements are frequent
- Failure to adhere to protocol RT guidelines is associated with patient's suboptimal outcome
- Non-protocol complient trials may waste time, effort and money and could more importantly harm patients.
- Quality assurance levels are defined for RT trial QA to decrease trial non-compliance

Further reading

- Weber DC et al, Quality assurance for prospective EORTC radiation oncology trials: The challenges of advanced technology in a multicenter international setting, Radiotherapy and Oncology 100 (2011) 150–156
- Bekelman JE, et al. Redesigning Radiotherapy Quality Assurance: Opportunities to Develop an Efficient, Evidence-Based System to Support Clinical Trials-Report of the National Cancer Institute Work Group on Radiotherapy Quality Assurance. *Int J Radiat Oncol Biol Phys* 2012 Mar 15.
- Fairchild A et al, EORTC Radiation Oncology Group quality assurance platform: Establishment of a digital central review facility. Radiother Oncol. 2012 Jun;103(3):279-86.

Trial Quality Assurance

Coen Hurkmans

Learning objectives

After this talk, one should be able to:

- Recall the trial specific RTQA levels used for clinical trials
- Describe the purpose of these RTQA levels
- Value the information collected by Individual Case Reviews
- Recognize the importance and diversity of Complex Treatment Dosimetry Checks
- Illustrate the need for RTQA harmonisation

Outline

RTQA levels

Harmonisation of RTQA

Conclusion

(EORTC) Levels of RTQA

1. Facility Questionnaire (FQ)
   Beam Output Audit (BOA)
2. Benchmark Case (BC)
3. Retrospective Individual Case Review (R-ICR)
4. Prospective Individual Case Review (P-ICR)
5. Complex Treatment Dosimetry Check
   Virtual Phantom Procedure

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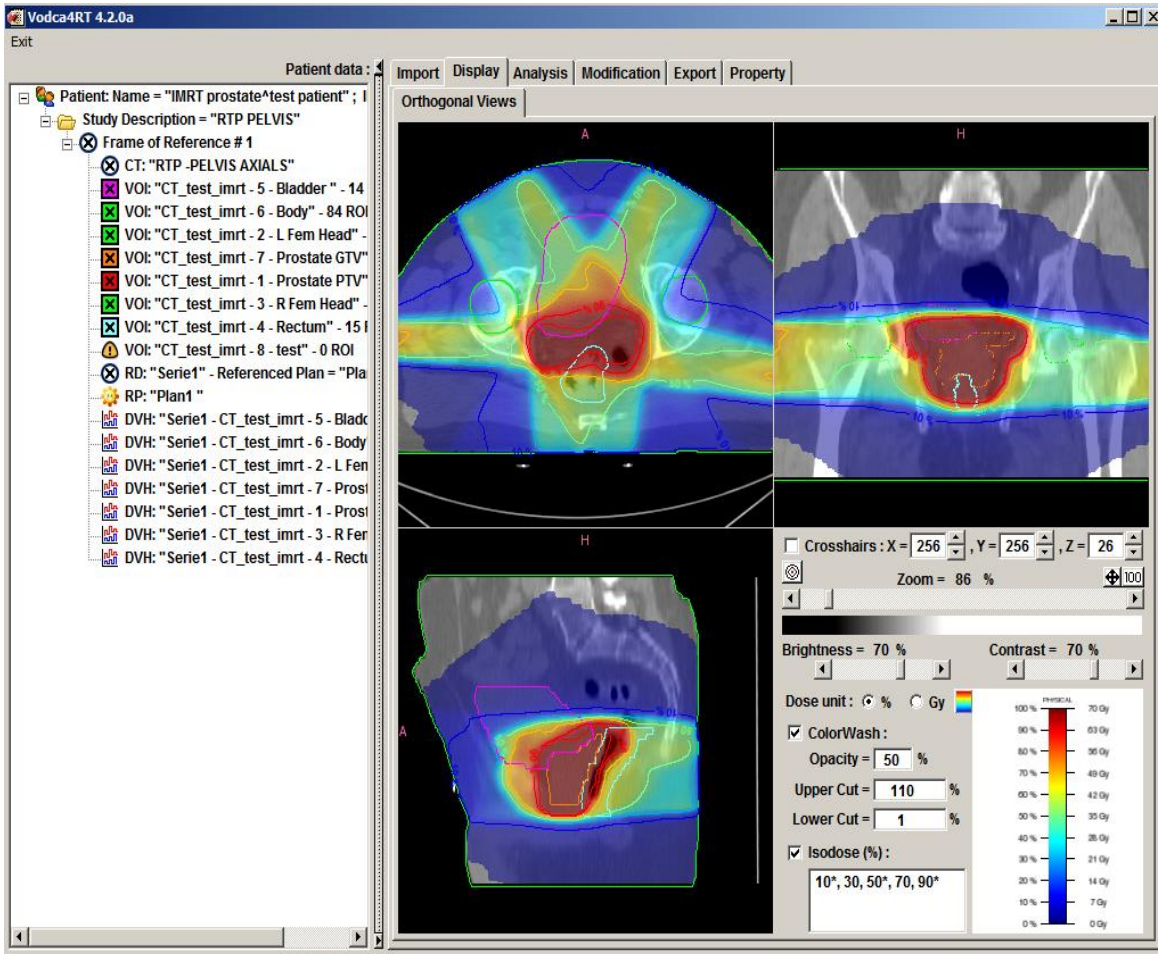
Benchmark case



Tests application of protocol (and protocol itself)

Allows correction of technique for future (real) cases

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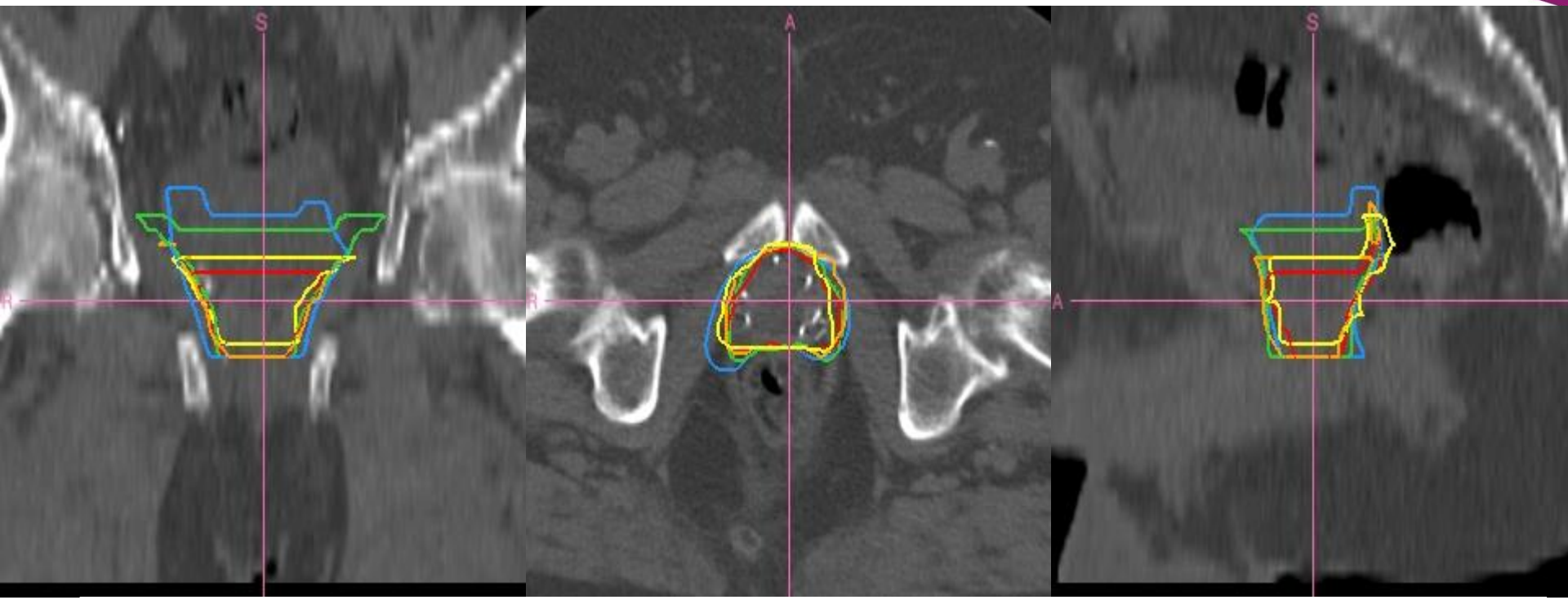
Benchmark case – planning exercise



Variation in Clinical Target Volume in EORTC 22043 DR

Cause: protocol and EORTC guidelines not being followed

Action: communication to all sites and individual feedback

prior to first patient entry

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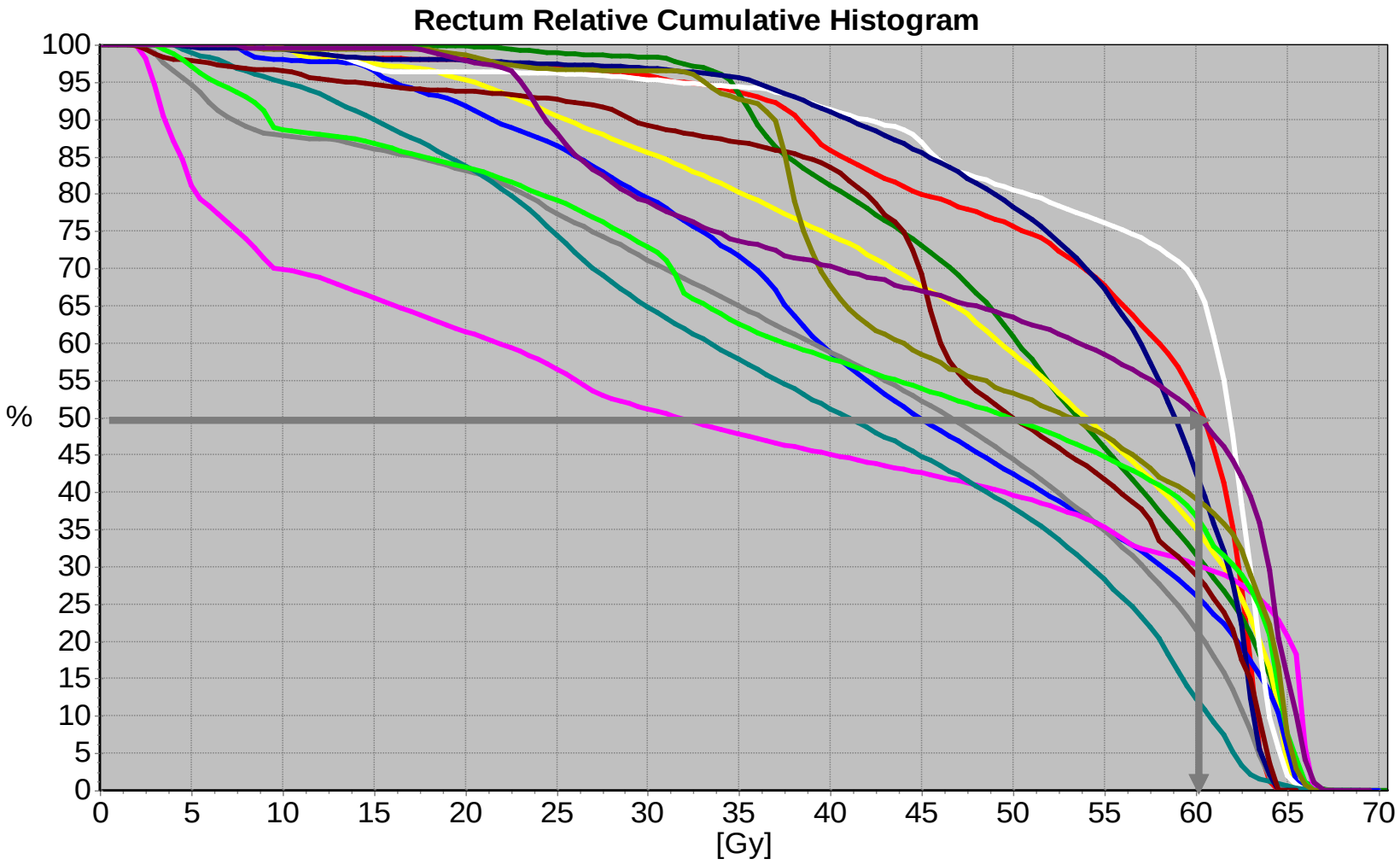
Benchmark case: rectum delineation

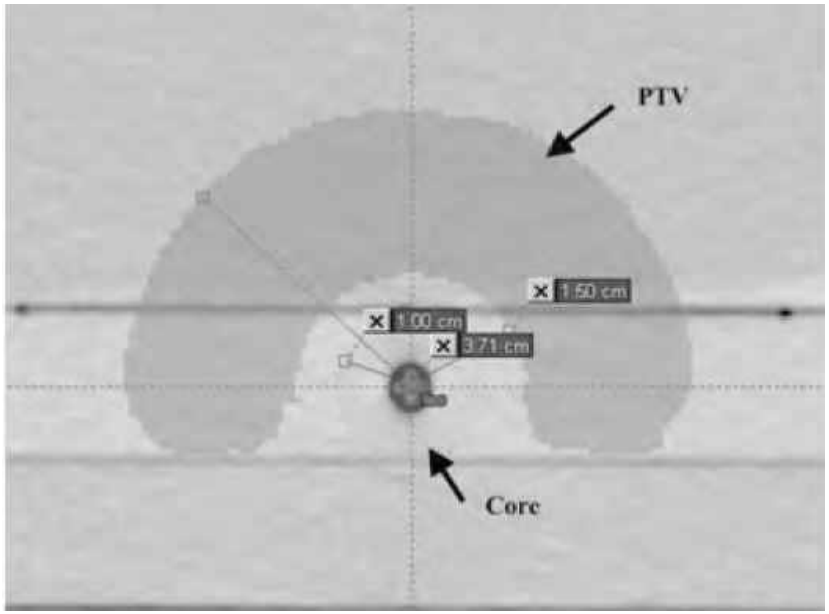


QA benchmarks

IMRT commissioning: Multiple institution planning and dosimetry comparisons, a report from AAPM Task Group 119

TABLE II. Treatment plan statistics for multitarget.

Planning parameter	Plan goal (cGy)	Mean (cGy)	Standard deviation (cGy)	Coefficient of variation
Central target D99	>5000	4955	162	0.033
Central target D10	<5300	5455	173	0.032
Superior target D99	>2500	2516	85	0.034
Superior target D10	<3500	3412	304	0.089
Inferior target D99	>1250	1407	185	0.132
Inferior target D10	<2500	2418	272	0.112



(Retrospective) Individual Case Reviews

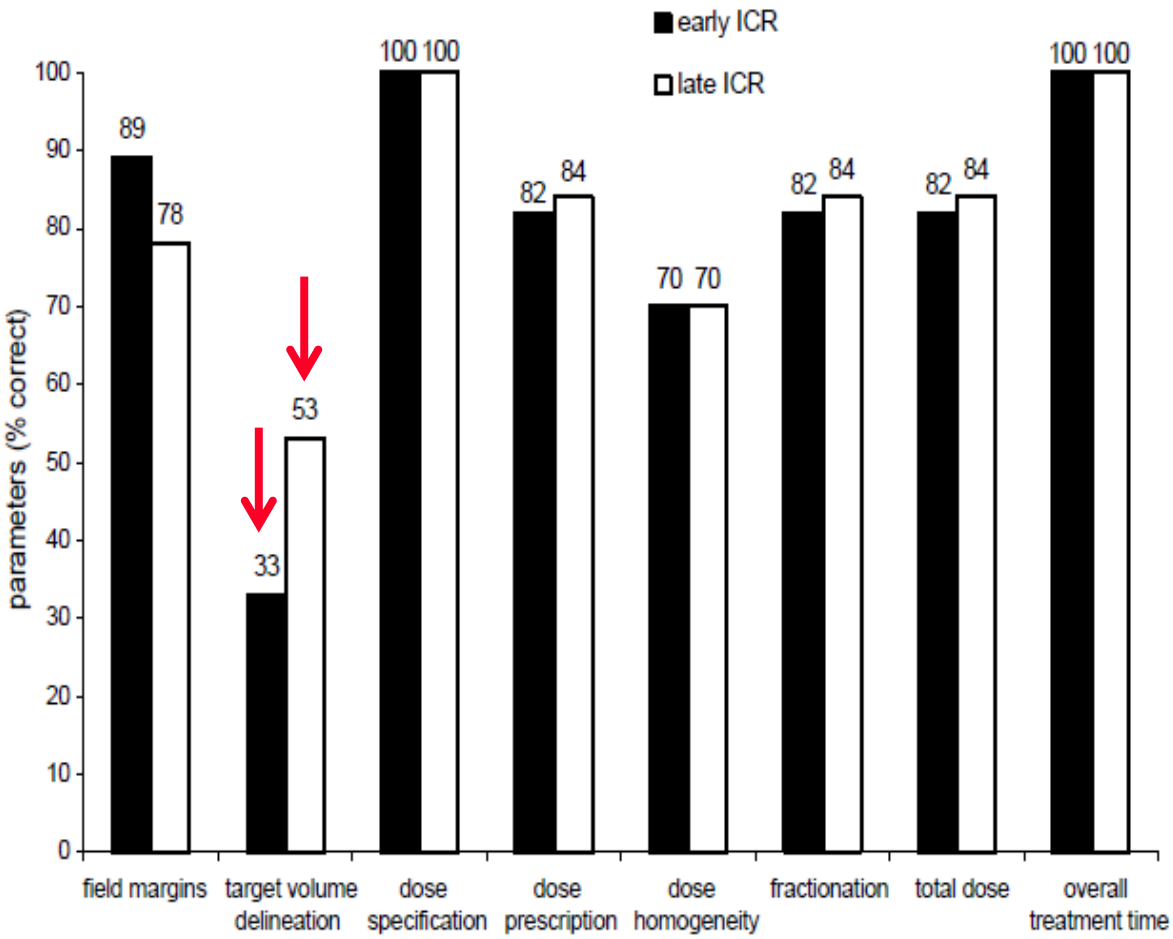


Fig. 2. Comparison of the early and the late ICR for RT parameters (nine centres).

Test Protocol compliance, detect changes

ICR of EORTC 22881-10882
When QA?
Early QA needed!

Poortmans et al. (2005) R&O

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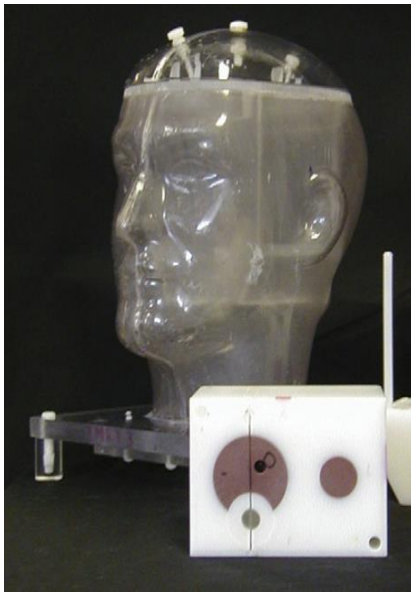
Complex Dosimetry Check

Table 1. Institution passing rates with the Radiological Physics Center phantoms

Phantom	Head and neck	Prostate	Thorax	Liver
Irradiations	250	64	24	4
Pass	179	55	17	3
Fail	71	9	7	1
Year introduced	2001	2004	2004	2005



"roughly 30% of institutions failed to deliver a dose distribution to the head-and-neck phantom that agrees with their own treatment plan to within 7% or 4 mm"

Ibbott et al. (2008) Int. J. Radiation Oncology Biol. Phys.

Complex Dosimetry Check

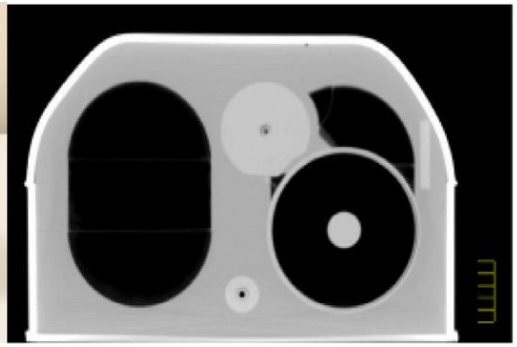
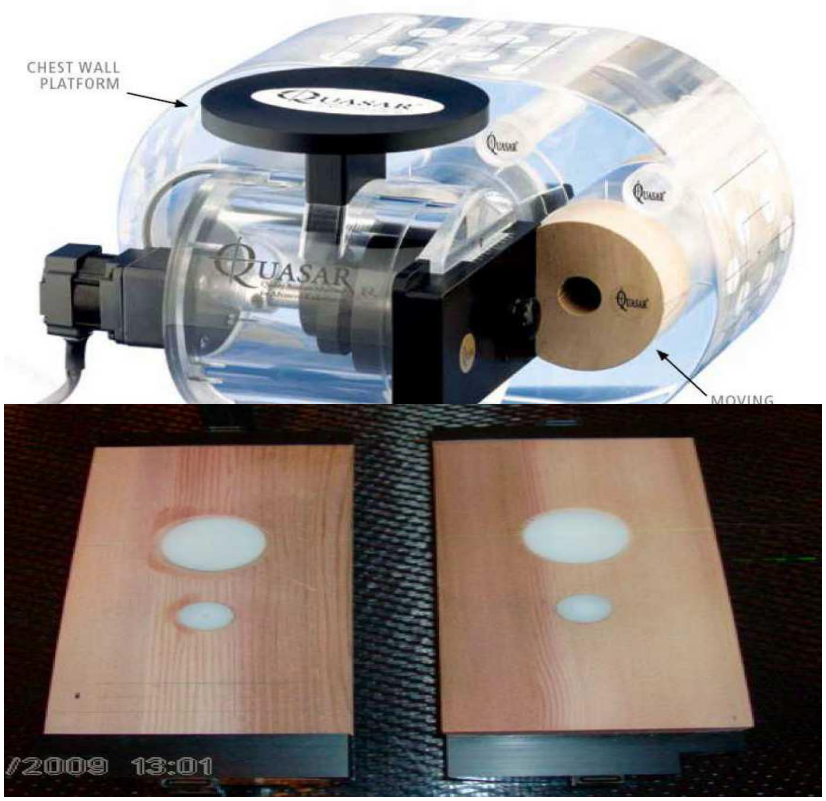



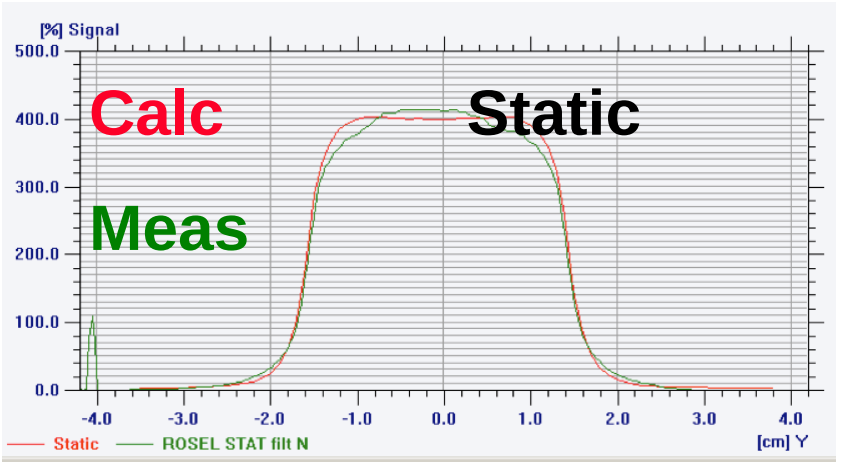

Table. Deviation between measured and calculated dose in lung

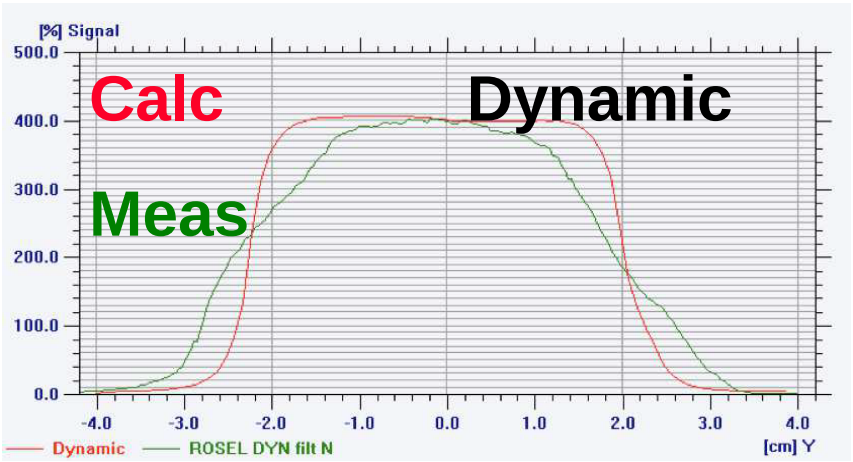
Algorithm	N	Mean	St. dev.
AAA	417	0.962	0.026
S/C	360	0.968	0.025
MC	89	0.982	0.032
Acuros	63	0.991	0.031

Clark et al. EJMP 947, 2017

Dynamic Complex Dosimetry Check







Report of a dosimetry audit for lung SBRT in a multicentre phase III trial of surgery versus stereotactic radiotherapy

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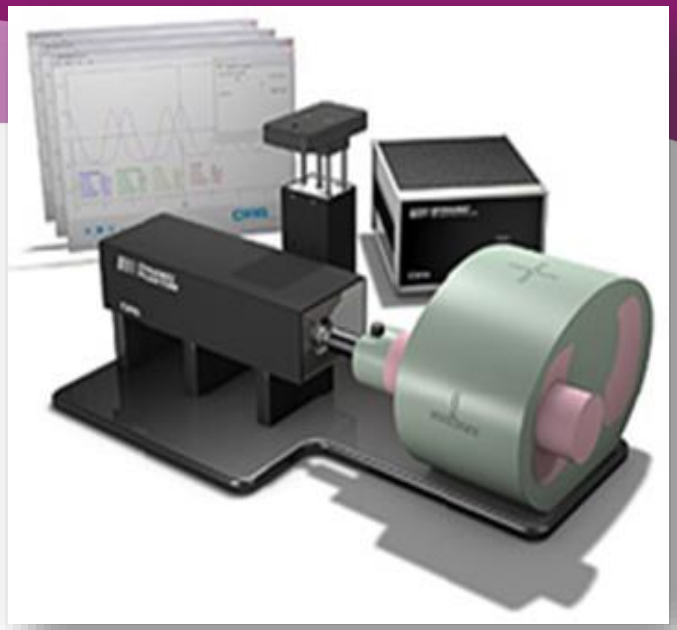
Dynamic Complex Dosimetry Check



Linac: Elekta synergy

TPS: Pinnacle

CIRS phantom with 2 spheres

	1.5cm sphere	2.5cm sphere
Static plan 4°/cp 2°/cp	 **3.8 %** **2.8 %**	 **4.7 %** **0.0 %**
Dynamic plan – 15mm/3s 4°/cp 2°/cp	 **8.6 %** **3.2 %**	


"HOW ARE YOU DOING ON YOUR SIDE?"
PAIROLINI

Global Harmonization of RTQA

QA RT Harmonisation in clinical trials

Global Harmonization Group

Working together in the pursuit of international radiotherapy QA harmonization for clinical trials

www.rtqaharmonization.com

EORTC European Organisation for Research and Treatment of Cancer

ESTRO European SocieTy for RADIOTHERAPY & ONCOLOGY

NCRI RADIOTHERAPY CLINICAL TRIALS QUALITY ASSURANCE GROUP

TROG

IROC™ IMAGING AND RADIATION ONCOLOGY CORE

Global Leaders in Clinical Trial Quality Assurance

RTOG RADIATION THERAPY ONCOLOGY GROUP

NCIC Clinical Trials Group

NCIC Groupe des essais clini

JCOG Japan Clinical Oncology Group

IAEA International Atomic Energy Agency

Australian Clinical Dosimetry Service

An Australian Government Initiative

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The QA of RT in clinical trials Global Harmonisation Group

Bring together, homogenize and distribute information regarding the RTQA standards of various trial groups in clinical trials.

Provide a platform for prospective discussions on new RTQA levels, software tools, guidelines and policies of trial groups.

Provide a framework to endorse existing and future RTQA levels and guidelines between various trial groups.

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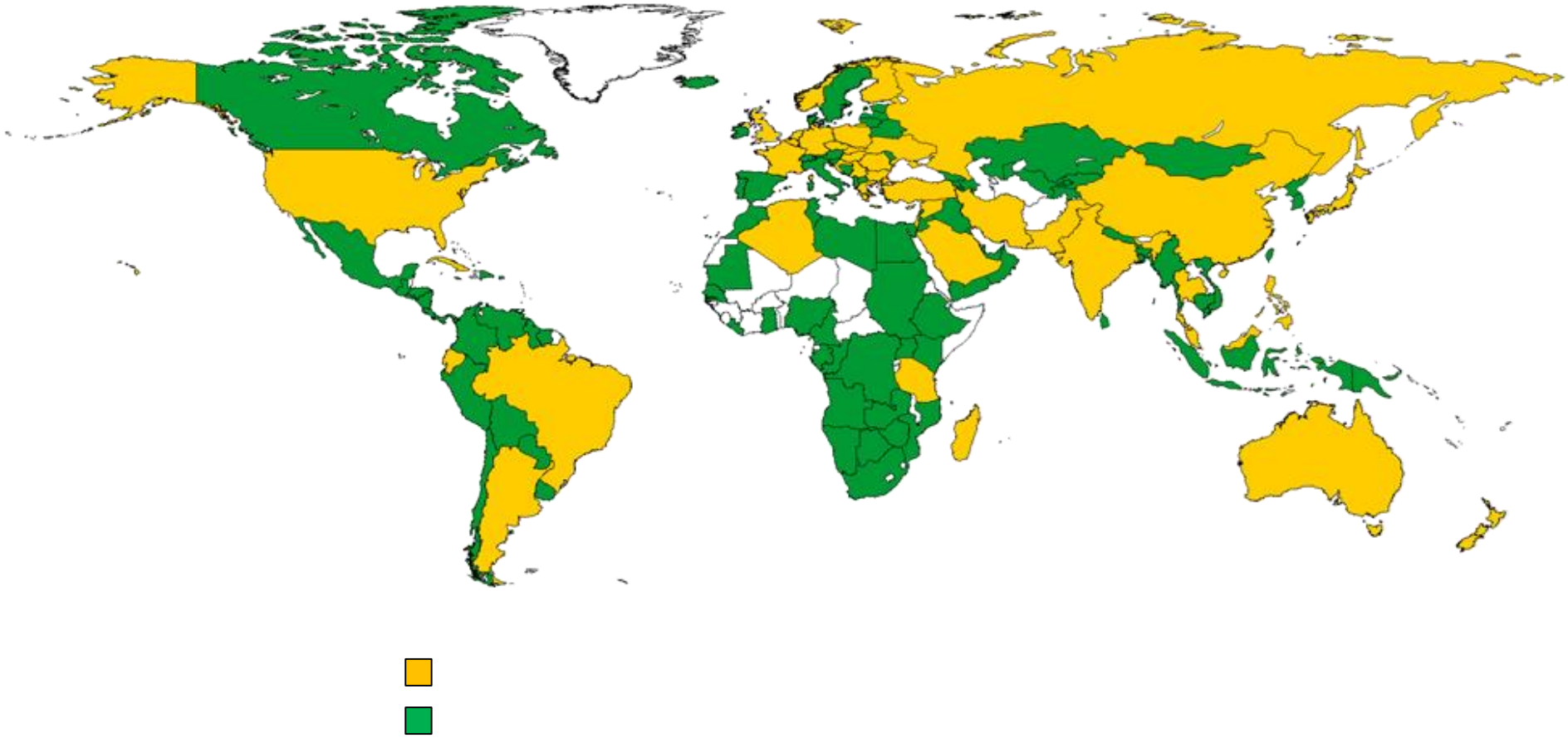
BOA: Dosimetry Audit Networks



Dosimetry Audit Networks: Harmonisation

Global harmonisation:

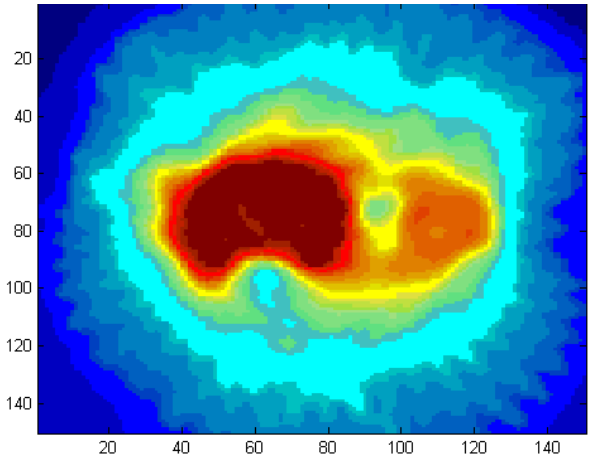
Combine and share data about independent dose audits

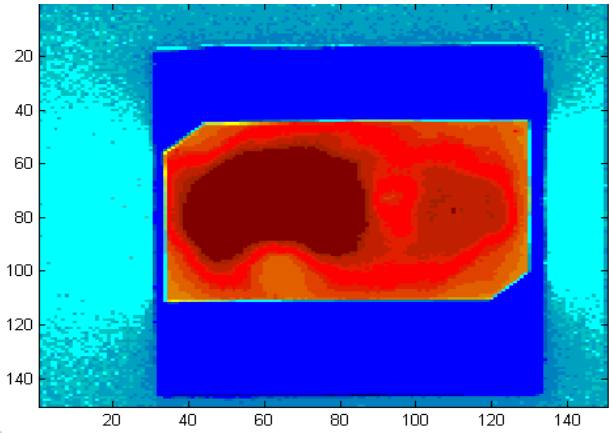
Build database (hosted by IAEA)

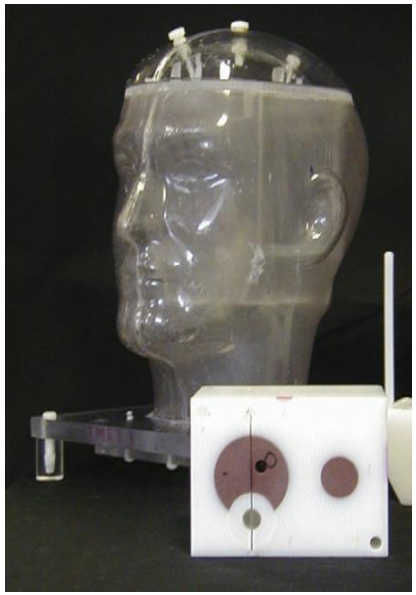
Endorsement of dosimetry auditing groups

Database open to international trial organizations

Complex Dosimetry Check







- Mailed reference phantom
- Easy comparison between institutions

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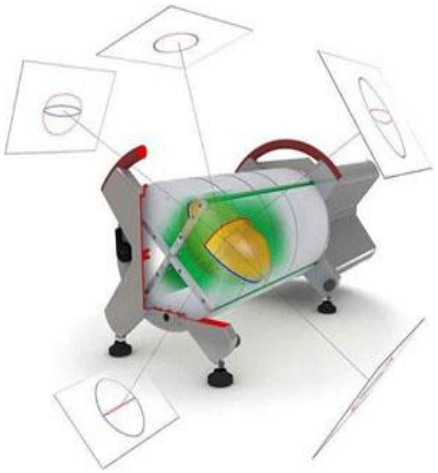
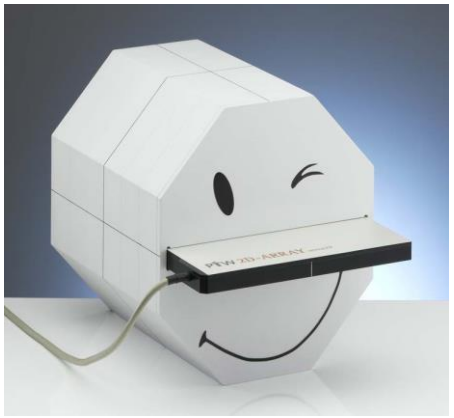
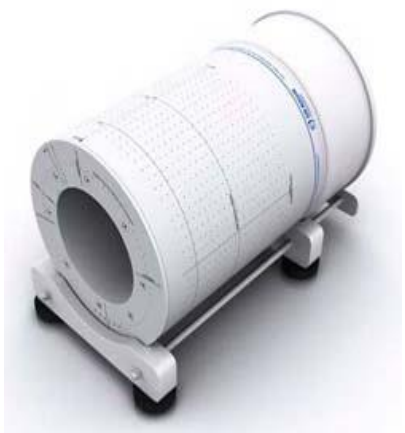
Institutions own phantom







Advantages:

Less time consuming

Less costly

Less prone to user errors

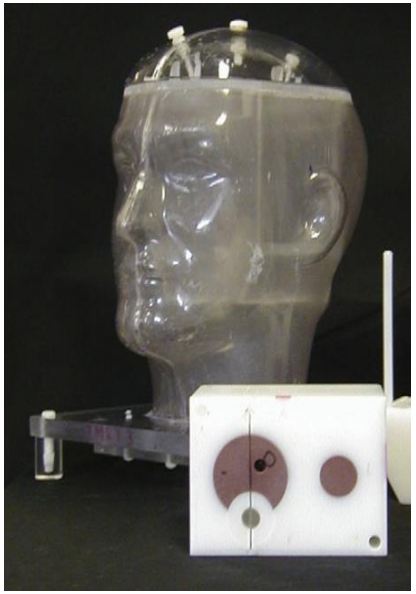
Disadvantage:

No experience yet

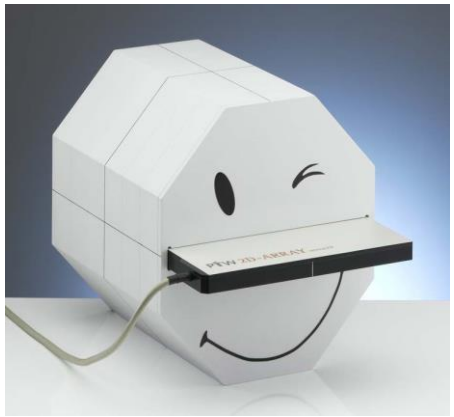
Phantom dependent results

Institutions' phantom vs reference phantom

Phantom dependent results



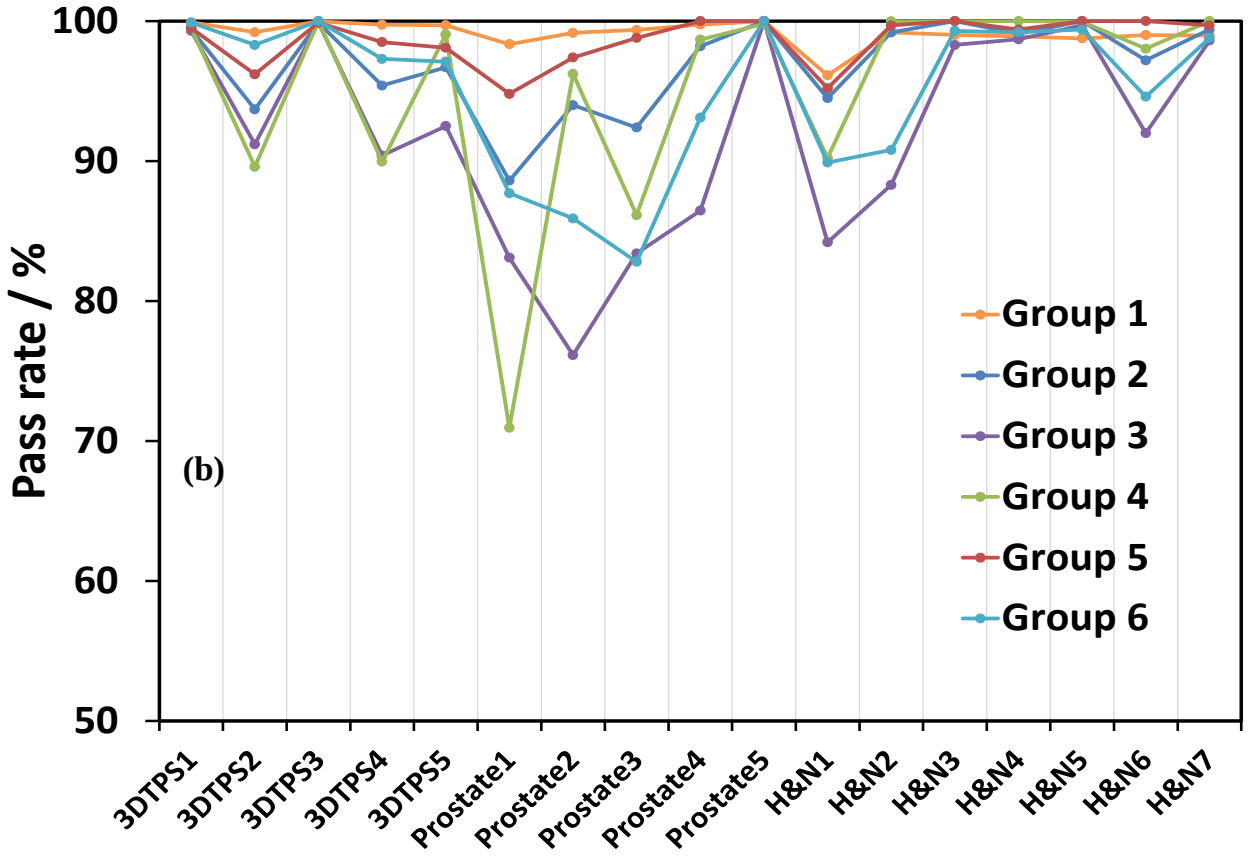
Inst QA	IROC Houston: Fail	IROC Houston: Pass
Fail	19	57
Pass	84	585



Kry S. et al. (2014) IJROBP

Institutions' phantom

Software dependent results



- 6 groups
- Plans for various disease sites
- **Same input measurement data**
- **Same analysis parameters…**

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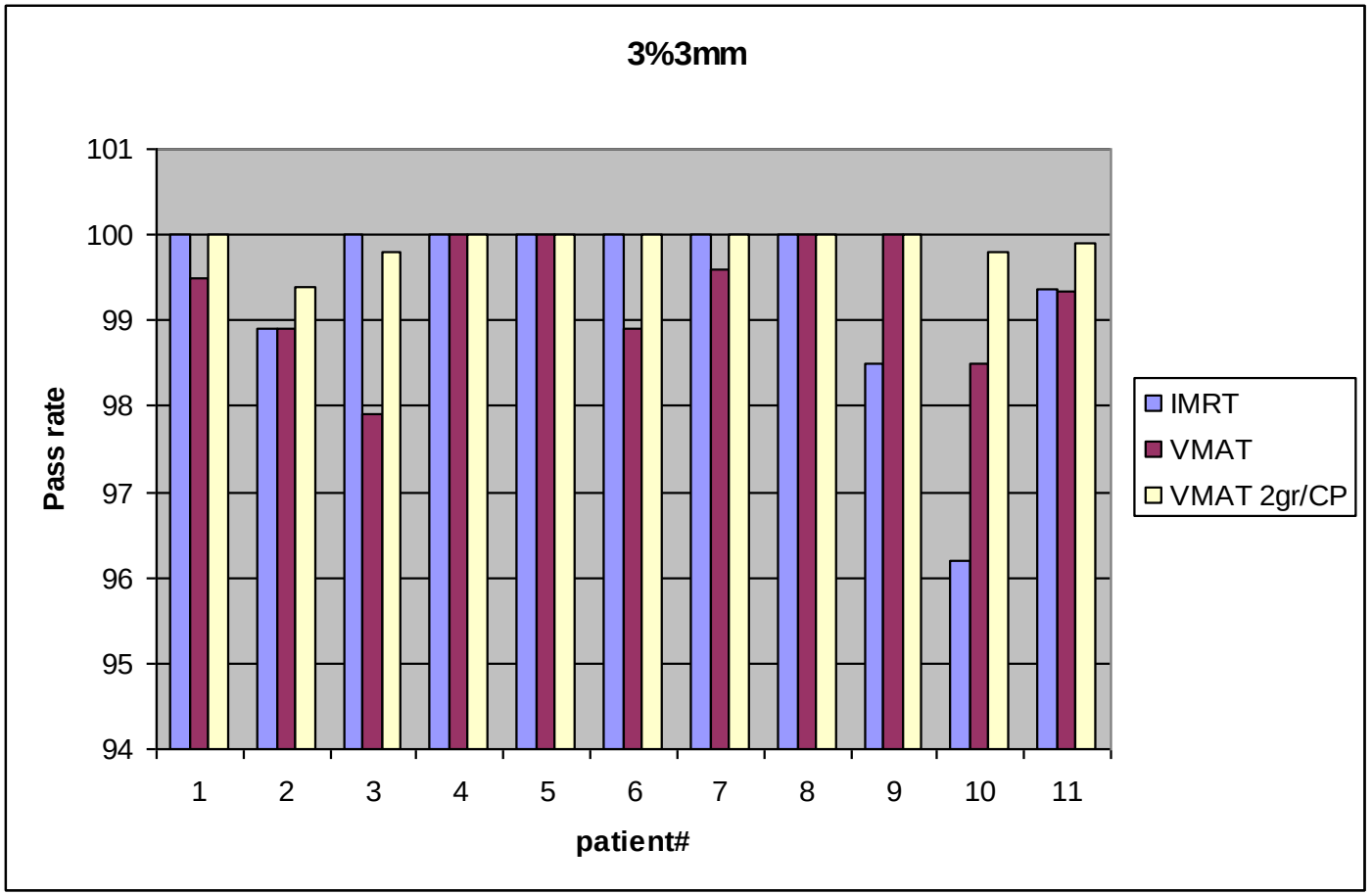
QA results depend on calculation details



Standard Naming Convention

Physics Contribution

Standardizing Naming Conventions in Radiation Oncology

Lakshmi Santanam, Ph.D.,* Coen Hurkmans, Ph.D.,† Sasa Mutic, Ph.D.,* Corine van Vliet-Vroegindeweij, Ph.D.,‡ Scott Brame, Ph.D.,* William Straube, M.S.,* James Galvin, D.Sc.,‡ Prabhakar Tripuraneni, M.D.,§ Jeff Michalski, M.D.,* and Walter Bosch, D.Sc.*,¶

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Received May 23, 2011, and in revised form Sep 17, 2011. Accepted for publication Nov 21, 2011

Standard Naming Convention

Table 1 Examples of target volume (TV) names

TV ICRU name	Primary/ node	Single/ multiple	Number	Prescription dose (cGy)	Proposed name
PTV	Primary	Single	N/A	5000	PTV_5000
PTV	Node	Multiple	1	5000	PTVn1_5000
CTV	Node	Multiple	2	4000	CTVn2_4000
PTV	Node	Multiple	2	4000	PTVn2_4000
PTV	Primary	Multiple	1	5000	PTVp1_5000

Abbreviation: ICRU = International Commission on Radiation Units and Measurements.

