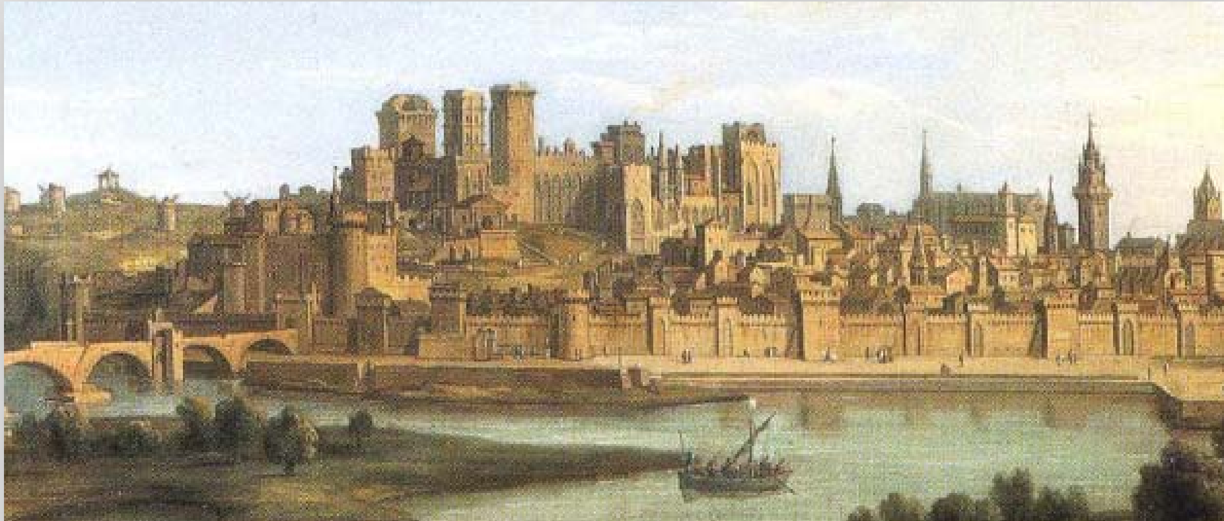


WHAT IS RISK AND WHAT IS MAKING MISTAKES.

ESTRO – AVIGNON OCT 1-4TH, 2016

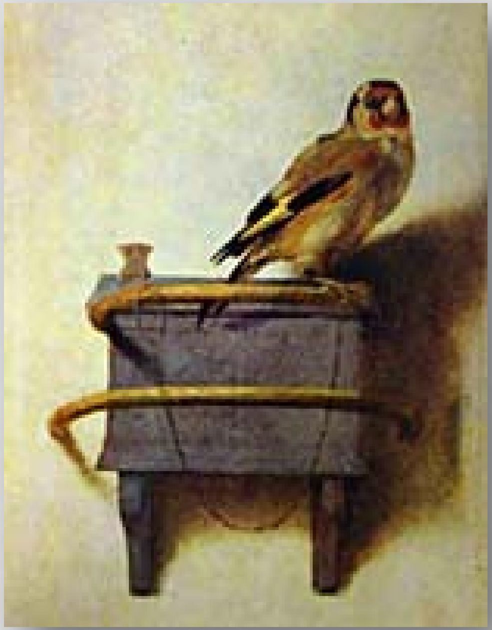
WHAT IS RISK AND WHAT IS MAKING MISTAKES.

ESTRO – POZNAN JUNE 26-29TH, 2014

DELFT, OCTOBER 12TH, 1654

Van de Poel

- 90.000 lb gunpowder

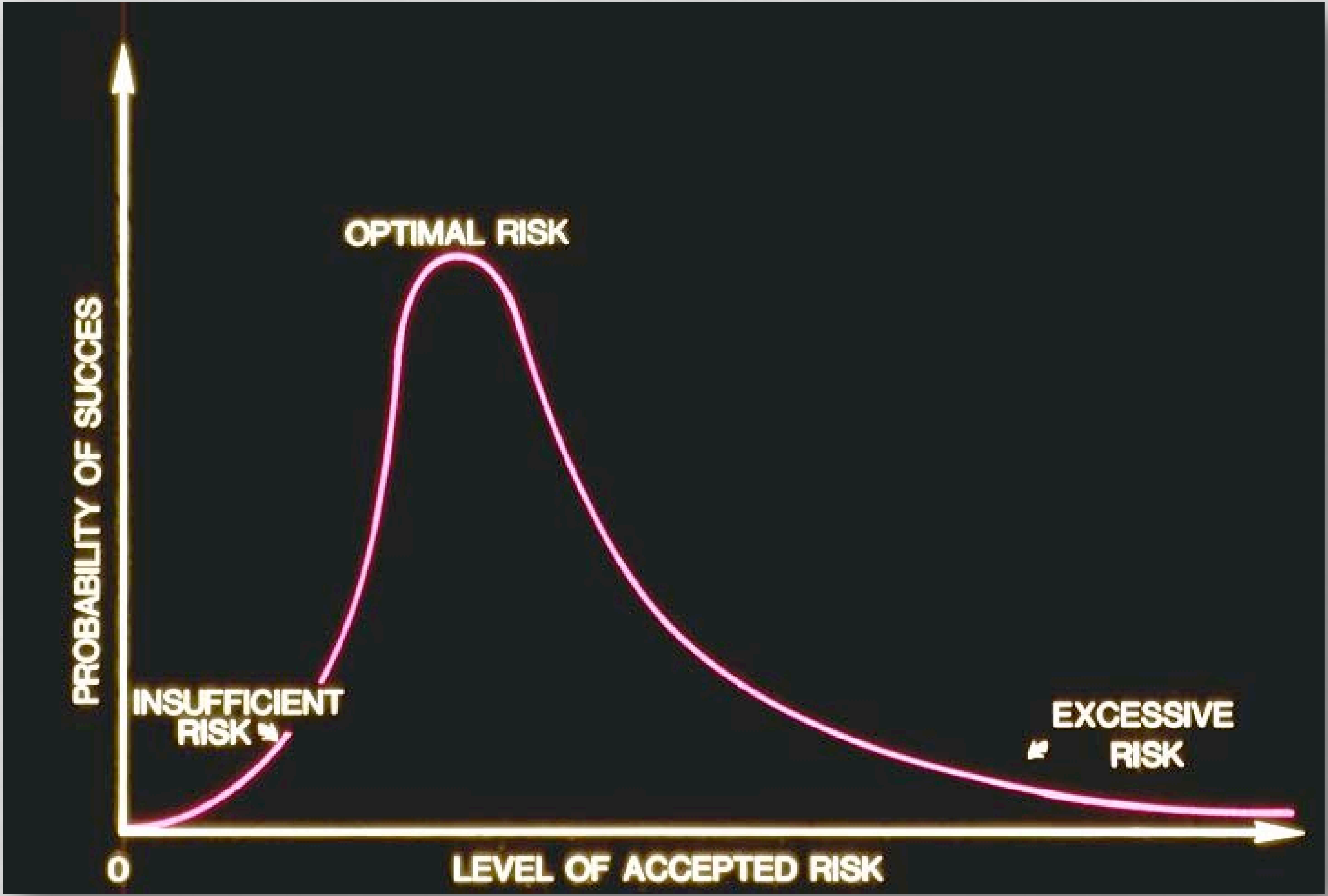


DANGER

Since conscience emerged in humans, many hundreds of thousands years ago, the sense of danger was an important part of it.

Danger in the environment from wild neighbours (mammoths, tigers, etc), danger from climatic convulsions, danger from other humans.

Managing the ubiquitous danger was a condition for survival and life propagation. Quite obviously, humans have been good (too good ?) at managing danger in their daily life.


OPTIMAL RISK
PROBABILITY OF SUCCES
INSUFFICIENT
RISK
EXCESSIVE
RISK
0
LEVEL OF ACCEPTED RISK

RISK OR DANGER?

Risk

- When you plan to act
- You estimate a risk
- You can calculate risk as a continuum.
- Statistics apply

Danger

- When you act
- You run a danger
- Danger is binary

WHAT ARE STATISTICS?

What are the odds ?

WHAT ARE STATISTICS?

- Statistics is the mathematics of probabilities.
- It can be used prospectively to assess risk levels.
- If danger is captured in numbers, it becomes risk.
- It can be managed (increasing, decreasing risk…).

FIRST APPLICATION

Life expectancy and life insurance

WHAT IS RISK?

Toulouse Sept 21 2001

A complex system
and
a human error

Human errors…
The source of all ills

You want this and you take that instead

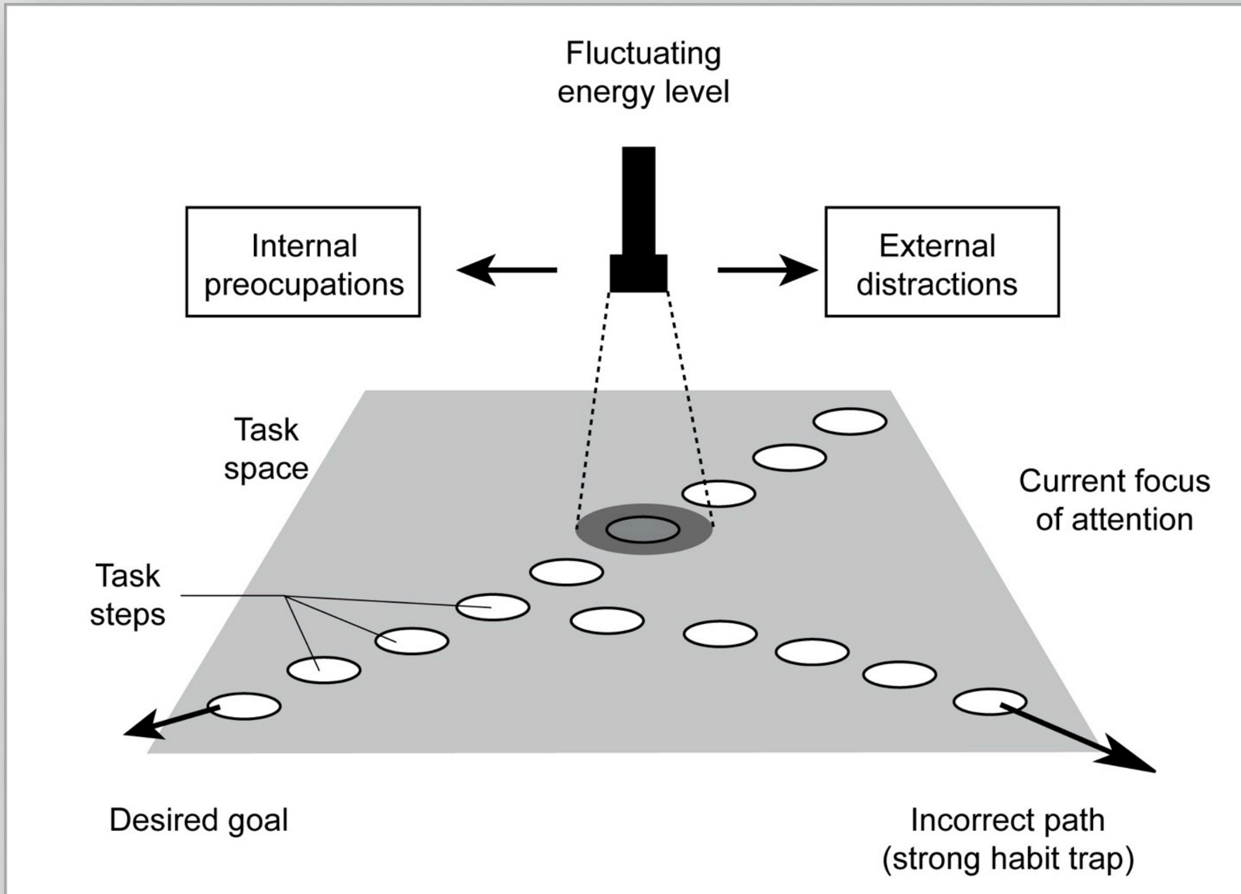
There is intention prior to action but the action does not proceed as planned

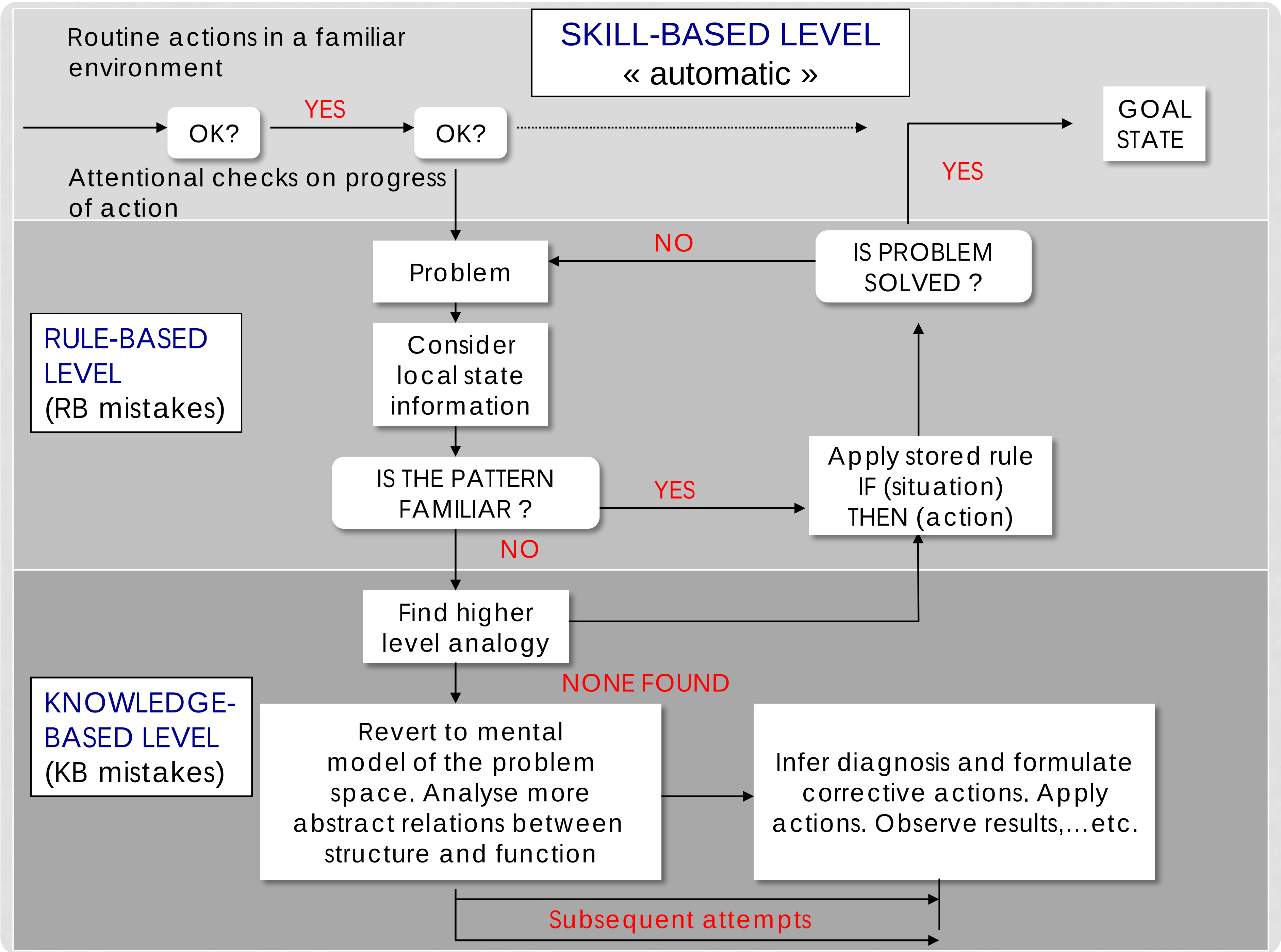
It's a slip or lapse

TOP 10 HEALTH TECHNOLOGY HAZARDS FOR 2013

- Alarm hazards.
- Medication errors with infusion pumps.
- Exposure from diagnostic radiology.
- Patient/data mismatch in health IT.
- Air embolism hazard.
- Interoperability failure between devices and IT.
- Paediatric patients and "adult technology".
- Inadequate reprocessing of endoscopes.
- Distraction from smartphones.
- Surgical fires.