Table 3a Standardized organ at risk names

Standard names	Description
AnalCanal	Anal Canal
A_Pulmonary	**Pulmonary Artery**
A_Carotid	**Carotid Artery**
A_Brachiocephali	**Brachiocephalic Artery**
A_Coronary	**Coronary Artery**
A_Subclavicular	**Subclavicular Artery**
A_Hypophyseal	**Hypophyseal Artery**
Aorta	**Aorta**
AnalSphincter	**Anal Sphincter**
Atrium	**Atrium**
Bladder	Bladder
BladderWall	**Bladder Wall**
BrachialPlexus	Brachial Plexus
Brain	Brain
BrainStem	Brain Stem
Breast	Breast
BronchialTree	Bronchial Tree

Table 2 Planning organs at risk volumes

Organ at risk name	Left/right	Margin (mm)	Proposed name
SpinalCord	N/A	Nonuniform	SpinalCord_PRV
SpinalCord PRV	N/A	5	SpinalCord _05
Parotid	Left	0	Parotid_L
Parotid	Right	0	Parotid_R
Total parotid	Left+Right	0	Parotids
Kidney	Left	10	Kidney_L_10

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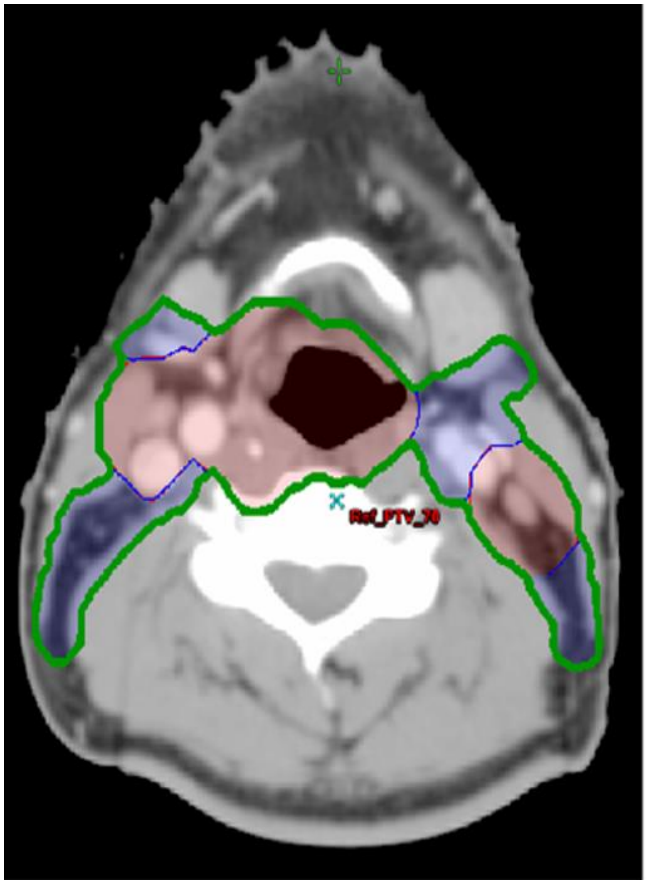
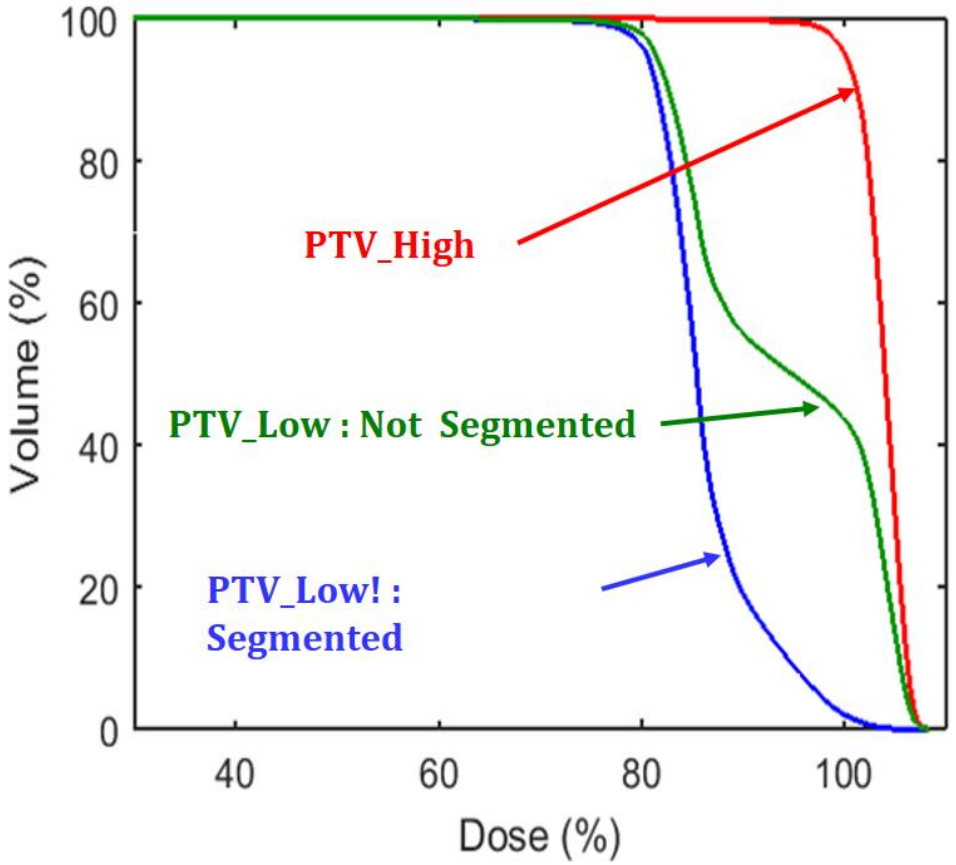
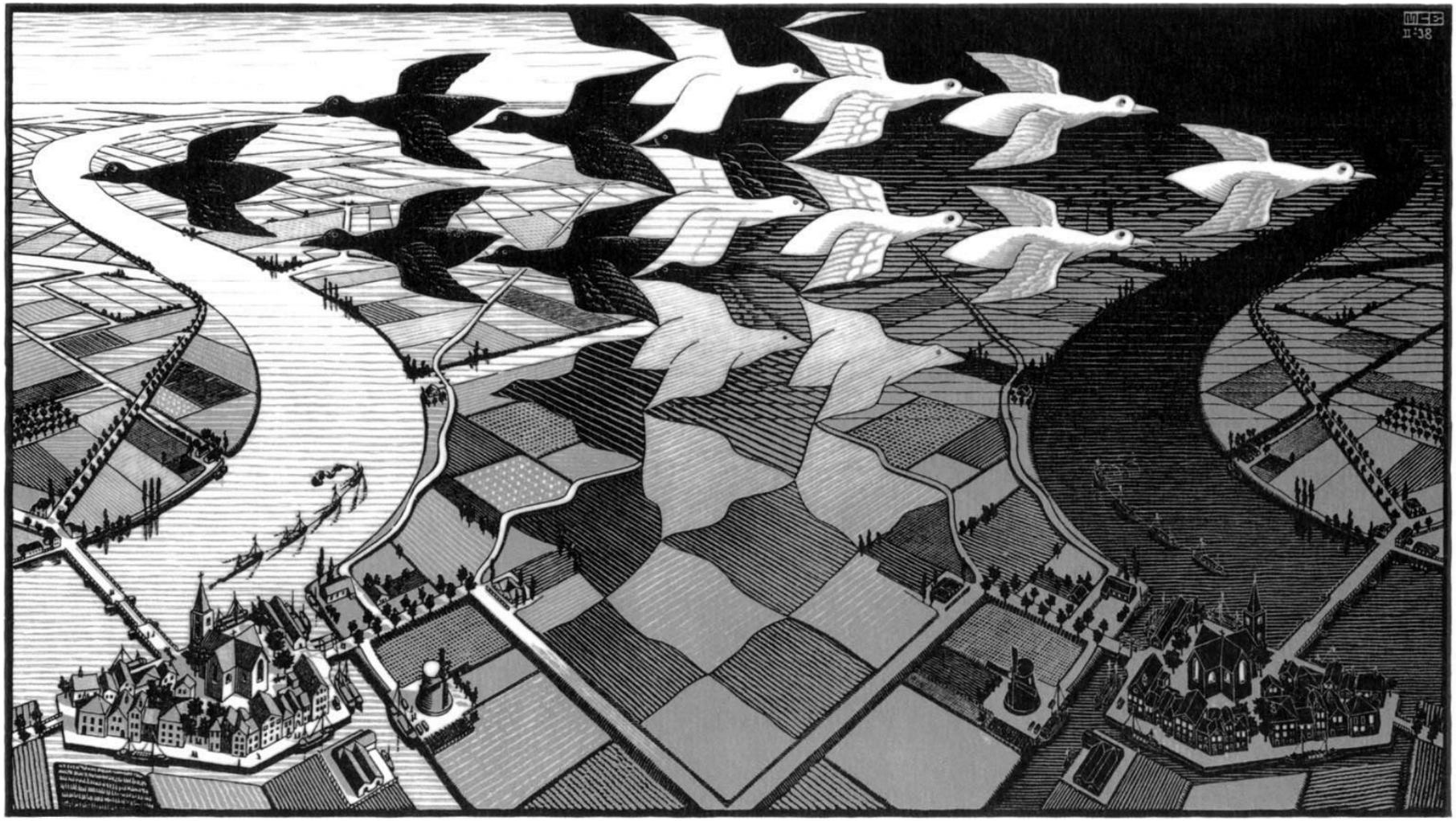
Standard Naming Convention: AAPM TG 263





Use exclamation point to differentiate between segmented and non-segmented structures

Conclusion



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Acknowledgments

All Members of the Global Harmonisation Group

My colleagues at the Catharina Hospital Eindhoven, The Netherlands

EORTC HQ RT staff and QA team

Further reading

- Global harmonization of quality assurance naming conventions in radiation therapy clinical trials. Melidis C, Bosch WR, Izewska J, Fidarova E, Zubizarreta E, Ulin K, Ishikura S, Followill D, Galvin J, Haworth A, Besuijen D, Clark CH, Miles E, Aird E, Weber DC, Hurkmans CW, Verellen D. Int J Radiat Oncol Biol Phys. 2014 Dec 1;90(5):1242-9
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- IMRT credentialing for prospective trials using institutional virtual phantoms: results of a joint European Organization for the Research and Treatment of Cancer and Radiological Physics Center project.Weber DC, Vallet V, Molineu A, Melidis C, Teglas V, Naudy S, Moeckli R, Followill DS, Hurkmans CW. Radiat Oncol. 2014 May 29;9:123
- Outcome impact and cost-effectiveness of quality assurance for radiotherapy planned for the EORTC 22071-24071 prospective study for head and neck cancer. Weber DC, Hurkmans CW, Melidis C, Budach W, Langendijk JH, Peters LJ, Grégoire V, Maingon P, Combescure C. Radiother Oncol. 2014 Jun;111(3):393-9
- Radiation therapy quality assurance in clinical trials--Global Harmonisation Group. Melidis C, Bosch WR, Izewska J, Fidarova E, Zubizarreta E, Ishikura S, Followill D, Galvin J, Xiao Y, Ebert MA, Kron T, Clark CH, Miles EA, Aird EG, Weber DC, Ulin K, Verellen D, Hurkmans CW. Radiother Oncol. 2014 Jun;111(3):327-9
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Practical Exercise;
Applying Lean Thinking in radiotherapy

Marjolein van Os

Radiation Technologist,

Erasmus MC, Rotterdam, NL

Quality Assessment & Improvement

Brussels, 2-5 October 2017

Erasmus MC University Medical Center Rotterdam Cancer Institute

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Introduction

Aim of this Practical Exercise:

- Experience the methodology of Lean Thinking
- Apply Lean Thinking to Process Optimization and Quality Improvement within a patient flow chart.
- Multiprofessional collaboration, respect for eachother's contribution to both the patient process and the applied Quality Improvement.

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Learning Objectives

- Assemble information from a general patient flow chart into a Value Stream Map
- Recognize waste within a process
- Identify bottlenecks within a process
- Apply Lean Continuous Improvement to improve the quality within a patient flow chart
- Value multiprofessional approach in Lean Quality Improvement

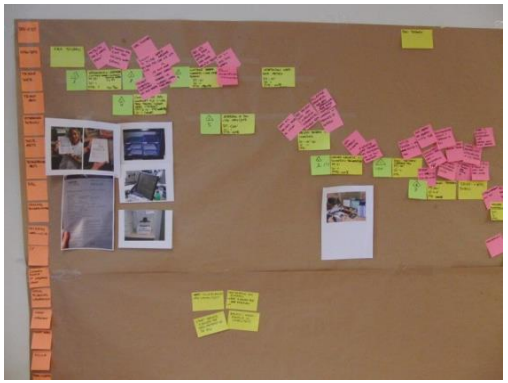
Exercise 1

Process optimization

1. Practice:

Use the patient flow chart and complete with own detailed information (multi-institutional).

Translate the process into a Value Stream Map and visualize on a brown paper.



2. Discussion:

-What kind of Muda can you define within the process?

-Define the "*ideal state*" and how much / what value would be added

- Who do you need aboard to achieve a succesfull future state?

3. Result:

A new value stream map of the future state; what did your patient gain?

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Exercise 2

Quality improvement

1. Practice:

Translate the information from the patient flow chart into a Value Stream Map and visualize on a brown paper.

Define where you encounter issues / where you want to improve quality.

2. Discussion:

Which Lean tool(s) would you use for Quality Improvement in your case?

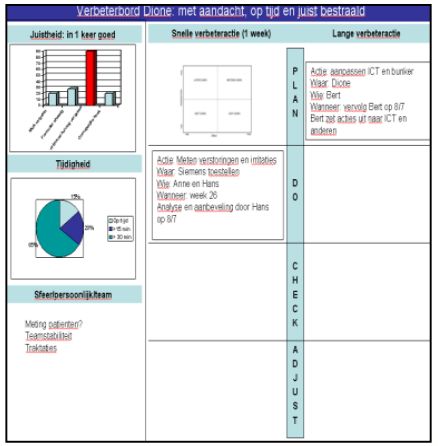
3. Result:

Visualize your improvement plan on a Kaizen-board

Define starting point PDCA (measure),

appoint a problem owner, make communication plan

What do you need to succeed / describe risks



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Reminders

- Will your intervention in the suggested process add value for the patient??
- Identify waste; remember “DOWNTIME”
- Use info from experts for bottom-up multiprofessional approach
- Beware of the circle of influence: don’t try to change others
- Define endpoints for your Quality Improvement and celebrate your success.

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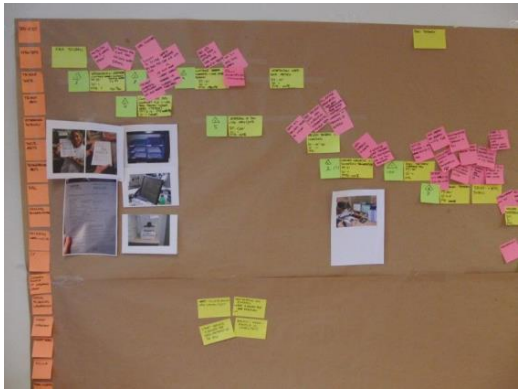
Exercise 7 groups

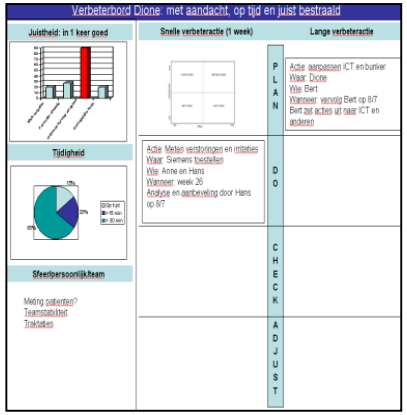
Each group gets a brown paper, sticky notes in 4 colors and markers in 3 colors.

Use the sticky notes to distinguish between activity, actor, time, issue.

After defining the process on brown paper Exercise 1 continues with process optimization, Exercise 2 with quality improvement.

Group 1	Ex 1: Process optimization Patient referral - CT	Coffee area
Group 2	Ex 1: Process optimization Patient referral - CT	Oslo 1
Group 3	Ex 1: Process optimization CT – first treatment	Coffee area
Group 4	Ex 1: Process optimization CT – first treatment	Oslo 1
Group 5	Ex 2: Quality improvement	Oslo 1
Group 6	Ex 2: Quality improvement	Oslo 1
Group 7	Ex 2: Quality improvement	Oslo 1





EU and quality in Radiation Oncology
What is on ?

Prof. Philippe MAINGON

GHU La Pitié Salpêtrière - Charles Foix

Sorbonne Université

Paris

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Objectives

- To be informed about the status of european regulations
- To discover the role of the EC in the field of radioprotection
- To know the positioning of radiotherapy in radioprotection
- To learn about the updating of the current laws
- To integrate the culture of recording and reporting adverse events
- The role of analysis of near misses
- The proactive and the failure modes analysis

Rome, 25 March **1957**

Article 2: "… the Community shall …

establish **uniform standards**

to protect the health of workers

and of the general public"

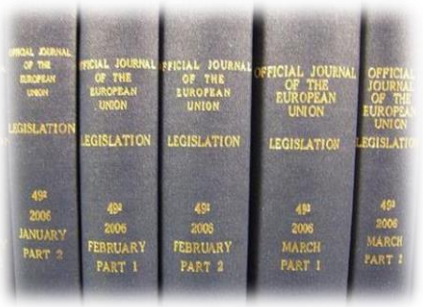
- **Article 31**: "The basic standards shall be worked out by the Commission after it has obtained the opinion of a **group of … scientific experts**
  - 'Art.31 GoE', **WP on Medical Exposure**

Euratom "**Basic Safety Standards**" (BSS) Directives

- **Binding Law** for all EU Member States
- First adopted in **1959**, covers workers and public
- Regular revision, past **Directive 96/29/Euratom**

Supplementing legislation in **other areas**

- **Medical**, Directives 84/466/Euratom and **97/43/Euratom**
- Outside workers, Directive 90/641/Euratom
- Public Information, Directive 89/618/Euratom
- Foodstuff contamination
- Control of radioactive sources
- Etc.



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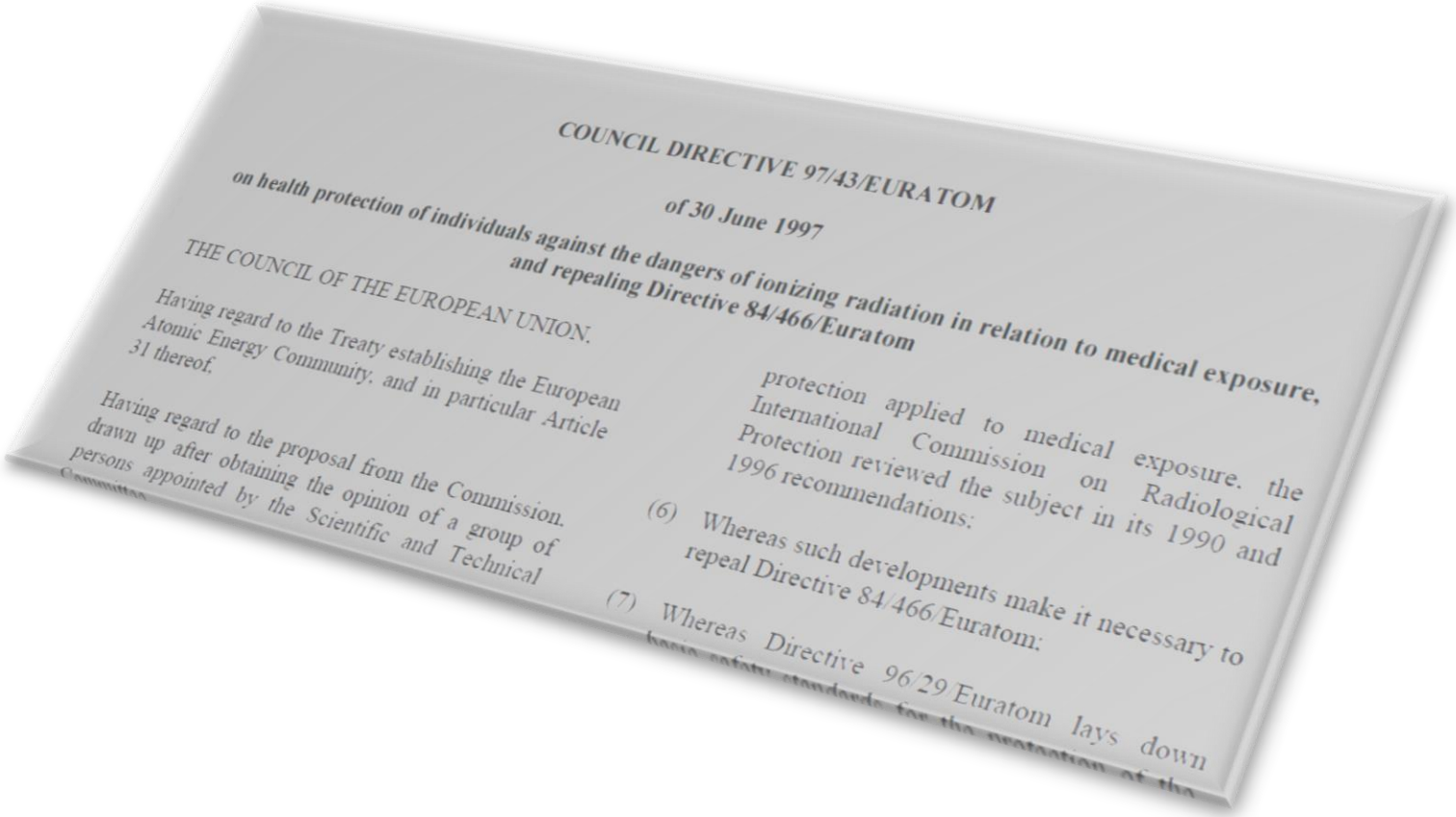
97/43/Euratom, MED – **Medical Exposure Directive**



COUNCIL DIRECTIVE 97/43/EURATOM

of 30 June 1997

on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 31 thereof,

Having regard to the proposal from the Commission, drawn up after obtaining the opinion of a group of persons appointed by the Scientific and Technical

protection applied to medical exposure, the International Commission on Radiological Protection reviewed the subject in its 1990 and 1996 recommendations;

(6) Whereas such developments make it necessary to repeal Directive 84/466/Euratom;

(7) Whereas Directive 96/29/Euratom lays down

Article 11 of MED
Potential exposure

Member States shall ensure that all reasonable steps to reduce the probability and the magnitude of accidental or unintended doses of patients from radiological practices are taken (…).

The main emphasis in accident prevention should be on the equipment and procedures in **r a d i o t h e r a p y** (…).

Working instructions and written protocols (…) and quality assurance programmes (…) and the criteria of acceptability of equipment are of particular relevance for this purpose.

- **Justification**
  - Medical exposure shall show a sufficient net benefit (…) against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionizing radiation

- **Optimization**
  - All doses due to medical exposure for radiological purposes except radiotherapeutic procedures shall be kept as low as reasonably achievable consistent with obtaining the required diagnostic information (…)

- **Responsibilities, Procedures, Training, Equipment, Special Practices, Special protection during pregnancy and breastfeeding, Potential exposure**

Revision of Euratom RP Law

European Commission **draft proposal, September 2011** http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0593:FIN:EN:PDF

European Commission **proposal, May 2012**

http://ec.europa.eu/energy/nuclear/radiation_protection/doc/2012_com_242.pdf

"Revised Euratom (EU) BSS"

Grouping **five current RP Directives**

- Euratom BSS, 96/29/Euratom
- MED, 97/43/Euratom
- Etc.

Taking into account latest ICRP recommendations, etc.

Proposing changes, including in **'Medical' Chapter VII**

Discussion in the Council of the EU

Working Party on Atomic Questions – **WPAQ**

Since 2011 – PL, DK, CY, IE Presidency

Chapter VII and related articles and definitions **actively discussed and negotiated**

Adoption by WPAQ – 30 May 2013, by COREPER – 5 June 2013

Formal adoption by the Council and by the European Parliament **in December 2013 (5th)**

Accidental and unintended exposures in Revised BSS
Considerably expanded and strengthened

Member States shall ensure that:

- all reasonable measures are taken to minimise the probability and magnitude of accidental or unintended exposures of individuals subject to medical exposure

- for radiotherapeutic practices the quality assurance programme includes a study of the risk of accidental or unintended exposures

- for all medical exposures the undertaking implements an appropriate system for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice;

EC funded project 2012-2013

http://www.accirad.eu

Objectives

- to perform an EU-wide study on the implementation of the MED requirements aiming at reduction of the probability and the magnitude of accidents in radiotherapy

- to develop guidelines on a risk analysis of accidental and unintended exposures in radiotherapy aiming at improving patient safety

Radiotherapy

- highly complex
- multi-step process
- requires the input of many different staff groups in the planning and delivery of the treatment

Complexity arises

- wide range of conditions treated
- technologies used
- professional expertise needed

Complexity compounded

- fact that processes are continually changing in the light of research and the introduction of new technologies

Purpose of the guidelines

EC project ENER/11/NUCL/S12.612180160

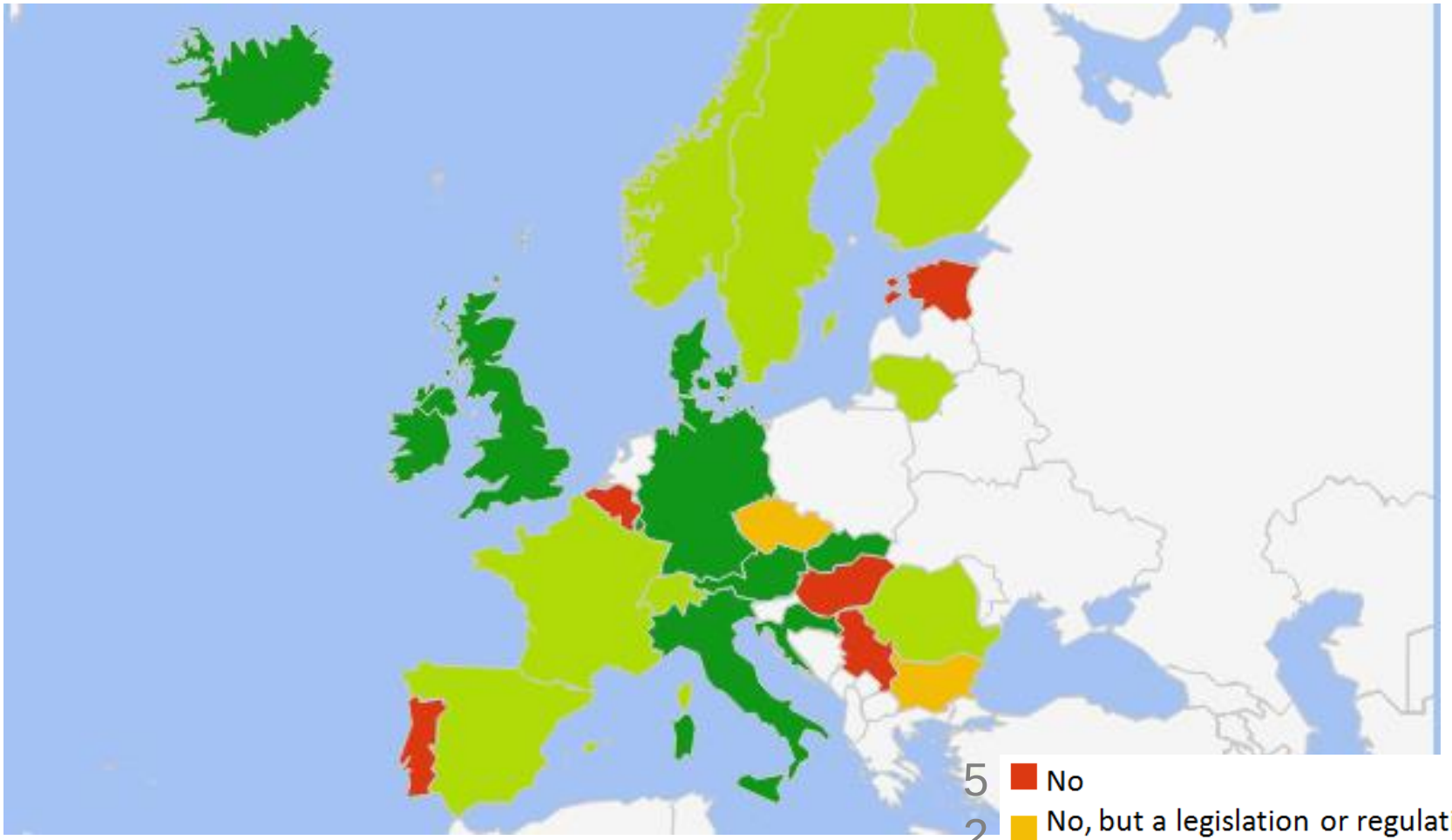
Funded by the European Commission

- Support Member States in the implementation of the legislative requirement (Article 11 of MED and the future BSS), for reduction of the probability and the magnitude of adverse events in radiotherapy
- Review the status and methods of risk management (proactive and reactive analysis) and classification and reporting of events
- Give a set of conclusions and recommendations

Recording

http://www.accirad.eu

Legislation (2.3.1.1.)

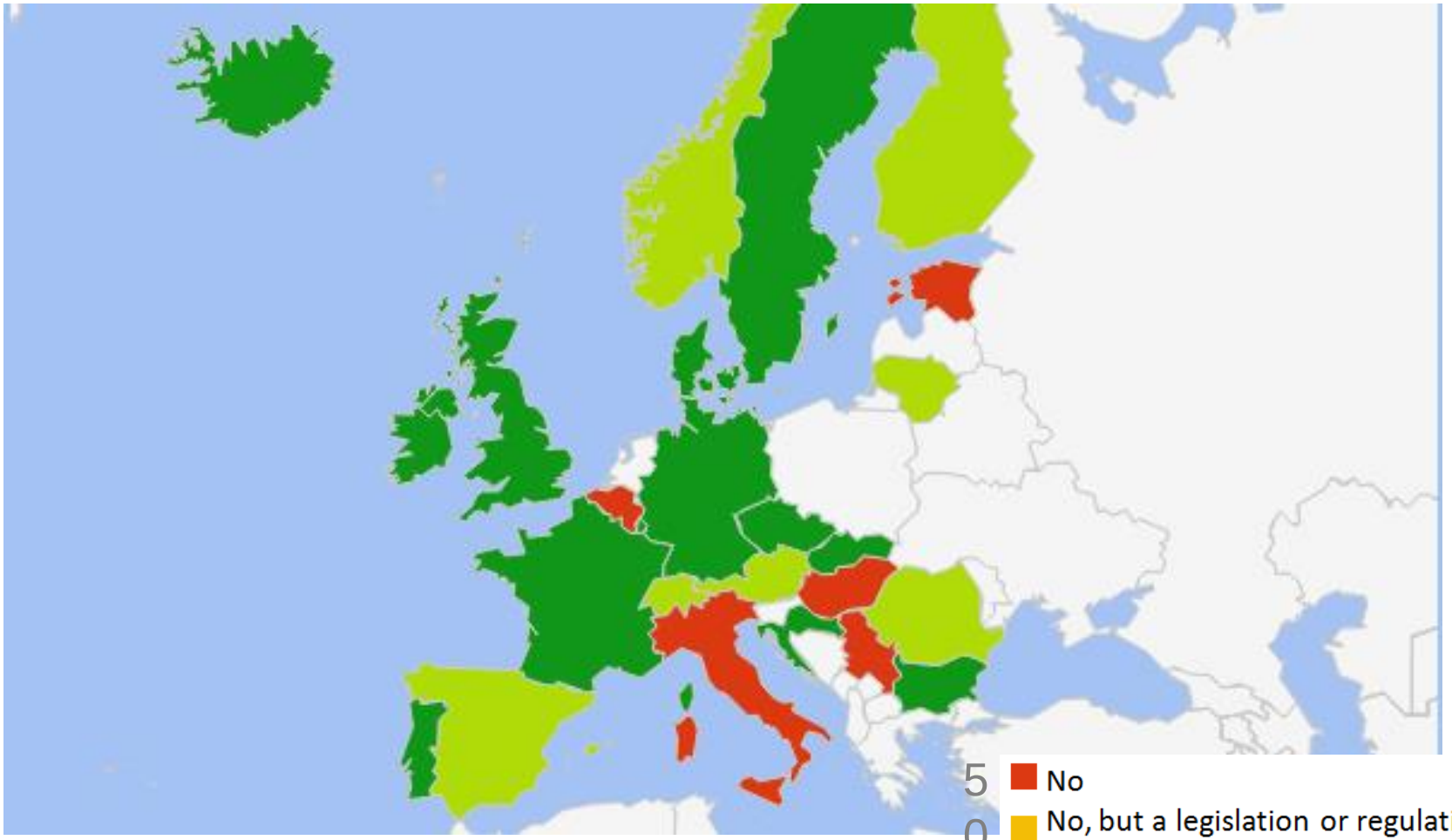


5	No
2	No, but a legislation or regulation is under preparation
8	Yes, dedicated to RT
12	Yes, but these are part of a more general document

Reporting-Adverse events

http://www.accirad.eu

Legislation (2.4.1.1.)



5	No
0	No, but a legislation or regulation is under preparation
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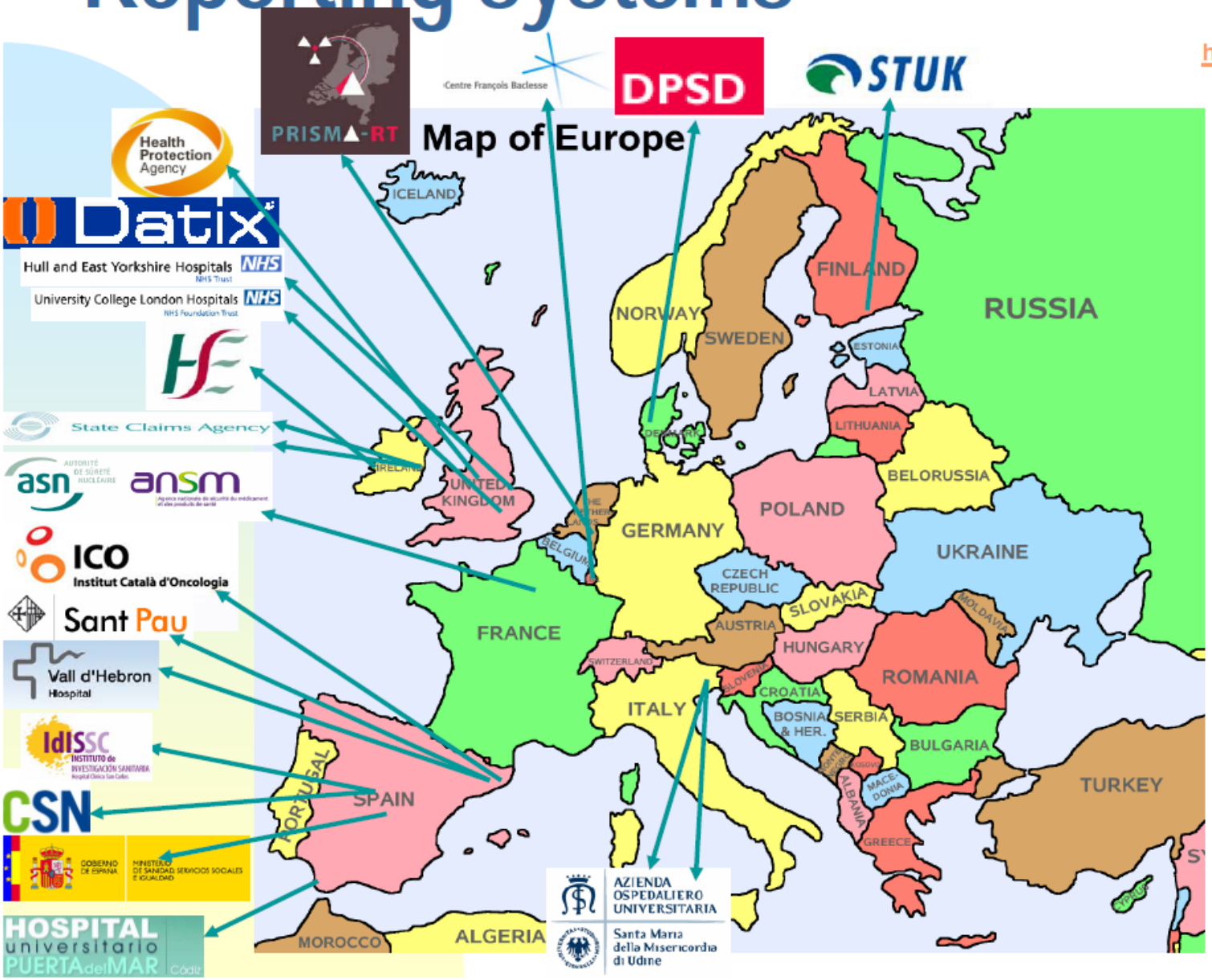
15	Yes, but these are part of a more general document

Reporting systems



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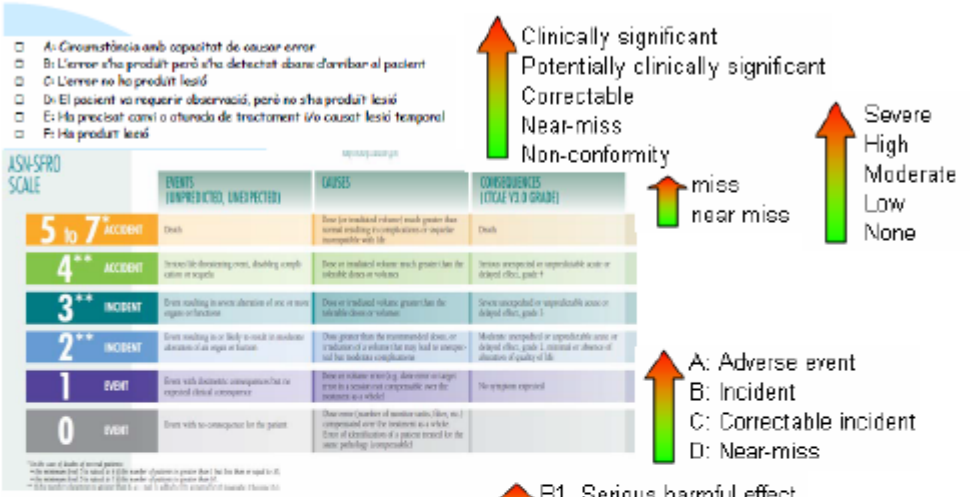
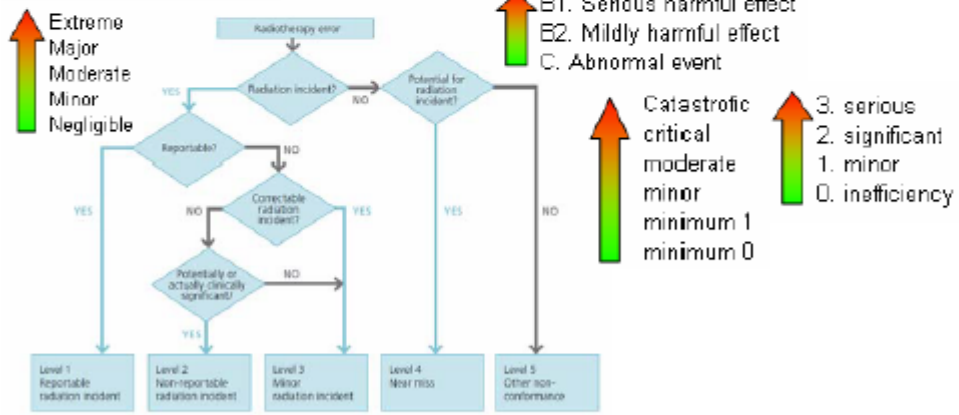
Classification-Severity

http://www.accirad.eu





SAC MATRIX

Hyppighed / Alvorlighedsgrad	Katastrofal	Betydende	Moderat	Minimal
Hyppig	3	3	2	1
Mindre hyppig	3	2	1	1
Sjælden	3	2	1	1
Meget sjælden	3	2	1	1

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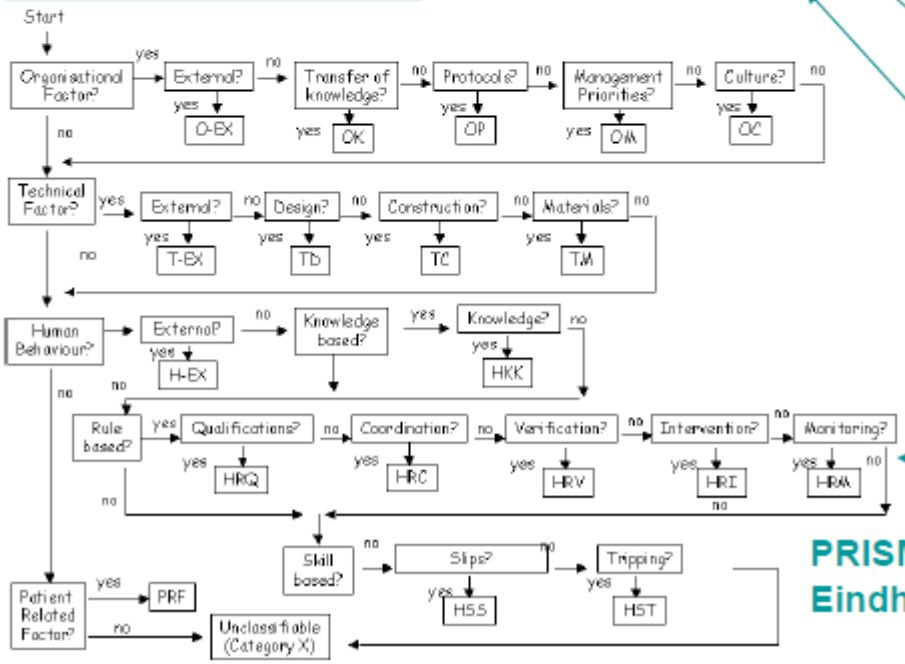
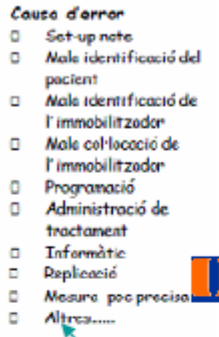
Classification-Causes

- Staff (knowledge, execution, inadequate behaviour, communication, emotional, social)
- patient (knowledge, execution, inadequate behaviour, communication, emotional, social)
- working environement (infrastructure, distance, risk evaluation of the environement, regulations, specifications)
- organization (protocols/procedures/processes, decisions, discipline, team organisation, emergency plan, resources/workload)
- External factors (natural hazards, products/technologies/infrastructure, services/systems/political)
- Others

According JCI Standards:
- Patient related (5 subclassifications)
- Staff related (7 subclassifications)
- Organization related (11 subclassifications)





PRISMA: For root cause classification the Eindhovens-Classification Model (ECM) is used.