Emergency care research institute


Fluctuating energy level
Internal preoccupations
External distractions
Task space
Current focus of attention
Task steps
Desired goal
Incorrect path (strong habit trap)

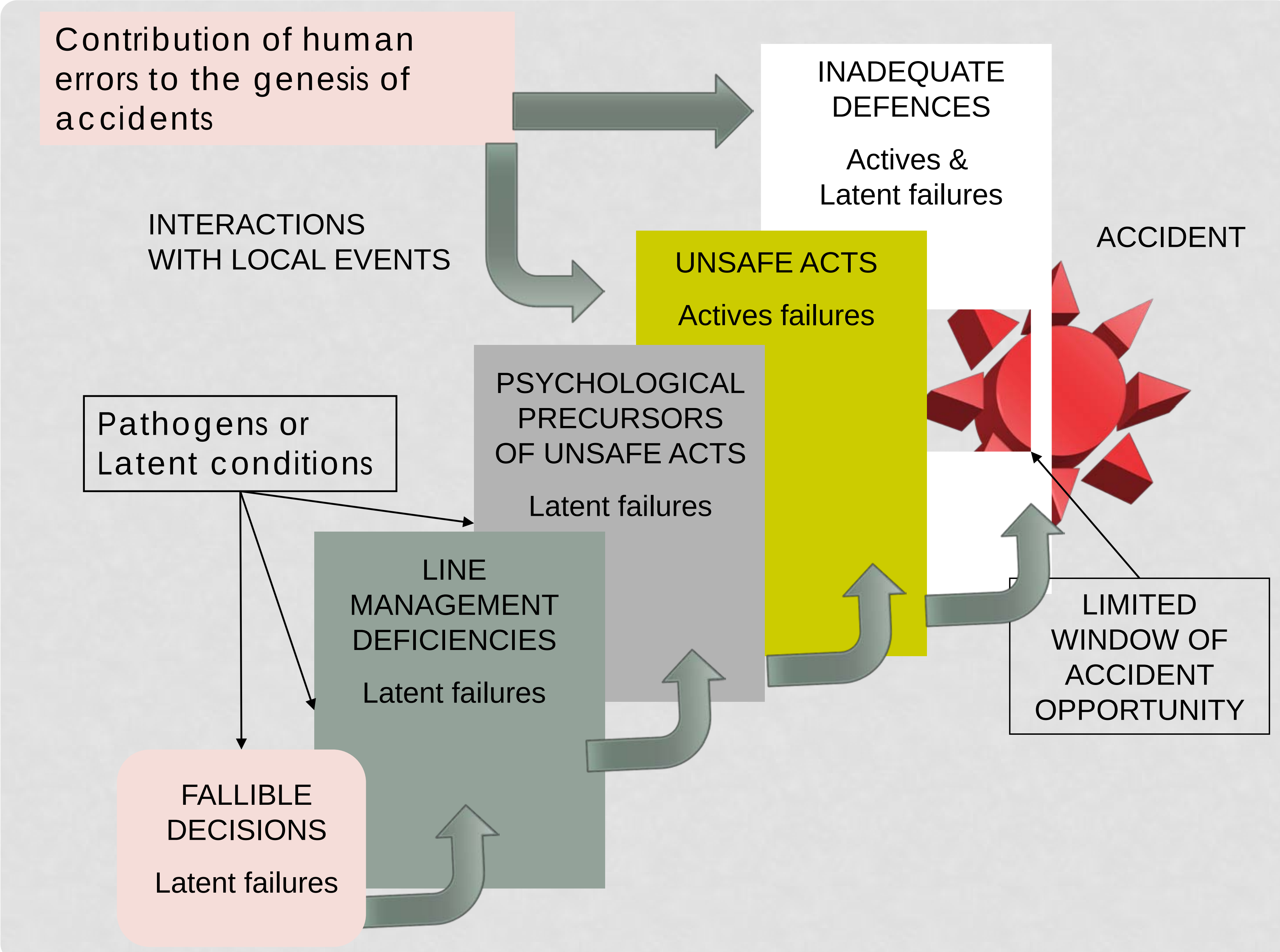

SKILL-BASED LEVEL
« automatic »
Routine actions in a familiar environment
OK?
YES
OK?
GOAL STATE
YES
Attentional checks on progress of action
NO
Problem
IS PROBLEM SOLVED ?
RULE-BASED LEVEL
(RB mistakes)
Consider local state information
IS THE PATTERN FAMILIAR ?
YES
Apply stored rule IF (situation) THEN (action)
NO
Find higher level analogy
NONE FOUND
KNOWLEDGE-BASED LEVEL
(KB mistakes)
Revert to mental model of the problem space. Analyse more abstract relations between structure and function
Infer diagnosis and formulate corrective actions. Apply actions. Observe results,...etc.
Subsequent attempts


PARIS
IN THE
THE SPRING

QUIZZ…

- What is the colour of snow?
- What is the colour of sugar?
- What is the colour of the White House in Washington?
- What is drinking the cow?

?

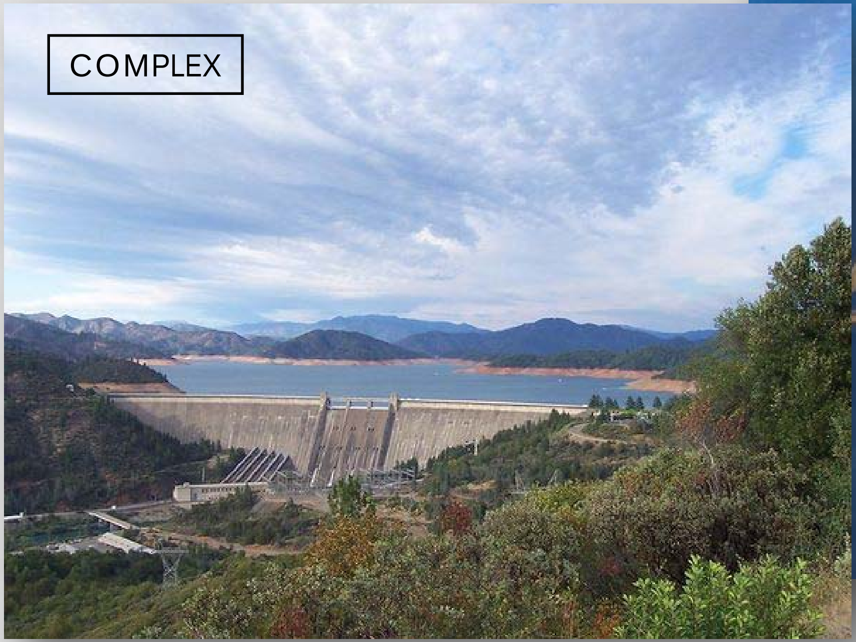

Contribution of human errors to the genesis of accidents
INADEQUATE DEFENCES
Actives & Latent failures
INTERACTIONS WITH LOCAL EVENTS
ACCIDENT
UNSAFE ACTS
Actives failures
PSYCHOLOGICAL PRECURSORS OF UNSAFE ACTS
Latent failures
Pathogens or Latent conditions
LINE MANAGEMENT DEFICIENCIES
Latent failures
LIMITED WINDOW OF ACCIDENT OPPORTUNITY
FALLIBLE DECISIONS
Latent failures

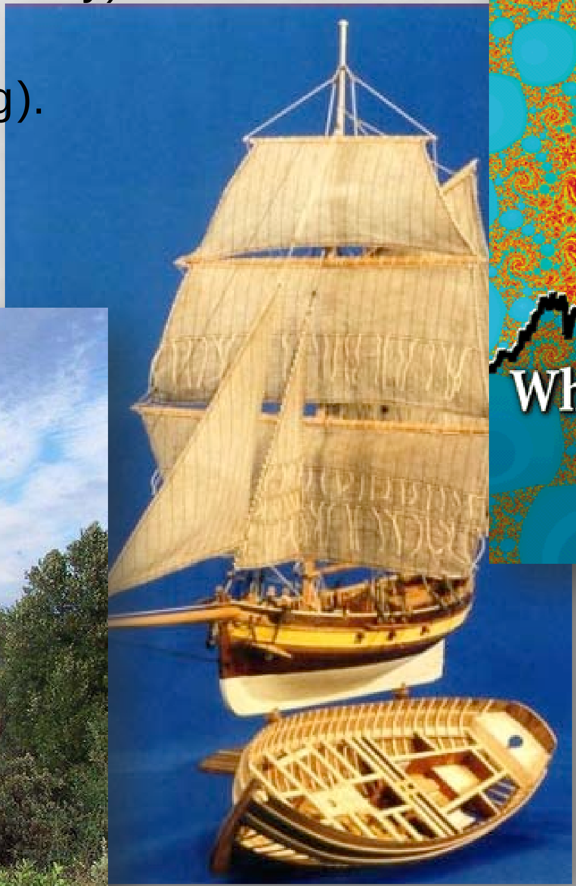
TOULOUSE, SEPT 21, 2001

Human error?
Complex system

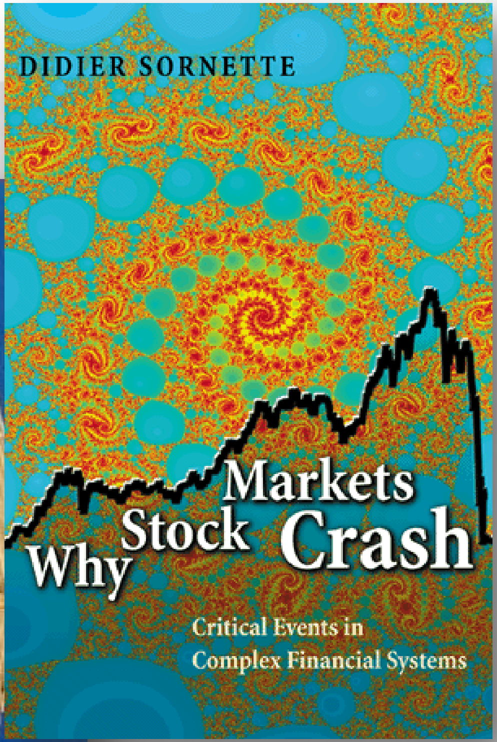
COMPLEX SYSTEMS ?

- Complexity (separate from difficulty).
- Interdependence (common-mode, tight coupling).
- Dynamics.
- Intransparency.





COMPLICATED



COMPLEX

COMPLEX SYSTEMS ?

- Complexity (separate from difficulty).
- Interdependence (common-mode, tight coupling).
- Dynamics.
- Intransparency.

Radiotherapy ?

COMPLEX SYSTEMS NEED ELABORATE MONITORING AND SAFETY

ADS : automatic safety devices.

Increase safety of normal operating conditions.

Decrease attention of operators.

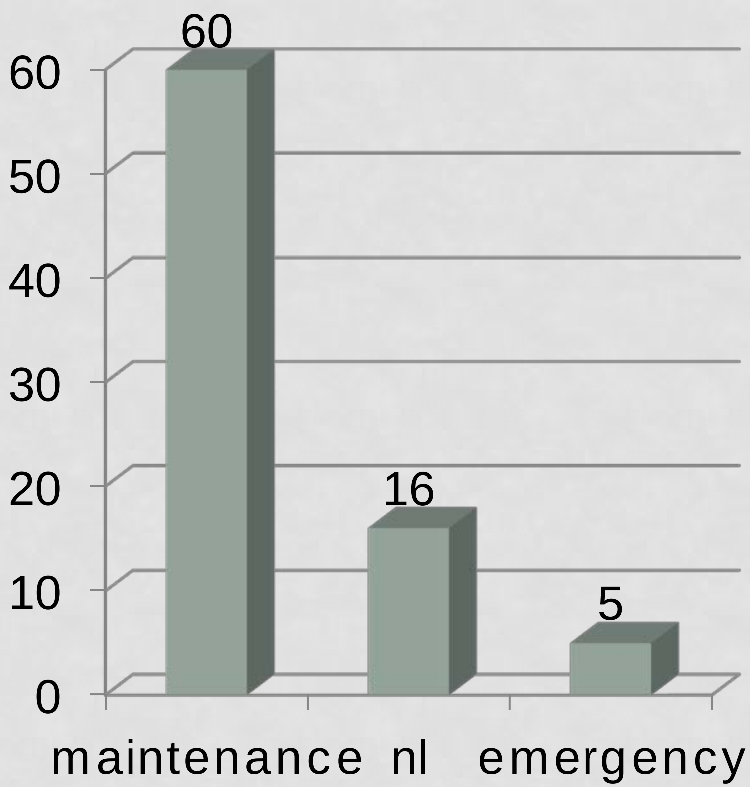
Do security devices *improve* safety?

No, they *encourage* to take more risk!
Routine violation of procedure becomes the rule…

PARADOX OF AUTOMATION

- Designers intend to get rid of fallible operators.
- Human-machine interface is not positively but negatively designed.
- Therefore the interface is poor.

MAINTENANCE CAN SERIOUSLY DAMAGE YOUR SYSTEM…

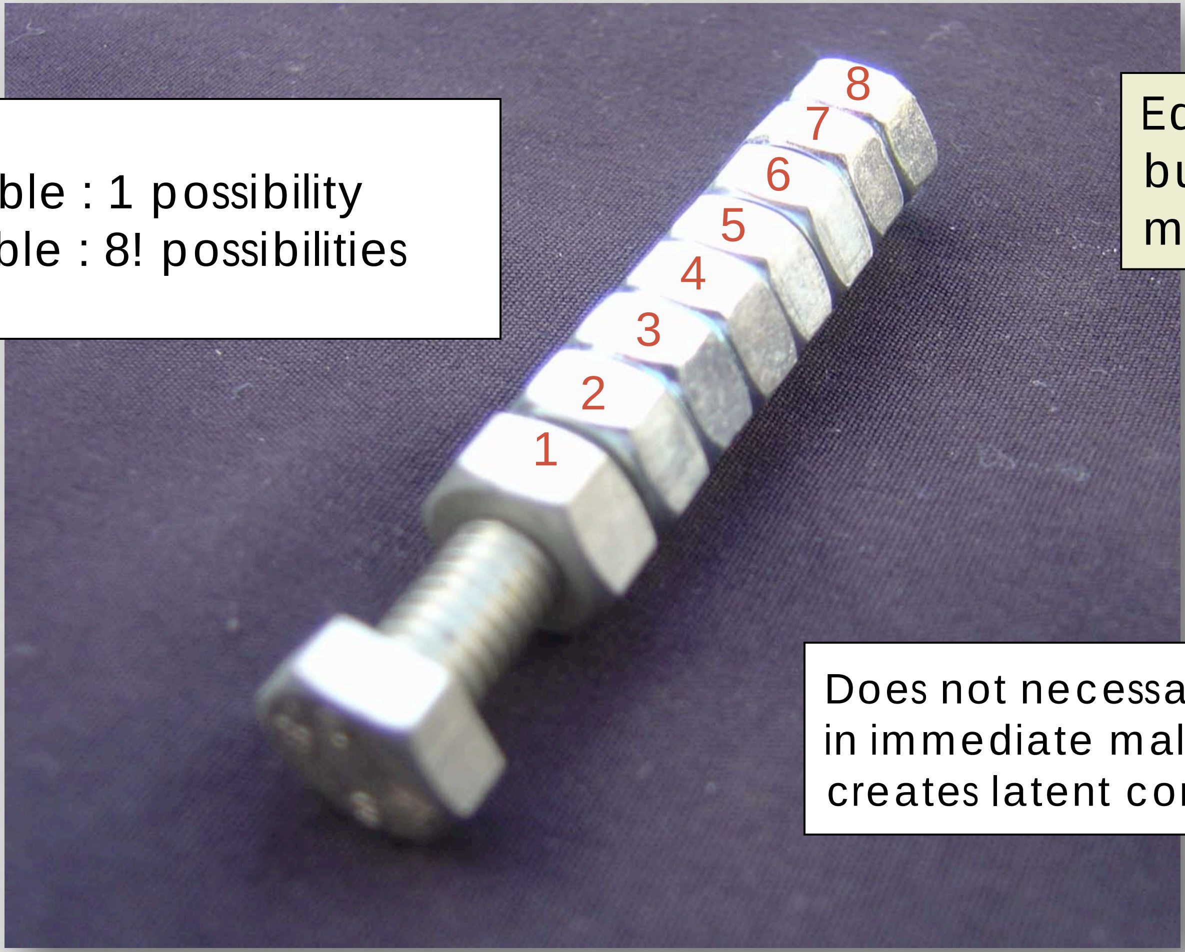


Maintenance-related work is the most likely to generate human performance problems (fiddle with the system, disassemble and assemble…)

Compilation of the results of three studies showing the relationship between activities and performance problems in nuclear industry

WHICH ASPECT OF MAINTENANCE IS THE MOST ERROR PRONE?