Classification-Actions taken

http://www.accirad.eu

- Patient related (ask for help, information provided to the patient, performed treatment or assistance)
- Staff related (supervision adequate, giving help to staff involved, appropriate work team, training by the correct professionals, effective communication)
- Organization related (protocols available, good management and accessibility of products/equipment, documentation error corrected)
- Improvement suggestions

Table 3. Classification/Action Matrix [Personal communication with van der Schaaf; March 2005].

Classification code	Technology / Equipment	Procedures	Information and Communication	Training	Motivation	Escalation	Reflection
T-EX						x	
TD	x						
TC	x						
TM	x						
O-EX						x	
OK						x	
OP		x					
OM						x	
OC							x
H-EX						x	
HKK			x		NO		
HRQ				x			
HRC				x			
HRV				x			
HRI				x			
HRM				x			
HSS	x				NO		
HST	x				NO		
PRF[1]							
X							

[1]If particular patient related factors (such as language problems) that cannot be prevented by the patients themselves recur, then these problems should be solved at an organisational level (i.e. escalation).

Classification Actions
✓
✓

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RISK management

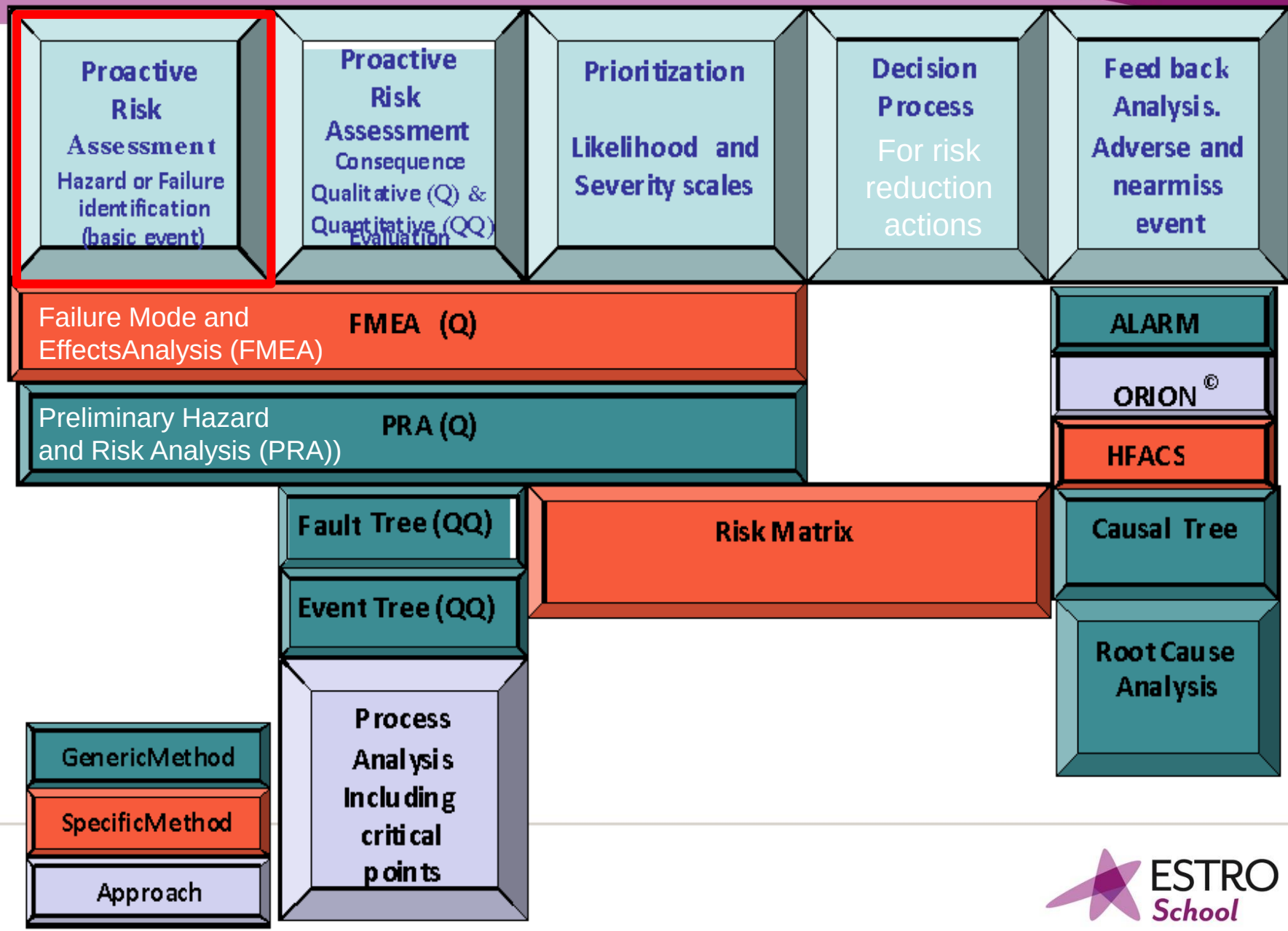
Recommendations on risk management

- Methods should be chosen so that both proactive risk assessment and reactive analysis of events are introduced (a complete or integrated approach).

- A methodology dedicated to radiotherapy should be worked out jointly by professional societies and national authorities.

- Professional societies, in collaboration with national authorities in charge of Radiation Protection and Healthcare, should undertake training actions, both initial and continuous training.

Targets and methods of risk management



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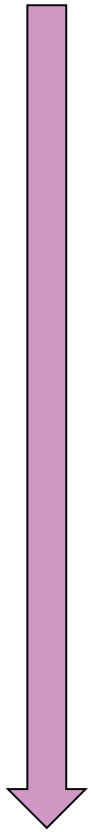
Recommendations on risk management

For **proactive** **risk assessment**, the following is recommended as the *minimum approach:*

- **Potential failures or hazards are identified** with peer experts' advice, analysis of feedback data or making use of checklists available of published risk assessment studies
- **Evaluation of consequencies** is carried out by deductive (bottom up approach) and qualitative methods using either Failure Mode and Effect Analysis (FMEA or FMECA) or Preliminary Hazard and Risk Analysis (PRA)

In both methods, an additional step of the **criticality (C) evaluation** is carried out.

Criticality data is then used **to evaluate if the situation is acceptable or not**, and **actions** taken to reduce the risk



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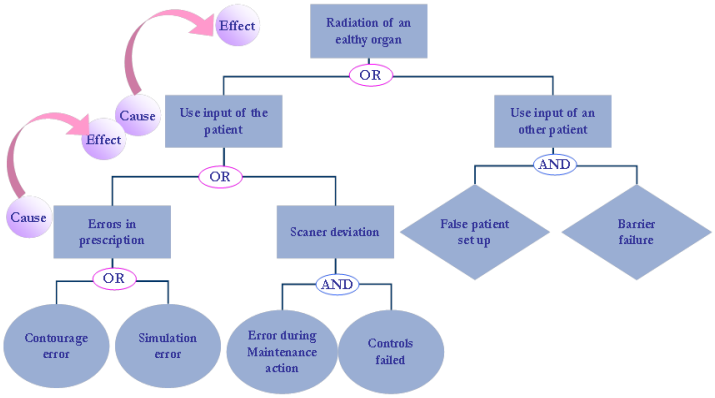
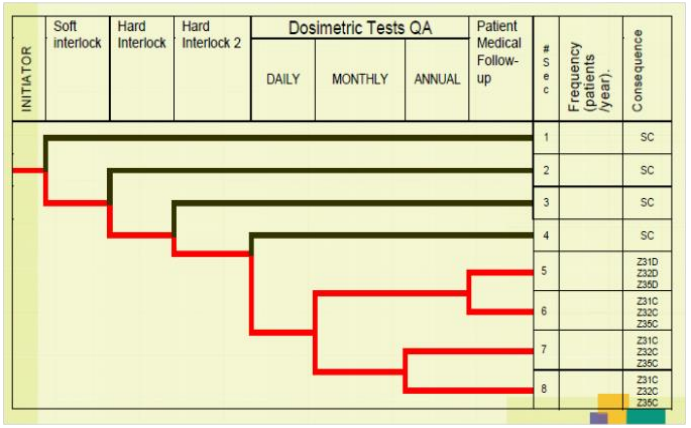
Recommendations on risk management

- After having received experience on this minimum approach, a *deeper analysis* is recommended

  to take into account combinations of failures and probabilistic assessment and also the failures of barriers

  either **Fault Tree** or **Event Tree** method, or the **Probabilistic Risk Matrix** method can be used





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Classification and reporting of adverse and near miss events

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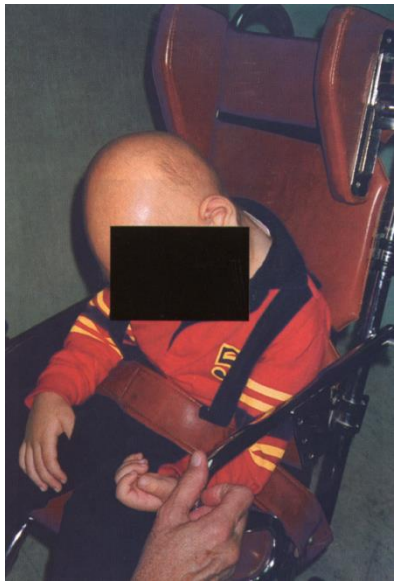
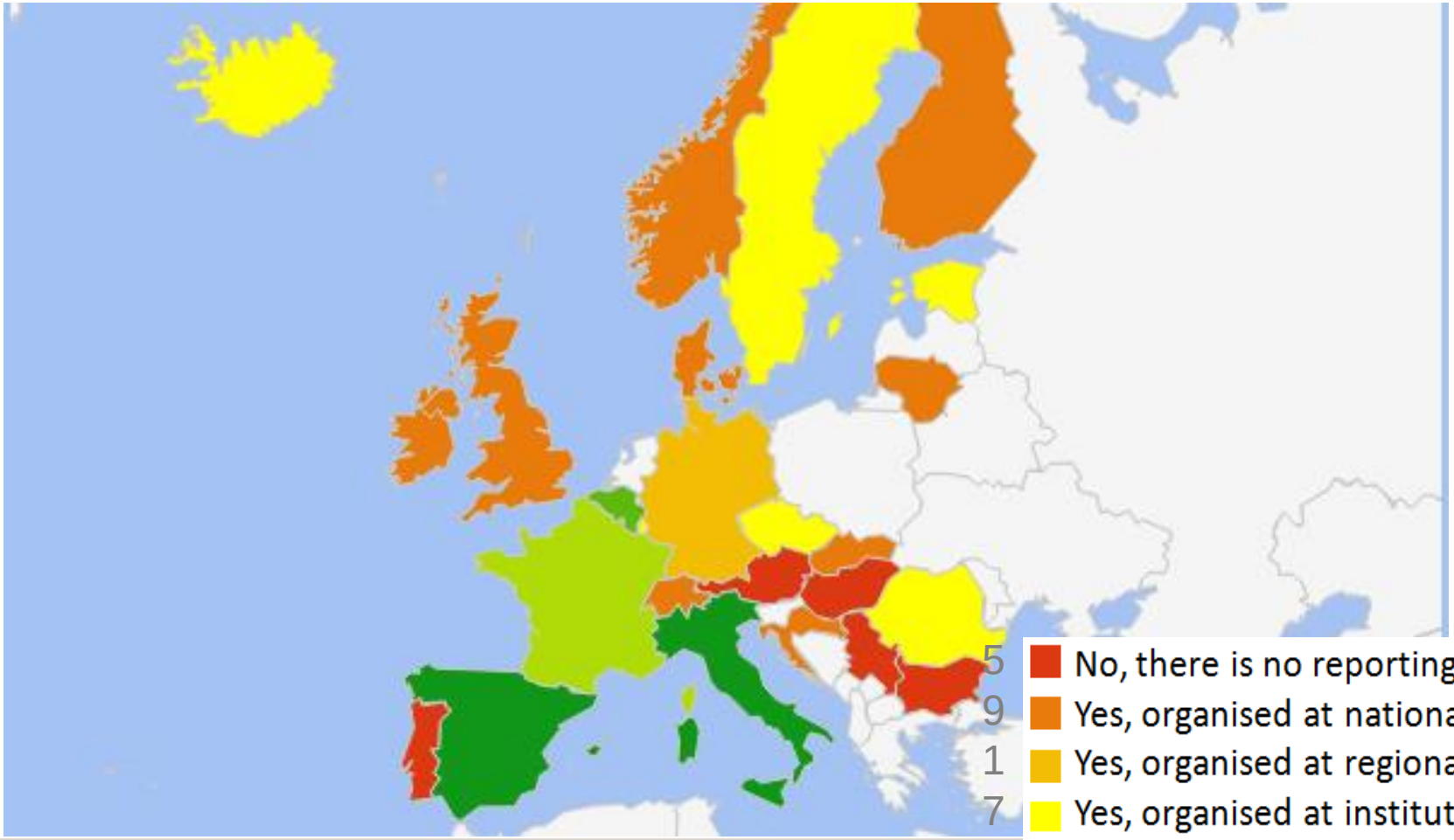
Classification and reporting of events

- Events (near miss events, no harm or minor events, or adverse events) in radiotherapy need to be addressed promptly and appropriately to avoid future repetition and to diminish the expected effects
- Events in radiotherapy have a significant media and public attention



- Challenge is to move from a culture of reporting events to a culture of learning from events.

Organization reporting systems



Reporting

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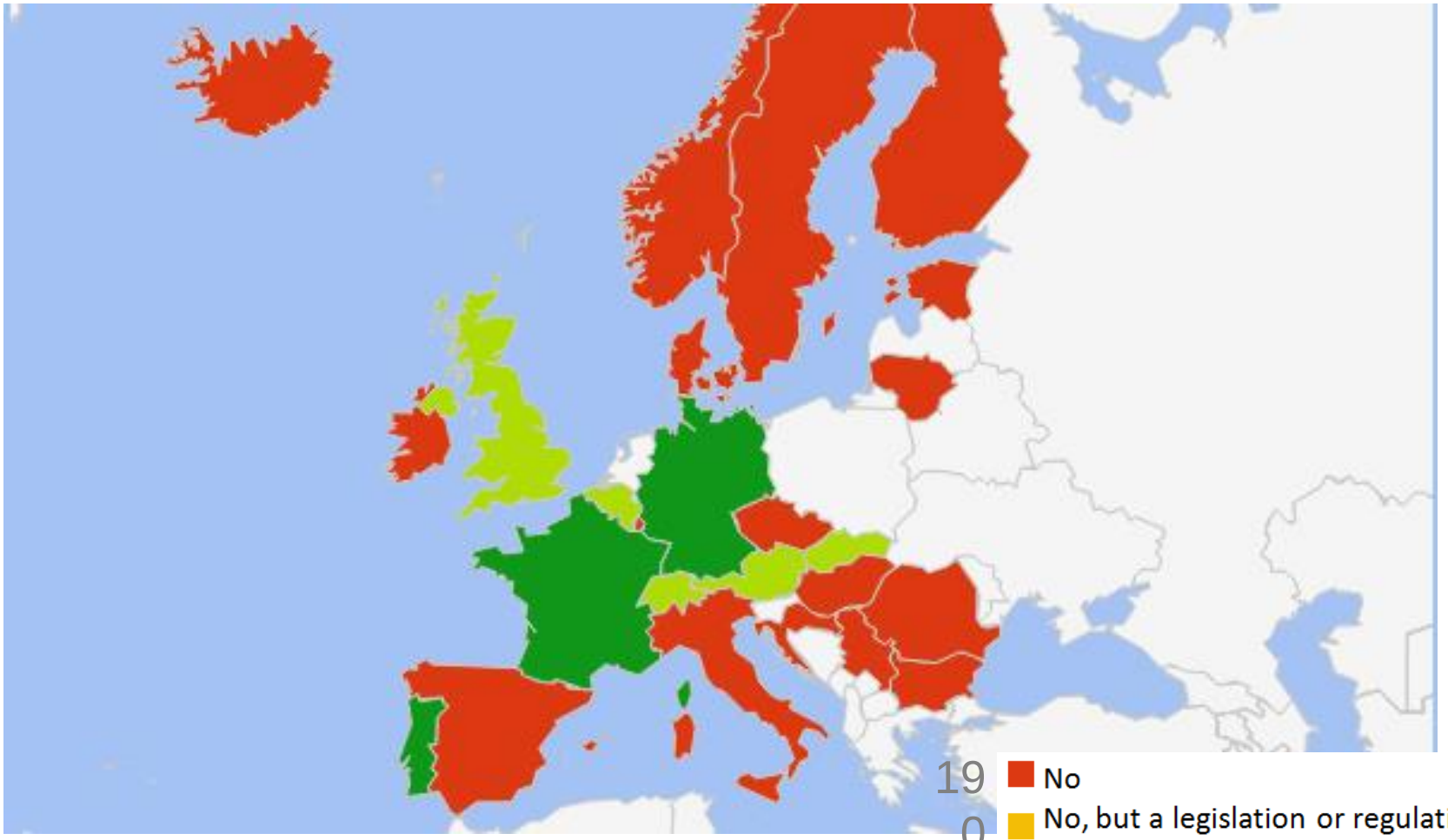
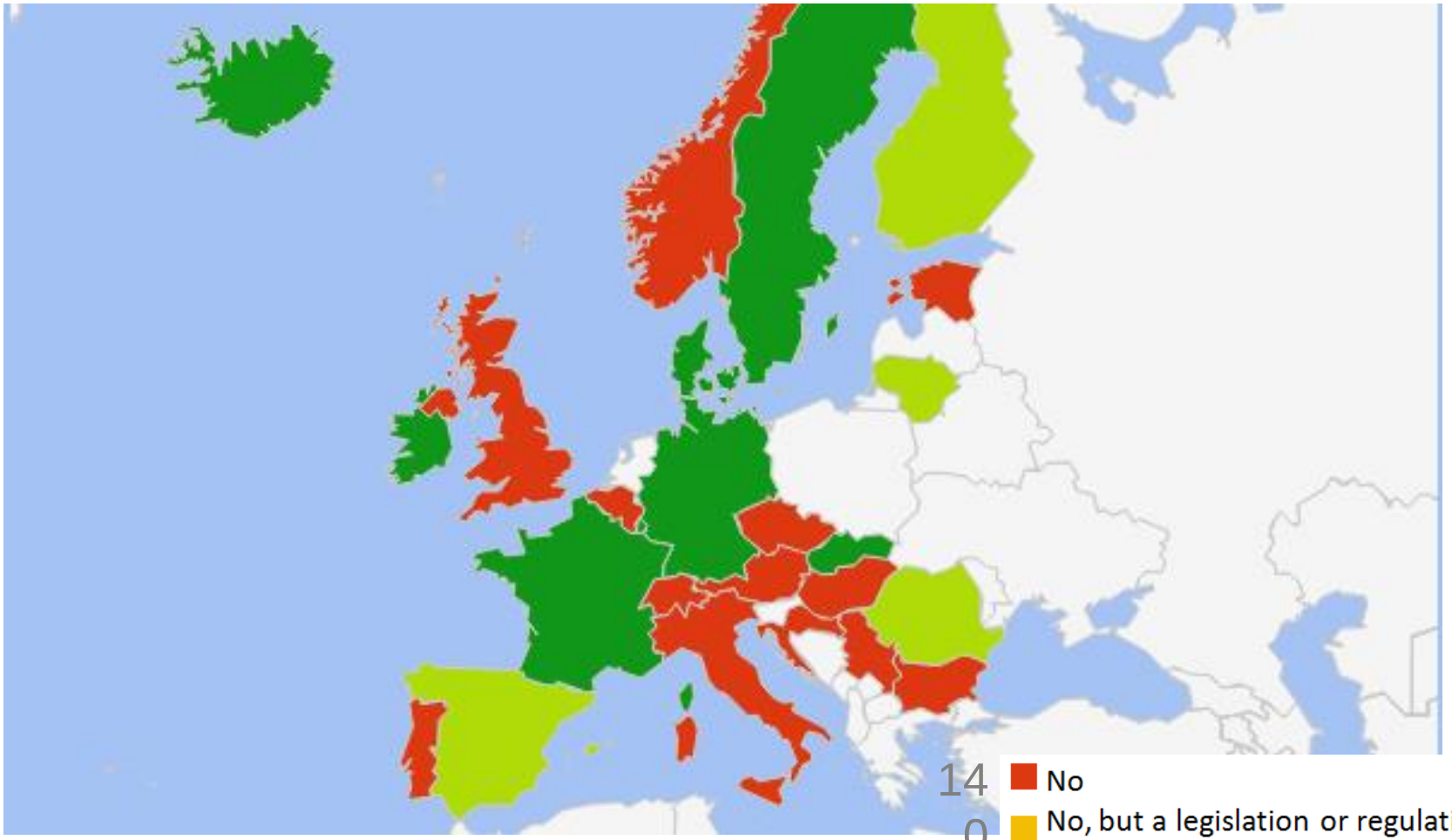
Guidelines (Adverse events & Near misses)



Reporting-Near misses

http://www.accirad.eu

Legislation (2.4.1.1.)



Information to the patient-Adverse events

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Existing classification/reporting systems

	General systems	RT specific systems
International	ICPS (WHO) AIMS (Int., Australia)	ROSIS RT risk profile (WHO) SAFRON (IAEA)
National or other	Portailuri et al. (HFACS, US Navy) ARIR (Australia) AHRQ WebM&M (USA) JCAHO (USA) NRC (USA) ASN/ANSM (FR, ..) DPSD (UK) ICHT/NRSL (UK)SNASP (ES)	Ekaette et al Towards safer RT (RCR) AHFRM HTA ILS (Canada) PRISMA-RT (The Netherlands) Swiss ROSIS

Recommendations on terminology and classification

- Common terminology should be used, to facilitate the analysis and comparison of reported data from different sources
  - It is a key to compare the risk of radiotherapy with other health care areas.
- Existing general healthcare taxonomies, with specific codes for radiotherapy, should be used as much as possible in order to integrate radiotherapy reporting in existing general healthcare reporting systems with an important save of resources.

ICPS

World Health Organization

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Recommendations on terminology

Term	Use	Definition
Accident	Not to be used	An unplanned, unexpected, and undesired event, usually with adverse consequences.
Adverse event	To be used instead of ”accident”	An event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient. Any side effects related to the accepted treatment are excluded.
Near miss event		An event which does not reach the patient
No harm or minor event		An event that reaches the patient but does not result in harm to the patient

Recommendations on reporting

- Event reporting systems should preferably be called event reporting and learning systems, to emphasize that reporting is only one step in a process aimed at learning from events.
- Institutions must have a supportive environment for event reporting that protects the privacy of the reporter.
- Departmental reporting and learning systems should be part of the safety culture and a module in radiotherapy information systems.

Recommendations on reporting

- Event investigation should be positive, constructive and sensitive and look for solutions not for culprits.
- Monitoring is fundamental to demonstrate the implementation of remedial actions, to close the cycle of learning and improving safety after an event.
- Public should be provided with assurance that there is a track of errors and a design of solutions.

Information to the public-Adverse events & Near misses

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Recommendations on reporting

- Authorities and professional societies both on national and European Union level should cooperate to
  - establish harmonized classification scales (severity, probability, risk, etc)
  - to define what is a significant event that should be reported to authorities.

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European SocieTy for
RADIOTHERAPY
& ONCOLOGY

Report to an international register (e.g. ROSIS)


Thank you for your attention!

REFERENCES:

1- Patient safety in external beam radiotherapy – Guidelines on risk assessment and analysis of adverse error-events and near misses:
Introducing the ACCIRAD project
Julian Malicki et al Radiother Oncol 2014;112:194-198

2- Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom,96/29/Euratom, 97/43/Euratom and 2003/122/Euratom. Official Journal of the European Union. L13. Vol. 57. 17 January 2014. http://eur-lex.europa.eu/ legal-content/EN/TXT/PDF/?uri=OJ:L:2014:013:FULL&from=EN

3-. Patient safety in external beam radiotherapy, results of the ACCIRAD project: Current status of proactive risk assessment, reactive analysis of events, and reporting and learning systems in Europe.
Malicki J, Bly R, Bulot M, Godet JL, Jahnen A, Krengli M, Maingon P, Prieto Martin C, Przybylska K, Skrobała A, Valero M, Jarvinen H.
Radiother Oncol. 2017;123:29-3

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Reporting adverse events to the public

a. Is mandatory
b. Is recommended
c. Will be mandatory
d. Is not recommended

ANSWER = b

RISK MANAGEMENT IN EU : What is on ?

Radiation therapy activities are :

a. Validated by the European Medecine Agency
b. Under the supervision of the EC
c. Under the responsibility of each member states
d. Part of the Euratom Directive

ANSWERS = c and d

Recording near miss events

a. Is a proactive process
b. Should be described in the QA programme
c. Will be mandatory
d. Should use a validated classification

ANSWERS = b,c

Recording adverse events

a. Is a proactive process
b. Is mandatory
c. Will be mandatory
d. Will be mandatory on national and international levels

ANSWER = c

Staffing levels in radiation oncology: what are they, what should they be?

ESTRO Teaching Course
"Quality Assessment and Improvement"

Brussels – October 2017

Yolande Lievens, MD, PhD
Department of Radiation Oncology, Ghent University Hospital, Belgium

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learning objectives

- Be aware of the **available personnel** resources in various countries and other world regions
- Understand the **factors determining** geographical variability
- Know the **guidelines** for radiotherapy professionals
- Understand the potential of **staffing models**
- Recognize the challenges and opportunities in estimating future radiotherapy resource needs

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" If the institution has **inadequate staffing**, in terms of quantity and quality, there will undoubtedly be a **higher propensity of errors**. In reference staffing levels, no national organization has been able to evaluate needs fast enough to keep up with the technology explosion. Facilities are trying to hire additional staffing, particularly physicists, who in many cases, are not properly trained."

Eric Klein, IJROBP 2009

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recommendations for safer radiotherapy

Table 1 | Citations for the top twelve recommendations.

Recommendation	TSF	WHO	ICRP	NPSF	ASTRO	H–H	TG100
Training	✓	✓	✓	✓	✓	✓	✓
Staffing	✓	✓	✓	✓		✓	✓
Documentation/SOP	✓		✓	✓		✓	✓
Incident learning	✓	✓	✓		✓	✓	
Communication/ questioning	✓		✓	✓		✓	
Check lists	✓	✓		✓		✓	
QC/PM	✓	✓	✓				✓
Dosimetric audit	✓	✓	✓			✓	
Accreditation	✓	✓			✓	✓	
Minimizing interruptions	✓		✓			✓	
Prospective risk assessment	✓		✓			✓	
Safety culture			✓	✓		✓	

Dunscombe et al, Frontiers in Oncology 2012

- Radiotherapy is **labour intensive**: technological complexity along with need for accuracy and safety
- Radiotherapy is a **rapidly evolving** field
- The radiotherapy **patient population is diverse**:
  - different tumour sites, stages and treatment intent
  - various co-morbidities
  - different psychological and social status
- The European **cancer landscape is heterogeneous**:
  - population density and cancer epidemiology
  - legal and economic context
  - staffing structure, roles and responsibilities

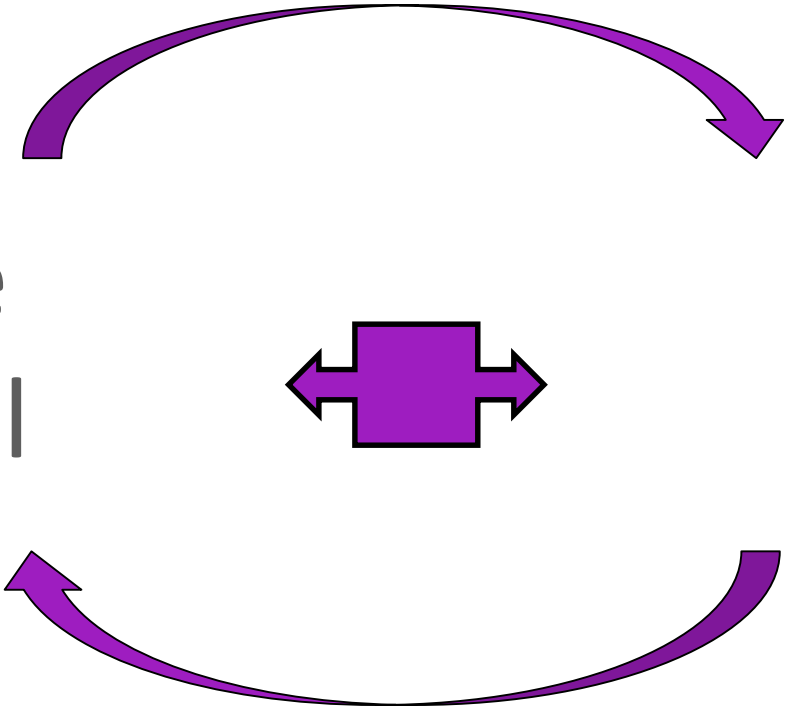
Cancer Control Plans

Where are we now?
Where do we want to be?
How do we get there?

1. Assessment of the present situation
2. Evaluation of evidence-based demand
3. Forecast of the future needs
4. Definition of costs
5. Reimbursement modalities / budget impact

WHO: National Cancer Control Programmes: Policies and Managerial Guidelines - 2002

Evaluation required treatments
Projection into the future



Available Personnel

Required Personnel

Planning
Training and education

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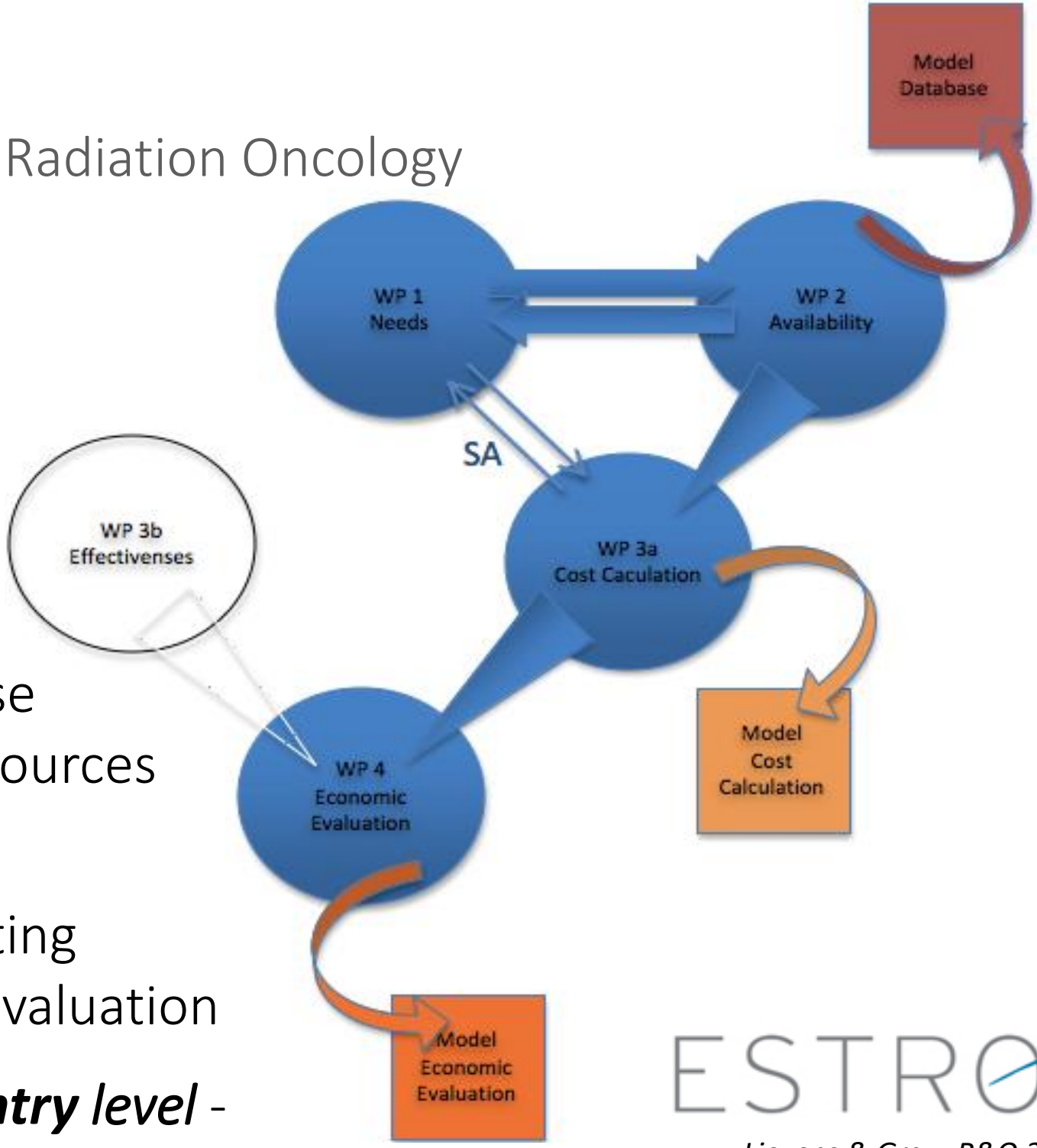
Health Economics in Radiation Oncology



knowledge base
of radiotherapy resources

model
for cost accounting
for health economic evaluation

- ***at the European country level*** -

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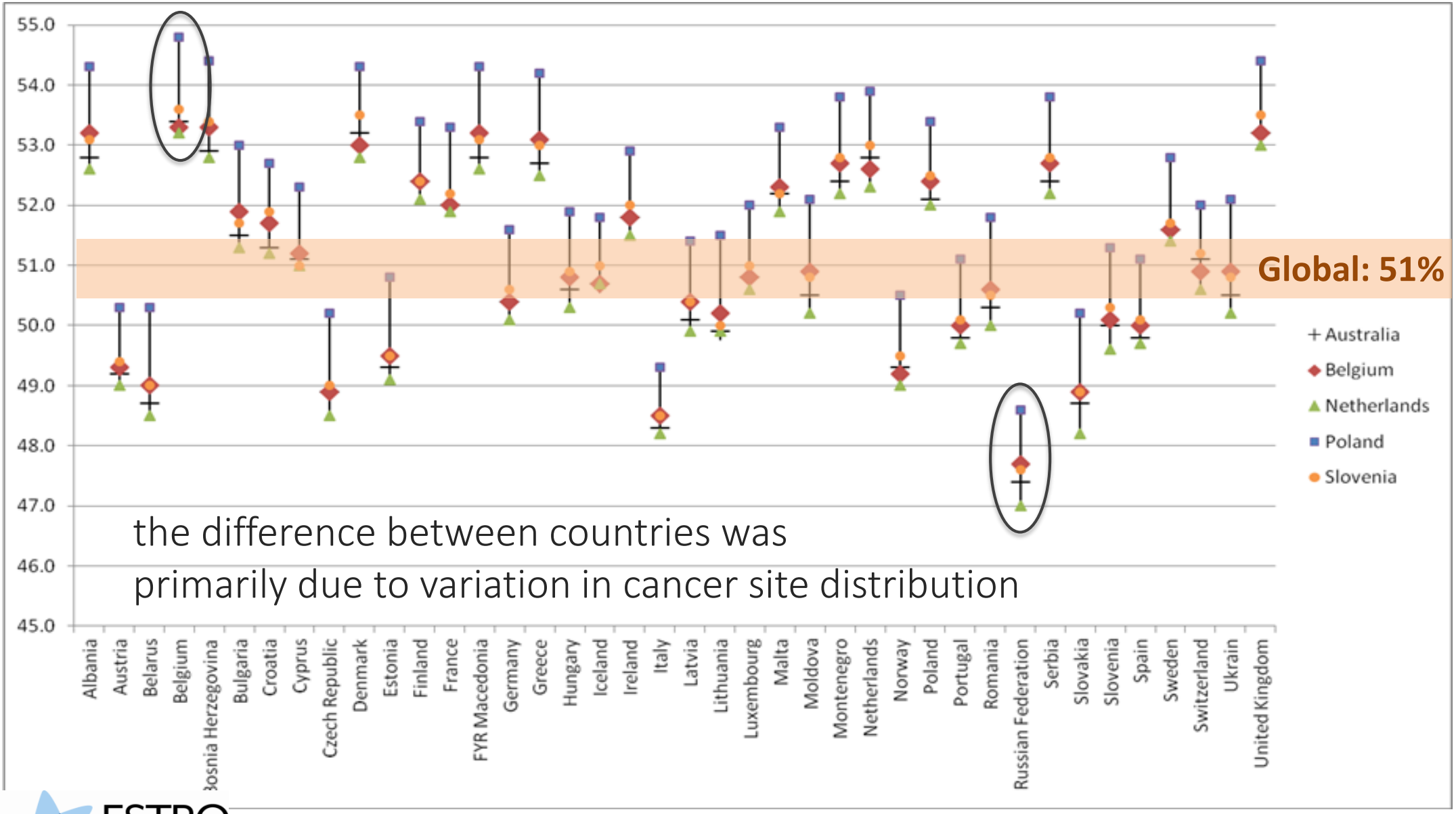
Lievens & Grau. R&O 2012

optimal radiotherapy utilization *(by country)*



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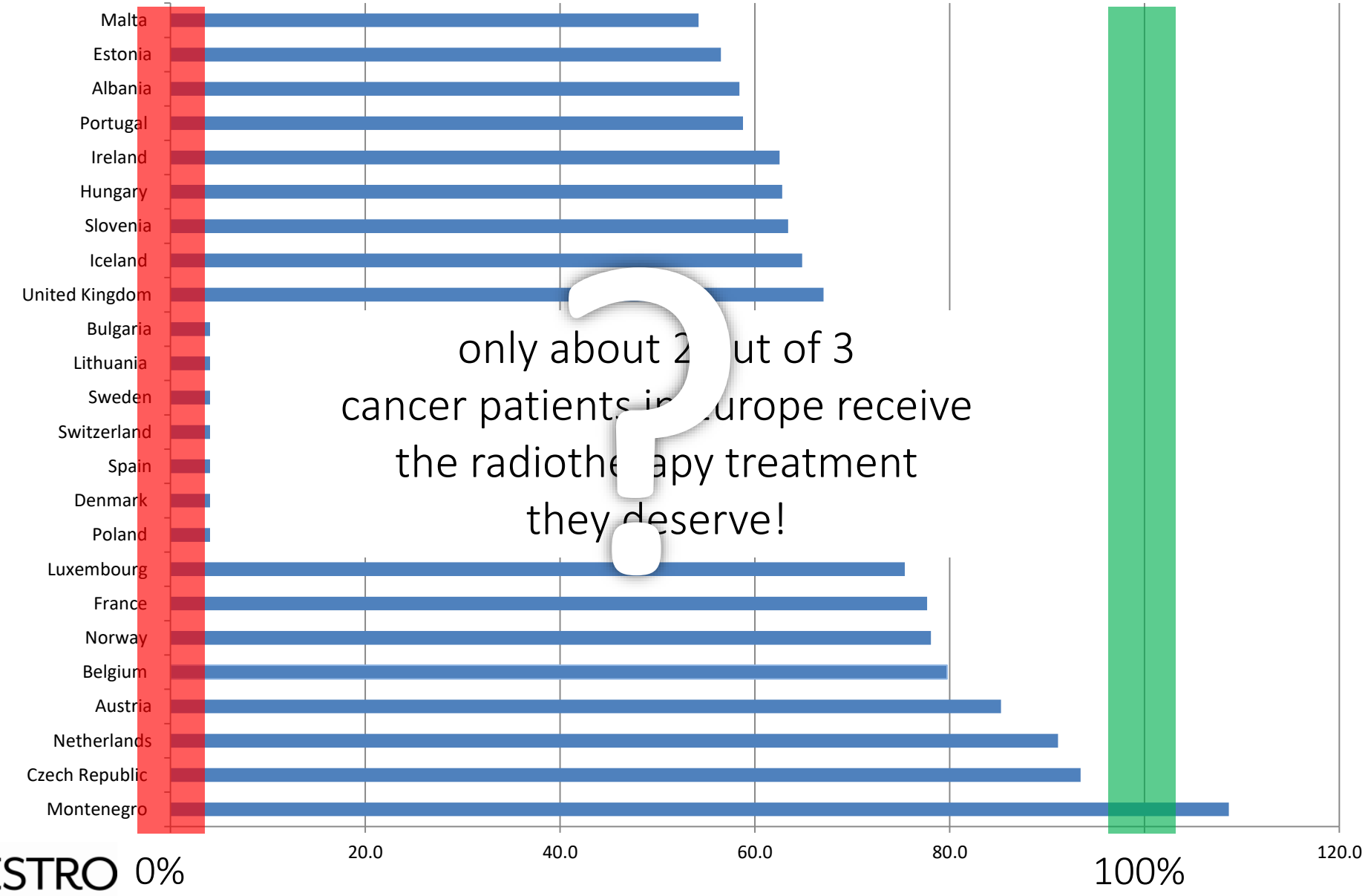
& ONCOLOGY

Borras et al, R&O 2015

how is the actual use of radiotherapy, compared to the calculated optimum?