Disassemble : 1 possibility
Reassemble : 8! possibilities

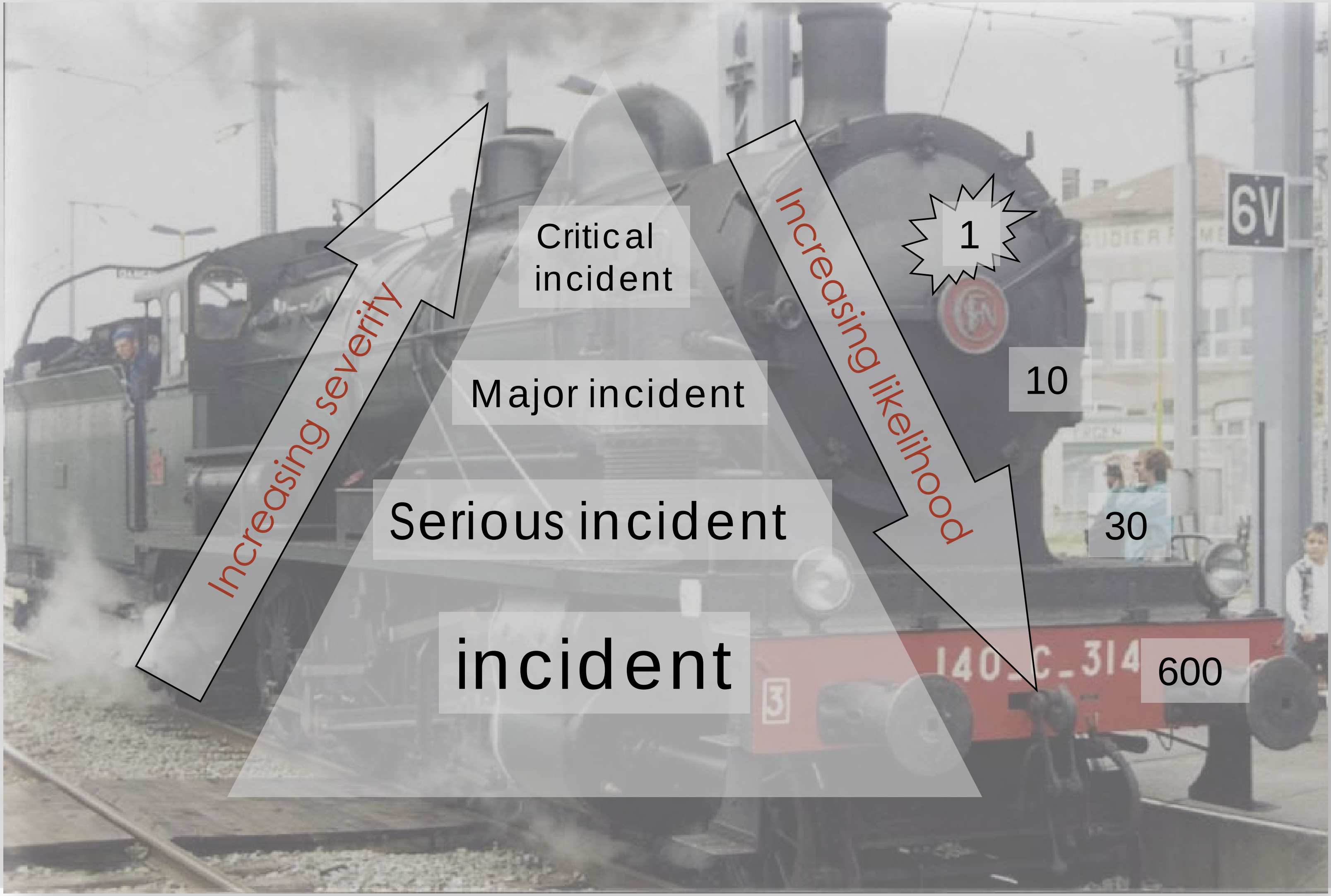


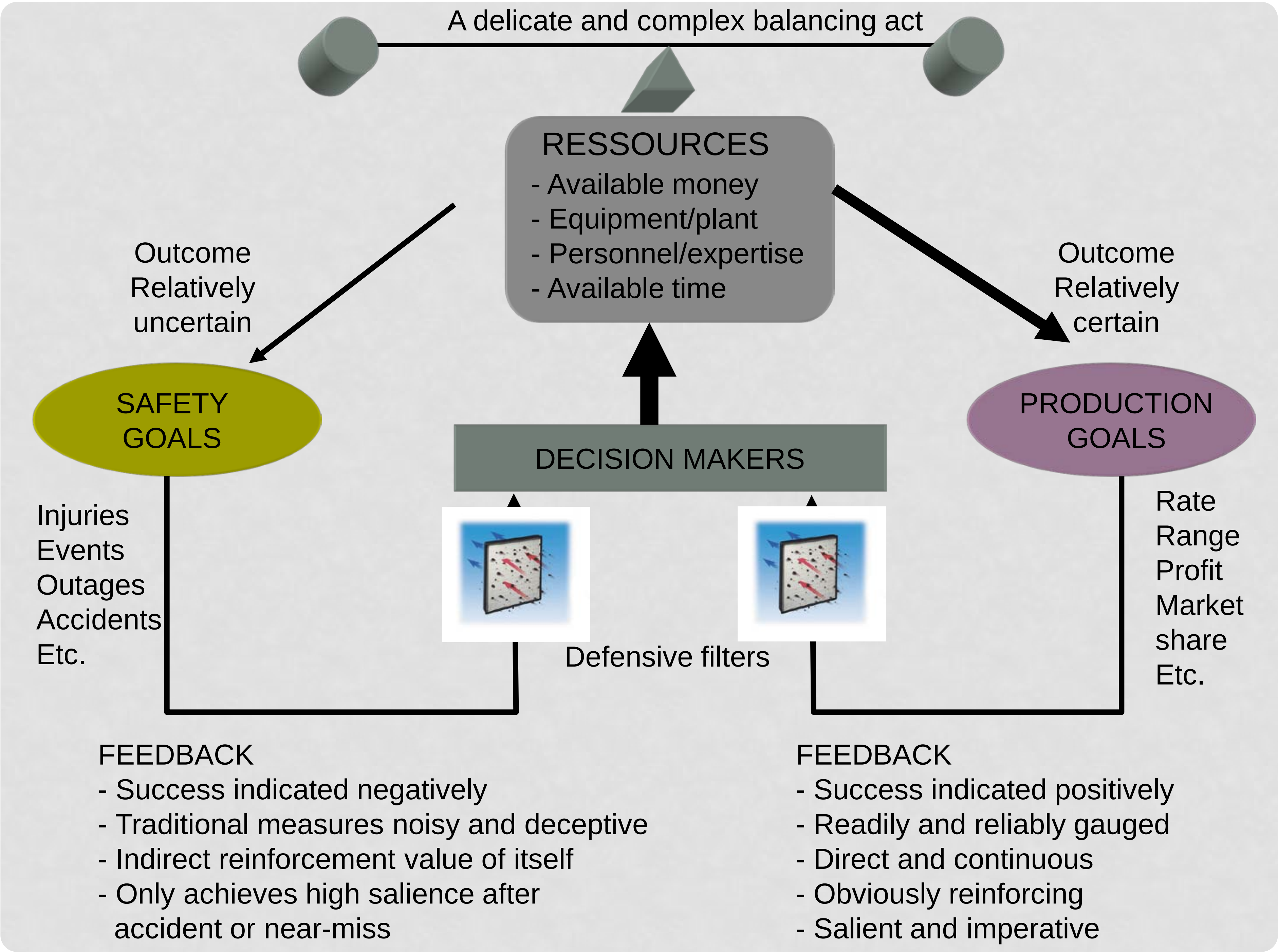
Equipment is never built for maintenance.

Does not necessarily result in immediate malfunction but creates latent conditions