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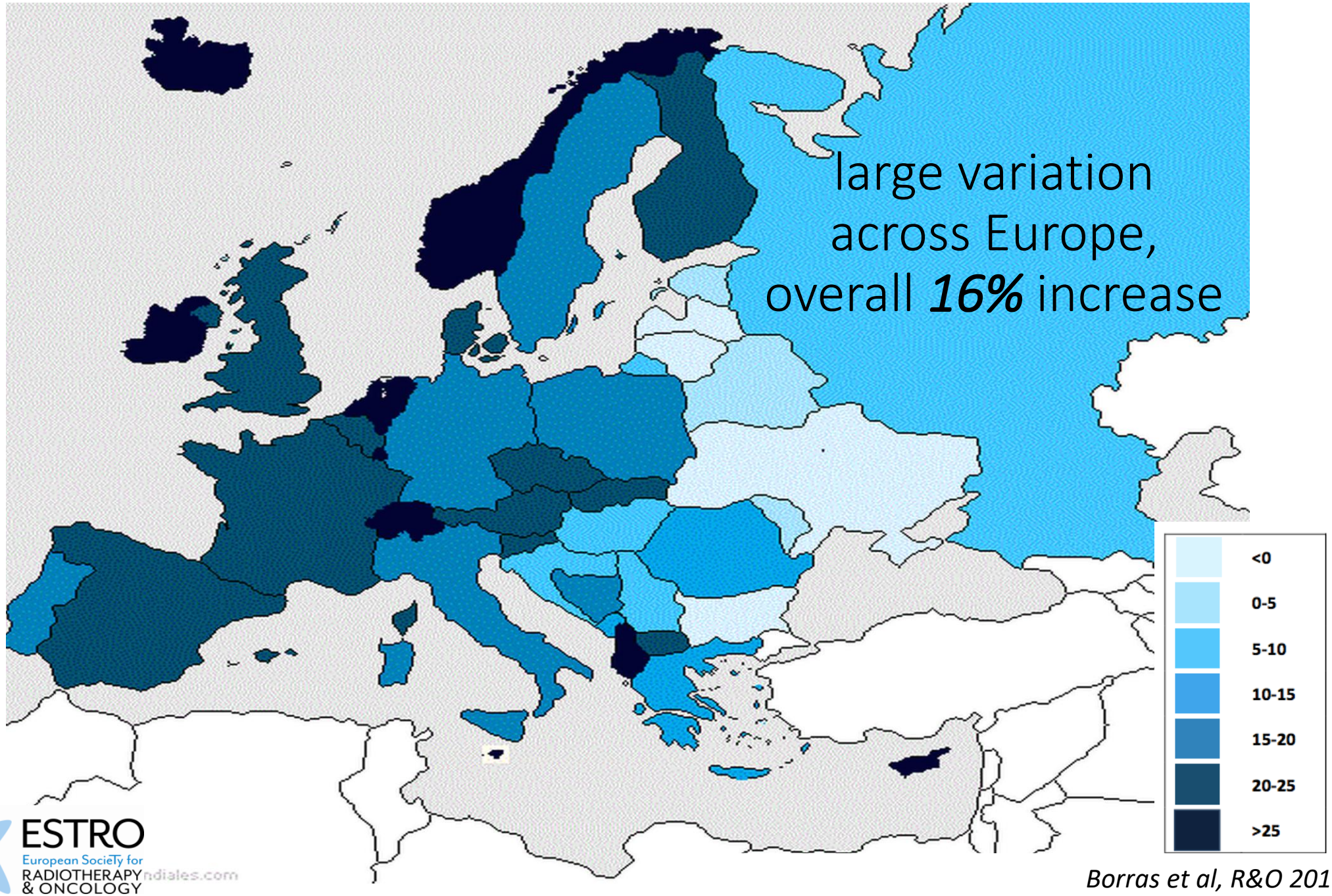
Borras et al, R&O 2015

needs are increasing *(radiotherapy demand 2025)*



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Borras et al, R&O 2016

long-term investment and planning

education and training
highly qualified personnel
different professional backgrounds
working in various national environments

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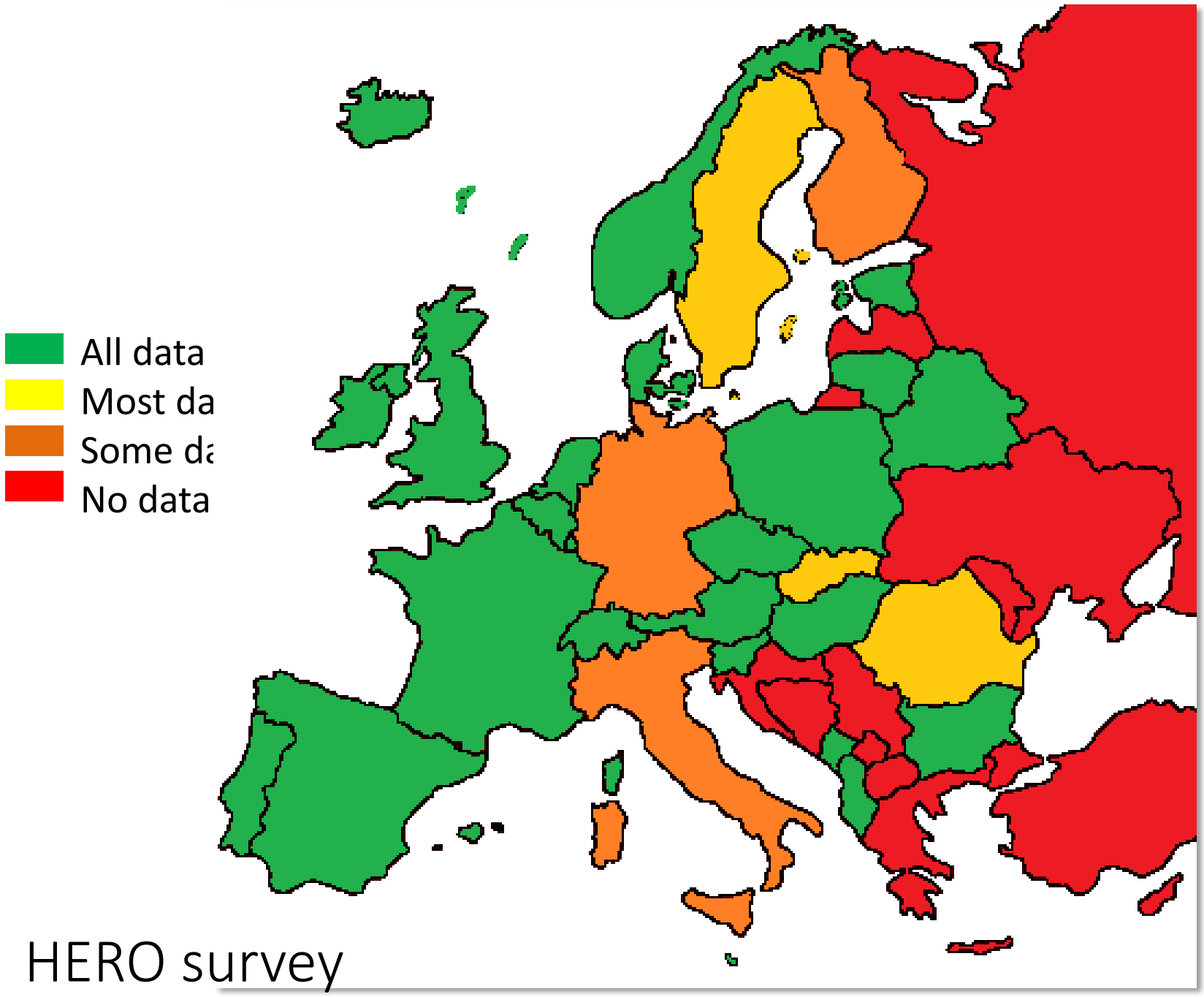
available human resources



Responses were obtained from:

Equipment
28 countries

Staffing
24 countries

Guidelines
29 countries

HERO survey

Thanks to all National Societies for their great interest in the HERO project

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& ONCOLOGY

available staffing in Europe

Countries	Population (*2011*)	GNI per capita (*USD, 2011*)	Ref. year courses	RT courses	Ref. year staffing	Radiation oncologists		Medical physicists		Dosimetrists		Radiation technologists		Radiotherapy nurses		Radio-biologists	
						N	FTE	*N*	FTE	*N*	FTE	*N*	FTE	*N*	FTE	*N*	FTE
Albania	2,829,337	4,050	2010	2,195	2010	**7**	7.0	**6**	6.0	n.a.	n.a.	**13**	13.0	**1**	1.0	**n.a.**	n.a.
Austria	8,406,187	48,170	2010	21,481	2010 2013	**n.r.**	95.0	**n.r.**	40.0	n.a.	n.a.	**301**	280.0	**n.a.**	n.a.	**n.r.**	8.0
Belarus	9,473,000	6,270	2009	n.r.	2009	**117**	n.r.	**60**	n.r.	20	n.r.	**140**	n.r.	**150**	n.r.	**n.a.**	n.a.
Belgium	11,047,744	45,840	2012	34,672	2013	**154**	138.5	**113**	107.9	52	45.3	**21**	20.6	**471**	403.1	**4**	4.0
Bulgaria	7,348,328	6,640	2012	13,794	2012	**n.r.**	49.0	**n.r.**	23.0	n.a.	n.a.	**n.r.**	113.0	**n.r.**	98.0	**n.a.**	n.a.
Czech Republic	10,496,088	18,720	2009	32,630	2009	**254**	n.r.	**56**	n.r.	n.a.	n.a.	**251**	n.r.	**n.r.**	n.r.	**20**	n.r.
Denmark	5,570,572	60,160	2010	17,680	2010	**n.r.**	172.0	**n.r.**	89.0	n.r.	15.0	**n.r.**	55.0	**n.r.**	340.0	**n.r.**	1.0
Estonia	1,327,439	15,260	2008	2,122	2012	**14**	14.0	**10**	10.0	1	1.0	**16**	16.0	**6**	6.0	**n.r.**	n.r.
France	65,343,588	42,690	2012	187,172	2012	**670**	510.0	**n.r.**	528.0	n.r.	342.0	**n.r.**	1,950.0	**n.r.**	n.r.	**25**	n.r.
Hungary	9,971,727	12,840	2011	19,951	2011	**90**	n.r.	**60**	n.r.	8	n.r.	**207**	n.r.	**n.r.**	n.r.	**3**	n.r.
Iceland	319,014	35,260	2010	595	2010	**3**	2.6	**3**	2.2	4	3.0	**1**	0.8	**10**	7.0	**n.r.**	n.r.
Ireland	4,576,794	38,960	2009	8,373	2009	**30**	30.0	**54**	54.0	12	12.0	**291**	249.0	**35**	35.0	**n.a.**	n.a.
Lithuania	3,028,115	13,000	2011	6,268	2011	**37**	35.5	**31**	27.0	5	5.0	**70**	67.0	**10**	10.0	**1**	0.5
Luxembourg	518,347	77,380	2010	1,180	2011	**5**	4.9	**4**	4.0	3	2.5	**14**	13.5	**2**	2.0	**n.a.**	n.a.
Malta	416,268	19,780	2012	1,395	2012	**4**	4.0	**3**	3.0	0[a]	0.0[a]	**8**	8.0	**2**	2.0	**n.a.**	n.a.
Montenegro	620,644	6,810	2011	1,500	2011	**6**	5.0	**0**[a]	0.0[a]	n.a.	n.a.	**4**	4.0	**11**	11.0	**n.a.**	n.a.
The Netherlands	16,693,074	49,660	2011	55,683	2011	**256**	231.0	**119**	115.0	n.a.	n.a.	**1,302**	1,079.0	**n.a**	n.a	**n.r.**	n.r.
Norway	4,953,088	88,500	2010	13,483	2011	**n.r.**	135.0	**n.r.**	46.0	n.a.	n.a.	**n.r.**	267.0	**n.a**	n.a	**n.r.**	n.r.
Poland	38,534,157	12,340	2010	73,500	2012	**471**	471.0	**97**	97.0	n.a.	n.a.	**900**	900.0	**19**	19.0	**n.r.**	n.r.
Portugal	10,557,560	21,420	2012	19,858	2013	**90**	n.r.	**65**	n.r.	53	n.r.	**239**	n.r.	**108**	n.r.	**2**	n.r.
Slovenia	2,052,843	23,940	2012	6,023	2013	**31**	27.0	**11**	11.0	10	10.0	**81**	78.5	**n.a.**	n.a.	**n.a.**	n.a.
Spain	46,742,697	30,930	2011	98,525	2013	**702**	579.0	**282**	n.r.	249	n.r.	**n.r.**	n.r.	**n.r.**	n.r.	**n.r.**	n.r.
Switzerland	7,912,398	76,350	2009	19,000	2009	**110**	98.3	**83**	75.3	7	6.0	**312**	274.0	**110**	72.3	**3**	3.0
United Kingdom	63,258,918	37,840	2010 2011	n.r.	2010 2011	**683**	580.3	**1,246**	1,264.6	43	41.7	**2,763**	2,957.2	**403**	440.0	**22**	2.0
England	52,234,045	n.a.	2010	121,289	2010	**561**	482.0	**1,206**	1,096.7	n.a.	n.a.	**2,222**	2,468.0	**388**	437.0	**20**	n.r.
Scotland	5,254,800	n.a.	2011	n.r.	2011	**61**	58.75	**143**	133.0	n.a.	n.a.	**267**	243.6	**12**	n.r.	**n.a.**	n.a.
Wales	3,060,000	n.a.	2011	6,445	2011	**42**	39.5	**27**	24.9	27	25.7	**187**	163.2	**3**	3.0	**n.a.**	n.a.
Northern Ireland	1,800,000	n.a.	2010	4,180	2011	**19**	n.r.	**13**	10.0	16	16.0	**87**	82.4	**n.r.**	n.r.	**2**	2.0
No. entries	24	24	24	22	24	**20**	20	**19**	19	22	20	**19**	19	**18**	18	**16**	14
Total	331,997,927			635,179		**3,734**	3,189.1	**2,303**	2,503.0	467	483.5	**6,934**	8,345.6	**1,338**	1,446.4	**80**	18.5
Average	13,833,247	33,034	2010	28,872	2011	**187**	159.5	**121**	131.7	33	40.3	**365**	439.2	**96**	103.3	**10**	3.1
Median	7,630,363	27,435	2010	15,737	2011	**90**	72.0	**56**	40.0	9	8.0	**140**	78.5	**15**	15.0	**3**	2.5
Min	319,014	4,050	2008	595	2009	**3**	2.6	**0**	0.0	0	0.0	**1**	0.8	**1**	1.0	**1**	0.5
Max	65,343,588	88,500	2012	187,172	2013	**702**	580.3	**1,246**	1,264.6	249	342.0	**2,763**	2,957.2	**471**	440.0	**25**	8.0

n.r. = not reported; n.a. = not applicable.

Figures are rounded to the closest decimal number. Computation of totals, medians and ranges are for the available countries and use UK total figures, except for RT courses.

[a] Montenegro reported 0 MP although the position exists. There are to date no specialists, but 3 MP trainees. In Malta there are no dosimetrists although the position exists.

Lievens et al, R&O 2014

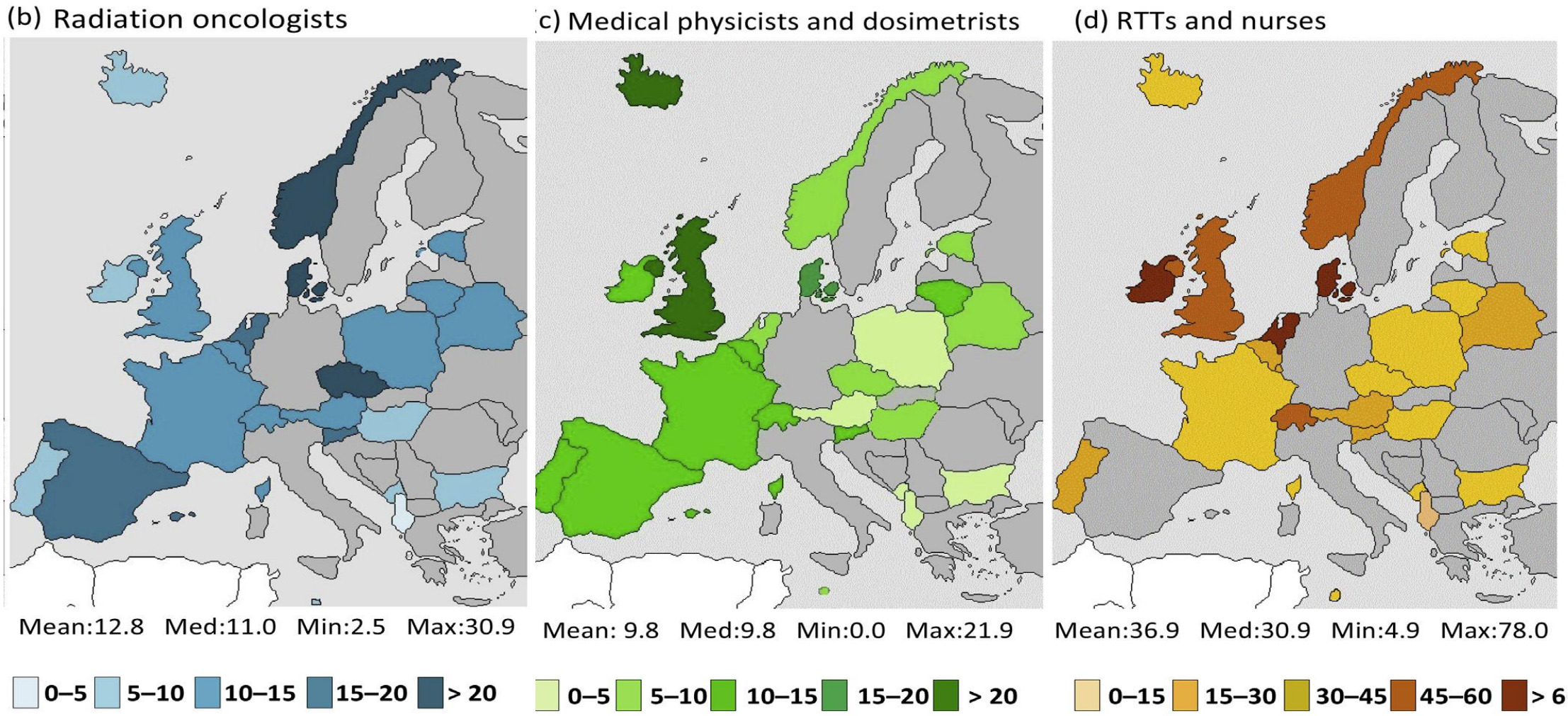
key parameters for staffing in Europe

Countries	Personnel type/million inhabitants							Courses/personnel type						
	RO	MP	DO	MP + DO	RTT	RN	RTT + RN	RO	MP	DO	MP + DO	RTT	RN	RTT + RN
Albania	**2.5**	2.1	n.a.	**2.1**	4.6	0.4	**4.9**	**313.6**	365.8	n.a.	**365.8**	168.8	2,195.0	**156.8**
Austria	**11.3**	4.8	n.a.	**4.8**	35.8	n.a.	**35.8**	**226.1**	537.0	n.a.	**537.0**	71.4	n.a.	**71.4**
Belarus	**12.4**	6.3	2.1	**8.4**	14.8	15.8	**30.6**	**–**	–	–	**–**	–	–	**–**
Belgium	**13.9**	10.2	4.7	**14.9**	1.9	42.6	**44.5**	**225.1**	306.8	666.8	**210.1**	1651.0	73.6	**70.5**
Bulgaria	**6.7**	3.1	n.a.	**3.1**	15.4	13.3	**28.7**	**281.5**	599.7	n.a.	**599.7**	122.1	140.8	**65.4**
Czech Republic	**24.2**	5.3	n.a.	**5.3**	23.9	–	**23.9**	**128.5**	582.7	n.a.	**582.7**	130.0	–	**130.0**
Denmark	**30.9**	16.0	2.7	**16.0**	9.9	61.0	**70.9**	**102.8**	198.7	1,178.7	**198.7**	321.5	52.0	**44.8**
Estonia	**10.5**	7.5	0.8	**8.3**	12.1	4.5	**16.6**	**151.6**	212.2	2,122.0	**192.9**	132.6	353.7	**96.5**
France	**10.3**	8.1	5.2	**13.3**	29.8	–	**29.8**	**279.4**	354.5	547.3	**215.1**	96.0	–	**96.0**
Hungary	**9.0**	6.0	0.8	**6.8**	20.8	–	**20.8**	**221.7**	332.5	2,493.9	**293.4**	96.4	–	**96.4**
Iceland	**9.4**	9.4	12.5	**21.9**	3.1	31.3	**34.5**	**198.3**	198.3	148.8	**85.0**	595.0	59.5	**54.1**
Ireland	**6.6**	11.8	2.6	**14.4**	63.6	7.6	**71.2**	**279.1**	155.0	697.7	**126.9**	28.8	239.2	**25.7**
Lithuania	**12.2**	10.2	1.7	**11.9**	23.1	3.3	**26.4**	**169.4**	202.2	1,253.6	**174.1**	89.5	626.8	**78.4**
Luxembourg	**9.6**	7.7	5.8	**13.5**	27.0	3.9	**30.9**	**236.0**	295.0	393.3	**168.6**	84.3	590.0	**73.8**
Malta	**9.6**	7.2	0.0	**7.2**	19.2	4.8	**24.0**	**348.8**	465.0	–	**465.0**	174.4	697.5	**139.5**
Montenegro	**9.7**	0.0	n.a.	**0.0**	6.4	17.7	**24.2**	**250.0**	–	n.a.	**–**	375.0	136.4	**100.0**
The Netherlands	**15.3**	7.1	n.a.	**7.1**	78.0	n.a.	**78.0**	**217.5**	467.9	n.a.	**467.9**	42.8	n.a.	**42.8**
Norway	**27.3**	9.3	n.a.	**9.3**	53.9	n.a.	**53.9**	**99.9**	293.1	n.a.	**293.1**	50.5	n.a.	**50.5**
Poland	**12.2**	2.5	n.a.	**2.5**	23.4	0.5	**23.8**	**156.1**	757.7	n.a.	**757.7**	81.7	3,868.4	**80.0**
Portugal	**8.5**	6.2	5.0	**11.2**	22.6	10.2	**32.9**	**199.5**	276.3	338.8	**152.2**	75.1	166.3	**51.7**
Slovenia	**15.1**	5.4	4.9	**10.2**	39.5	n.a.	**39.5**	**194.3**	547.5	602.3	**286.8**	74.4	n.a.	**74.4**
Spain	**15.0**	6.0	5.3	**11.4**	–	–	**–**	**140.3**	349.4	395.7	**185.5**	–	–	**–**
Switzerland	**13.9**	10.5	0.9	**11.4**	39.4	13.9	**53.3**	**172.7**	228.9	2,714.3	**211.1**	60.9	172.7	**45.0**
United Kingdom	**10.8**	19.7	0.7	**20.4**	43.7	6.4	**50.1**	**212.1**	105.9	3,067.8	**102.3**	52.8	337.4	**45.7**
England	**10.7**	23.1	n.a.	**23.1**	42.5	7.4	**50.0**	**216.2**	100.6	n.a.	**100.6**	54.6	312.6	**46.5**
Scotland	**11.6**	27.2	n.a.	**27.2**	50.8	2.3	**53.1**	**–**	–	–	**–**	–	–	**–**
Wales	**13.7**	8.8	8.8	**17.6**	61.1	1.0	**62.1**	**153.5**	238.7	238.7	**119.4**	34.5	2,148.3	**33.9**
Northern Ireland	**10.6**	7.2	8.9	**16.1**	48.3	–	**48.3**	**220.0**	321.5	261.3	**144.1**	48.0	–	**48.0**
No. entries	**24**	24	24	**24**	23	20	**23**	**23**	22	22	**22**	22	19	**22**
Average	**12.8**	7.6	3.5	**9.8**	26.6	14.8	**36.9**	**208.9**	356.0	1,187.2	**303.3**	208.0	647.3	**76.8**
Median	**11.0**	7.2	2.7	**9.8**	23.1	8.9	**30.9**	**212.1**	319.7	682.2	**213.1**	92.8	239.2	**72.6**
Min	**2.5**	0.0	0.0	**0.0**	1.9	0.4	**4.9**	**99.9**	105.9	148.8	**85.0**	28.8	52.0	**25.7**
Max	**30.9**	19.7	12.6	**21.9**	78.0	61.0	**78.0**	**348.8**	757.7	3,067.8	**757.7**	1651.0	3,868.4	**156.8**

n.r. = not reported; n.a. = not applicable.
Figures are rounded to the closest decimal number. Computation of totals, medians and ranges are for the available countries and use UK total figures, except for RT courses/personnel.

Lievens et al, R&O 2014

personnel per million inhabitants



Lievens et al, Clin Oncol 2015

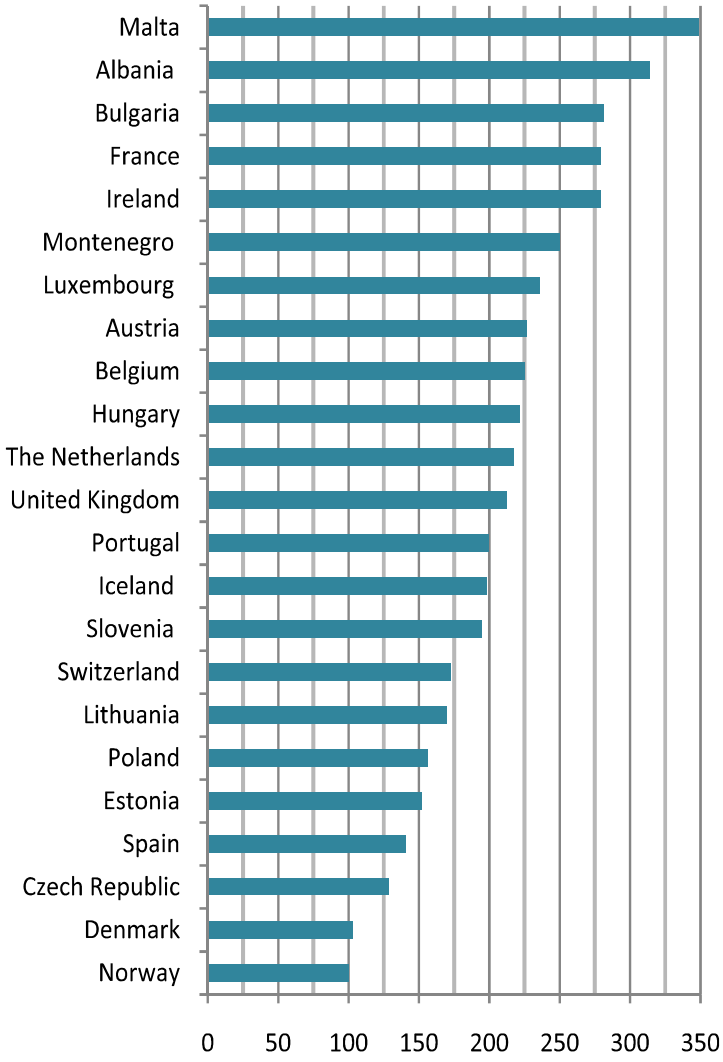
key parameters for staffing in Europe

Countries	Personnel type/million inhabitants							Courses/personnel type						
	RO	MP	DO	MP + DO	RTT	RN	RTT + RN	RO	MP	DO	MP + DO	RTT	RN	RTT + RN
Albania	**2.5**	2.1	n.a.	**2.1**	4.6	0.4	**4.9**	**313.6**	365.8	n.a.	**365.8**	168.8	2,195.0	**156.8**
Austria	**11.3**	4.8	n.a.	**4.8**	35.8	n.a.	**35.8**	**226.1**	537.0	n.a.	**537.0**	71.4	n.a.	**71.4**
Belarus	**12.4**	6.3	2.1	**8.4**	14.8	15.8	**30.6**	**–**	–	–	**–**	–	–	**–**
Belgium	**13.9**	10.2	4.7	**14.9**	1.9	42.6	**44.5**	**225.1**	306.8	666.8	**210.1**	1651.0	73.6	**70.5**
Bulgaria	**6.7**	3.1	n.a.	**3.1**	15.4	13.3	**28.7**	**281.5**	599.7	n.a.	**599.7**	122.1	140.8	**65.4**
Czech Republic	**24.2**	5.3	n.a.	**5.3**	23.9	–	**23.9**	**128.5**	582.7	n.a.	**582.7**	130.0	–	**130.0**
Denmark	**30.9**	16.0	2.7	**16.0**	9.9	61.0	**70.9**	**102.8**	198.7	1,178.7	**198.7**	321.5	52.0	**44.8**
Estonia	**10.5**	7.5	0.8	**8.3**	12.1	4.5	**16.6**	**151.6**	212.2	2,122.0	**192.9**	132.6	353.7	**96.5**
France	**10.3**	8.1	5.2	**13.3**	29.8	–	**29.8**	**279.4**	354.5	547.3	**215.1**	96.0	–	**96.0**
Hungary	**9.0**	6.0	0.8	**6.8**	20.8	–	**20.8**	**221.7**	332.5	2,493.9	**293.4**	96.4	–	**96.4**
Iceland	**9.4**	9.4	12.5	**21.9**	3.1	31.3	**34.5**	**198.3**	198.3	148.8	**85.0**	595.0	59.5	**54.1**
Ireland	**6.6**	11.8	2.6	**14.4**	63.6	7.6	**71.2**	**279.1**	155.0	697.7	**126.9**	28.8	239.2	**25.7**
Lithuania	**12.2**	10.2	1.7	**11.9**	23.1	3.3	**26.4**	**169.4**	202.2	1,253.6	**174.1**	89.5	626.8	**78.4**
Luxembourg	**9.6**	7.7	5.8	**13.5**	27.0	3.9	**30.9**	**236.0**	295.0	393.3	**168.6**	84.3	590.0	**73.8**
Malta	**9.6**	7.2	0.0	**7.2**	19.2	4.8	**24.0**	**348.8**	465.0	–	**465.0**	174.4	697.5	**139.5**
Montenegro	**9.7**	0.0	n.a.	**0.0**	6.4	17.7	**24.2**	**250.0**	–	n.a.	**–**	375.0	136.4	**100.0**
The Netherlands	**15.3**	7.1	n.a.	**7.1**	78.0	n.a.	**78.0**	**217.5**	467.9	n.a.	**467.9**	42.8	n.a.	**42.8**
Norway	**27.3**	9.3	n.a.	**9.3**	53.9	n.a.	**53.9**	**99.9**	293.1	n.a.	**293.1**	50.5	n.a.	**50.5**
Poland	**12.2**	2.5	n.a.	**2.5**	23.4	0.5	**23.8**	**156.1**	757.7	n.a.	**757.7**	81.7	3,868.4	**80.0**
Portugal	**8.5**	6.2	5.0	**11.2**	22.6	10.2	**32.9**	**199.5**	276.3	338.8	**152.2**	75.1	166.3	**51.7**
Slovenia	**15.1**	5.4	4.9	**10.2**	39.5	n.a.	**39.5**	**194.3**	547.5	602.3	**286.8**	74.4	n.a.	**74.4**
Spain	**15.0**	6.0	5.3	**11.4**	–	–	**–**	**140.3**	349.4	395.7	**185.5**	–	–	**–**
Switzerland	**13.9**	10.5	0.9	**11.4**	39.4	13.9	**53.3**	**172.7**	228.9	2,714.3	**211.1**	60.9	172.7	**45.0**
United Kingdom	**10.8**	19.7	0.7	**20.4**	43.7	6.4	**50.1**	**212.1**	105.9	3,067.8	**102.3**	52.8	337.4	**45.7**
England	**10.7**	23.1	n.a.	**23.1**	42.5	7.4	**50.0**	**216.2**	100.6	n.a.	**100.6**	54.6	312.6	**46.5**
Scotland	**11.6**	27.2	n.a.	**27.2**	50.8	2.3	**53.1**	**–**	–	–	**–**	–	–	**–**
Wales	**13.7**	8.8	8.8	**17.6**	61.1	1.0	**62.1**	**153.5**	238.7	238.7	**119.4**	34.5	2,148.3	**33.9**
Northern Ireland	**10.6**	7.2	8.9	**16.1**	48.3	–	**48.3**	**220.0**	321.5	261.3	**144.1**	48.0	–	**48.0**
No. entries	**24**	24	24	**24**	23	20	**23**	**23**	22	22	**22**	22	19	**22**
Average	**12.8**	7.6	3.5	**9.8**	26.6	14.8	**36.9**	**208.9**	356.0	1,187.2	**303.3**	208.0	647.3	**76.8**
Median	**11.0**	7.2	2.7	**9.8**	23.1	8.9	**30.9**	**212.1**	319.7	682.2	**213.1**	92.8	239.2	**72.6**
Min	**2.5**	0.0	0.0	**0.0**	1.9	0.4	**4.9**	**99.9**	105.9	148.8	**85.0**	28.8	52.0	**25.7**
Max	**30.9**	19.7	12.6	**21.9**	78.0	61.0	**78.0**	**348.8**	757.7	3,067.8	**757.7**	1651.0	3,868.4	**156.8**

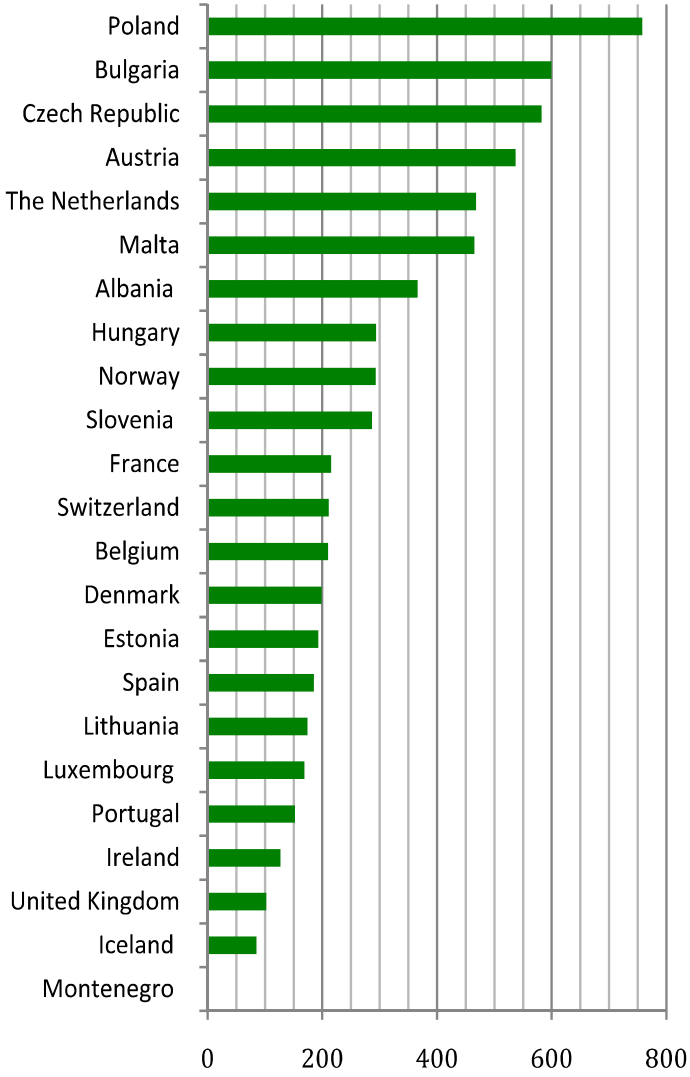
n.r. = not reported; n.a. = not applicable.
Figures are rounded to the closest decimal number. Computation of totals, medians and ranges are for the available countries and use UK total figures, except for RT courses/personnel.

Lievens et al, R&O 2014

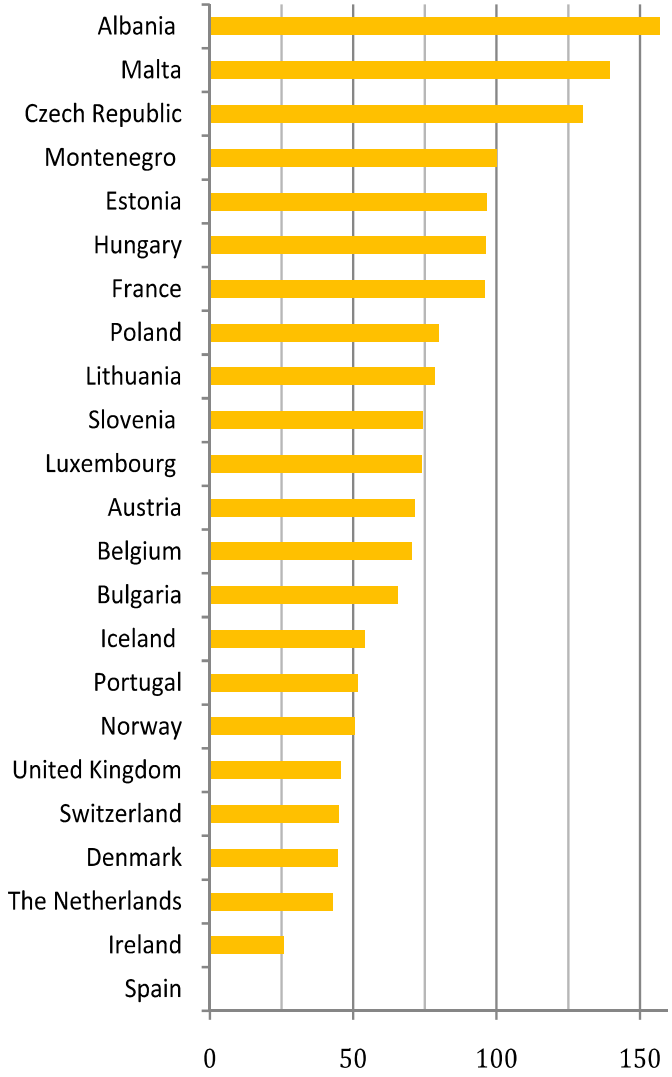
radiotherapy courses per personnel



a. Radiotherapy courses per RO



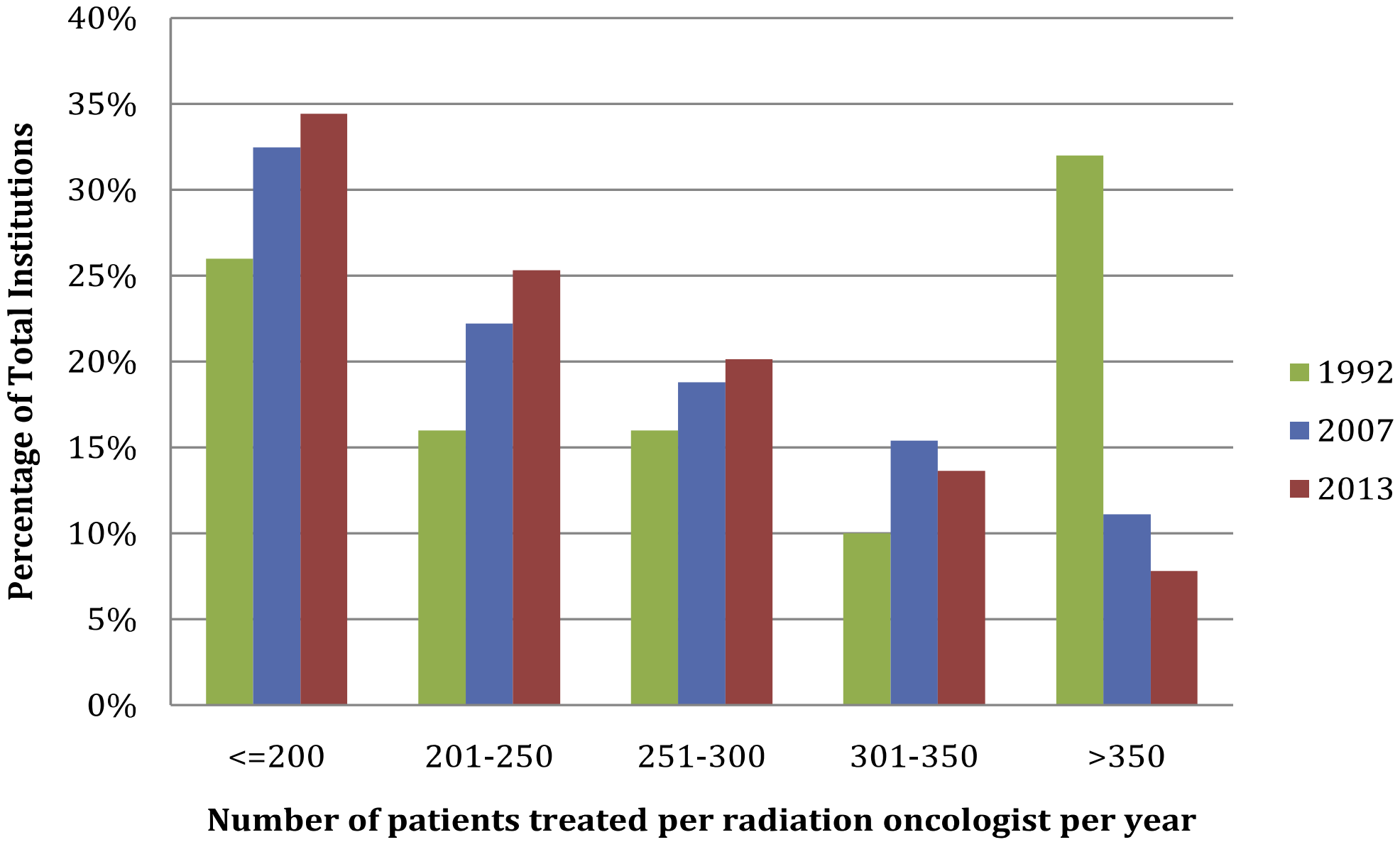
b. Radiotherapy courses per MP+DO



c.Radiotherapy courses per RTT+RN

Lievens et al, R&O 2014

EORTC facility questionnaire



Warren et al, R&O 2014

EORTC facility questionnaire

	Mean	Median	Range	SD
2013 (156 institutions)				
No. patients treated/year	2381.4	1938	350–12,000	1671.3
No. FTE ROs per inst.	10.8	8	1–41	7.9
No. FTE physicists per inst.	7.4	6	1–35	5.3
No. RTTs per inst.	36.1	23	3–227	32.9
No. patients per RO	243.2	232	78–617	94.7
No. patients per physicist	354.3	320	114–870	154.3
No. patients per RTT	85.7	77	7–350	48.1
No. RTT per treatment unit	2.9	3	2–6	0.9
2007 (98 institutions)				
No. patients treated/year	2016.0	1696	470–7300	1272.3
No. FTE ROs per inst.	8.5	7	2–26	5.3
No. FTE physicists per inst.	5.2	4	1–22	3.4
No. RTTs per inst.	26.1	17	3–120	22.2
No. patients per RO	258.0	248	99–480	84.5
No. patients per physicist	426.0	413	124–827	142.8
No. patients per RTT	107.0	86	34–734	96.0
No. RTT per treatment unit	2.4	2	1–5	1.0
1992 (50 institutions)				
No. patients treated/year	1452.0		300–3600	783.0
No. FTE ROs per inst.	6.0		1–22	
No. FTE physicists per inst.			1–8	
No. RTTs per inst.				
No. patients per RO	316.0	263	60–1243	
No. patients per Physicist	464.0	370	166–1052	
No. patients per RTT	131.0	100	36–420	
No. RTT per treatment unit	2.8			

FTE = full time equivalent, RO = radiation oncologist, RTT = radiation therapy technologist, Inst. = institution.

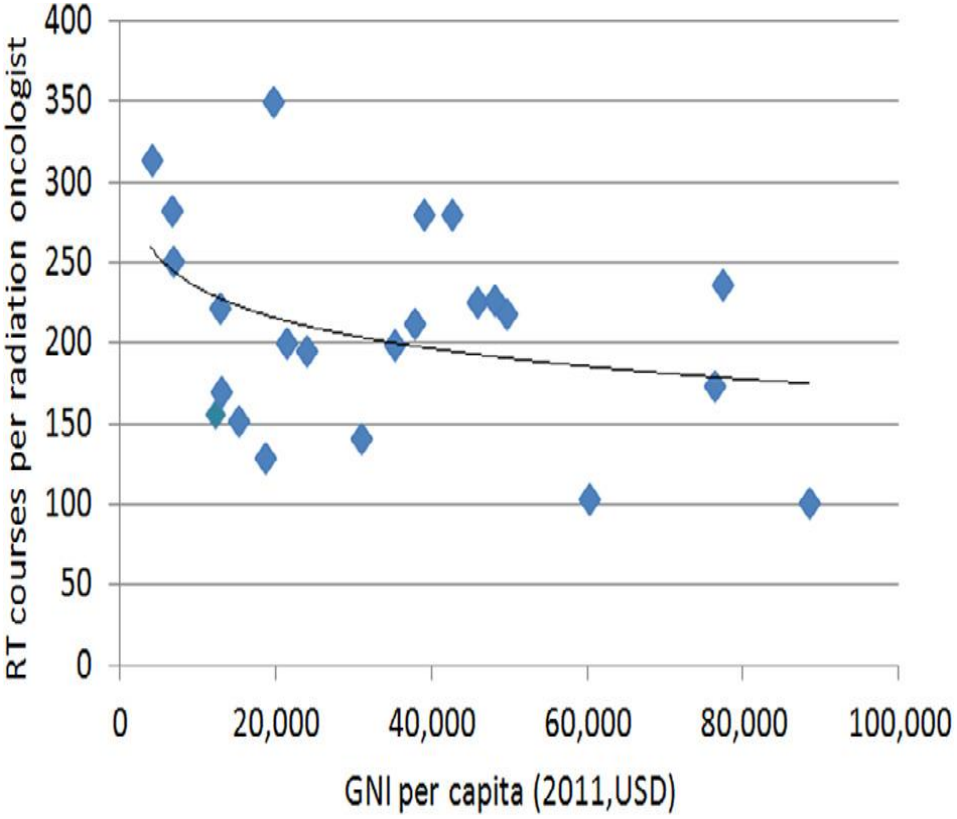
Warren et al, R&O 2014

the impact of national welfare

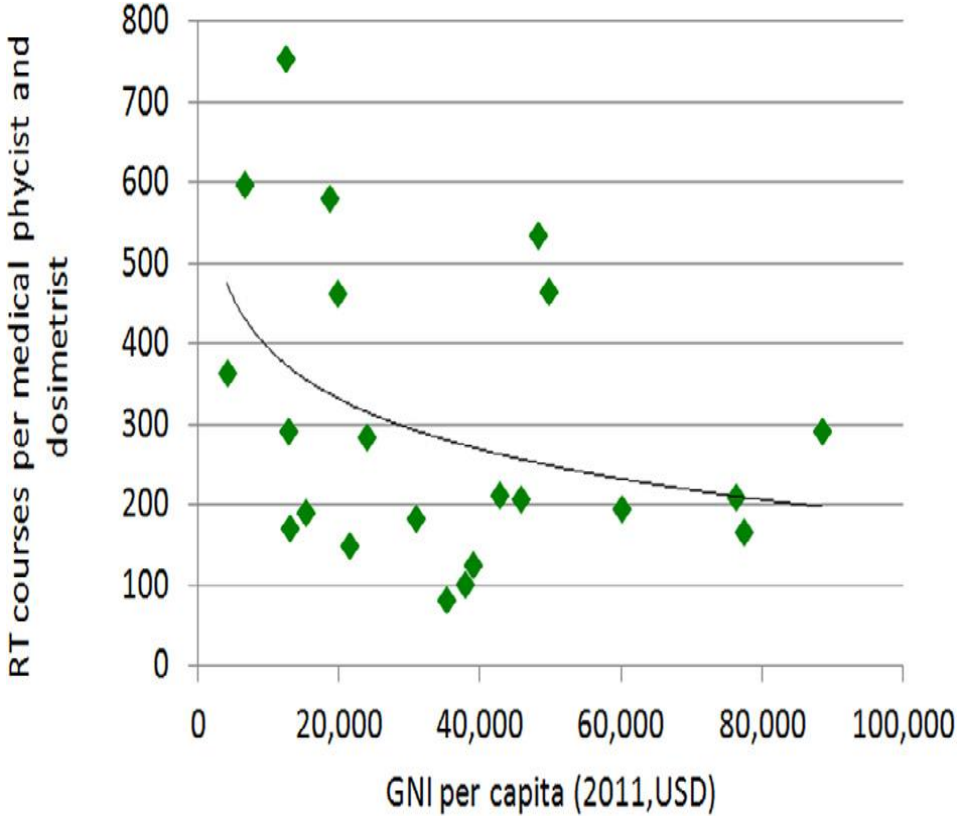
ESTRO School

GNI per capita vs. radiotherapy courses

a. GNI/n vs. radiotherapy courses per radiation oncologist



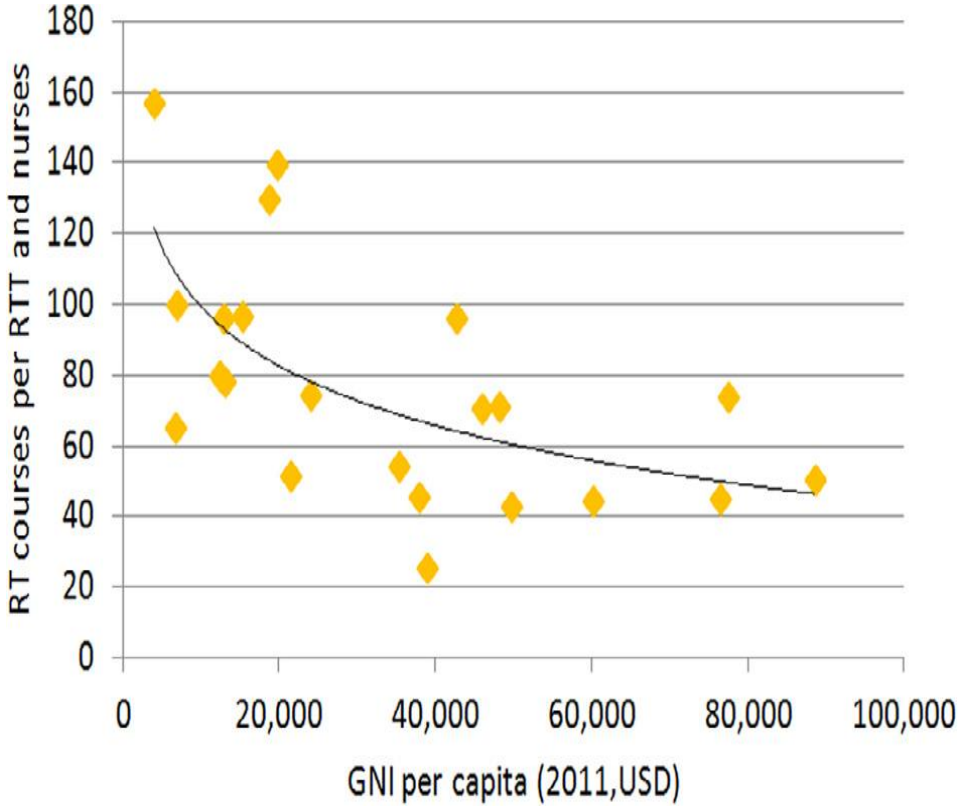
b. GNI/n vs. radiotherapy courses per medical physicist and dosimetrist

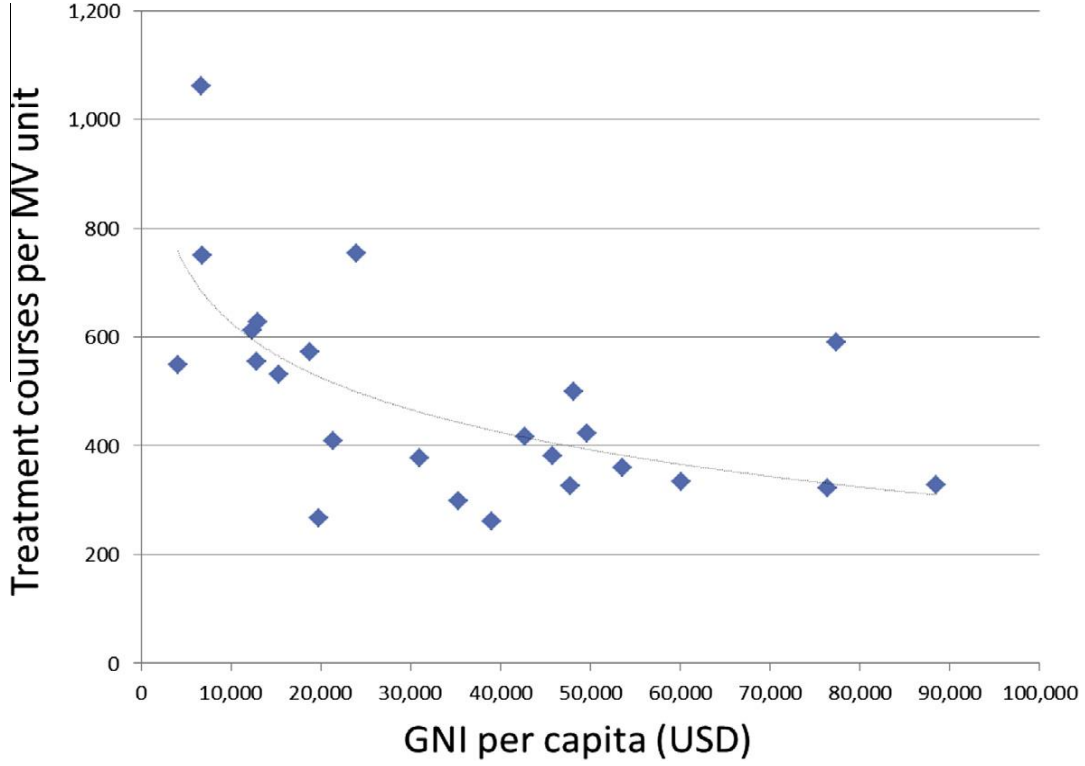


Lievens et al, R&O 2014

GNI per capita vs. radiotherapy courses

c. GNI/n vs. radiotherapy courses per RTTs and radiotherapy nurse



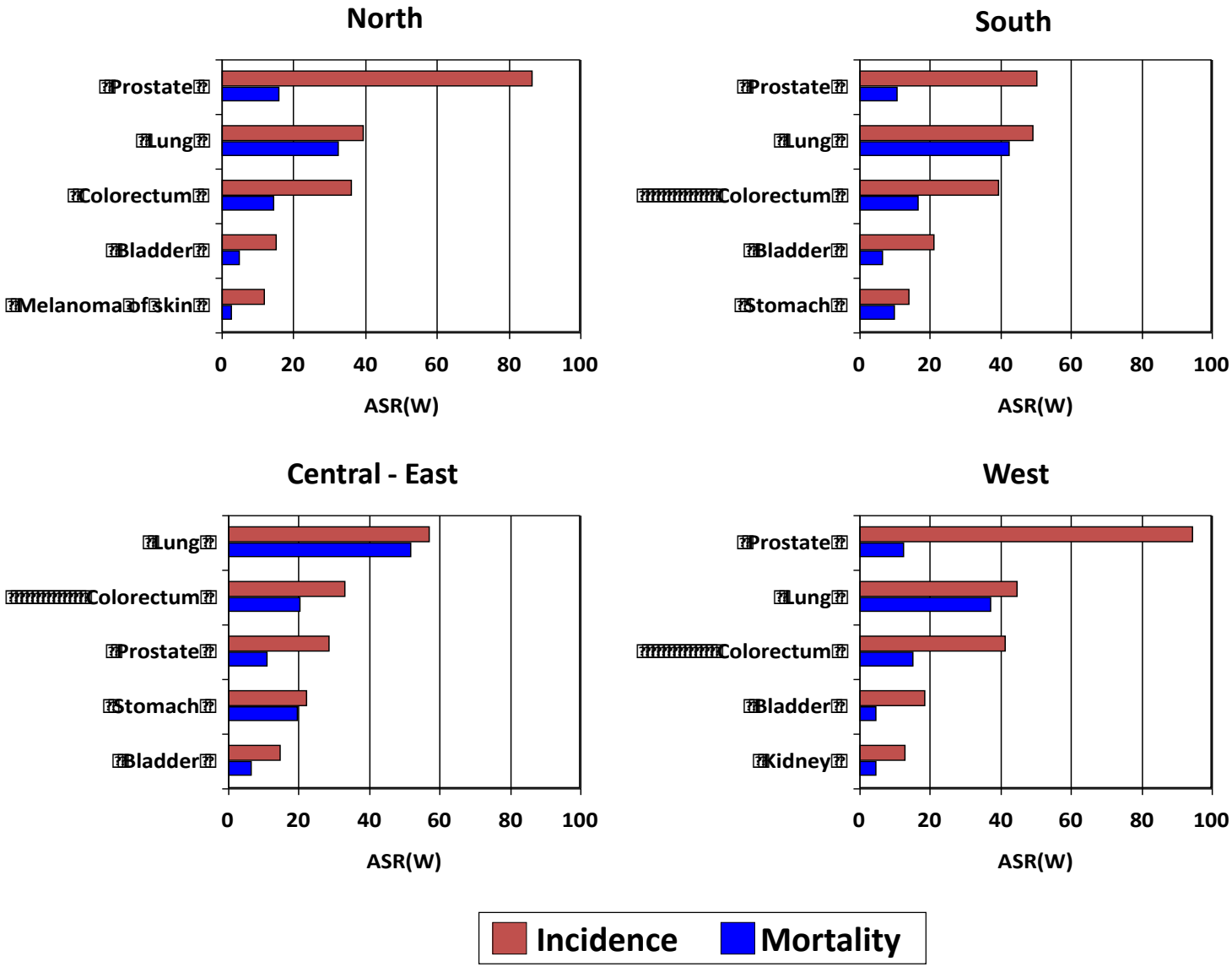


ıship between economic status (GNI per capita) and the average number of treatment courses per ra

Lievens et al, R&O 2014
Grau et al, R&O 2014

the impact of cancer incidence

cancers in Europe by geographical area

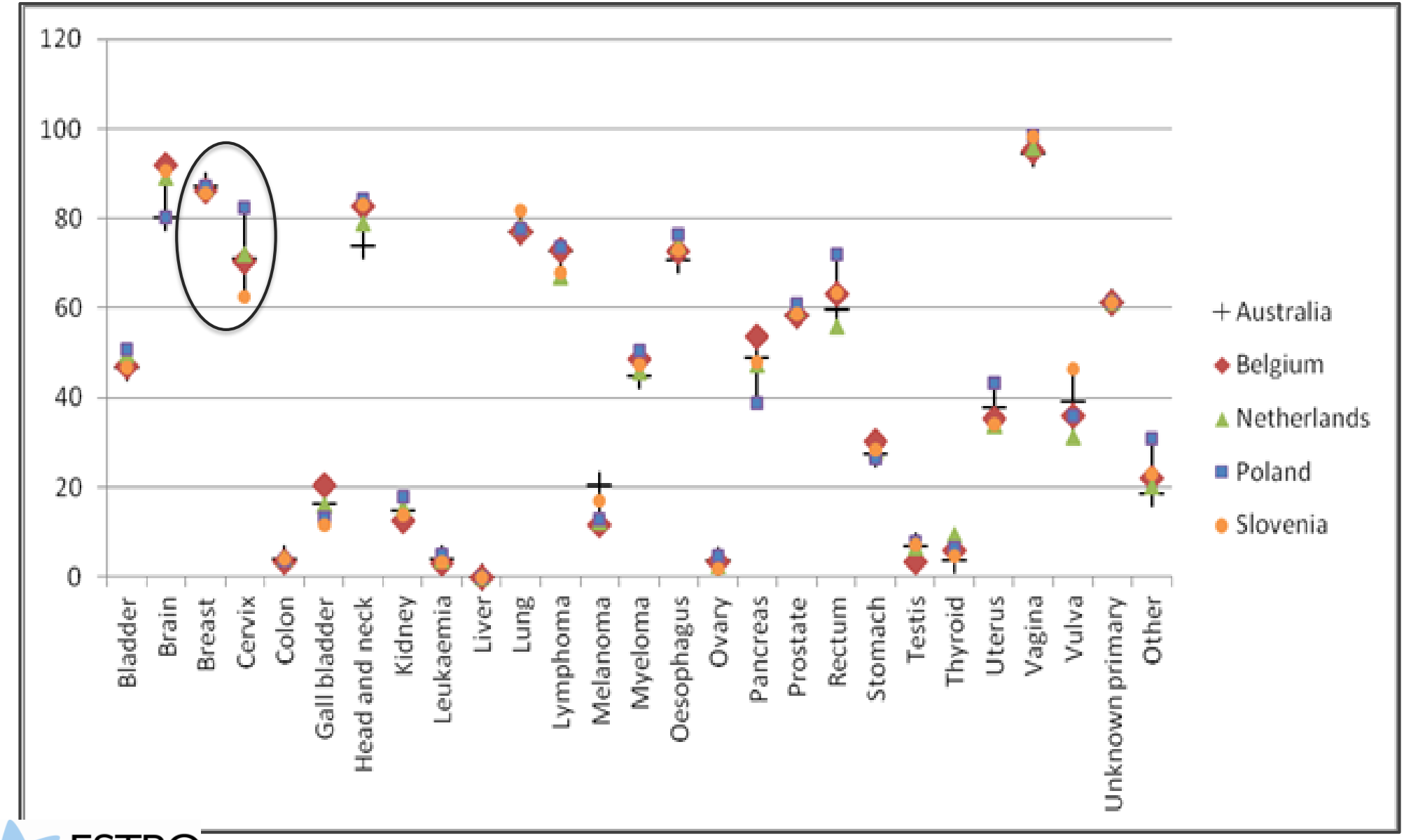


Source: GLOBOCAN 2008

North: Denmark, Estonia, Finland, Iceland, Ireland, Latvia, Lithuania, Sweden, United Kingdom, Norway; **South:** Albania, Bosnia Herzegovina, Croatia, Cyprus, Greece, Italy, Former Yugoslav Republic of Macedonia, Montenegro, Malta, Portugal, Slovenia, Spain, Serbia; **Central-East:** Belarus, Bulgaria, Czech Republic, Hungary, Republic of Moldova, Poland, Romania, Slovakia, Ukraine, Russian Federation; **West:** Austria, Belgium, France, Germany, The Netherlands, Switzerland, Luxembourg

Courtesy J. Borras

optimal radiotherapy utilization *(by tumour type)*



ESTRO European Society for RADIOTHERAPY & ONCOLOGY

Borras et al. R&O 2015

impact of cancer incidence and RT utilization

Table 2. Sensitivity Analysis to Determine How Changes in Model Assumptions Will Impact Percent Increase in Demand for RT

Model	2010			2020			
	No. of Cancers Diagnosed	No. of Patients Receiving Radiation*	% of Patients Receiving Radiation	No. of Cancers Diagnosed	No. of Patients Receiving Radiation*	% of Patients Receiving Radiation	% Increase in Demand for RT From 2010 to 2020
Baseline model	1,598,648	469,820	29	1,956,916	574,593	29	22
Sensitivity analysis 1: change in RT utilization							
RT utilization decreases by 10%	1,598,648	469,820	29	1,956,916	517,134	26	10
RT utilization decreases by 5%	1,598,648	469,820	29	1,956,916	545,863	28	16
RT utilization increases by 5%	1,598,648	469,820	29	1,956,916	603,323	31	28
RT utilization increases by 10%	1,598,648	469,820	29	1,956,916	632,052	32	35
Sensitivity analysis 2: change in cancer incidence							
1% per year decrease	1,518,716	440,428	29	1,663,379	482,380	29	10
0.7% per year decrease	1,542,695	447,382	29	1,751,440	507,918	29	14
0.4% per year decrease	1,566,675	454,336	29	1,839,501	533,455	29	17
0.4% per year increase	1,630,621	472,880	29	2,074,331	601,556	29	27
0.7% per year increase	1,654,601	479,834	29	2,162,392	627,094	29	31
1% per year increase	1,678,580	486,788	29	2,250,453	652,631	29	34

NOTE. Unrounded estimates are reported for transparency. Estimates are not thought to be significant beyond the two significant digits.
Abbreviation: RT, radiation therapy.
* No. of patients receiving radiation during the initial course of cancer therapy.

Smith et al, JCO 2010

the impact of retreatment

ESTRO School

patterns of retreatment by radiotherapy

	Cancer treatment facility				
	LM	RBWH	RIF	Combined	*P*-value
Study period	1997–2011	1994–2010	1991–2007		
Patients	9654	38 581	14 035	62 270	
Radiotherapy episodes	11 924	48 098	17 740	77 762	
Mean number of retreatments	0.24	0.25	0.26	0.25	0.47
Proportion of patients retreated	0.16	0.16	0.17	0.16	0.08
% Females	52.1	47.7	48.7	48.6	<0.001
Median age at first treatment (years)	64	63	66	64	
% Patients in age category					
<50	17.9	19.4	13.8	17.9	<0.001
50–70	48.2	49.2	48.0	48.8	
>70	33.9	31.4	38.2	33.3	
Survival probability at 2 years	0.67	0.73	0.64	0.70	<0.001
Survival probability at 5 years	0.57	0.67	0.49	0.61	<0.001

LM, Liverpool and Macarthur Cancer Therapy Centres; RBWH, Royal Brisbane and Women's Hospital; RIF, Radiotherapeutic Institution Friesland.

Barton et al, Clin Oncol 2014

patterns of retreatment by radiotherapy

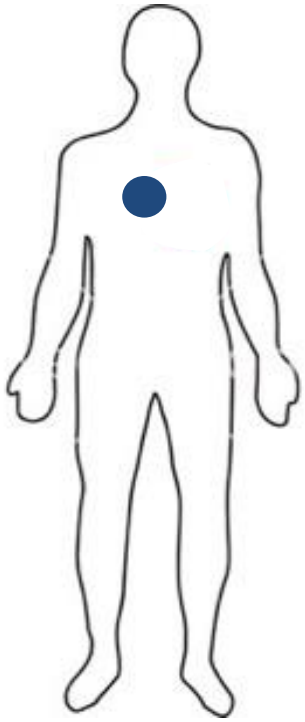
	Cancer treatment facility							
	LM		RBWH		RIF		Combined	
	n	Retreatment	*n*	Retreatment	*n*	Retreatment	*N*	Retreatment
Breast	2903	0.20	9480	0.21	4246	0.31	16 629	0.24
Lung	1582	0.34	6056	0.33	2364	0.29	10 002	0.32
Prostate	1237	0.22	4947	0.34	2022	0.33	8206	0.32
Head and neck	618	0.16	4239	0.13	941	0.08	5798	0.13
Colorectal	756	0.14	2390	0.18	993	0.14	4139	0.16
Lymphoma	452	0.21	1641	0.23	350	0.44	2443	0.25
Brain	280	0.03	1144	0.04	282	0.03	1706	0.04
Oesophagus	205	0.17	1051	0.20	438	0.19	1694	0.19
Bladder	182	0.20	862	0.20	476	0.17	1520	0.19
Cervix	155	0.24	963	0.17	155	0.12	1273	0.17
Melanoma	158	0.32	1005	0.39	90	0.31	1253	0.37
Endometrial	163	0.21	584	0.13	402	0.05	1149	0.11
Skin	96	0.28	723	0.32	64	0.28	883	0.31
Myeloma	109	1.05	498	0.72	192	0.80	799	0.78
Renal	81	0.47	478	0.51	143	0.55	702	0.51
Soft Tissue	141	0.33	392	0.32	124	0.31	657	0.32

LM, Liverpool and Macarthur Cancer Therapy Centres; RBWH, Royal Brisbane and Women's Hospital; RIF, Radiotherapeutic Institution Friesland.

Barton et al, Clin Oncol 2014

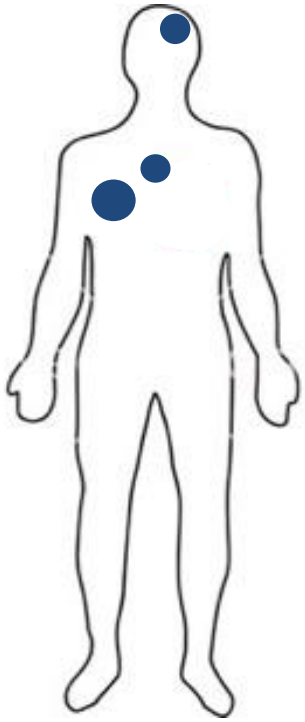
patterns of retreatment… an evolving field

localized



Cure with local treatment

oligometastatic



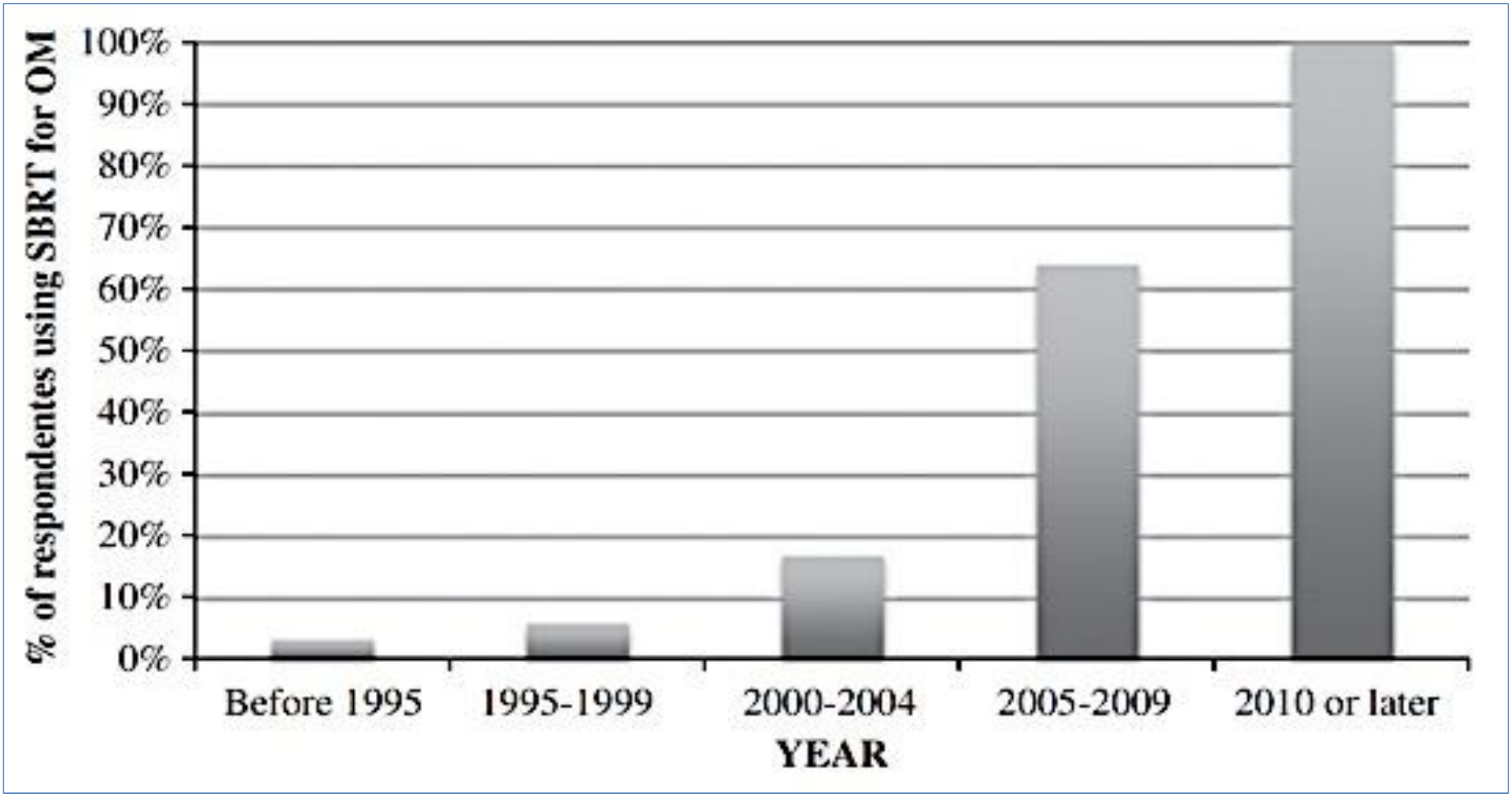
Cure with local treatment possible

systemic

Local Tx for symptom control

Hellman & Weichselbaum JCO 1995

patterns of retreatment… an evolving field



Lewis et al, Am J Clin Oncol

the impact of professional roles and responsibilities

ESTRO School

roles and responsibilities - Europe

Country	% ROs administering chemotherapy	Most treatment planning performed by	Most QA procedures performed by
Albania	0%	Medical physicists	Medical physicists, technicians/engineers
Austria	25–75%	Technologists, radiographers	Medical physicists
Belarus	25–75%	Medical physicists, but sometimes it's performed trained radiation oncologists	Medical physicists, technicians/engineers
Belgium	<25%	Dosimetrists	Medical physicists
Bulgaria	25–75%	Medical physicists	Medical physicists, technicians/engineers
Czech Republic	>75%	Medical physicists	Medical physicists
Denmark	>75%	Medical physicists	Medical physicists
Estonia	>75%	Medical physicists	Medical physicists
Finland	>75%	Medical physicists	Medical physicists
France	25–75%	Medical physicists, dosimetrists, technologists, radiographers	Medical physicists, technicians/engineers
Germany	25–75%	Medical physicists	Medical physicists, RTT
Hungary	25–75%	Medical physicists	Medical physicists
Iceland	>75%	Technologists, radiographers	Medical physicists
Ireland	0%	Technologists, radiographers	Medical physicists
Italy	>75%	Medical physicists	Medical physicists
Lithuania	0%	Medical physicists, radiation oncologists	Medical physicists
Luxembourg	>75%	Medical physicists, dosimetrist	Medical physicists, technicians/engineers
Malta	>75%	Medical physicists	Medical physicists
Montenegro	0%	Medical physicists	Medical physicists
The Netherlands	0%	Technologists, radiographers	Physics assistants
Norway	>75%	Technologists, radiographers	Medical physicists
Poland	<25%	Medical physicists	Medical physicists
Portugal	0%	Dosimetrists	Medical physicists, technologist/radiographers
Romania	25–75%	Medical physicists	Medical physicists
Slovak Republic	25–75%	Medical physicists	Medical physicists
Slovenia	>75%	Medical physicists, dosimetrists	Medical physicist with the help of technicians/engineers
Spain	<25%	Medical physicists, dosimetrist	Medical physicists, technicians
Switzerland	<25%	Medical physicists, dosimetrists, technologists, radiographers	Medical physicists, technicians/engineers, technologist/radiographers, dosimetrist
United Kingdom	>75%	Medical physicists, dosimetrists, technologists, RTT	Medical physicists, technicians/engineers
England	>75%, About 50% time of radiation oncologist devotes their time to supervising chemotherapy	Dosimetrists, technologists, radiographers	Medical physicists, technicians/engineers
Scotland	>75%	Medical physicists, dosimetrists, RTTs, it varies between departments depending on skill mix	Medical physicists, technicians/engineers
Wales	>75%	Medical physicist, technologists	Medical physicists, technicians
Northern Ireland	>75%	Medical physicists, dosimetrists	Daily machine checks are carried out by radiographers, medical physicists, technicians/engineers, technologists/radiographers

Dunscombe et al, R&O 2014

roles and responsibilities - USA

	RADIATION ONCOLOGIST	MEDICAL PHYSICIST	MEDICAL DOSIMETRIST	RADIATION THERAPIST	NONPHYSICIAN PROVIDERS (NP/PA)	ONCOLOGY NURSE
Clinical evaluation	x				x	x
Ongoing psycho/social evaluation	x				x	x
Decision to deliver external radiation therapy (XRT)	x					
Patient +/- family education	x			x	x	x
Interdisciplinary coordination of care	x			x	x	x
Patient positioning and image acquisition	x	x	x	x		
Fusion and registration	x	x	x			
Contouring/segmentation	x	x	x			
Dose-volume constraints	x	x	x			
Dose calculation	x	x	x			
Review of final treatment plan	x	x	x	x		
Patient-specific QA	x	x	x	x		
Treatment delivery	x	x	x	x		
Special procedures (SRS, SBRT, HDR, etc.)	x	x	x	x		
Monitor accuracy of delivery (ports, dose, etc.)	x	x	x	x		
Weekly evaluation	x	x	x	x	x	x
Follow-up	x				x	x
Survivorship	x				x	x
Equipment, software and systems acceptance testing, maintenance and commissioning	x	x	x	x		

Safety is no accident – ASTRO 2012

the impact of treatment complexity and fractionation

ESTRO School

radiotherapy productivity: the Netherlands

T-equivalents:
T1 = simple (0.3) - T2 = standard (Ref 1) - T3 = 3D-CRT (1.7) - T4 = intensive (2.9)

	1998	2001	2004	2007	2010
Absolute number					
Per radiation oncologist	274	272	262	254	248
Per clinical physicist	625	654	584	554	540
Per radiation technologist	56	55	51	53	56
Per linear accelerator	533	526	465	440	451
Weighted treatment series					
Per radiation oncologist	277	292	333	385	412
Per clinical physicist	633	704	742	841	895
Per radiation technologist	57	59	65	81	93
Per linear accelerator	539	566	591	668	747

Slotman and Vos, R&O 2013

so,
taking all that into account,
what is recommended?

recommendations for staffing in Europe

	Rad. Oncologists		Med. Physicists	Dosimetrists		RTT / nurses
European and International guidelines						
QUARTS [6]	No	No	No	250 patients / yr , Increasing complexity: 1 / 200 - 250 patients / yr	450 - 500 patients / yr	No	Great diversity makes comparison between countries impossible
IAEA [11]	No	No	No	250 - 300 patients / yr / RO	300 - 400 patients / yr / MP	No	100 - 150 patients / yr / RTTs
EORTC [13]	No	No	No	≤ 300 patients / FTE	≤ 500 patients / FTE	No	≥ 2 / treatment unit
IPEM [14]	No	No	No	No	Complex algorithm	No	No
EFOMP [12]	No	No	No	No	0.37 WTE / L + 0.11 WTE / 100 patients / yr	No	No

n.r. = not reported, not available or no evaluable response was given to the question.
Light shaded: guideline was declared to the HERO survey.
Dark shaded: an explicit guideline was declared to the HERO survey. See text for definition of explicit.
Italics: an explicit guideline had been previously been declared to the QUARTS survey (6).

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Dunscombe et al, R&O 2014

ESTRO-QUARTS

Guideline	Per patient
Linear accelerators	
General	1 per 450 patients/year
With increasing complexity	1 per 400-450 patients/year
Radiation oncologists	
General	1 per 250 patients/year
With increasing complexity	1 per 200-250 patients/year
Physicists	
General	1 per 450-500 patients/year

Slotman et al, R&O 2005

EORTC facility questionnaire

		1993	2008
Human resource: workload	No. FTE radiation oncologists per institution	Min 2.5	Min 3
	No. patients treated per year/FTE radiation oncologist	Max 300	Max 250–300
	No. FTE qualified radiation physicist per institution	1.3	2
	No. patients treated per year/FTE radiation physicist	500	500
	No. radiation technologists per treatment unit	2	2
Equipment: numbers	Simulator (classical and/or CT)	1	1(including access to CT)
	Megavoltage treatment units (preferably <10 years old)	2	2
Equipment: workload (based on normal working hours)	Patients per year/megavoltage unit	700	600
	Patients per year/conventional simulator	1500	1200
	Patients per year/CT simulator	–	2400

FTE = full time equivalent, CT = computed tomography.

Warren et al, R&O 2014
Budiharto et al, R&O 2008

recommendations for staffing in Europe

	Rad. Oncologists		Med. Physicists		Dosimetrists	RTT / nurses
European and International guidelines						
QUARTS [6]	No	No	No	250 patients / yr , Increasing complexity: 1 / 200 - 250 patients / yr	450 - 500 patients / yr	No	Great diversity makes comparison between countries impossible
IAEA [11]	No	No	No	250 - 300 patients / yr / RO	300 - 400 patients / yr / MP	No	100 - 150 patients / yr / RTTs
EORTC [13]	No	No	No	≤ 300 patients / FTE	≤ 500 patients / FTE	No	≥ 2 / treatment unit
IPEM [14]	No	No	No	No	Complex algorithm	No	No
EFOMP [12]	No	No	No	No	0.37 WTE / L + 0.11 WTE / 100 patients / yr	No	No

n.r. = not reported, not available or no evaluable response was given to the question.
Light shaded: guideline was declared to the HERO survey.
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Dunscombe et al, R&O 2014

EFOMP Policy Statement

The European Federation of Organisations for Medical Physics. Policy Statement No. 7.1: The roles, responsibilities and status of the medical physicist including the criteria for the staffing levels in a Medical Physics Department approved by EFOMP Council on 5th February 2016 ☆

Stephen Evans [a], Stelios Christofides [b], Marco Brambilla [c]

[a] EFOMP, Fairmount House, 230 Tadcaster Road, York YO24 1ES, UK
[b] SC Biomedical Research Foundation, P.O. Box 24039, 1700 Nicosia, Cyprus
[c] Medical Physics Department, University Hospital of Novara, 28100 Novara, Italy

Subjects	Medical physicist (WTE)
Equipment dependent factors per item	
Linear accelerator (multi-mode) (per unit)	0.6
Linear accelerator (single-mode)/cobalt (per unit)	0.2
Major items (per unit)	0.2
Minor items (per unit)	0.1
Other items (per unit)	0.05
Patient dependent factors	
Conventional (2D) external beam radiotherapy (per 100 procedures)	0.05
3D conformal radiotherapy (per 100 procedures)	0.2
Special techniques (per 100 procedures)	0.4
Brachytherapy (per 100 procedures)	0.4

a. Major items include: TPS, IMRT, CT simulator, HDR/PDR, data network and equivalent.
b. Minor items include: IGRT, SABR, advanced TPS features, LDR, simulator and equivalent.
c. Other items include: EPID, MLC, automatic outlining, block cutting, orthovoltage/superficial units and equivalent.
d. Special techniques include: SABR, IMRT, TBI, total skin electron techniques and equivalent.
e. For a list of frequently asked questions visit the EFOMP website (www.efomp.eu).