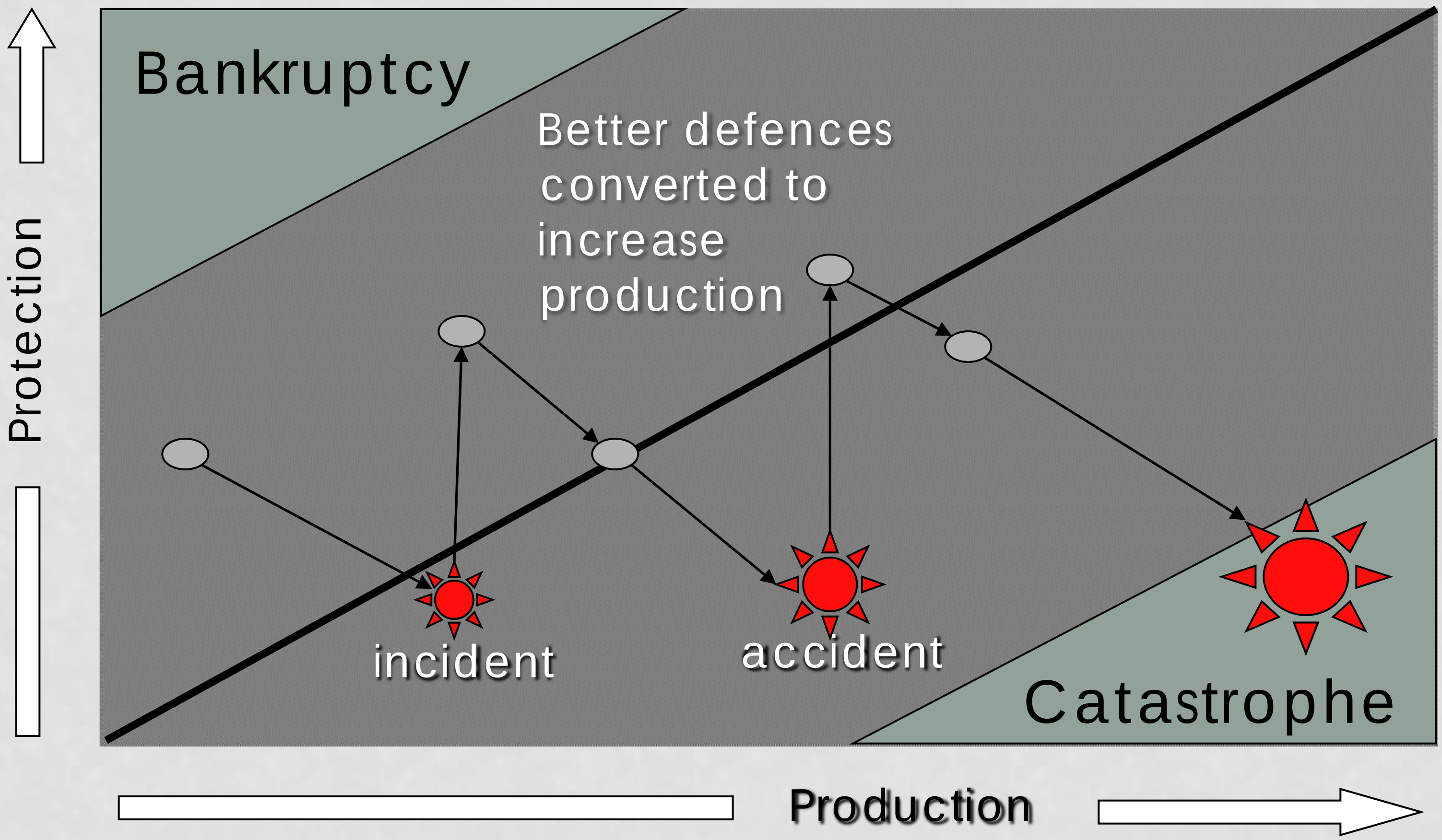
The bolt-and-nuts example

THE HEINRICH TRIANGLE




A delicate and complex balancing act
RESSOURCES
- Available money
- Equipment/plant
- Personnel/expertise
- Available time
Outcome
Relatively
uncertain
Outcome
Relatively
certain
SAFETY
GOALS
PRODUCTION
GOALS
DECISION MAKERS
Injuries
Events
Outages
Accidents
Etc.
Rate
Range
Profit
Market
share
Etc.
Defensive filters
FEEDBACK
- Success indicated negatively
- Traditional measures noisy and deceptive
- Indirect reinforcement value of itself
- Only achieves high salience after
accident or near-miss
FEEDBACK
- Success indicated positively
- Readily and reliably gauged
- Direct and continuous
- Obviously reinforcing
- Salient and imperative

THE LIFESPAN OF A HYPOTHETICAL ORGANISATION THROUGH THE PRODUCTION-PROTECTION SPACE



Setting the Scene

Tommy Knöös

Skåne University Hospital and Lund University

Sweden

Learning objectives

- Accident happens in radiotherap
- They are very few
- When the happen they can be very serious
- Many factors contributes/combines to make the adverse events happen
- By learning from others we may be better

Six major accidents will be reviewed

Erroneous commissioning

- Toulouse, France

Incorrect repair of accelerator

- Zaragoza, Spain

Accelerator interlock failure

- Bialystok, Poland

Mis-calibration of beam

- Exeter, UK

In-correct use of a TPS

- North Staffordshire, UK

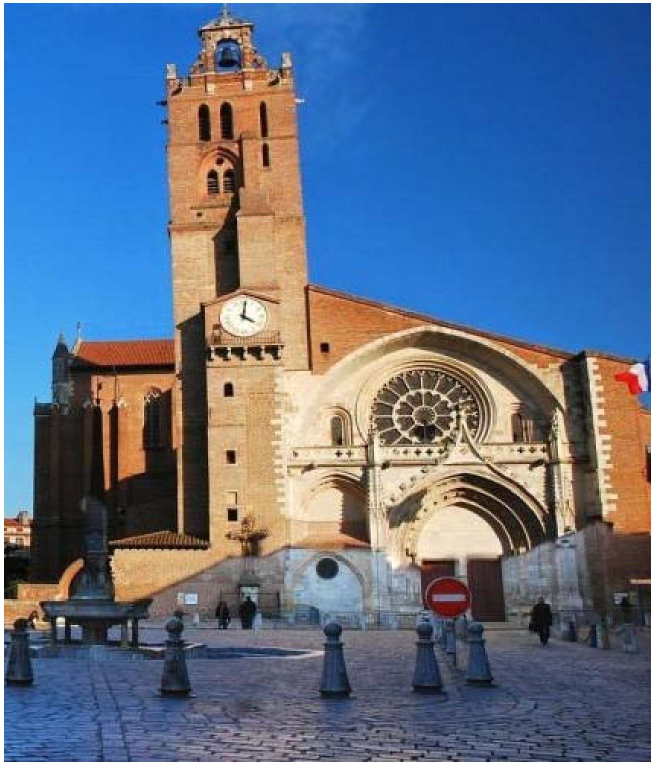
Non-updated data route

- Glasgow, UK

Conclusion

1 – Erroneous commissioning of a linear accelerator for stereotactic treatments

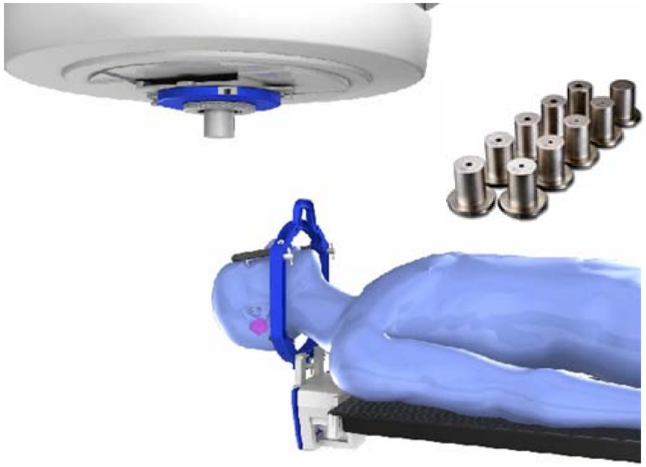
France



Inappropriate calibration

- Reported 2007 at Hôpital de Rangueil in Toulouse, France

- In April 2006, the physicist in the clinic commissioned the new BrainLAB Novalis stereotactic unit
  - This unit can operate with microMLC's (3 mm leaf-width) or conical standard collimators



Background

- Very small fields can be defined with the microMLC's
  - High dose to a 6 x 6 mm field is within capability
  - The TPS requires percent depth doses, beam profiles and relative scatter factors down to this field size
  - Care must be taken when measuring small fields!

- Different measuring devices were used by the physicist
  - A measuring device not suitable for calibrating the smallest microbeams was used
  - "…an ionisation chamber of inappropriate dimensions…" according to Nuclear Safety Authority (ASN) inspectors

- The incorrect data was entered into the TPS
  - All patients treated with micro MLC were planned based on this incorrect data
  - Patients treated with conical collimator were not affected

Discovery and impact of the accident

- BrainLAB* discovered that the measurement files did not match up with those at other comparable centres, during a worldwide intercomparison study

- Treatment based on the incorrect data went on for a year (Apr´06 – Apr´07)
- All patients treated with microMLC were affected (145 of 172 stereotactic patients)
- The dosimetric impact was evaluated as small in most cases, with 6 patients identified for whom over 5% of the volume of healthy organs may have been affected by dose exceeding limits

*It should be noted that the company does not validate or hold any responsibility for local measurements or implementation

Lessons to learn

- Ensure that staff
  - Understand the properties and limitations of the equipment they are using
  - “know and understand your dosimetry system completely, including its limitations, before applying it to a particular validation task” – was pointed out by John Schreiner*

- Include in the Quality Assurance Program
  - Intercomparison with other hospitals, i.e. independent check of new equipment by independent group (using independent equipment) before equipment is clinically used

*J Med Phys 2011;36:189-91

References

- Report concerning the radiotherapy incident at the university hospital centre (CHU) in Toulouse – Rangueil Hospital. ASN – Autorité de Sûreté Nucléaire (2007)