Evans et al, Phys Med 2016

recommendations for staffing in Europe

Country	Cancer plans for RT needs	Guideline for personnel	Are working hrs for RT personnel limited by radiation protection regulations	Radiation Oncologists	Medical Phycisists	Dosimetrists	RTT
				Criterion	Criterion	Criterion	Criterion
Albania	No	Yes, not specified	Only in public sector all the RT personnel are working 6 hrs a day: 30 hrs / week; 48 weeks / yr	n.r.	n.r.	n.a.	2 / L & 2 / CT sim (private sector)
Austria	Regional	National	Technicians/radiographers: 40 hrs / week, No. weeks / yr is not regulated, usually 46	*6 / 800 patients*[1]	*Per number of L + 1*[1]	n.a.	≥ 13 / 800 patients, nurses (in addition to RTT) : 3.5 / 800 patients[1]
Belarus	National	National	RO, MP, engineers, RTT, dosimetrists: 30 for RO; 35 for MP / engineers	*1 / 10 patients or 1 / 1 RT unit*	*2 / L*	1 / RT unit	4 / RT unit
Belgium	No	National	No	*1 / 200 - 250 patients (ifo complexity)*	*1 / 750 patients (more if complex treatment)*	No	3 / MV, 2 / sim, 0,3 FTE / 100 brachytherapies
Bulgaria	Society	National	For all staff working with IR: 36 hrs / week	Based on the center technological level /RT modalities/ and staff skills	Based on the center technological level /RT modalities/ and staff skills	n.a.	Based on the center technological level /RT modalities/ and staff skills
Czech Republic	Society	Society[2]	No	*1 / 200 Npts*	*EFOMP 07/1997*	n.a.	Based on treatment machine
Denmark	Society	National	No	2.5 / L	*1.8 / accelerators*	Local needs	6 / L + 1.8 secretaries
Estonia	National	National	No	Based on the centre's practice	IAEA TECDOC	Local needs	3 - 4 / treatment unit
Finland	No	National	No	1 / 250 patients	1 / 400 patients	n.a.	2 / L during treatment
France	National	Society[3]	No	*Enough to be present during all treatments*	*≥ 2 /center*	n.r.	2 / RT machine
Germany	No	National[4]	It is forbidden to continuing work if a borderline exposure to ionizing	1 / device + 1 RO[5], if more than 1 method: + 1 RO, If – on annual average- > 350	> 1 / L + 1 MP, thus > 2 MP when one shift,[6] if more than 1 method: + 1	n.r.	> 2 / machine[4]

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Dunscombe et al, R&O 2014

			irradiation is exceeded.	treatment series / device: + 1RO	MP; If –on annual average - > 350 treatment series / device: + 1 MP		
Hungary	National	National	RO, physicist, and RTT as well: 40 hrs / week	*1 / 300 patients*	1 / 500 patients	Local policy	1 / 200 patients
Iceland*	National	No	No	4 / dept.	4 / dept.	4 / dept.	12
Ireland	National	National	No	1 / 250 Npts	11 / dept. with 4L	No	Hollywood report, p 182, 194
Italy	Regional	National	European directives and national regulations	*1 / 200 patients*	*1 / 400 patients*	n.a.	1 / 150 patients / yr
Lithuania	Society	National	Radiation oncologists, physicists, RT technologists, nurses:38 hrs / weeks, 47 weeks / yr	*1 / 250 patients*	1 / 400 patients	Center needs	Center needs
Luxembourg*	No	No	No	*Needs of the center*	*Center needs*	Center needs	Center needs
Malta*	National	Literature	n.r.	*Literature*	Literature	Literature	Literature
Montenegro*	National	n.r.	40 hrs / week	According to country needs, 1 national dept.	Hospital recommendation	No	No
The Netherlands	National	National	No	*1 / 250 Npts or N = 8 / 250 treatments, FTE = 6.4*	*1 / 650 patients (previously T2Neq)*	n.a.	1 / 55 treatments (previously T2Neq)
Norway	No	No	No	*n.r.*	*n.r.*	n.r.	4 / L
Poland	National	National	From July 2014 Nurse work 5 hrs shift / daily RT, physicians 7.5 hrs / day	Per activity	Per activity based on min requirement by IAEA	Per activity	Per activity
Portugal	National	National	No	*ESTRO (patients treated)*	*n.r.*	Patients treated	2 / machine during treatment period
Romania	No but QUARTS	No but QUARTS	RT oncologist, physicists, RTT:30 hrs / week, 45 weeks / yrs	Treatment machine and patients treated	MV machine & patients	n.r.	Based on treatment machine & patients treated
Slovak Republic	No	National	Radiation oncologists, medical physicists and RTTs: 32,5 hrs / week	*≥ 1 FTE*	*EFOMP 1997*	Not specified	3 / L ; > 2 cobalt
Slovenia*	National	ESTRO	RO, MP, RTT, dosimetrists, radiographers: 36 hrs / week, 44 weeks /yr	IAEA	IAEA	IAEA	Per treatment machine+2 shifts vacation
Spain	National	National	No	Per number of patients	n.r.	Collecting it now.	2 / machine & turn
Switzerland	Regional	No	No	ESTRO ; EORTC	ESTRO ; EORTC	ESTRO ; EORTC	ESTRO ; EORTC
	[illegible]onal	National	No	*Needs, patients, personnel*	IPEM	IPEM	Yes

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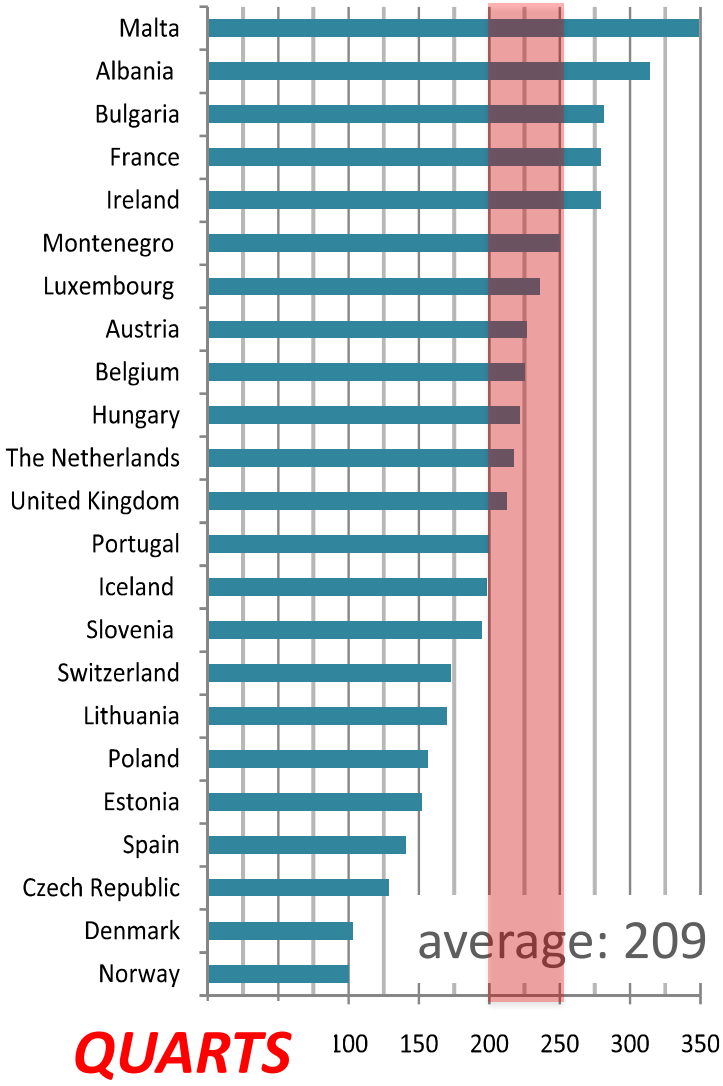
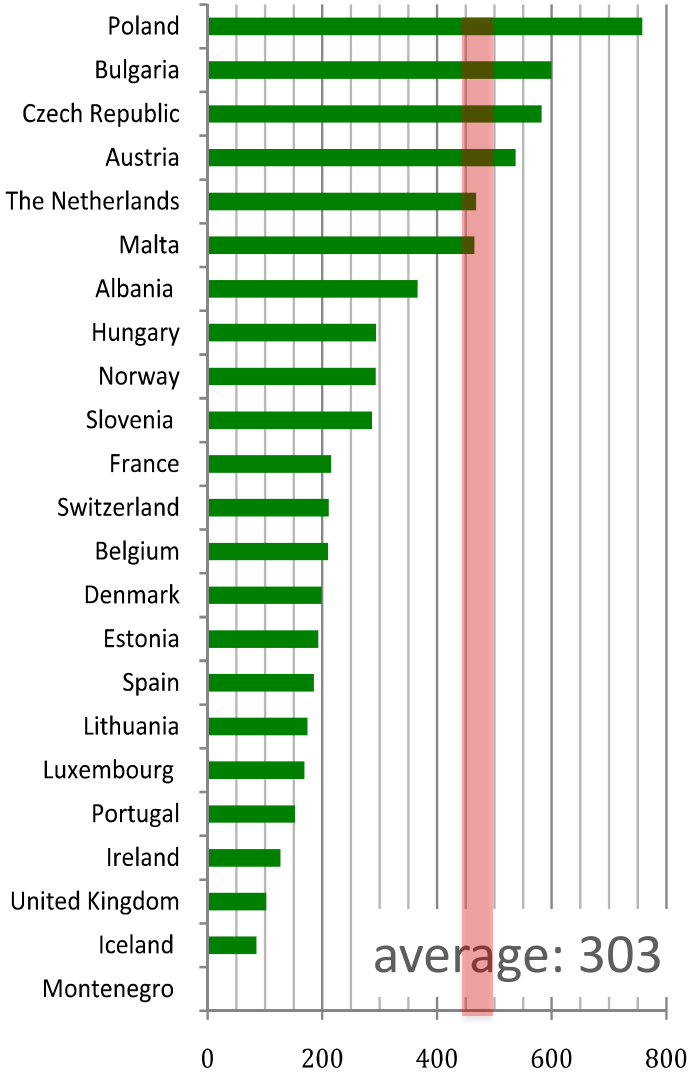
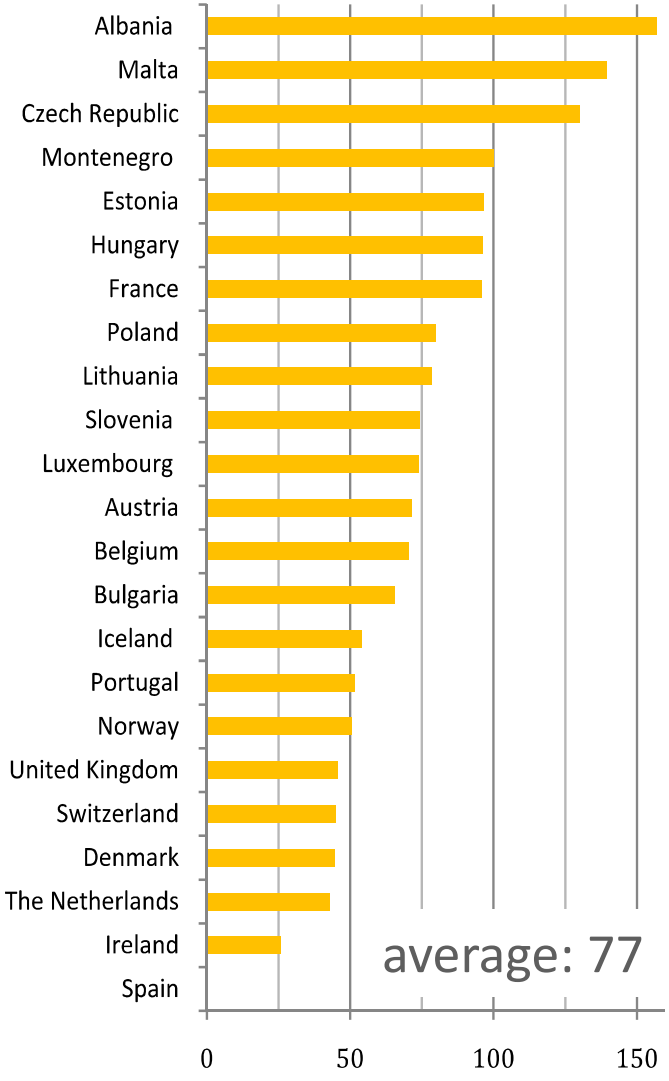
Dunscombe et al, R&O 2014

radiotherapy courses per personnel







QUARTS

a. Radiotherapy courses per RO

b. Radiotherapy courses per MP+DO

c.Radiotherapy courses per RTT+RN

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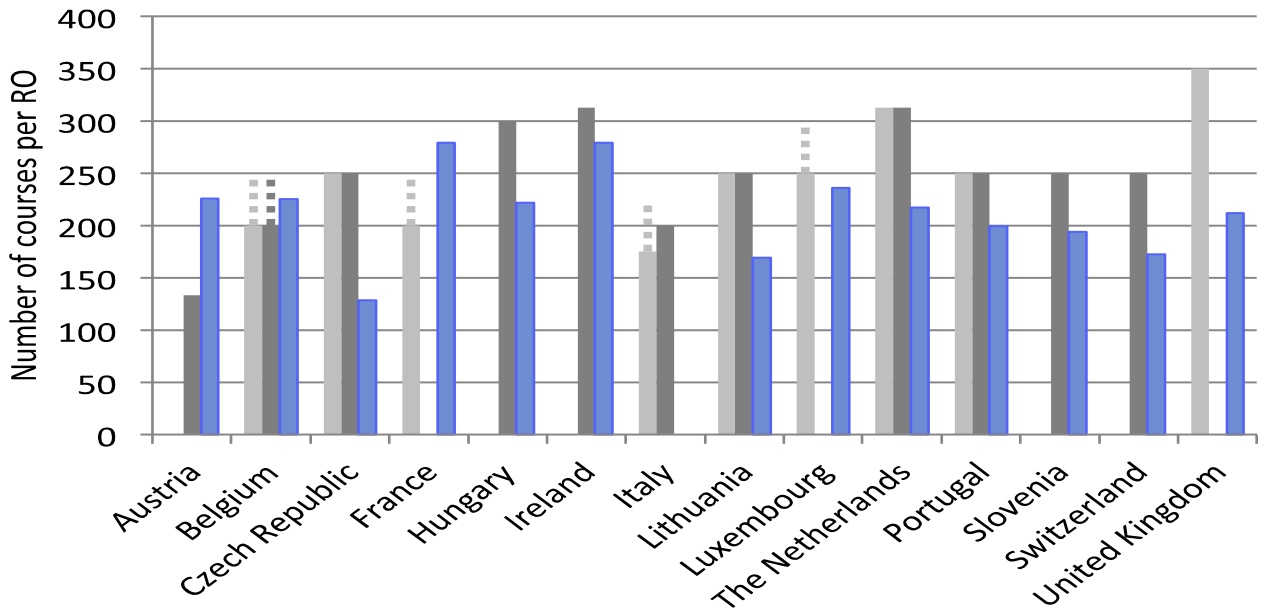
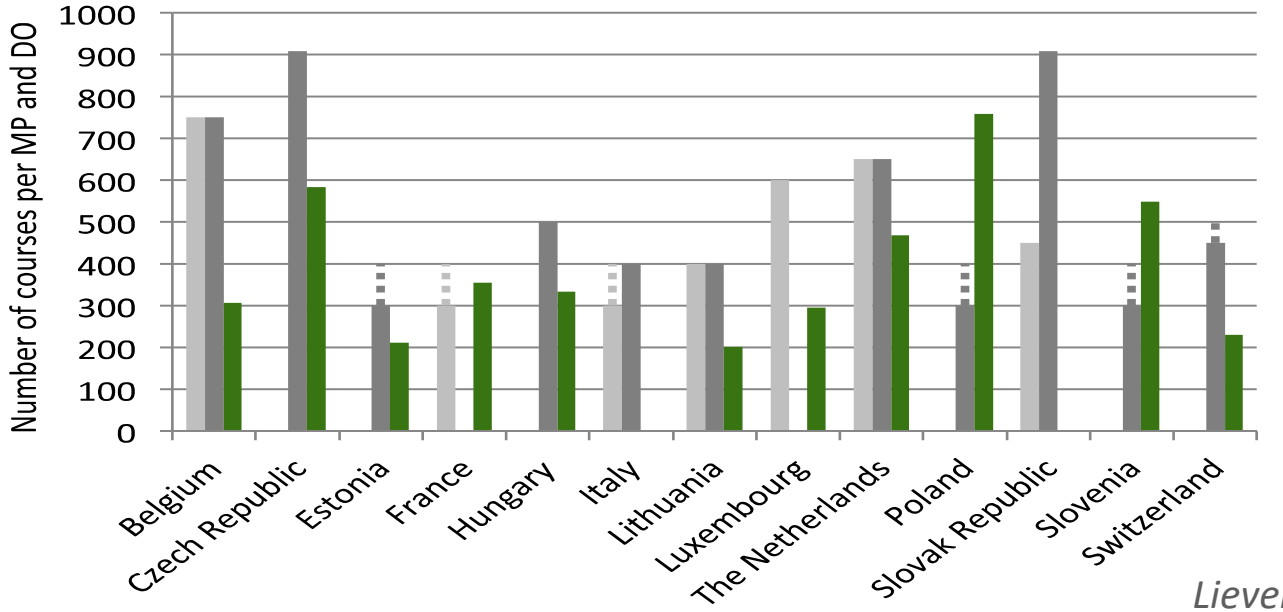
Lievens et al, R&O 2014

availability vs. recommendations

(b) Radiation oncologists



(c) Medical physicists and dosimetrists



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Lievens et al, Clin Oncol 2015

how to compute the human resources needed?

you take

cancer incidence

radiotherapy utilisation: 62,5%

(50% new patients – 12,5% retreatment)

resource use recommendations

(ESTRO-QUARTS – IAEA)

you shake!

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Nos.	Country	TRT per million	Present access to RT (%)[a]	Present deficit (number) of RT infrastructure and staffing[b]				Additional number required by 2020 of RT infrastructure and staffing[c]			
				TRT unit	RO	MP	RTT	TRT unit	RO	MP	RTT
1.	Albania	2.22	70.56	−3	−5	−3	−16	5	9	5	22
2.	Austria	5.59	82.30	−10	38	4	52	18	−24	4	−28
3.	Belarus	2.95	62.18	−17	39	9	−26	18	−38	−8	28
4.	Belgium	8.59	103.57	3	−97	−46	−115	8	118	57	150
	HERO / IAEA-DIRAC			91/94		154/66		113/45		492/156	
9.	Denmark	10.45	115.62	8	−16	6	27	−1	28	1	−6
10.	Estonia	3.85	58.85	−3	−4	2	−5	4	4	−1	6
11.	FYR Maced.	1.90	39.29	−6	4	−4	−12	8	−1	6	16
12.	Finland	8.38	113.97	6	−31	−8	26	0	41	14	−9
13.	France	7.64	93.57	−33	−266	−14	2692	101	388	82	−2489
14.	Germany	6.41	77.57	−154	−180	85	−499	226	310	−13	716
15.	Greece	4.32	84.35	−9	26	7	1	13	−18	−3	11
16.	Hungary	3.30	47.07	−37	−19	−21	−83	40	25	24	93
17.	Iceland	6.29	99.38	0	−1	1	−2	0	1	−1	3
18.	Ireland	5.82	89.97	−3	−23	4	−42	9	34	2	59
19.	Italy	6.68	82.06	−88	332	80	75	137	−245	−31	70
20.	Latvia										10
21.	Lithua										1
22.	Luxem										−2
23.	Malta										−2
24.	Moldo										28
25.	Monte										5
26.	Nether										−451
27.	Norwa										−183
28.	Poland										−36
29.	Portug										−3
30.	Roma										245
31.	Russia										1894
32.	Serbia										85
33.	Slovak										8
34.	Sloven										−19
35.	Spain										590
36.	Swede										−82
37.	Switze										114
38.	United										1393
39.	Ukraine										535
	Total	4.91	74.3	−1222	−1573	−1087	−1529	1698	2429	1563	2596

50% of new cancer cases require radiotherapy?

25% retreatment rate still accurate?

recommendations courses by equipment / personnel?

complexity? fractionation schedules?

Datta et al, Eur J Cancer 2014

be aware !
be cautious !
be critical !

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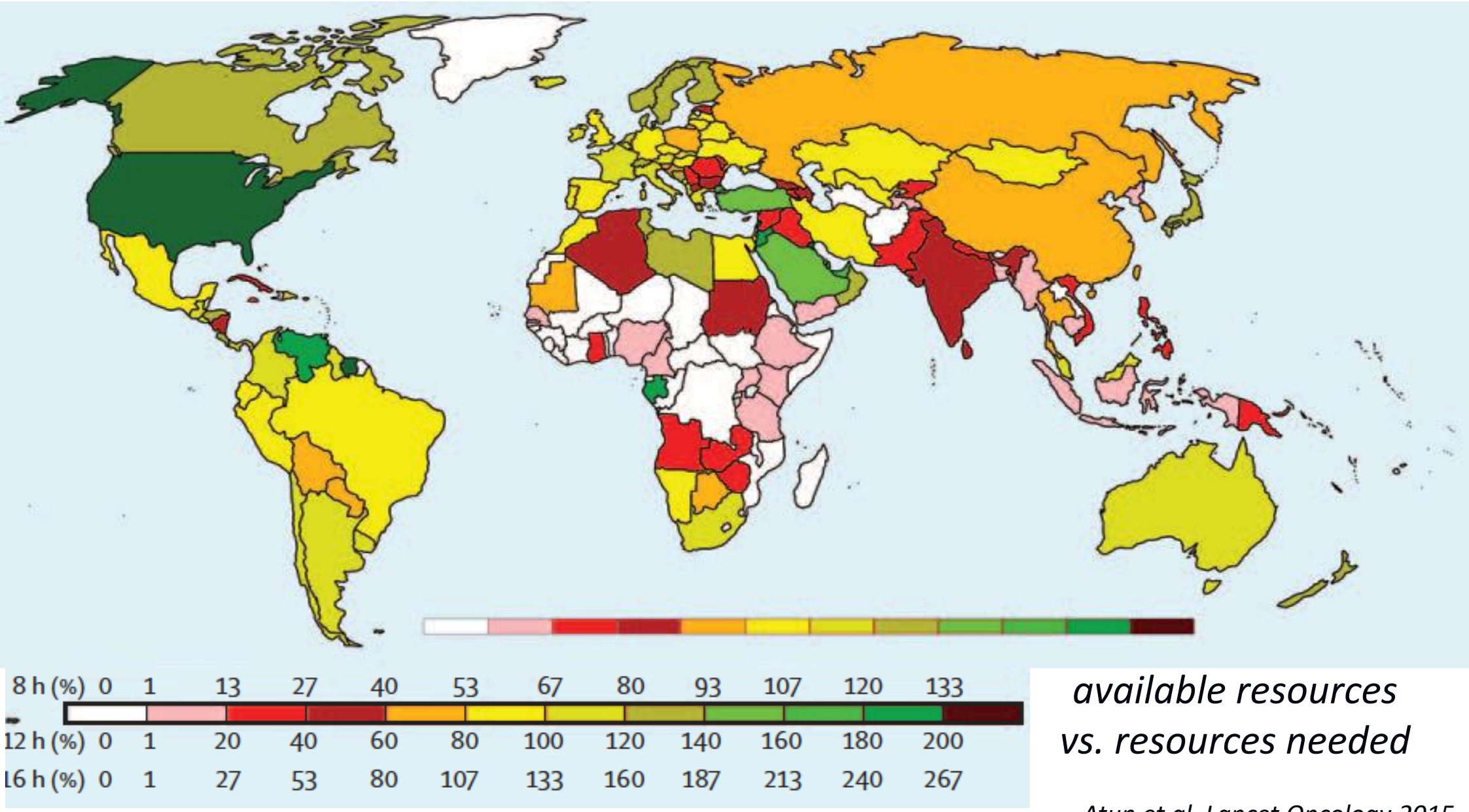
coverage of radiotherapy world wide



available resources vs. resources needed

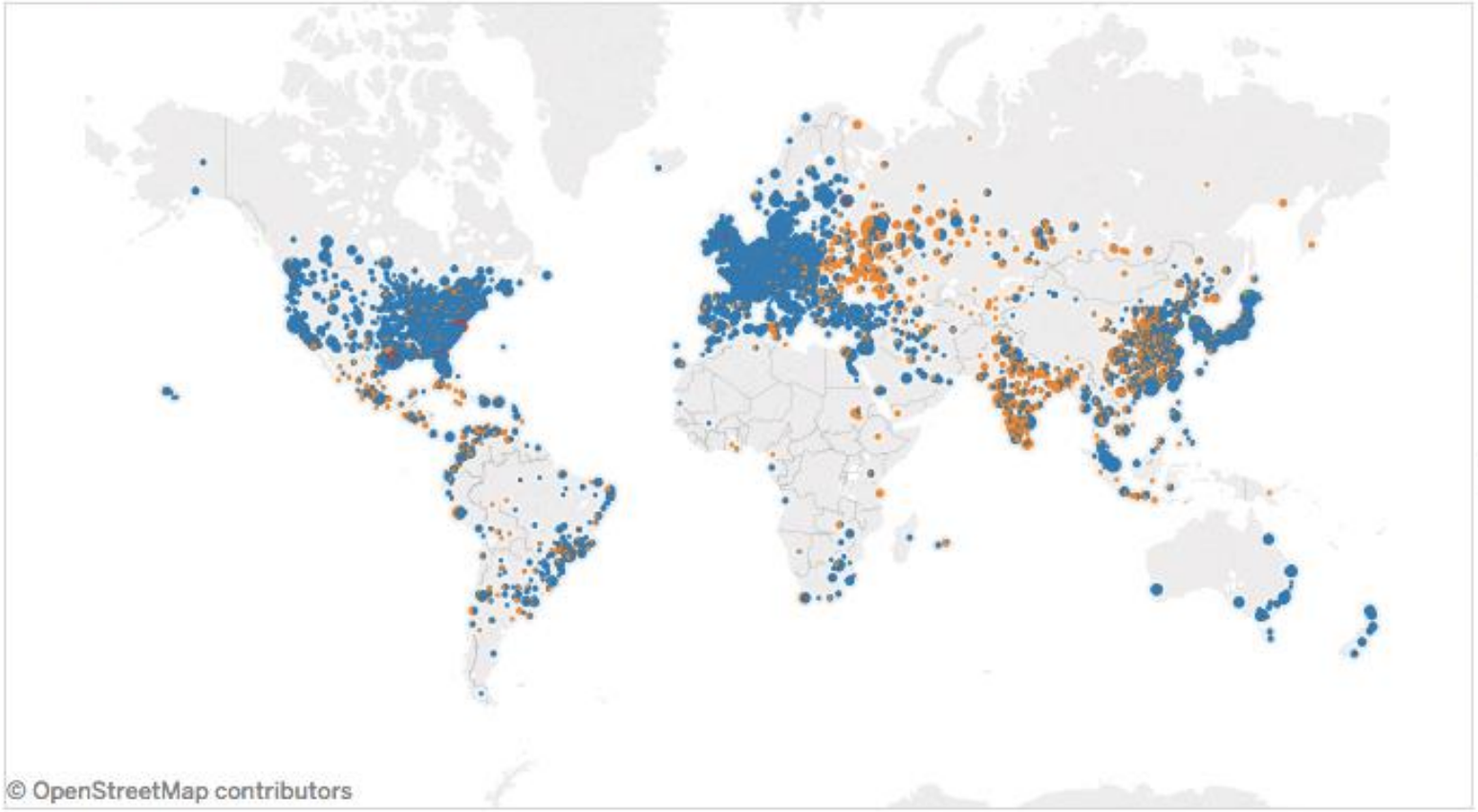
Atun et al, Lancet Oncology 2015

human resources needed to be trained world wide!

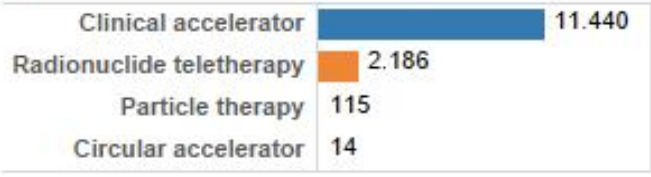
2035	High-income countries	Upper-middle-income countries	Lower-middle-income countries	Low-income counties
Fractions	76 424 000	77 014 000	40 974 000	13 268 000
Radiotherapy departments	4600	3700	2000	600
Megavoltage machines	9200	7400	3900	1300
CT scanners	4600	3700	2000	600
Radiation oncologists to be trained	15 500	16 800	9900	3300
Medical physicists to be trained	17 200	12 500	7200	2400
Radiation technologists to be trained	51 900	45 300	24 900	8100

IAEA DIRAC *(Directory of Radiotherapy Centres)*

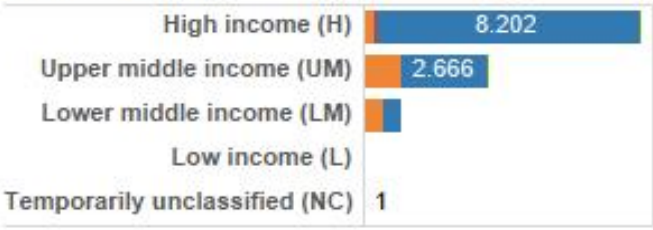
Radiation therapy centers
(Updated on : 1-6-2017 07:11:24)

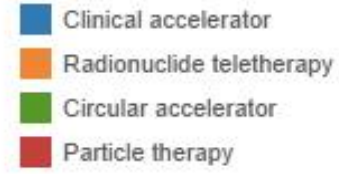


Equipment type
(Updated on : 1-6-2017 07:11:24)



Income groups





Countries	RT centers	Equipment	Linac	Radionuclide Therapy	Circular Accelerator	Particle Therapy
139	7041	13755	11440	2186	14	115

various sources, voluntary collaboration
of radiotherapy centres and clinical institutions

https://dirac.iaea.org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& ONCOLOGY
IAEA
International Atomic Energy Agency

some examples of staffing estimators

sample worksheet to calculate physics staff - US

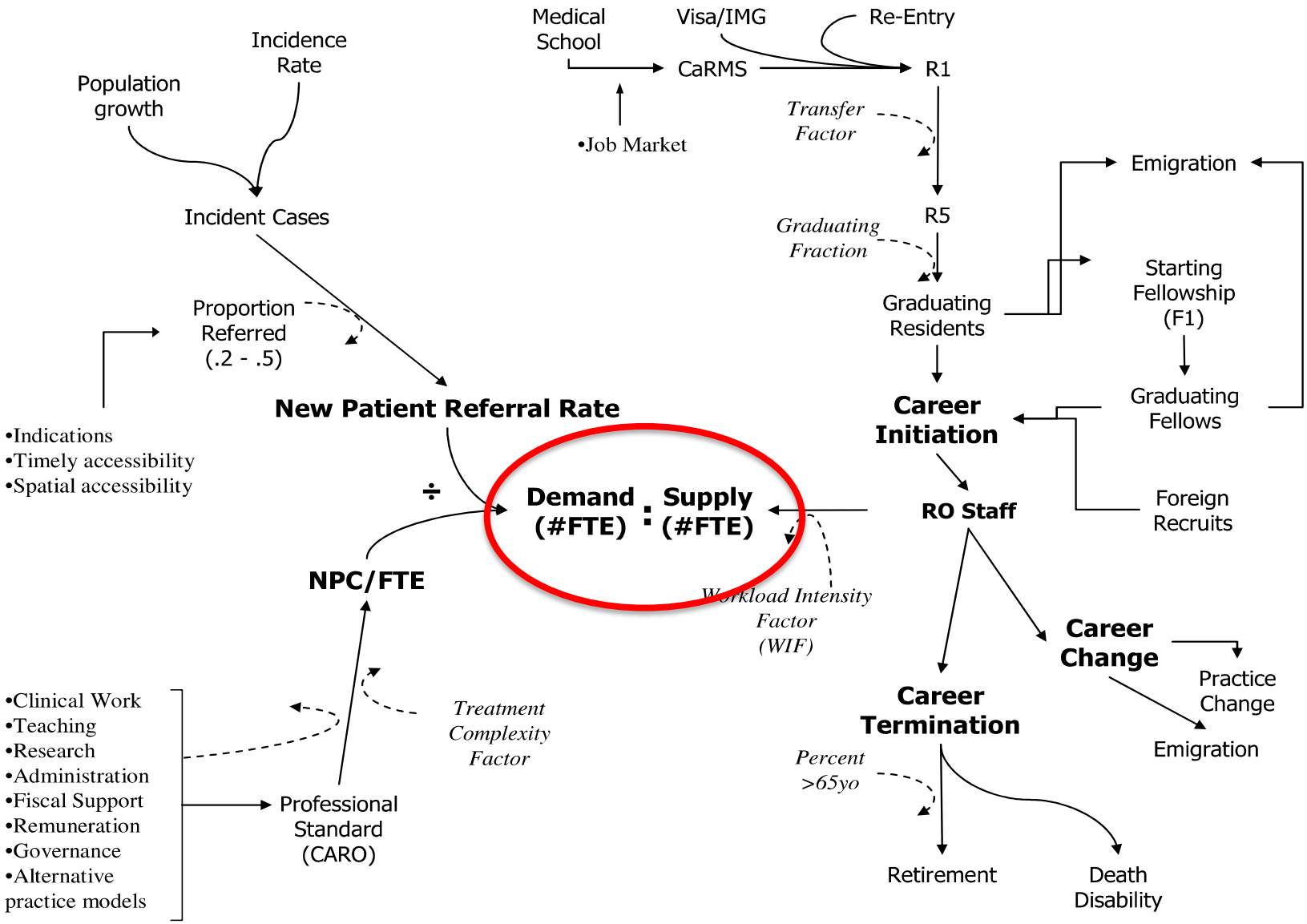
			Relative FTE Factor		Required FTE		Required Total FTE	
	Services — # of Units or Licenses*	No. of systems*	Physicist	Dosimetrist	Physicist	Dosimetrist	Physicist	Dosimetrist
Equipment, Sources and Systems	Multi energy accelerators		0.25	0.05				
	Single energy accelerators		0.08	0.01				
	Tomotherapy, CyberKnife, GammaKnife		0.3	0.03				
	Cobalt Units, IMRT, PACS, EMR & Contouring		0.08	0.03				
	Orthovoltage and superficial units		0.02	0.01				
	Manual brachytherapy; LDR Seed Implants		0.2	0.03				
	HDR brachytherapy		0.2	0.02				
	Simulator, CT-Simulator, PET, MRI Fusion		0.05	0.02				
	Computer planning system (per 10 workstations)		0.05	0.02				
	HDR planning system		0.2	0.01				
						Subtotal		
No. Patient Procedures	**Annual # of Patients undergoing Procedures****	**No. of patients****						
	External Beam RT with 3D planning		0.0003	0.003				
	External Beam RT with conventional planning		0.0002	0.002				
	Sealed source Brachytherapy (LDR & HDR)		0.008	0.003				
	Unsealed source therapy		0.008	0.005				
	IMRT, IGRT, SRS, TBI, SBRT		0.008	0.005				
						Subtotal		
Nonclinical - Estimated Total FTE Effort	**Estimated Total (Phys & Dosim) FTE Effort*****	**FTE Effort*****						
	Education & Training (FTE)		0.667	0.333				
	Generation of Internal Reports (FTE)		0.667	0.333				
	Committees & Meetings; Inc. Rad. Safety (FTE)		0.667	0.333				
	Administration and Management (FTE)		0.667	0.333				
						Subtotal		
						Total		

** Enter the sum of the number of therapy units, imaging systems, workstations, support systems and technologies in each category (column 3).*

*** Enter the annual number of new patients that undergo each of the following planning and treatment deliver procedures; count each new patient one time (column 3).*

****Enter the summed total medical physicist and medical dosimetrist estimated FTE effort in each of the following categories. See Component FTE table for typical FTE (column 3)*

a Canadian workforce planning model



Stuckless et al, R&O 2012

a Canadian workforce planning model

Domain	Parameter	Description	Base assumption	Range evaluated in sensitivity analysis
Demand	Incident cases	Rate of incident cases *(Canadian Cancer Statistics)*	Data as published, Growth 1.3% an.	Not applicable
	Proportion referred	Proportion of incident cases referred to radiation oncology (ref Delaney, Mackillop) *(CARO MPS and CCS)*	0.40	0.3–0.5
	NPC/FTE	Ratio of NPC per FTE based on workload factors that modify the standard professional workload *(CARO MPS)*	285	200–315
Supply (career initiation)	Resident graduates taking RO positions	Number of residents successfully completing training and entering workforce	Calculated annually from survey data	Not applicable
	RO fellows taking RO positions	Estimated number of RO fellows entering workforce on fellowship completion	Calculated annually from survey data	Not applicable
	Residents/fellows emigrating	Proportion of RO residents and fellows leaving the country at completion of training (estimated based on trends during seeding period) *(CAPER)*	0.12	0–0.15
	Resident transfer factor	Proportion of RO residents transferring into other training programs (estimated based on trends during seeding period).	0.9	Not applicable
	Foreign recruits	Estimated number of RO positions filled by neither RO residents nor fellows *(CMA)*	3	1–5
	Work intensity	Estimated proportion of RO positions that will be FTE (e.g., due to part-time or administrative positions) based on survey data	0.875	0.80–0.95
Supply (career change or termination)	RO emigration	Estimated number of ROs leaving practice in Canada for positions elsewhere *(CMA)*	5	2–9
	RO practice change	Estimated number of ROs changing practice to other specialty	0	N/A
	Death/Disability	Estimated number of ROs unable to practice	1	N/A
	Retirement	Estimated number of retirees from workforce *(CMA and CARO MPS)*	Calculated annually from survey data, retirement age 65	Retirement age 60–65

Stuckless et al, R&O 2012

a Canadian workforce planning model

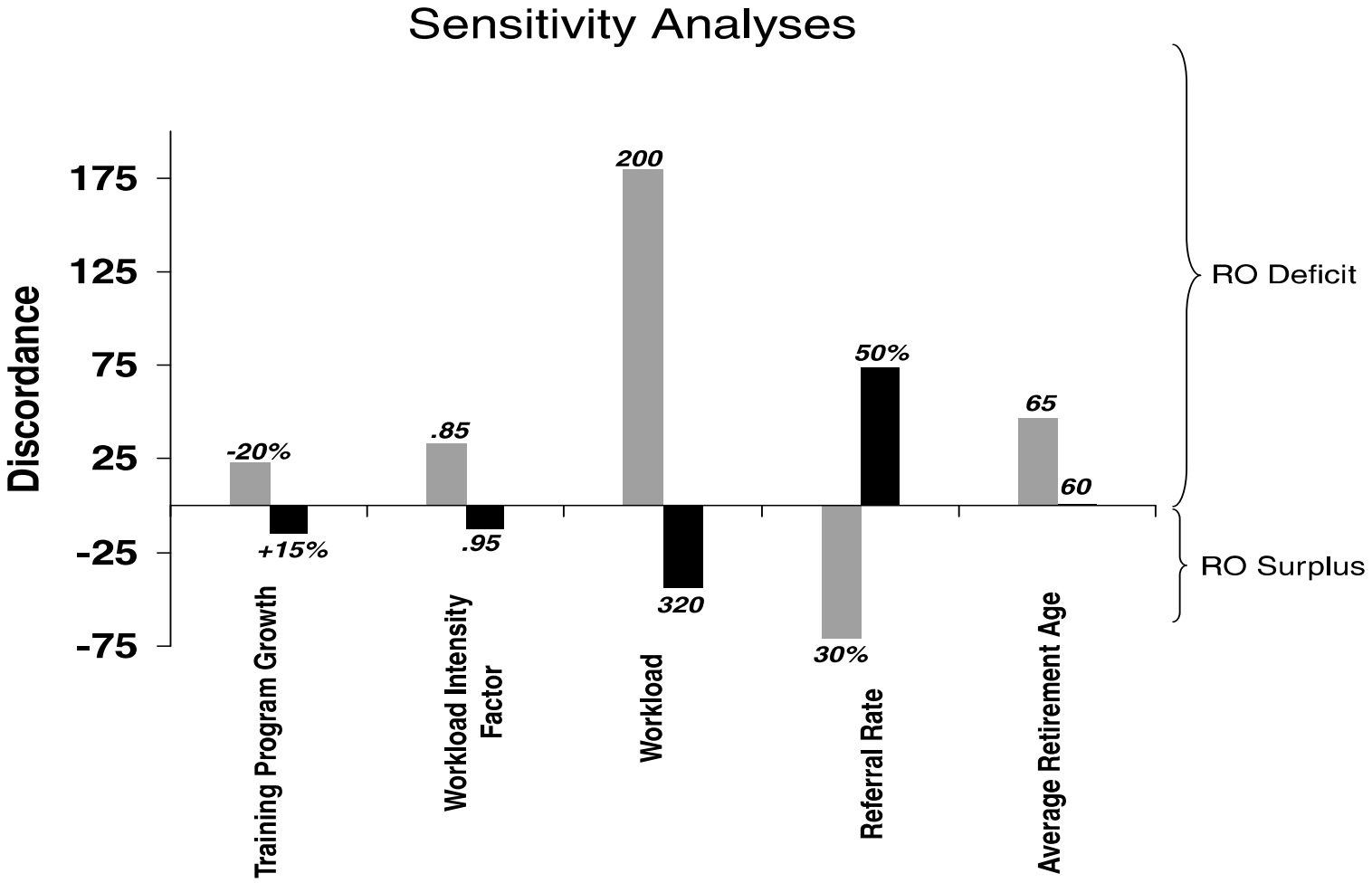


Fig. 3. Five factors most influencing discordance between supply and demand. Numbers at the bar ends refer to extremes of the range of plausible values used in the sensitivity calculations.

Stuckless et al, R&O 2012

IAEA staffing estimator

			Radiation Oncology			Medical Physics			Radiation Therapy			Treatment Planning			Rad Onc Nursing			Information Technology			Mechanical Engineering			Electronics Engineering		
Working hours per day			8			8			8			8			8			8			8			8		
Working days per week			5			5			5			5			5			5			5			5		
Annual leave (working days) + holidays			40			40			40			40			40			40			40			40		
Total worked days per year			220			220			220			220			220			220			220			220		
Total hours worked per year			1760			1760			1760			1760			1760			1760			1760			1760		
*Not RT treatment related **			651			396			185			510			35			0			0			0		
Effective RT hours			1109			1364			1575			1250			1725			1760			1760			1760		
Number of RTTs per teletherapy machine									2																	
		total h/activity	h	factor	#staff	h	factor	#staff	h	factor	#staff	h	factor	#staff	h	factor	#staff	h	factor	#staff	h	factor		h	factor	#staff
Tasks related directly to patient number	***Number of Consultatio***	***h/activity***																								
Therapeutic decision/first consultation	400	1,00	1,00	1,00	0,36	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,10	0,10	0,02	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
EBRT: imaging, planning and first setup	***Number of Cases/y***	***h/activity***																								
2D	100	1,60	0,66	0,41	0,06	0,14	0,09	0,01	1,60	1,00	0,10	0,21	0,13	0,02	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
2D + TP	100	3,55	1,21	0,34	0,11	0,14	0,04	0,01	3,09	0,87	0,20	0,71	0,20	0,06	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
3D	200	6,55	1,44	0,22	0,26	0,85	0,13	0,12	2,62	0,40	0,33	3,47	0,53	0,56	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
IMRT (excluding 4D cases)	0	10,05	1,31	0,13	0,00	2,61	0,26	0,00	1,61	0,16	0,00	5,73	0,57	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
4D (excluding pure IMRT cases)	0	13,75	2,06	0,15	0,00	4,13	0,30	0,00	2,61	0,19	0,00	7,70	0,56	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
EBRT: additional activities	***Number of Procedures***	***h/activity***																								
Patient positioning/immobilisation for EBRT																										
simple	100	0,25	0,00	0,00	0,00	0,00	0,00	0,00	0,25	1,00	0,02	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
customised	200	0,50	0,00	0,00	0,00	0,00	0,00	0,00	0,75	1,50	0,10	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
complex	0	1,00	0,50	0,50	0,00	0,00	0,00	0,00	1,50	1,50	0,00	0,50	0,50	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
Additional image acquisition for EBRT																										
MRI/PET CT	0	0,75	0,00	0,00	0,00	0,00	0,00	0,00	0,75	1,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
Additional activities related to TV definition																										
Image fusion (PET/CT, MRS, etc)	0	0,50	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,50	1,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
Block cutting/accessories	200	1,25	0,00	0,00	0,00	0,25	0,20	0,04	1,00	0,80	0,13	0,00		0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
Treatment delivery																										
Portal imaging sessions	1600	0,10	0,10	1,00	0,14	0,00	0,00	0,00	0,20	2,00	0,20	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
Daily image guidance	0	0,10	0,00	0,00	0,00	0,00	0,00	0,00	0,20	2,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
In-vivo dosimetry	400	0,10	0,00	0,00	0,00	0,00	0,00	0,00	0,20	2,00	0,05	0,10	1,00	0,03	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
Total # fraction 1 slot	4000	0,20	0,00	0,00	0,00	0,00	0,00	0,00	0,40	2,00	1,02	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
2 slots	4000	0,40	0,00	0,00	0,00	0,00	0,00	0,00	0,80	2,00	2,03	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
3 slots	0	0,60	0,00	0,00	0,00	0,00	0,00	0,00	1,20	2,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
4D excluding SBRT	0	0,50	0,00	0,00	0,00	0,50	1,00	0,00	1,00	2,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
SBRT	0	0,75	0,75	1,00	0,00	0,75	1,00	0,00	1,50	2,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
Chart check	1600	0,40	0,16	0,40	0,23	0,40	1,00	0,47	0,16	0,40	0,16	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
Evaluation during treatment	1600	0,25	0,25	1,00	0,36	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,03	0,10	0,02	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
BRACHYTHERAPY	***Number of Procedures***	***h/activity***																								

http://nucleus.iaea.org/HHW/RadiationOncology/Makingthecaseforradiotherapyinyourcountry/Roleofradiotherapyincancercare/ Radiotherapyisacosteffectivesystemwhichneedsabalance/RO_Staffing_Calculator.xlt

Time-Driven Activity Based Costing model

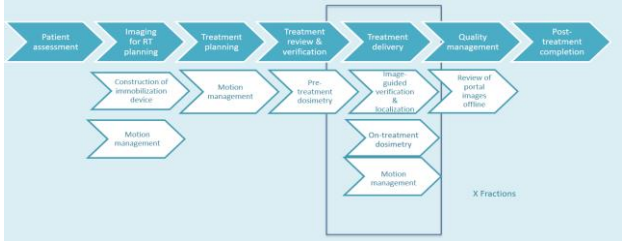
RESOURCES



- ✓ Taskforce
- ✓ Equipment
- ✓ Consumables

HERO data staffing & equipment
Literature data
Expert estimates

ACTIVITIES



- ✓ Times & frequency of activities

Literature data
Expert estimates

TREATMENTS

N° treatments per

- ✓ Localisation
- ✓ Technique
- ✓ Fractionation

CCORE model
Cancer registries data

ESTRO
European Society for RADIOTHERAPY & ONCOLOGY

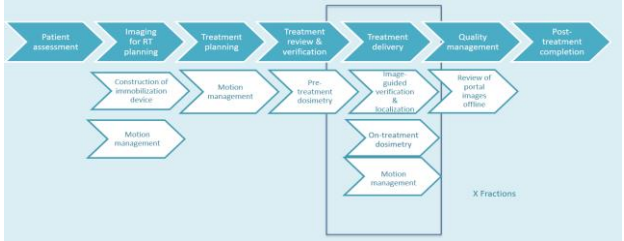
Time-Driven Activity Based Costing model

RESOURCES



- ✓ Taskforce
- ✓ Equipment
- ✓ Consumables

ACTIVITIES



- ✓ Times & frequency of activities

TREATMENTS

N° treatments per

- ✓ Localisation
- ✓ Technique
- ✓ Fractionation

Resource Utilisation & needs

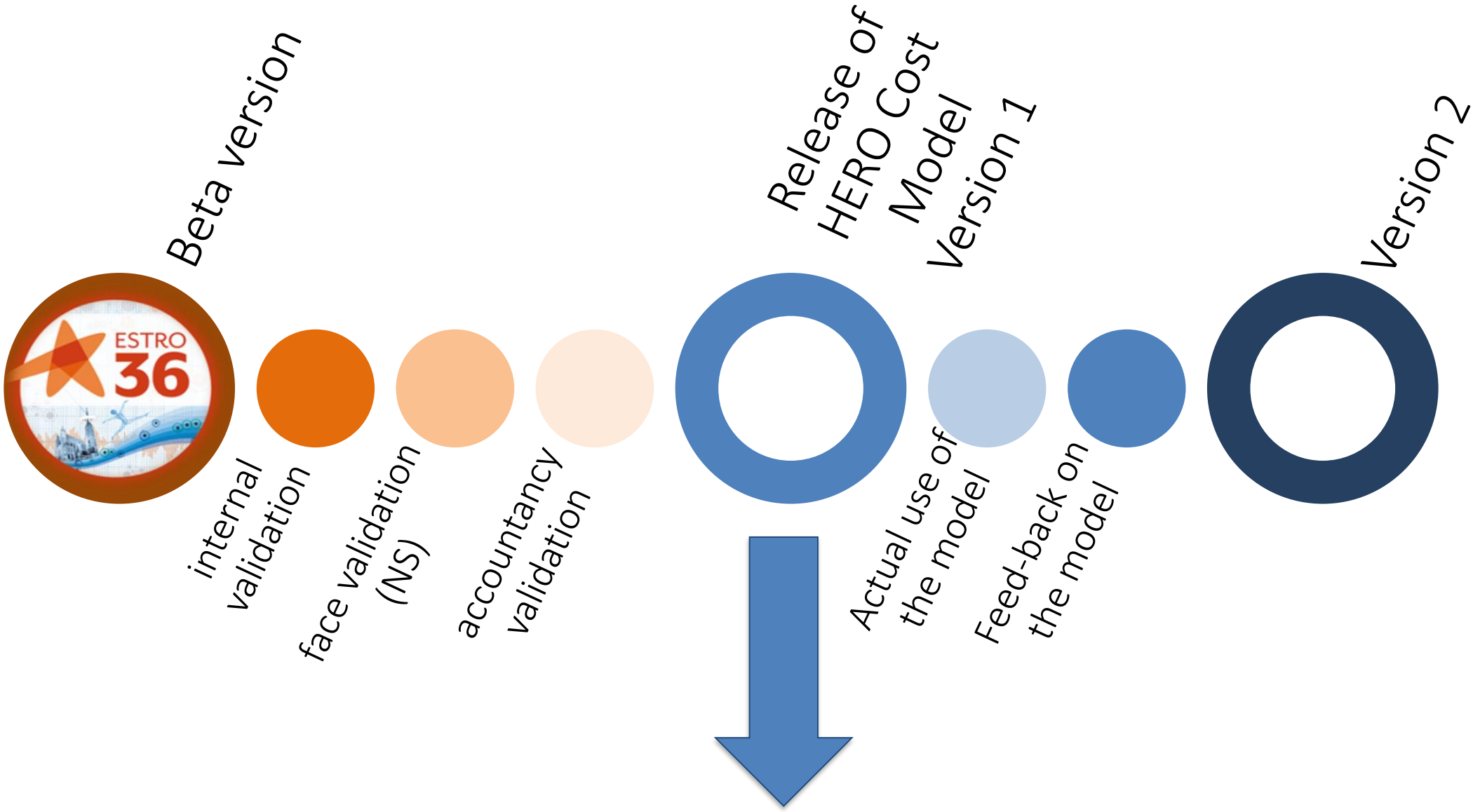
National Cost estimate

ESTRO European Society for RADIOTHERAPY & ONCOLOGY

Time-Driven Activity Based Costing model

Online tool for cost calculation and resource utilisation / needs
To be made available to National Radiotherapy Societies

ESTRO
European Society for
RADIOTHERAPY
& ONCOLOGY



release during ESTRO governance week

December 5th 2017, Brussels

ESTRO
European Society for RADIOTHERAPY & ONCOLOGY

take home messages

- **Correct staffing levels are necessary** to support high quality and safe radiotherapy, and to allow technological evolution.
- Although the average radiotherapy staffing levels in Europe are in line with international recommendations, there **is a wide range in available radiotherapy staff** in different European countries.
- The variability is related to a **number of factors**:
  - National welfare
  - Rules and regulations
  - Cancer incidence
  - Retreatment rates
  - Roles and responsibilities
  - Treatment complexity and fractionation
- Available recommendations are often outdated and adjusted post-hoc to the actual situation. There is an urgent **need for accurate predictive models.**

ESTRO School

Thank you
for your attention!

Questions?

ESTRO School

Health Technology Assessment and value for money of quality in radiotherapy.

ESTRO Teaching Course
"Quality Assessment and Improvement"

Brussels – October 2017

Yolande Lievens, MD, PhD
Department of Radiation Oncology, Ghent University Hospital, Belgium

ESTRO School

learning objectives

- To know the differences and relation between **Health Technology Assessment** and clinical and translational research
- To understand the basics of **cost calculation**, with a focus on radiation oncology
- To understand the basics of **economic evaluation**, with a focus on radiation oncology
- To be aware of the **difficulties** of performing cost calculations and economic evaluations in radiation oncology

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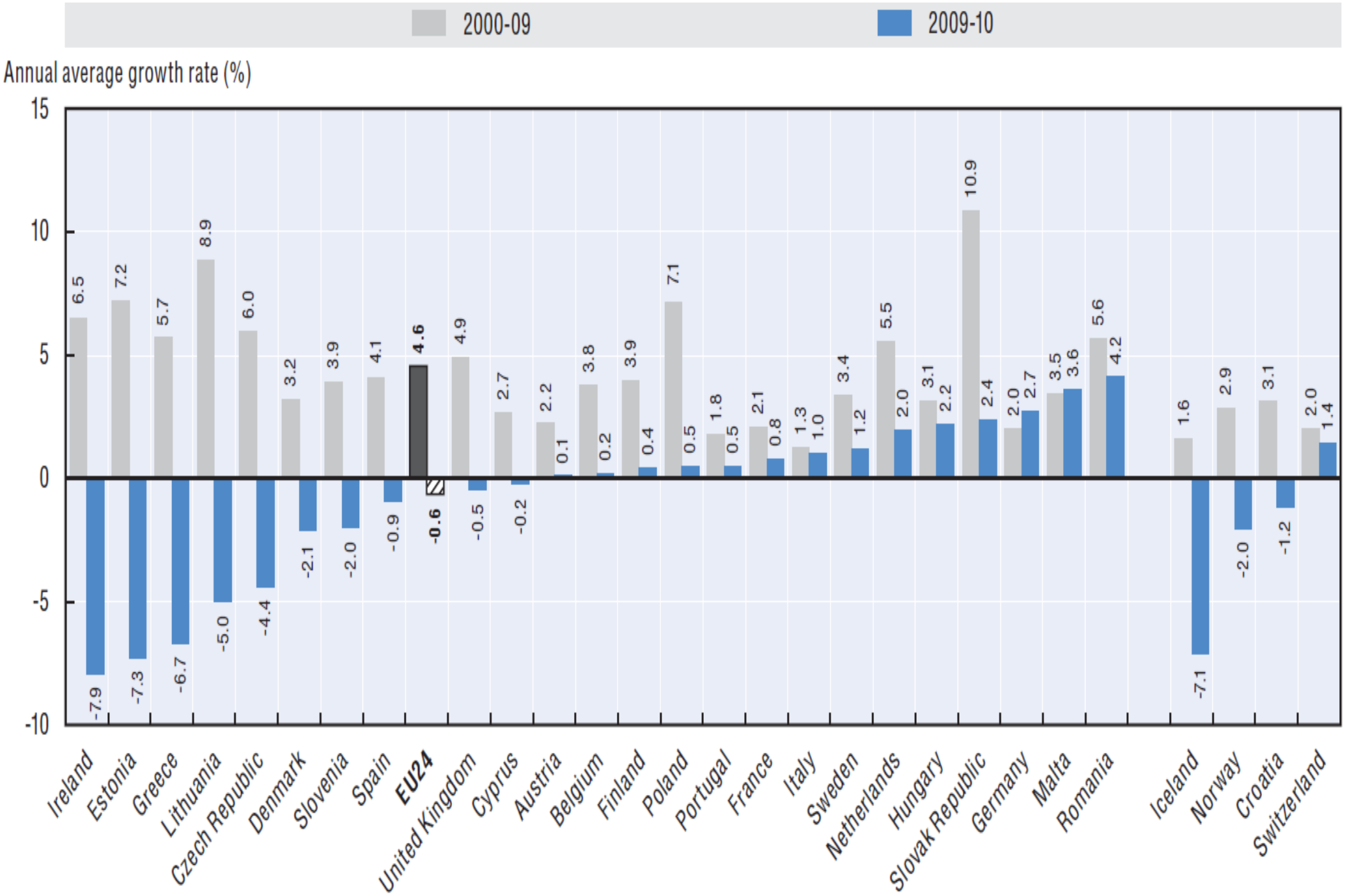
The aim of the healthcare policy
is to **maximise the health** of the population within
the limits of the **available means**
and within an **ethical framework**,
based on values such as fairness and solidarity.

Annemans, L. (2013) The health(care) system for the future generations.



OECD Health Statistics 2012

Health Technology Assessment (HTA)

HTA generally seeks answers to the following questions:

- **Efficacy** – can it work (under ideal circumstances)?
- **Effectiveness** – does it work (in routine practice)?
- **Efficiency** – is it worth it (compared with alternatives)?
- **Availability** – can it be made accessible?
- **Distribution** – does it meet ethical requirements?

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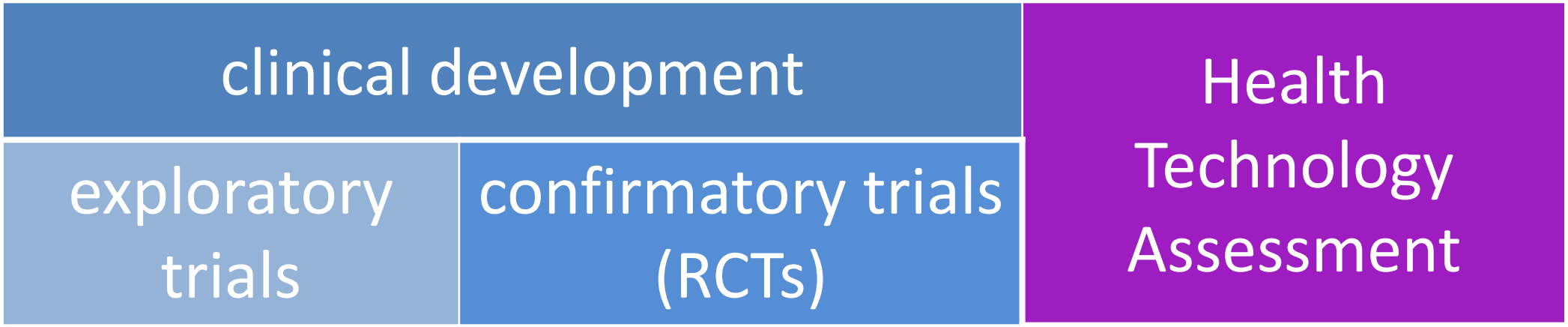


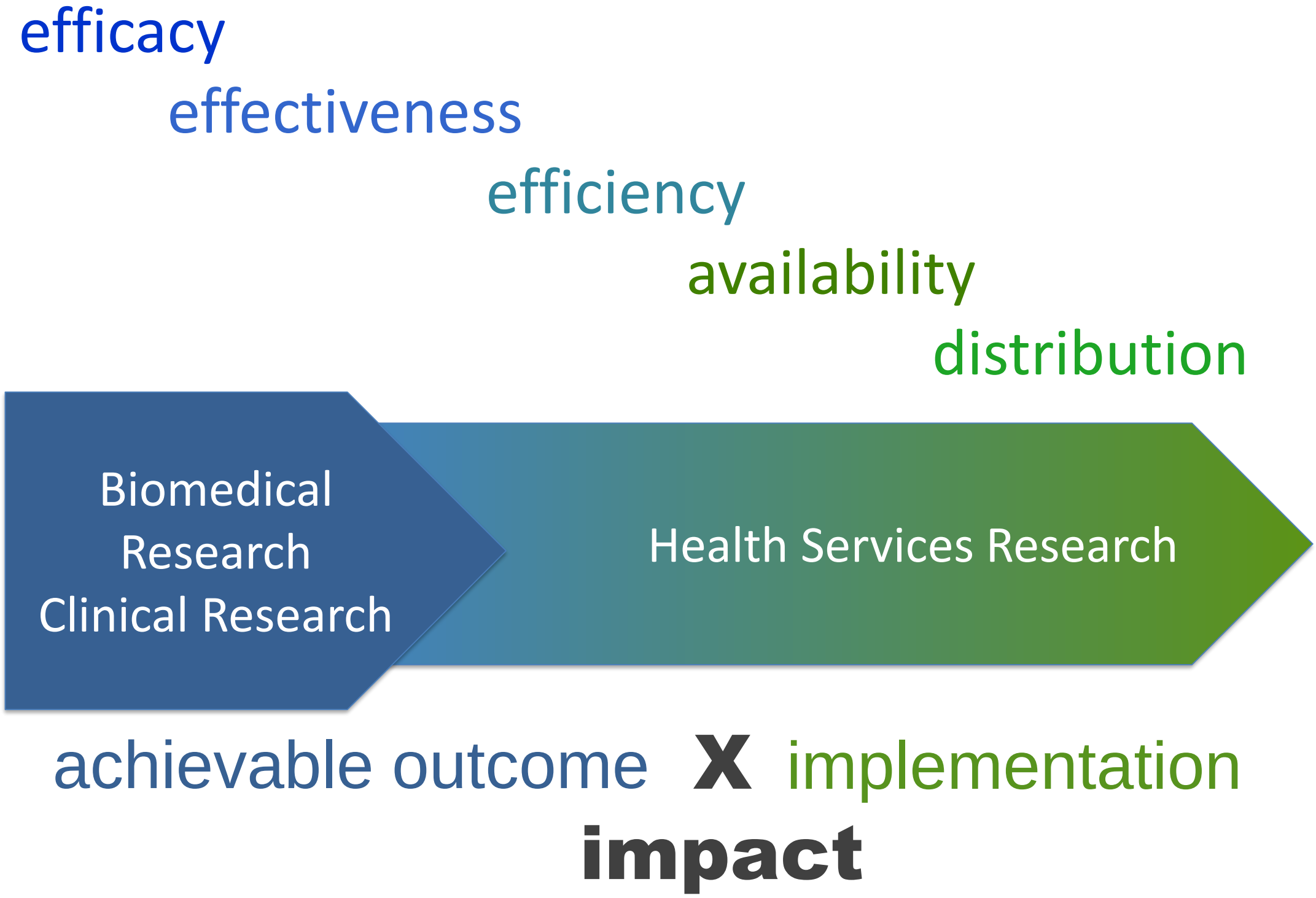
internal validity

- safety
- efficacy

external validity

- comparative effectiveness
- cost-effectiveness
- budget impact

Courtesy F. Hulstaert, KCE


efficacy
effectiveness
efficiency
availability
distribution
Biomedical
Research
Clinical Research
Health Services Research
achievable outcome X implementation
impact

health system performance

accessibility

quality

efficiency

cost?

effectiveness?

patient-specific QA

novel technologies & techniques

more complex treatments

more time

more resources

capital investments

sophisticated equipment

buildings

human resources

treatment

maintenance

quality assurance

more costly

cost of in vivo dosimetry

Resources ↓	Groups →	I	II	III	IV
	Initial resources (no in-vivo dosimetry)	Additional number of resources in each group vs. initial number of resources			
Detectors (used)	8	7	5	11	8
Dosimeters	4	1	1	4	4
Labour, FTE (radiotherapy technicians)	25	0	2	2	2
Labour, FTE (physicists)	8	2	1	1	1
Labour, FTE (physicians)	18	0.25	0.5	0.7	0.9
Labour, FTE (QA, other departments)	1	1	1	1.5	1.5
Labour, FTE (total)	52	3.25	4.5	5.2	5.4

Malicki et al, Physica Medica 2009

cost of in vivo dosimetry

Groups	I	II	III	IV
Number of patients[a] (per month, all tumour sites, *N*)	*117*	*131*	*185*	*198*
Labour (radiotherapy technicians)	0	1.400	1.608	1.752
Labour (physicists)	1.704	952	1.728	1.776
Labour (physicians)	352	752	1.272	1.552
Labour (others)	928	952	2.600	2.672
Consumed materials	24	72	48	104
Depreciation (equipment dedicated to in-vivo dosimetry)	224	448	552	504
Other costs (in the Radiotherapy department)	240	952	672	424
Overhead costs	904	1.376	2.128	2.200
Total cost increase	4.376	6.904	10.608	10.696
Total cost increase per radiotherapy procedure (patient)	37.5	52.7	57.3	54.2

[a] Numbers of patients per month (in this raw only) were rounded in order to avoid fractions.

mean deviations between measured and calculated doses decreased significantly

Malicki et al, Physica Medica 2009

cost of quality, patient-specific activities

Treatment parameters	n	Mean time (min)	Median (min)	SD
Total	324	11.6	10.0	5.9
Type of energy				
Electrons	24	5.4	5.5	1.7
Photons	300	12.1	11.0	5.8
Treatment technique				
IMRT	59	15.1	12.0	6.8
IMRT 5–7 fields	51	13.6	12.0	5.4
IMRT 9–14 fields	8	25.5	25.5	4.7
IMRT, no EPID	26	12.2	10.5	5.9
IMRT, EPID	33	17.3	14.0	6.7
No IMRT[a]	265	10.9	10.0	5.4
No IMRT, no EPID	179	8.8	8.0	3.8
No IMRT, with EPID	86	15.1	14.0	5.7
EPID				
EPID	119	15.7	14.0	6.1
EPID, no IMRT	86	15.1	14.0	5.7
EPID, IMRT	33	17.3	14.0	6.7
No EPID	205	9.3	8.0	4.3
No EPID, no IMRT	179	8.8	8.0	3.8
No EPID, IMRT	26	12.2	10.5	5.9
Fraction number				
Starter	17	19.5	19.0	
Non-starter	307	11.2	10.0	
Performance status				
Good performance	300	11.4	10.0	
Bad performance	24	15.0	14.0	

	extra time* (min)	extra time* (%)
IMRT	**2,54 min**	**30%**
PI's	**5,41 min**	**60%**

Van de Werf et al. R&O 2012

cost of quality, patient-specific activities

	2000 (€)	%	2009 (€)	%
Treatment preparation	839,247	31	1,480,112	27
First patient contact	137,066	5	197,612	4
Simulation	423,162	16	667,324	12
Delineation	25,540	1	114,611	2
Dose calculation	253,479	9	500,565	9
Treatment delivery	1,872,695	69	4,059,947	73
Quality assurance (QA)	283,192	10	1,252,789	23
General at start	40,561	1	102,459	2
Patient specific		0	48,678	1
Supervision plan	69,606	3	68,519	1
Portal imaging	60,324	2	791,248	14
In vivo dosimetry	32,423	1	76,064	1
Chart round	80,278	3	165,821	3
Daily radiotherapy delivery	1,508,306	56	2,501,649	45
Clinical follow up	44,820	2	116,816	2
Discharge	36,377	1	188,693	3
Total	2,711,942	100	5,540,059	100

Van de Werf et al. R&O 2012

cost of IGRT, prostate

	CBCT			EPI[b] with fiducial markers		
	Imaging frequency			Imaging frequency		
	Daily (n = 67) mean (SD)	Weekly (n = 61) mean (SD)	p-Value[a]	Daily (n = 26) mean (SD)	Weekly (n = 29) mean (SD)	p-Value[a]
Time required from staff (minutes)						
Radiation oncologist	3.2 (2.5)	1.1 (1.0)	0.06	0	0.1 (0.1)	$p < 0.01$
Physicist	0.8 (1.5)	0.4 (0.7)	0.12	0.1 (0.1)	0.1 (0.3)	0.99
Radiotherapists (number of 2 to 3 per fraction)	44.3 (7.5)	28.7 (5.8)	0.01	33 (3)	30 (4)	$p < 0.01$
Duration of treatment room occupation (minutes)						
Treatment room occupation	21.0 (3.9)	13.7 (3.2)	0.01	18.3 (3.9)	16.6 (3.7)	$p < 0.01$
Treatment room occupation with imaging control	21.2 (3.7)	20.9 (3.0)	0.08	18.2 (3.7)	18.8 (4.6)	$p < 0.01$
Treatment room occupation without imaging control	NA	11.2 (3.6)	NA	NA	15.5	NA

+9,7min **+3,3min**

Perrier et al. R&O 2013

Cost items		CBCT Imaging frequency				EPI[f] fiducial markers Imaging frequency			
		Daily (n = 67) mean (SD)	Weekly (n = 61) mean (SD)	Δ mean costs[a](SD)	p-Value[b]	Daily (n = 26) mean (SD)	Weekly (n = 29) mean (SD)	Δ mean costs[a] (SD)	p-Value[b]
Staff	Radiation oncologist	159 (42.8)	64 (59.1)	95 (9.2)	*p < 0.0001*	0 (0)	4 (7)	−4 (7)	*0.01*
	Physicist	14 (42.8)	10 (20.3)	4 (5.8)	*0.63*	3 (5)	4 (9)	−1 (1.9)	0.81
	Radiotherapist	706 (131.2)	500 (123.8)	206 (22.5)	*p < 0.0001*	628 (69)	559 (65)	69 (18.1)	*p < 0.001*
	Total	879 (197.5)	574 (127.3)	305 (29.1)	*p < 0.0001*	631 (71)	567 (70)	64 (19.0)	*p < 0.01*
Linear accelerator		728 (133.9)	538 (131.5)	190 (23.5)	*p < 0.0001*	539 (50)	485 (38)	54 (12.1)	*p < 0.01*
Maintenance and quality control (QC)	Internal maintenance and QC[c]	113 (20.9)	84 (20,5)	29 (3.7)	*p < 0.0001*	94 (9)	84 (7)	10 (2.2)	*p < 0.01*
	External maintenance and QC[d]	582 (107.0)	429 (105.1)	153 (18.8)	*p < 0.0001*	508 (47)	457 (36)	51 (11.4)	*p < 0.01*
	Registration software	9 (1.7)	7 (1.6)	2 (0.2)	*p < 0.0001*	0 (0)	0 (0)	0 (0)	1.000
	Total	704 (129.5)	520 (127.2)	184 (22.7)	*p < 0.0001*	602 (56)	541 (42)	61 (13.5)	*p < 0.01*
Fiducial markers	Urologist	na	na	na	na	20 (0)	22 (7.6)	−2 (1.4)	0.36
	Nurse	na	na	na	na	25 (0)	24 (4.6)	1 (0.9)	0.36
	Operating room	na	na	na	na	149 (45.9)	140 (52.0)	9 (13.2)	0.48
	Fiducial markers	na	na	na	na	99(0)	99(0)	0 (0)	1.0
	Total	na	na	na	na	293 (45.9)	285 (54.9)	8 (13.6)	0.61
Total[e]		2311 (418.7)	1632 (356.8)	679 (69.6)	*p < 0.0001*	2065 (157)	1878 (135)	187 (39.7)	*p < 0.0001*

1,600€ to 2,300€

Perrier et al. R&O 2013

more complex treatments

contain costs without impact on quality?

limit cost of resources

optimize use of resources

decrease total treatment time
(time per fraction X number of fractions)

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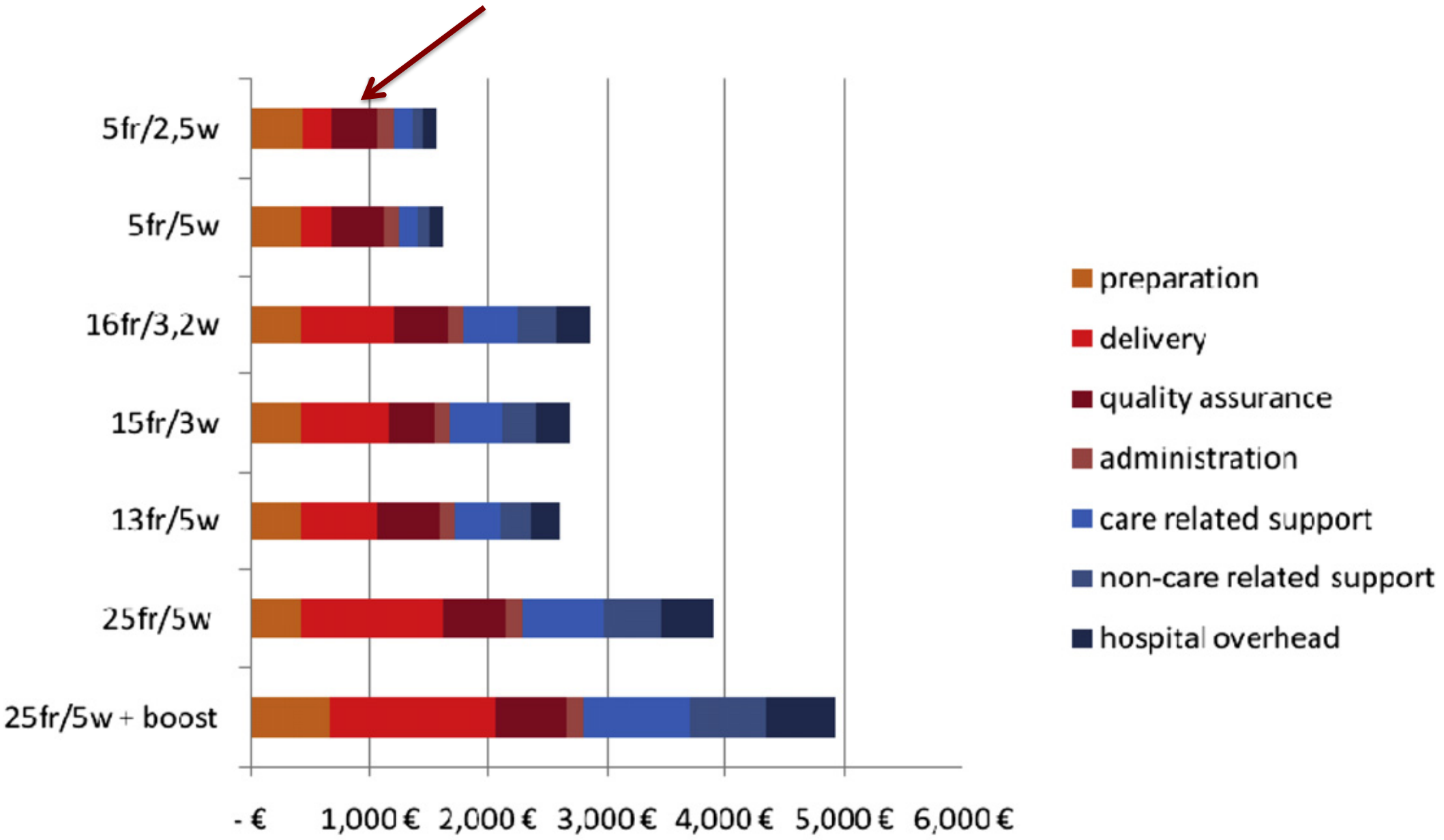
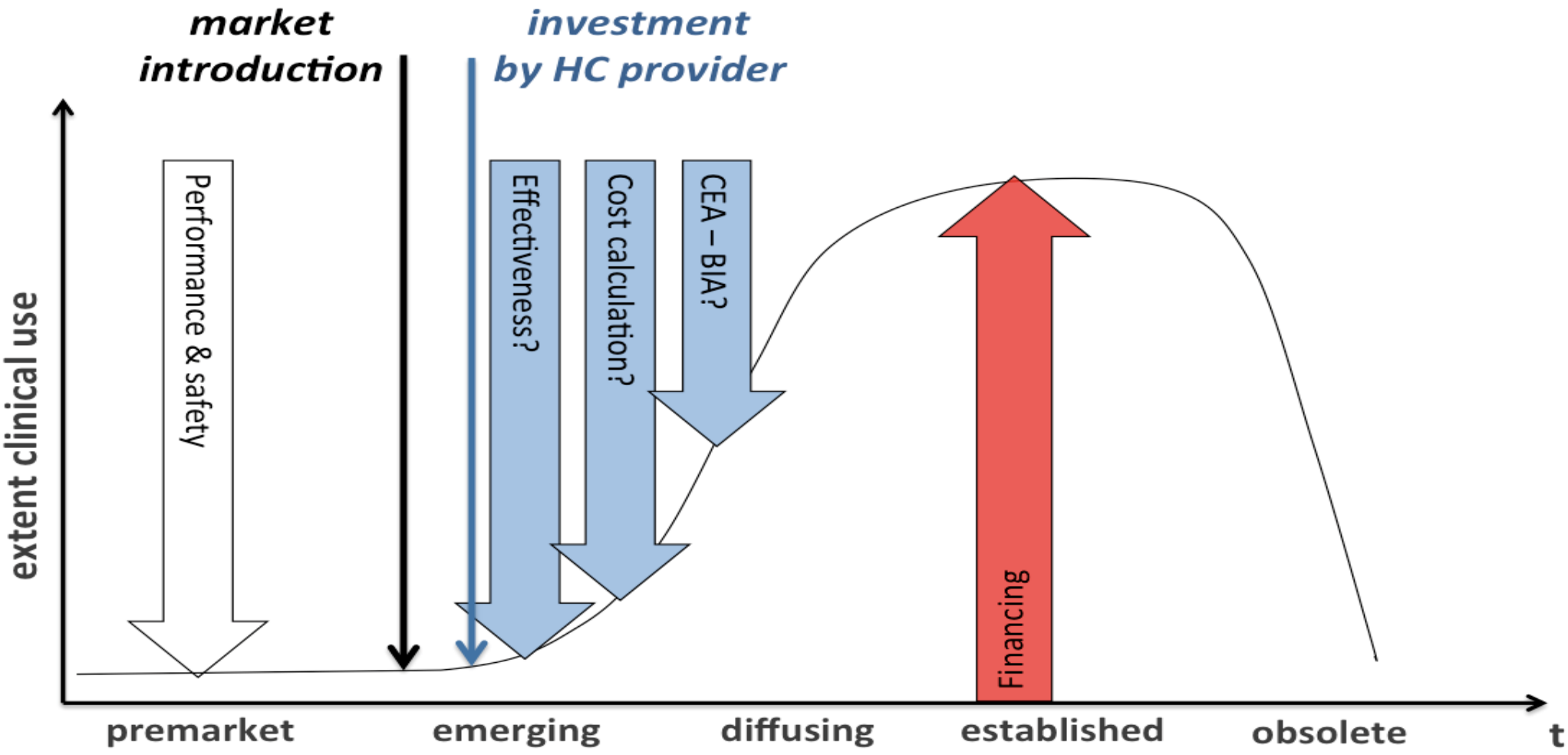
hypofractionation



Lievens, The Breast 2010

time is not on our side…

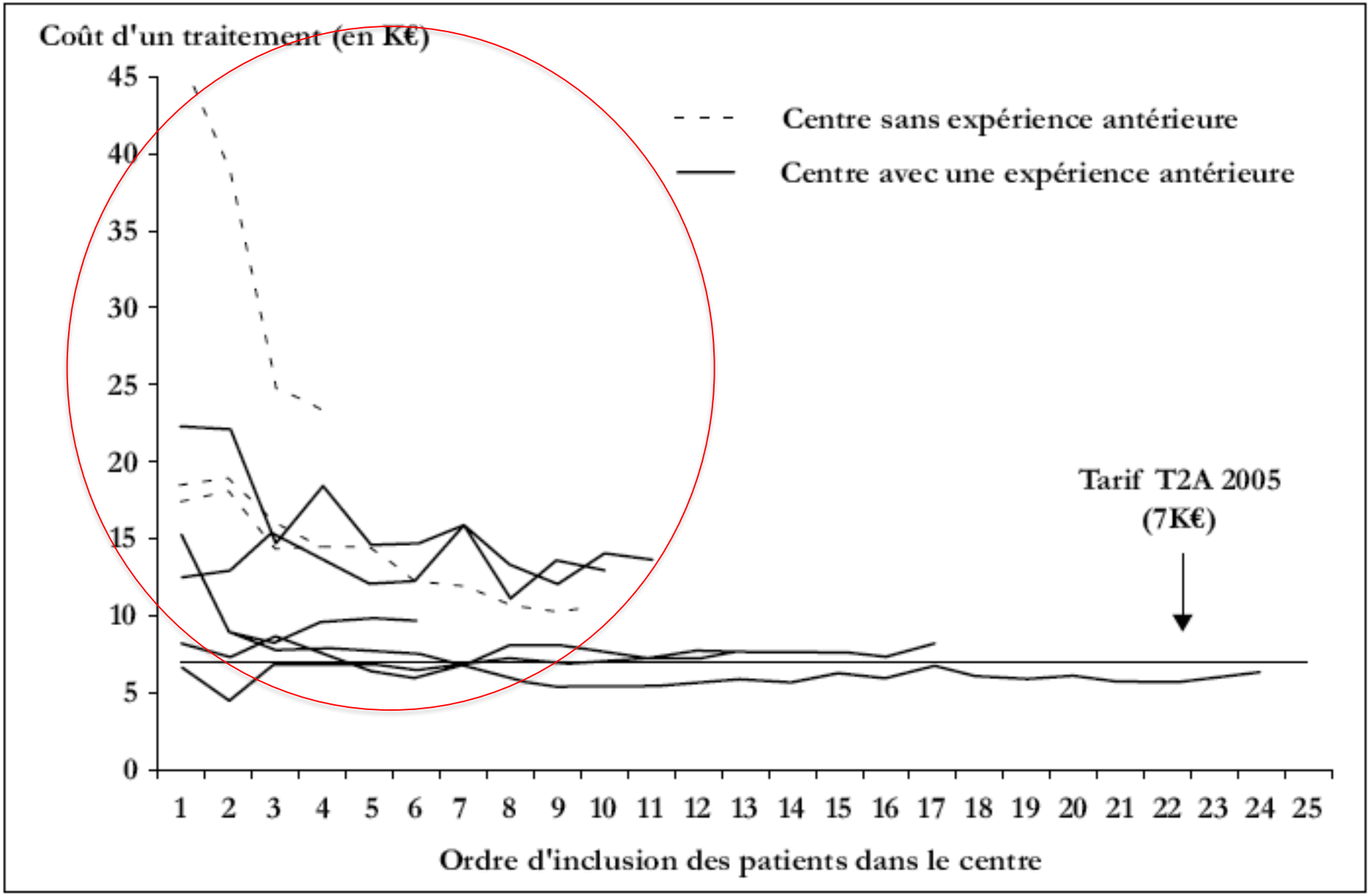


safety efficacy, effectiveness & efficiency

time

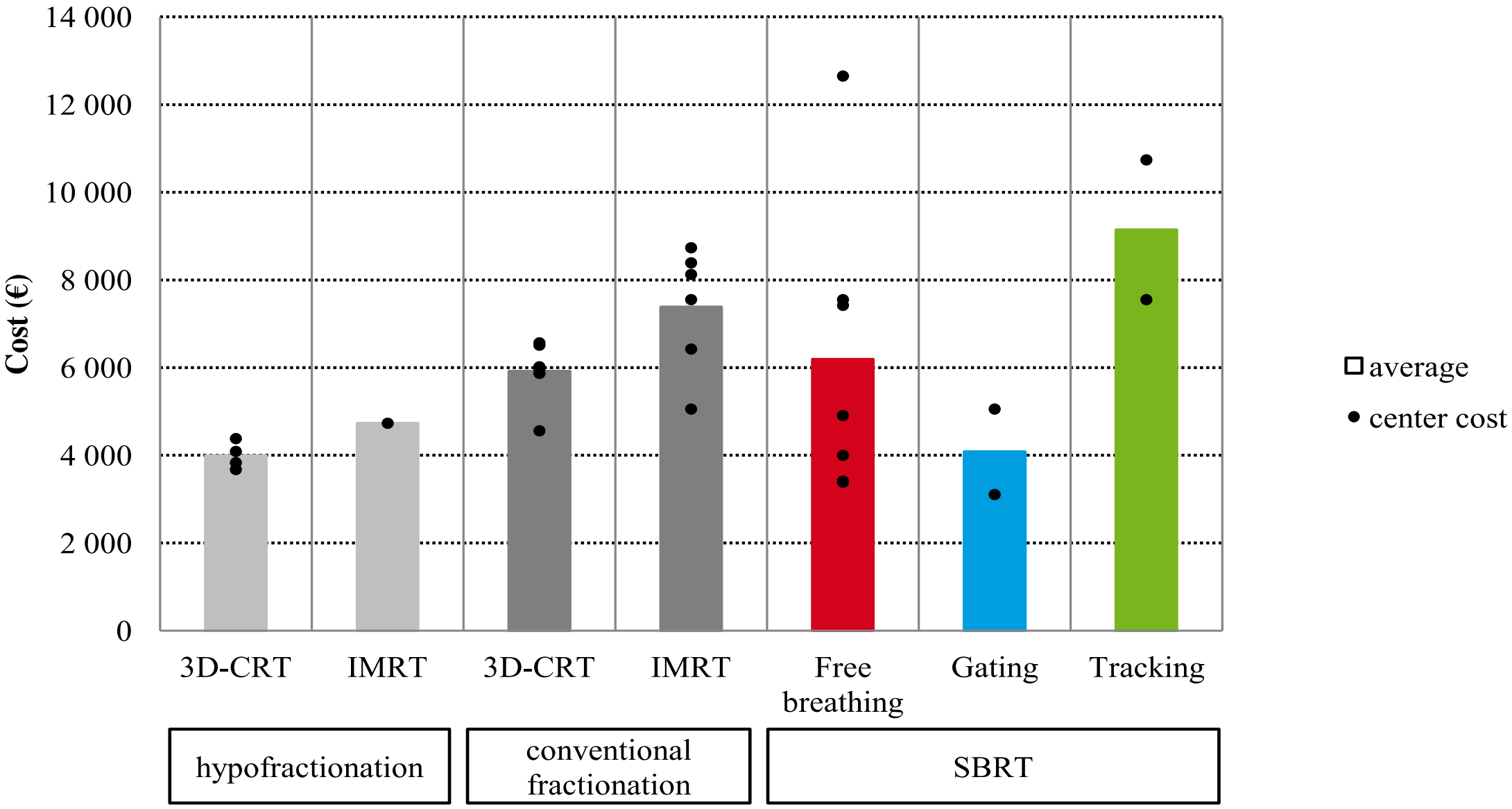
Lievens et al, Acta Oncol 2015

the cost of learning



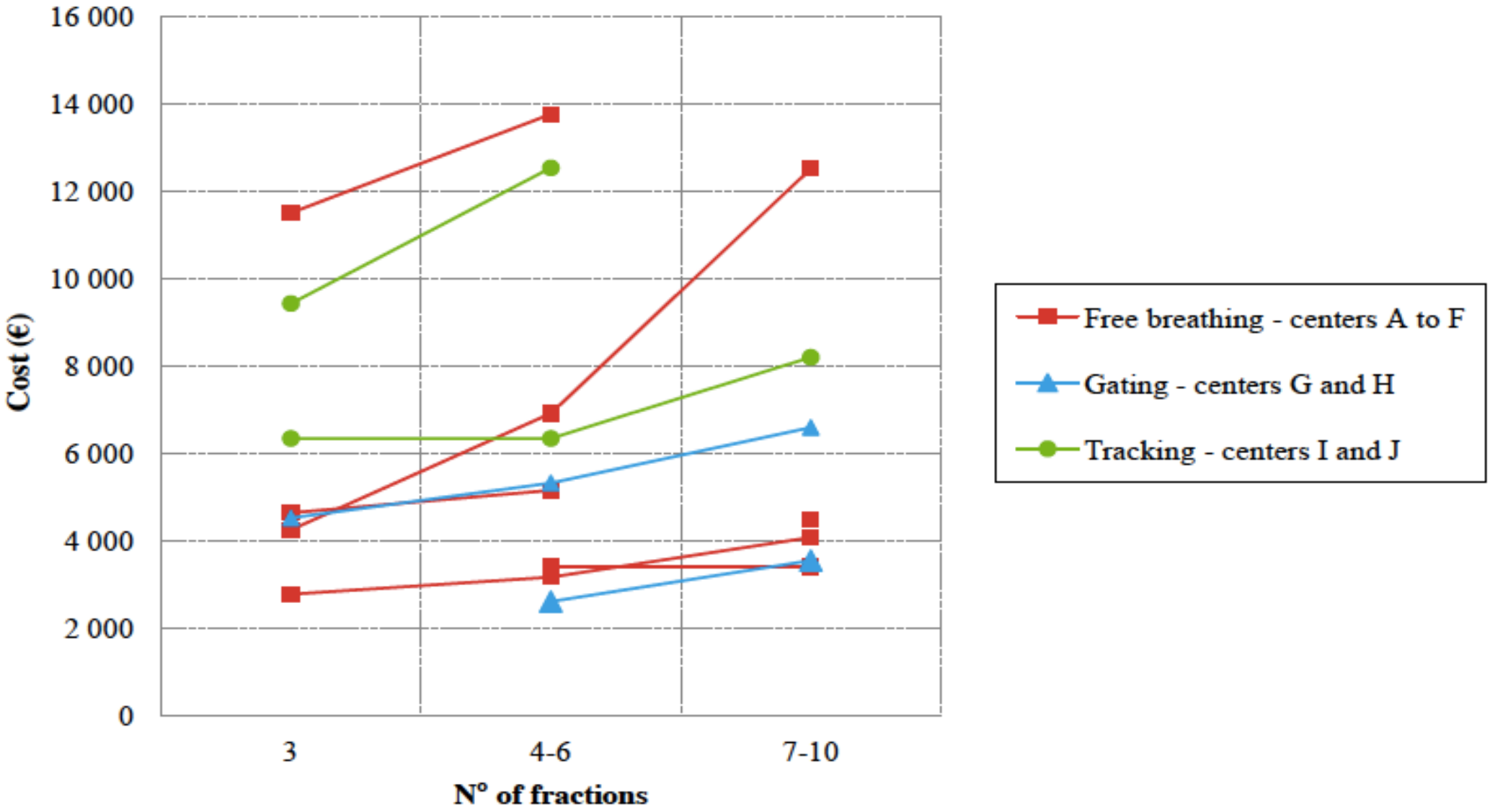
Bonastre et al. Bull cancer 2006

cost vs. fractionation and complexity



Lievens et al, J Thor Oncol 2015

the actual cost of lung SBRT in Belgium



KCE

Hulstaert et al, Report 198 KCE 2013
Lievens et al, J Thor Oncol 2015

the cost worldwide, per fraction

	High-income countries	Upper-middle-income countries	Lower-middle-income countries	Low-income countries
Operating cost per fraction	235	86	65	60
Upfront cost per fraction	803	357	349	352

Estimated on the basis of the activity-based model. Data are cost in US$. Operating cost=cost / fractions delivered. Upfront cost=one-off cost required to create the capacity, after which operating costs are incurred.