They are not alone
Small field dosimetry have some risks

Menu

2 – Incorrect repair of accelerator

Spain

Events: an overview

- 5th December 1990
  - no electron beam on linear accelerator
  - noted in the log containing data regarding the daily treated patients as:
    - "11:30; breakdown"
- A technician was at place from General Electric-CGR
  - Maintained a Co60 unit at the clinic
  - The clinic had a maintenance contract with GE/CGR
  - The technician had a first look and decided to postpone the work until the next workday

- 6th December 1990 – Holiday
- A repair was carried out by the technician the following day
  - the beam was recovered but ...
  - ..., an instrument on the control panel always indicated the maximum electron energy (36 MeV), regardless of the selected electron energy value 7, 10, 13 MeV etc
- Treatments resumed Monday the 10th December

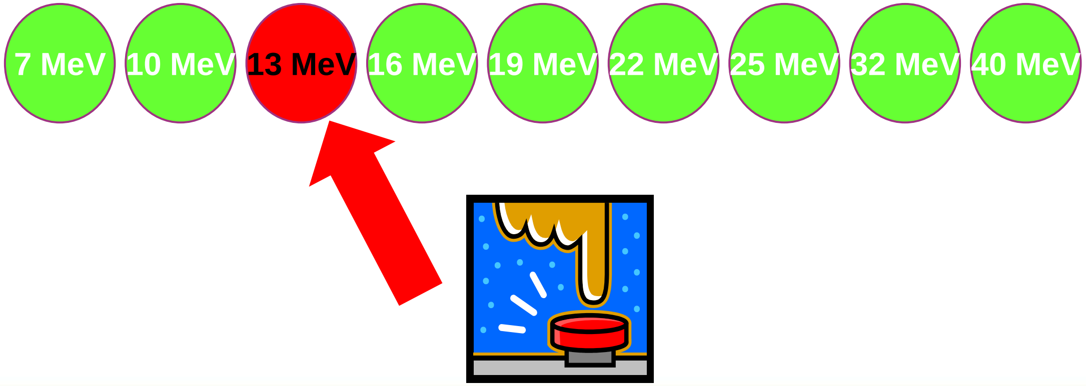
A “faulty display”

- The technologists observed the discrepancy between the energy selected and the one indicated on the instrument on the control panel
- The interpretation was
  - (the needle) “must have got stuck at 36 MeV”

    but

  - the energy must be as indicated on the energy selection keyboard

36 MeV



Events: an overview

- 20th December
  - the Physics and Radiation Protection Dept is informed about the incorrect energy display
- The linac is immediately taken out of service, observe - **after 10 days of treatment**
- Physicians starts to correlate the low tolerances and the reactions among patients with the event
- At this point, no information was given to the maintenance service of the hospital about the original breakdown of the linac or the repair by the technician
- This information was given a month later on the 20th Jan 1991

- 21st December
  - Dosimetry checks reveals the energy is 36 MeV! regardless of selection on the control desk...
- The company is informed and sends a technician to investigate and repair
- Investigation by CSN* the 5th Jan shows:
  - 7 MeV - Dose increase 7 times
  - 10 MeV - Dose increase 5 times
  - 13 MeV - Dose increase 3 times

*CSN - Consejo de Seguridad Nuclear

Consequences: an overview

- During the 10 days
  - 27 patients were treated using electrons with the faulty equipment

- Of the 27 patients
  - 15 died as a consequence of the overexposure
    - Most of them within 1 year
    - Radiation injuries of the lung and spinal cord
  - Two more died with radiation as a major contributor

			Clinical findings or Cause of death	Death	Radiation
MV	33	F	Radiation induced respiratory insufficency	1991-05-20	Yes
BC	69	F	Rupture of esophagus due to overexposure	1991-05-08	Yes
PS	45	F	Myelitis, paraplegic, esophageal stenosis	-	Yes
DR	59	F	Pneumonitos, hepatitis due to overexposure	1991-03-26	Yes
JC	60	M	Hypovolemic shoch due to radiation induced hemorrhage in neck	1991-09-14	Yes
FT	68	M	Myelopathy due to radiation	1991-04-15	Yes
MP	55	M	Myelopathy, lung metastases, respiratory insufficiency possibly due to radiation	1991-03-16	Yes
IL	65	M	Myelopathy postradiation	1991-12-25	Yes
JV	67	M	Left thigh and groin fibrosis		
AS	67	M	Ulcerated hypopharynx, cervical myelitis, radiation burn of neck		
JG	60	F	Respiratory insufficiency due to overexposure	1991-09-07	Yes
AG	60	F	Respiratory insufficiency due to overexposure	1991-07-28	Yes
BG	50	F	Healed skin burns of anterior chest		
CM	51	F	Respiratory insufficiency due to overexposure	1991-03-09	
AR	71	F	Skin burns, esophagitis, femoral vein thrombosis	1992-04-08	Probably not
IG	68	F	Paraneoplastic syndrome, metastases	1991-11-22	No
SA	45	?	Inguinal skin burns		
FS	59	F	Pneumonitis and myelopathy	1991-08-29	Yes
JS	42	M	Skin burns shoulder, fibrosis, necrosis		
TR	87	F	Respiratory and renal insufficiency and encephalopathy due to overexposure	1991-07-12	Yes
BF	39	F	Respiratory fibrosis and metastases	1992-05-20	Yes
NC	72	F	Skin burns chest, pleural and pericardial effusion		
PS	42	F	Respiratory insufficiency due to overexposure	1991-02-21	Yes
LS	72	F	Generalized metastases	1991-01-09	No
JG	80	F	Generalized cancer	1991-01-08	No
JS	56	M	Myelopathy due to overexposure	1991-02-16	Yes
SM	53	M	Myelopathy due to overexposure	1991-02-17	Yes

'From: Accidents in Radiation Therapy, FA Mettler Jr, P Ortiz-Lopez in 'Medical management of radiation accidents, Ed. IA Gusev, AK Guskova, FA Mettler. 'Published by CRC. ISBN 0-8493-7004-3

The Sagittaire accelerator

Technical and Physical Description of the Event - According to a report from the Spanish Society of Medical Physics

Electrons
- 7, 10, 13, 16, 19, 22, 25, 32, 40 MeV

Photons
- 25 MV

Traveling-wave guide

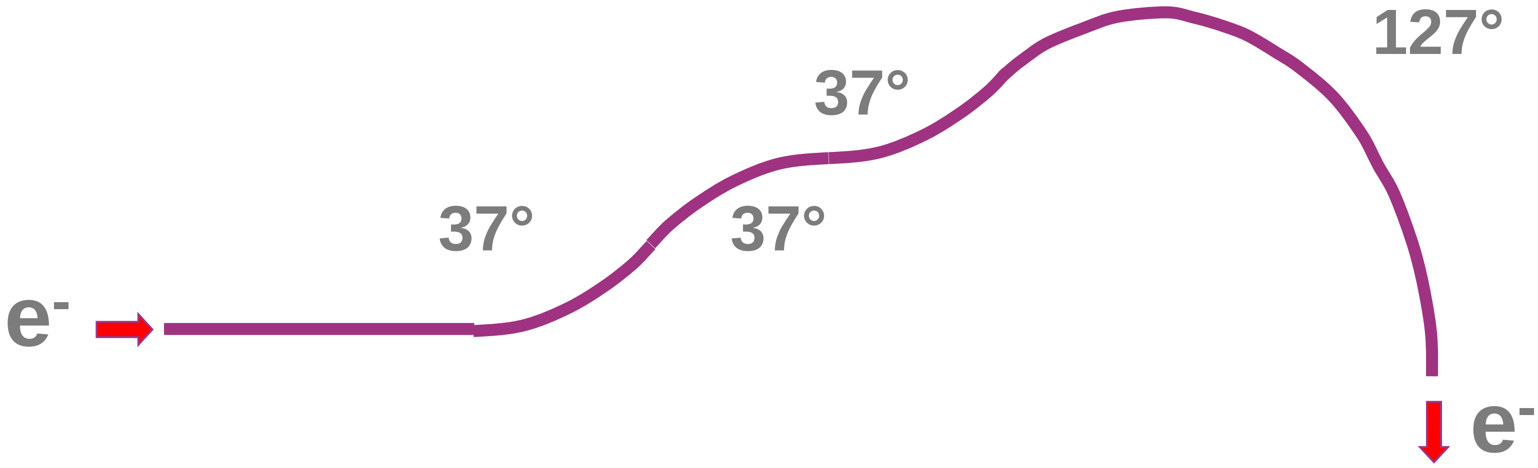
Bending magnet system - slalom type

No flattening filter
- Beam scanned (up to 36 x 36 cm^2)

Images acknowledged Rune Hafslund, Bergen, Norway

The electron path

- The path is controlled by electromagnetic field, bending magnet
- Higher current needed when electron energy increases
- Only one current is correct for a single electron energy (the deflection current)