Atun et al., Lancet Oncology 2015

potential to reduce operational costs

	Operating cost per fraction: sensitivity analysis			Cost savings relative to base scenario			
	Automation: efficiency	Longer hours	Bulk purchase	High-income countries	Upper-middle-income countries	Lower-middle-income countries	Low-income countries
Combination 1	X	..	..	25%	21%	21%	21%
Combination 2	..	X	..	13%	18%	23%	25%
Combination 3	..	..	X	8%	16%	21%	23%
Combination 4	X	X	..	33%	34%	39%	40%
Combination 5	..	X	X	19%	34%	38%	42%
Combination 6	X	..	X	31%	34%	38%	39%
Combination 7	X	X	X	37%	43%	51%	53%

The operating cost model allows for improved efficiency, longer treatment hours per day, and bulk purchasing savings. These factors can occur alone or in combination, resulting in seven different combinations. X shows the inclusion of a factor in the sensitivity analysis.

Atun et al, Lancet Oncology 2015

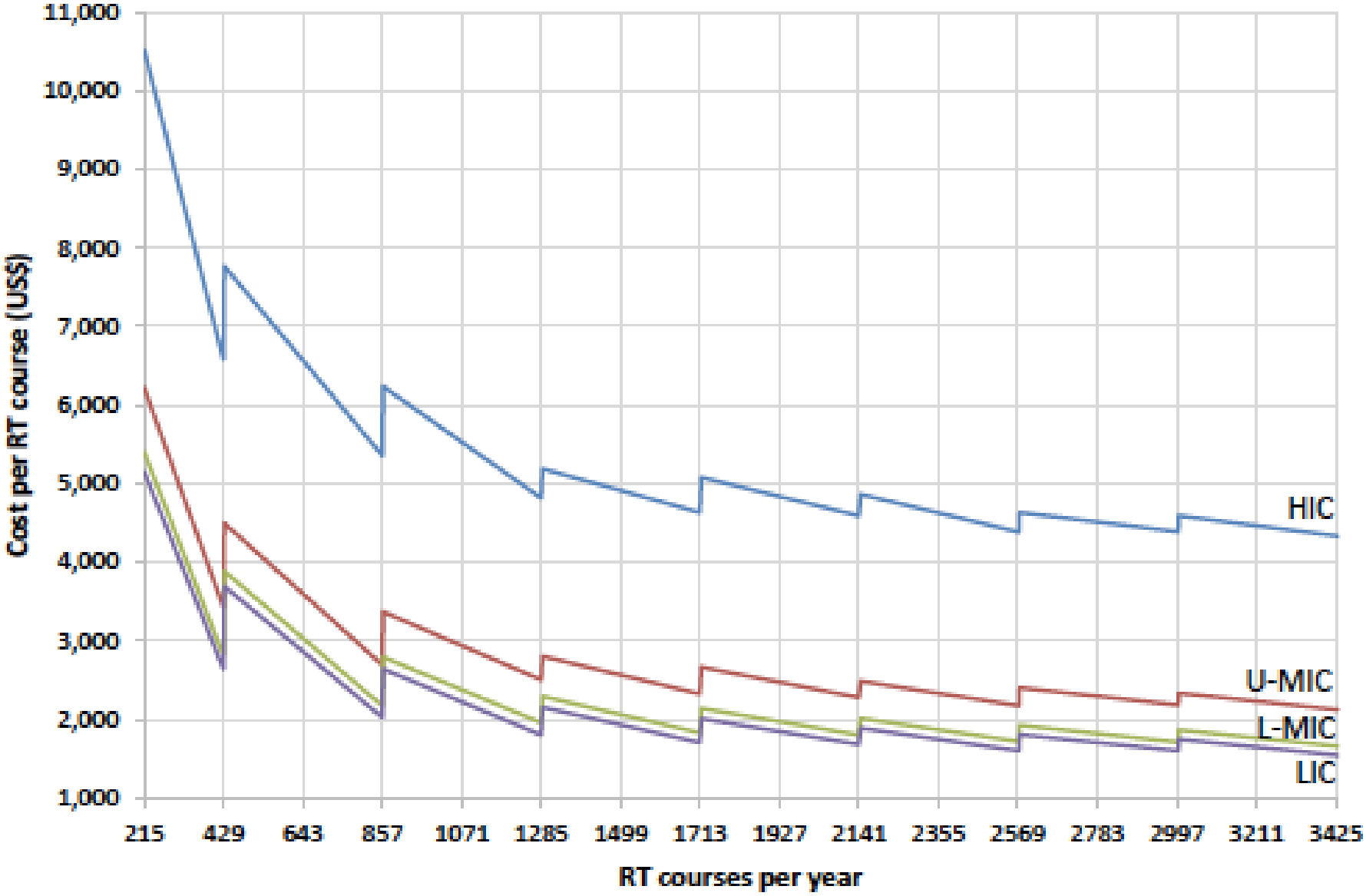
cost ifo operating hours per day

Income setting	HIC				LIC			
Working hrs/d	4 h	8 h	12 h	16 h	4 h	8 h	12 h	16 h
RT courses per year	285	571	856	1,142	285	571	856	1,142
Number of personnel required								
RO	2	3	4	5	2	3	5	6
MP	3	4	4	5	4	4	5	6
RTT	4	8	12	15	4	8	12	16
Dosimetrists	1	2	3	3	1	2	3	3
Costs*								
Operational cost/y (US$)	3,207,333 (-43%)	3,966,887 (-16%)	4,594,545	5,183,594 (+13%)	1,667,947 (-4%)	1,694,061 (-2%)	1,735,596	1,762,992 (+2%)
Cost/course (US$)	11,254 (+210%)	6,948 (+29%)	5,368	4,540 (-14%)	5,853 (+289%)	2,967 (46%)	2,028	1,544 (-24%)

* Relative increases and decreases compared to the base case of 12 working hours per day are given in brackets

Van Dyk et al, Radiother Oncol 2017

cost per course ifo department size



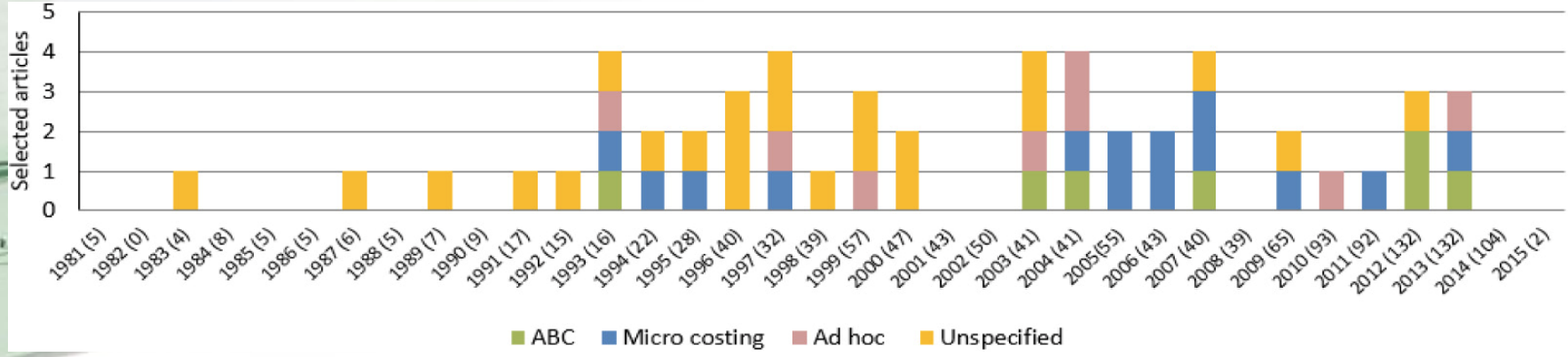
Van Dyk et al, Radiother Oncol 2017

How to Solve The Cost Crisis In Health Care

The biggest problem with health care isn't with insurance or politics. It's that we're measuring the wrong things the wrong way.

by Robert S. Kaplan and Michael E. Porter

PHOTOGRAPHS: MARK HOOPER



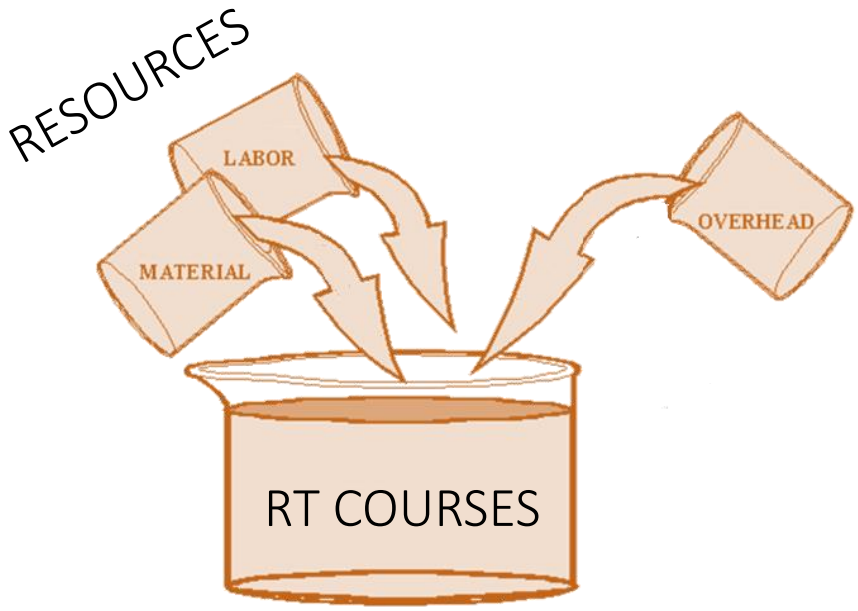
Kaplan and Porter, Harvard Business Review 2011

Defourny et al, R&O 2016

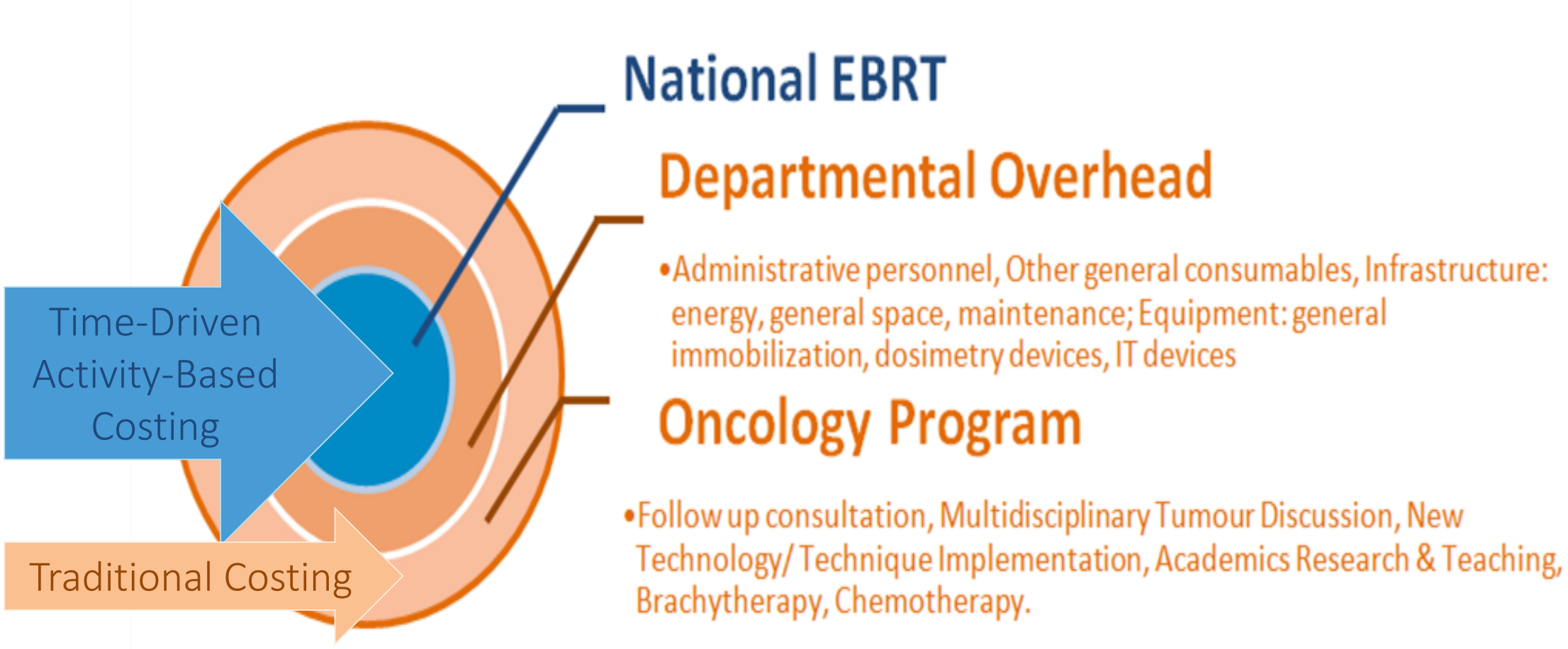
Time-Driven Activity Based Costing

Traditional Costing

Average cost estimates per course



Time-Driven Activity Based Costing model



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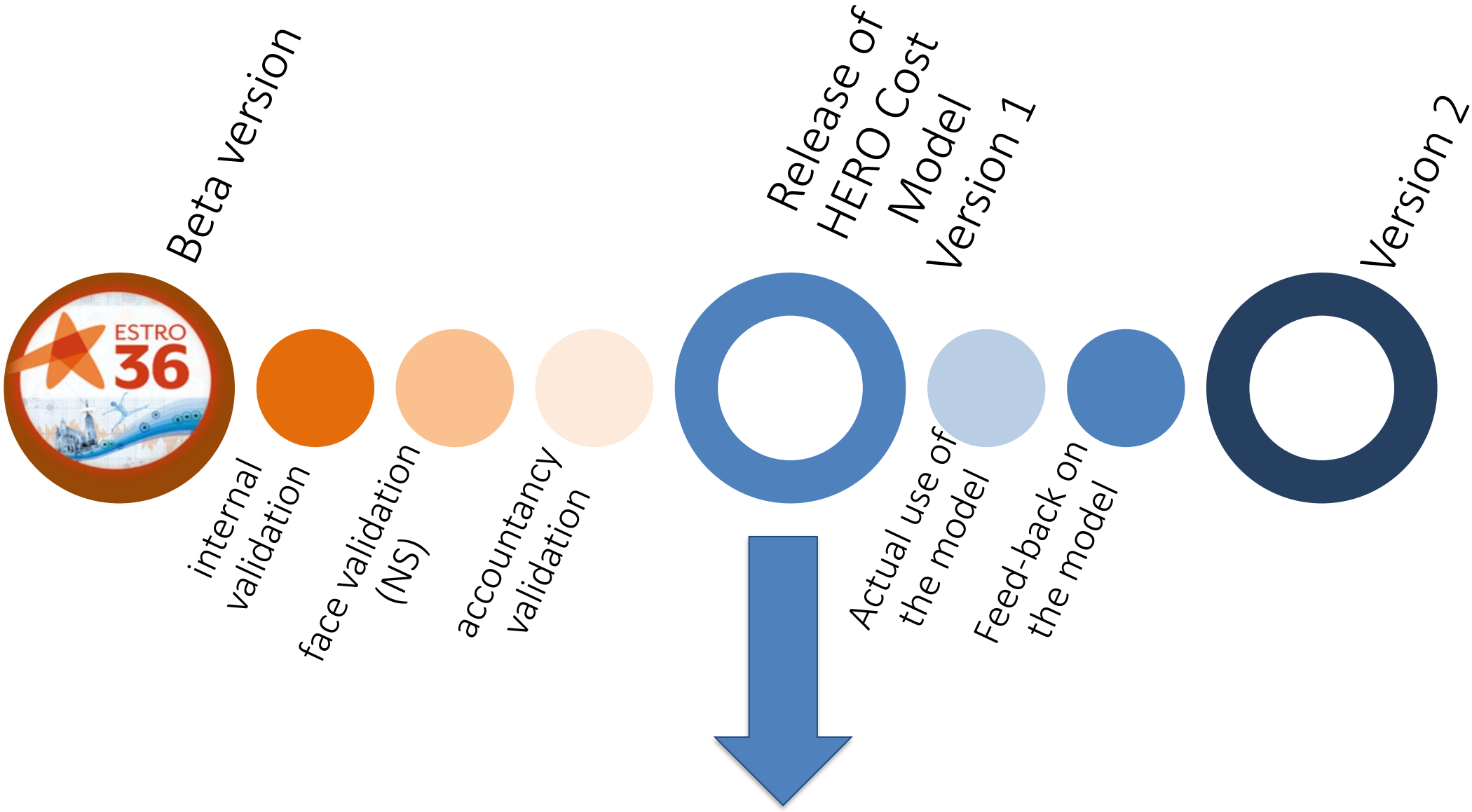

release during ESTRO governance week

December 5th 2017, Brussels

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extra cost
extra effect
new treatment

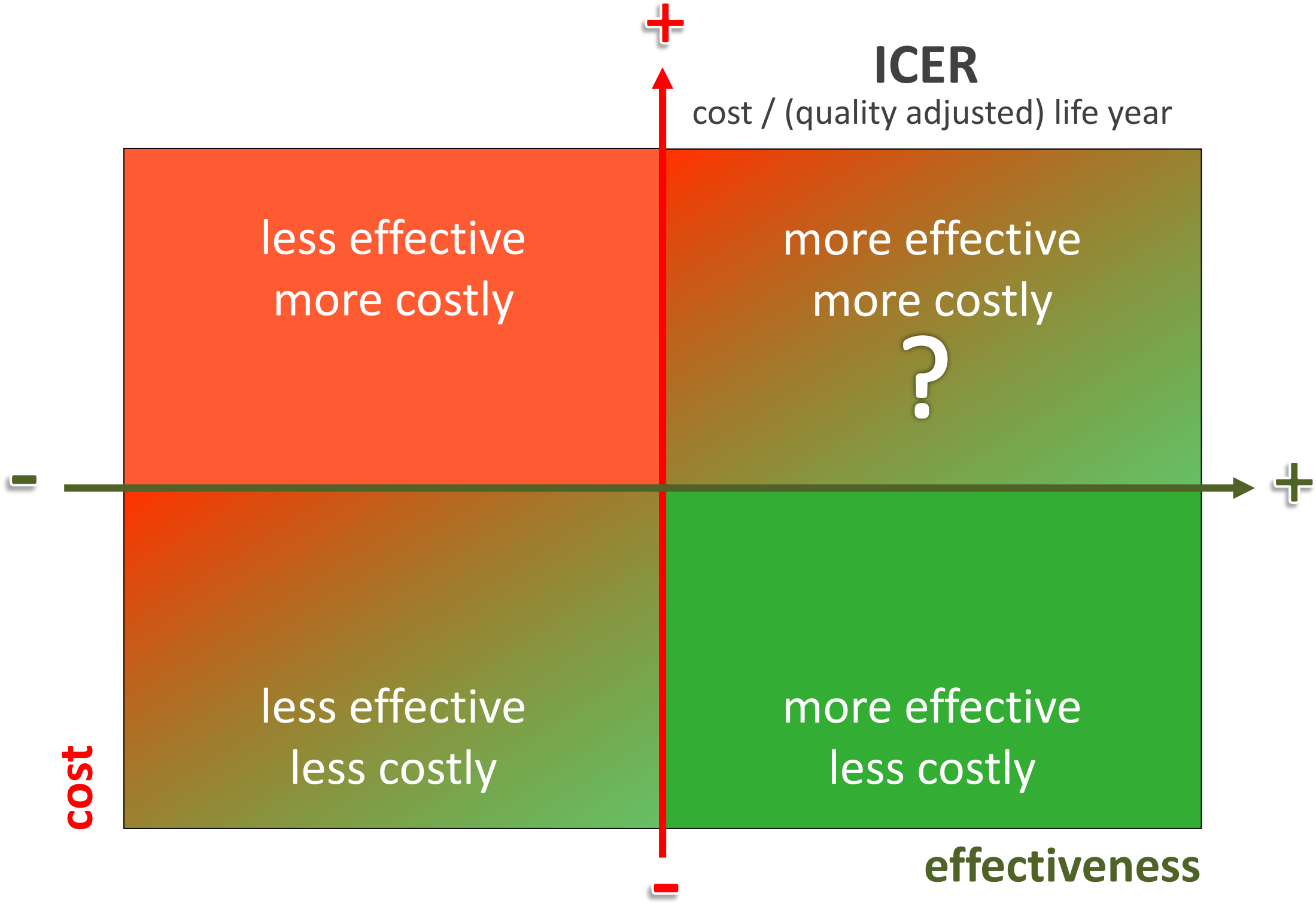
cost
effect
standard treatment

cost per (quality adjusted) life year gained

= incremental cost-effectiveness ratio (€/LYG)

= incremental cost-utility ratio (€/QALY)

= ICER (≈ willingness-to-pay of society)


+
ICER
cost / (quality adjusted) life year
less effective
more costly
more effective
more costly
?
-
+
less effective
less costly
more effective
less costly
cost
effectiveness
-

cost-effectiveness of lung SBRT

reference	country	study	treatment	cost	effect	ICER
Lanni (2011)	USA	CEA	SBRT	52,471$	3YOS 71%	SBRT dominates
			3D-CRT	55,705$	3YOS 42%	
			IMRT	136,570$	3YOS n.a.	
Sher (2011)	USA	CUA	SBRT	51,133$	1.91 QALY	
			3D-CRT	48,842$	1.53 QALY	SBRT vs. 3D-CRT: 6,000$/QALY
			RFA	44,648$	1.45 QALY	SBRT vs. RFA: 14,100$/QALY
Puri (2012)	USA	CEA	SBRT	14,153$	2.94 YOS	surgery vs. SBRT: 7,753$/LYS
			surgery	17,629$	3.39 YOS	
Grutters (2010)	The Netherlands		***inoperable***			
		CUA	SBRT	13,871€	2.59 QALY	
			3D-CRT	22,696€	1.98 QALY	SBRT and C-ions dominate 3D-CRT
			protons	27,567€	2.33 QALY	SBRT and C-ions dominate protons
			C-ions	19,215€	2.67 QALY	C-ions vs. SBRT: 67,257€/QALY
			operable			
		CUA	SBRT	8,485€	3.20 QALY	SBRT dominates C-ions
			C-ions	14,620€	3.16 QALY	

Grutters et al. J Cancer Treat Rev 2010
Adapted from Biljani et al. Frontiers Oncol 2013

cost-outcome of IGRT

Correction protocol	Imaging modality	Incremental cost		Cost-outcome 3D-CRT		Cost-outcome IMRT	
		Fractions					
		21	35	21	35	21	35
No Action Level	EPID	367	367	1872	1872	1596	1596
Regular Shrinking		414	460	2215	2461	957	1063
Weekly Shrinking		508	648	1969	2511	790	1007
Daily Shrinking		1117	1772	4166	6610	1456	2310
No Action Level	kV	446	445	2273	2270	1937	1934
Regular Shrinking		508	570	2717	3048	1173	1316
Weekly Shrinking		632	819	2451	3176	984	1274
Daily Shrinking		1444	2318	5389	8650	1883	3022
No Action Level	CBCT	484	484	2470	2470	2105	2105
Regular Shrinking		555	624	2966	3339	1281	1442
Weekly Shrinking		695	905	2694	3508	1081	1408
Daily Shrinking		1608	2592	6000	9670	2096	3379

ratio of incremental cost to ΔEUD, expressed in €/Gy

Ploquin et al. R&O 2009

survival !
quality of life !

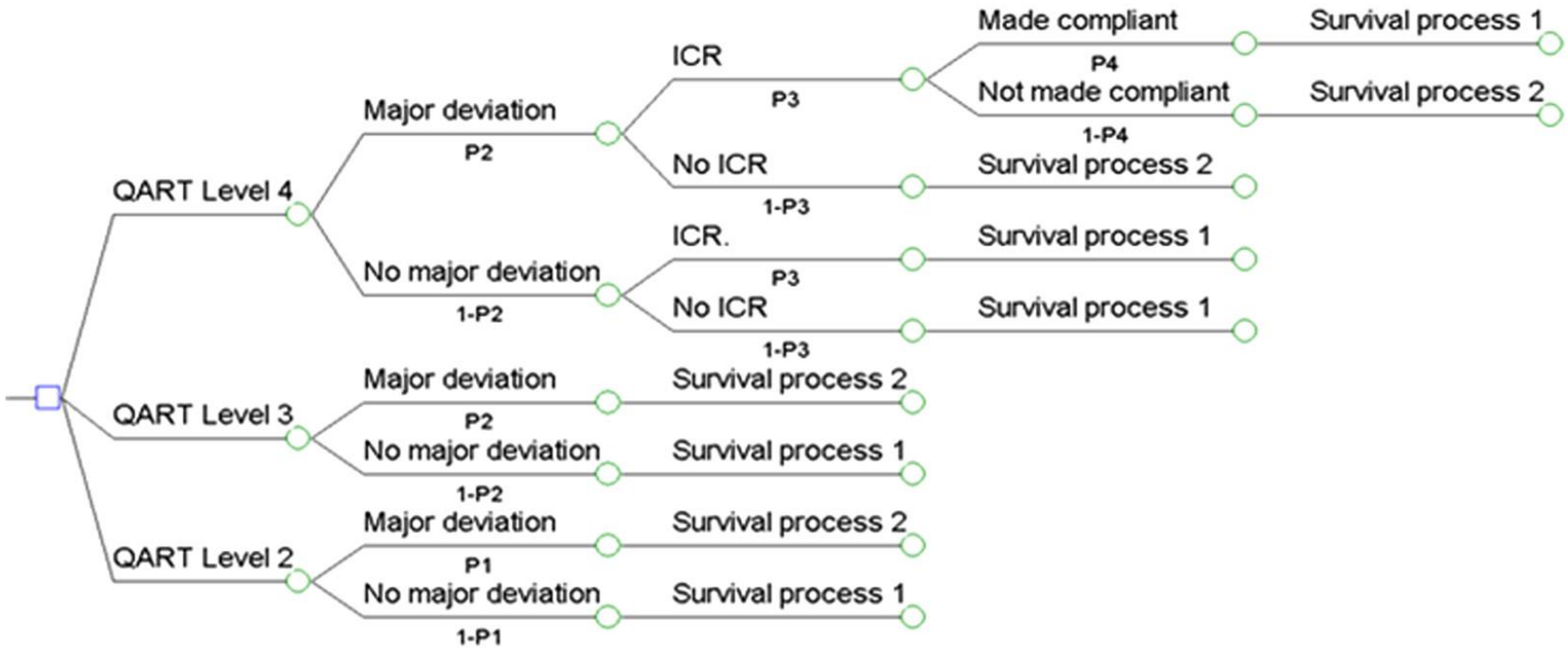
QART assessment with patient outcome in RCT

Study [ref]	Type of QA	Number of cases evaluated *n* (%)	Minor deviations *n* (%)	Major deviations *n* (%)	Technical issues with QA review *n* (%)	Impact on clinical outcome	*p* Value
HD 4 [5]	R	368 (98.0)	–	141 (37.5)*	8 (2.1)	7-year RFS with D: 72% *vs.* 7-year RFS with no D: 84%	0.004
Hodgkin							
EORTC 20884 [2]	R	135 (88.8)	–	63 (46.7)	46 (30.3)	5-year RFS with D: 90% *vs.* 5-year RFS without D: 84%	0.31
RTOG 0411 [4]	R	NS	–	13 (13.4)	NS	Grade GI ⩾ 3 toxicity with D:45%‡ *vs.* Grade GI ⩾ 3 toxicity without D:18%‡	0.05
Pancreatic Ca							
RTOG 9704 [1]	R	416 (92.2)	–	200 (48.0)**	14/35 (40.0)†	mOS with D: 1.46 yo *vs.* mOS without D: 1.74 yo	0.008
RTOG 0022 [8]	R	67 (97.0)	47 (89.0)	6(11.0)	14/67 (21.0)	LRF with major D: 50% *vs.* LRF with no major D: 6%	0.04
H&N Ca							
TROG 0202 [15]	P & R††	687 (80.5)‡‡	–	97 (11.8)	33/820 (4.0)	OS with major D: 70% *vs.* OS without major D: 50%	<0.001

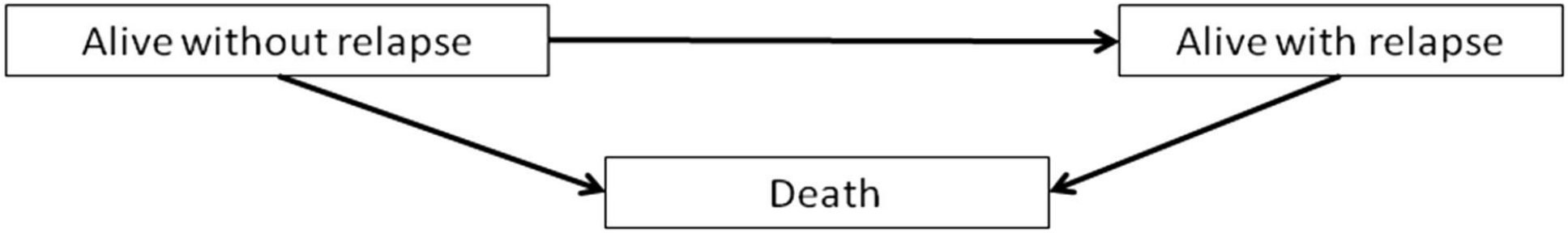
Weber et al. R&O, 2012

QART: outcome impact and cost-effectiveness

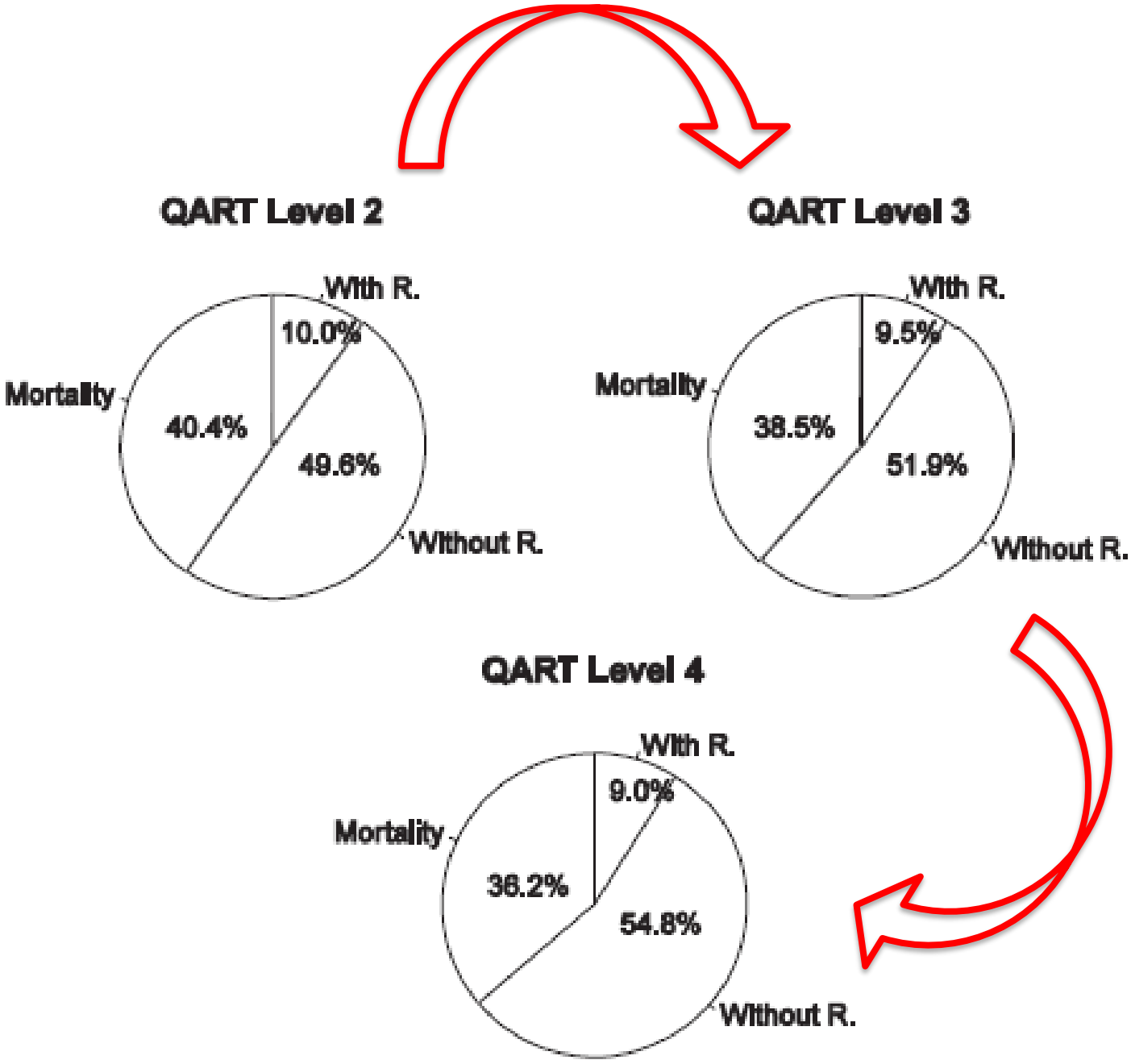
A First step of the model



B Second step of the model



Weber et al. R&O, 2014



Weber et al. R&O, 2014

	Mean Survival time (months) [95% CI]			Percentages [95% CI]		Costs (Euros)[b] [95% CI]		
	Total	Without recurrence	Quality of life adjusted[a]	Mortality	Recurrence	QART	Primary TTT and diagnosis	Recurrence TTT and diagnosis[a]
2-Years results								
QART								
Level 2	18.7 [17.9;19.4]	15.8 [15.0;16.7]	13.2 [12.5;14.0]	40.4 [35.7;45.3]	41.0 [36.2;46.0]	41.9	16,871	6247 [5515;7009]
Level 3	18.9 [18.2;19.6]	16.3 [15.4;17.1]	13.5 [12.7;14.2]	38.5 [34.3;43.4]	38.7 [34.3;43.7]	126.3	16,871	5901 [5224;6657]
Level 4	19.3 [18.7;19.8]	16.8 [16.1;17.5]	13.8 [13.1;14.4]	36.2 [32.7;39.9]	35.9 [32.3;39.7]	604.4	16,871	5465 [4921;6050]
Increment								
Level 3 – level 2	0.3 [−0.2;0.8]	0.4 [−0.3;1.2]	0.2 [−0.2;0.7]	−1.9 [−5.6;1.6]	−2.3 [−6.5;1.8]	84.4	0	−345 [−987;270]
Level 4 – level 3	0.3 [0.1;0.6]	0.5 [0.2;0.9]	0.3 [0.1;0.5]	−2.4 [−4.1;−0.9]	−2.9 [−4.7;−1.4]	478.1	0	−437 [−722;−209]
Level 4 – level 2	0.6 [0.1;1.2]	0.9 [0.3;1.6]	0.5 [0.1;1.0]	−4.2 [−7.9;−1.1]	−5.1 [−9.2;−1.4]	562.5	0	−782 [−1397;−219]
5-Years results								
QART								
Level 2	34.6 [32.0;37.1]	29.3 [26.7;31.6]	23.0 [21.0;24.9]	67.7 [62.0;73.2]	58.6 [52.2;64.7]	41.9	16,871	8733 [7786;9639]
Level 3	35.6 [33.0;37.9]	30.5 [27.8;33.0]	23.7 [21.7;25.6]	65.6 [60.0;71.3]	56.2 [50.0;62.2]	126.3	16,871	8361 [7453;9270]
Level 4	36.9 [34.8;38.8]	32.1 [29.8;34.3]	24.7 [23.0;26.4]	63.0 [57.9;68.0]	53.1 [47.7;58.2]	604.4	16,871	7891 [7092;8650]
Increment								
Level 3 – level 2	1.0 [−0.8;3.0]	1.2 [−1.0;3.6]	0.8 [−0.6;2.2]	−2.1 [−6.3;1.7]	−2.4 [−7.2;1.9]	84.4	0	−372 [−1085;296]
Level 4 – level 3	1.3 [0.6;2.2]	1.6 [0.8;2.5]	1.0 [0.5;1.6]	−2.7 [−4.6;−1.0]	−3.1 [−5.2;−1.3]	478.1	0	−470 [−783;−200]
Level 4 – level 2	2.3 [0.6;4.3]	2.8 [0.8;5.0]	1.8 [0.5;3.2]	−4.8 [−8.8;−1.2]	−5.5 [−10.2;−1.4]	562.5	0	−842 [−1543;−220]

QART	Incremental cost (Euros)	Incremental effectiveness at 2 years (QALYs) [95% CI]	ICER at 2 years (Euros/QALY) [95% CI]	Incremental effectiveness at 5 years (QALYs) [95% CI]	ICER at 5 years (Euros/QALY) [95% CI]
Level 3 – level 2	84.4	0.019 [−0.016;0.058]	[a]	0.066 [−0.052;0.186]	[a]
Level 4 – level 3	478.1	0.025 [0.011;0.041]	22,813 [13,688;51,328]	0.082 [0.038;0.137]	6844 [4106;14,665]
Level 4 – level 2	562.5	0.044 [0.011;0.079]	10,907 [6017;43,627]	0.148 [0.041;0.263]	3232 [1818;11,634]

Weber et al. R&O, 2014

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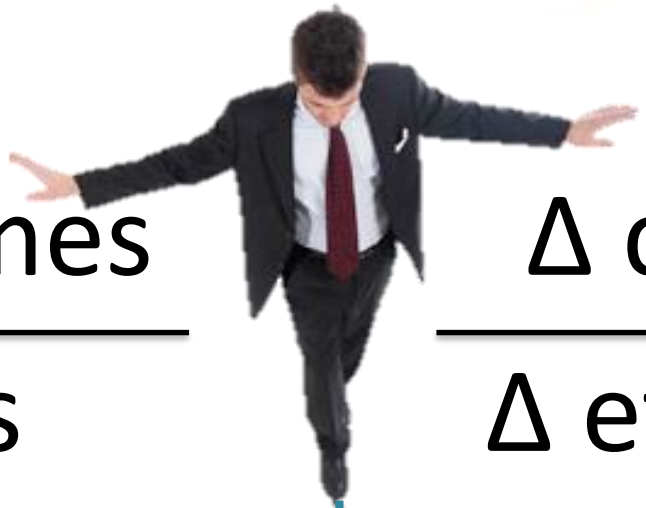
$$\frac{\text{outcomes}}{\text{costs}} \qquad \frac{\Delta\ \text{costs}}{\Delta\ \text{effects}}$$



Perspective

DECEMBER 23, 2010

What Is Value in Health Care?

Michael E. Porter, Ph.D.

= achieving the best outcomes at the lowest cost

take home messages

- Rapidly **increasing health care expenses** are no longer sustainable.
- Cost calculation in radiotherapy is feasible, accurate resource cost data however **remain scarce**.
- Optimising **efficiency** is important, hypofractionation compensates for the cost of higher complexity, while safeguarding the quality.
- **Cost-effectiveness analyses** are gaining attention in radiation therapy, but challenges remain
  - to define the adequate timing of the analysis
  - to collect the required outcome measures of survival and quality of life
- Cost calculations and economic evaluations gradually become a **prerequisite for financing** of innovative technologies and techniques.

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Thank you
for your attention!

Questions?

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