During the repair

- Energy was adjusted until beam was found
  - This was done for all energies
- Since running at maximum deflection current
  - => ~36 MeV for all electron beams
- Instead of finding the defect (short-circuited) transistor and restoring the correct deflection current in the bending magnet
- To do this adjustment
  - energy selection had to be switched to “manual mode”
- By doing so, the energy selection from the control panel was partly disabled

Lessons to learn: Radiotherapy Department

- Include in the Quality Assurance Programme
  - Formal procedures for
    - returning medical equipment after mainte…
    - making it mandatory to report to th… …efore resuming treatment with pati…
- Consideration of the nee… …tion beam by the Physics group, when a repair migh… …n parameters
- Proce… …ull review or investigation when unusual displays or b… …adiotherapy equipment occurs

COMMUNICATION

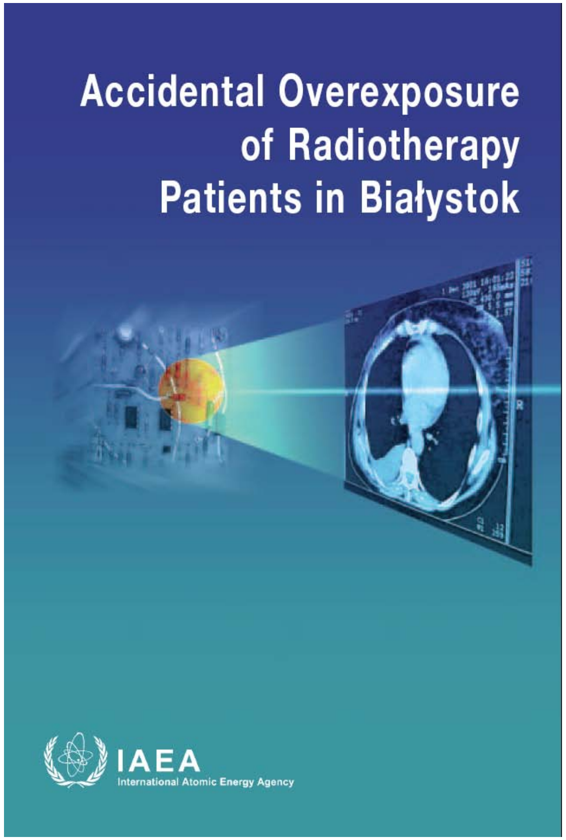
Aftermath

- A GE technician was found guilty of criminal negligence in a Spanish court for his role in what experts are calling the world's worst radiation therapy accident, in which 27 patients allegedly received overdoses from a malfunctioning radiation machine at a hospital in Zaragoza, Spain during a 10-day period in December 1990.
- A Zaragoza judge handed down the decision in April, determining that the overdoses resulted in 20 deaths and seven serious injuries.
- According to GE, the court found both the company's service technician, and GE-CGR España civilly liable for the $3.7 million award to the accident victims. Although the technician was found guilty of criminal negligence, GE-CGR España was not the subject to any criminal charges.

Menu

3 – Accelerator interlock failure

Poland



February 27, 2001

- Power failure at the department
- Five patients remained to treat that day
- Machine was restarted
- All machine tests completed without any error indication
- Analog dose rate indicator fluctuated around 150 MU/min, instead of the selected 300 MU/min
- Physicist adjusted the timer to a longer time because of the lower indicated dose rate
- He noted a minor beam asymmetry and readjusted for correction

Continue…

- All 5 remaining patients were treated
  - All had 8 MeV electrons
- Patients No. 3, 4 and 5 soon reported abnormal skin reaction
- Patient 5 returned to the radiotherapy department complaining of an itching and a burning sensation
- Radiation oncologist also noted erythema which was abnormal
- The machine was taken out of clinical use after the last patient

Built on license from CGR, France by The Institute of Nuclear Studies, Experimental establishment for Nuclear Equipment, Swerk, Poland

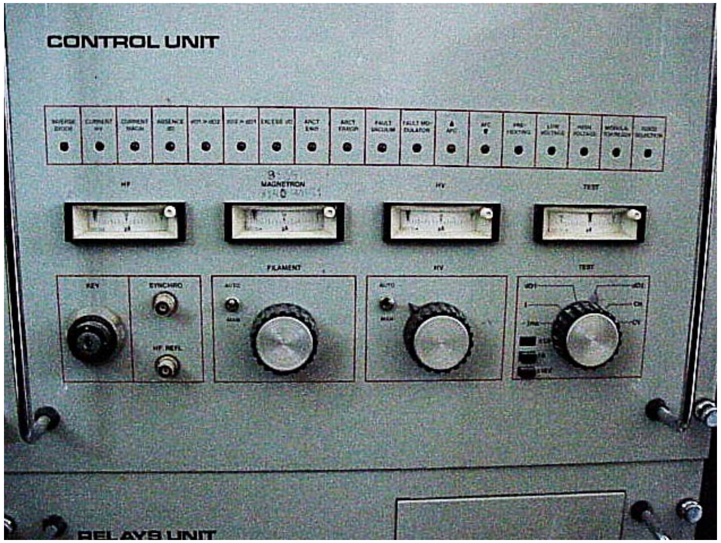
Action of the physicist

- Physicist did measurements
- Reading was off scale
- Dose rate, without correction for recombination, was
  - 37 times higher than normal (for 8 MeV electrons)
  - 17 times higher (for 10 MeV electrons)
  - 3.5 times higher (for 9 MV photons)

The Neptun 10 P in Bialystok

Action of the physicist

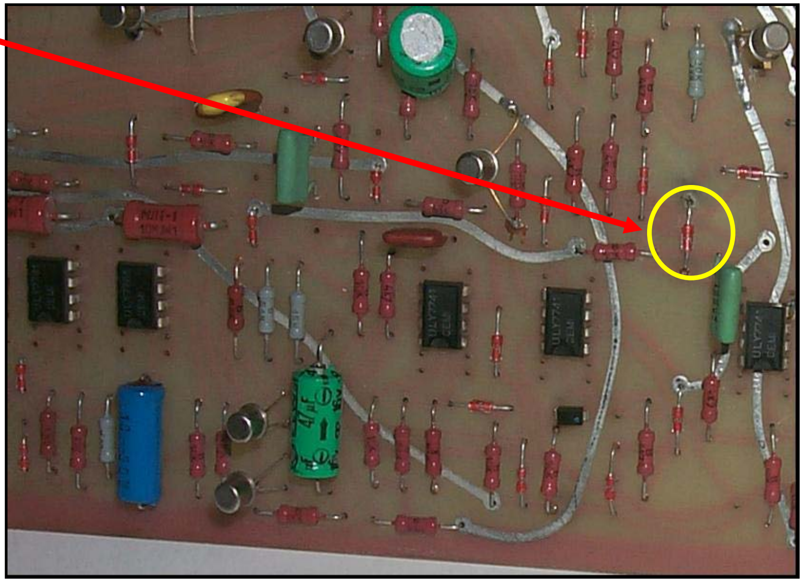
- Physicist noted increased current in filament of electron gun (from 1.20 to 1.46 for 8 MeV)
- The accelerator indicated low dose rate



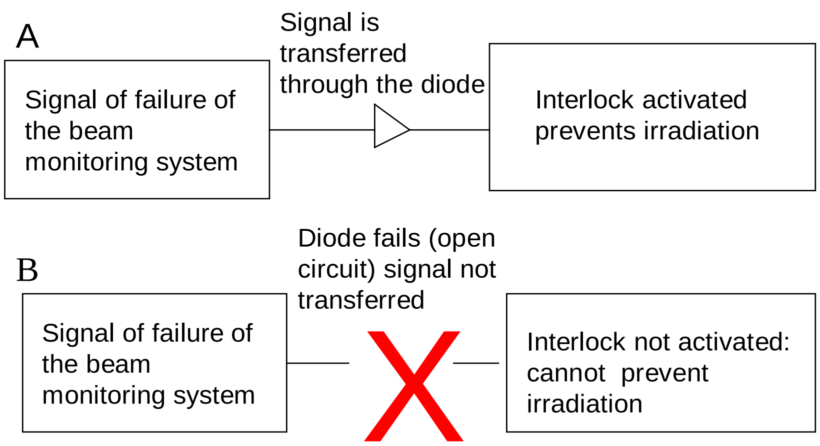
Electronic cabinet

Vendor came in the next day

- Broken fuse
  - no power to dosimetry system
- Diode broken in interlock chain
  - indicates problems in dosimetry system
- Low signal from ion chamber
  - gun current increased to compensate the low dose rate



Steps to initiate radiation

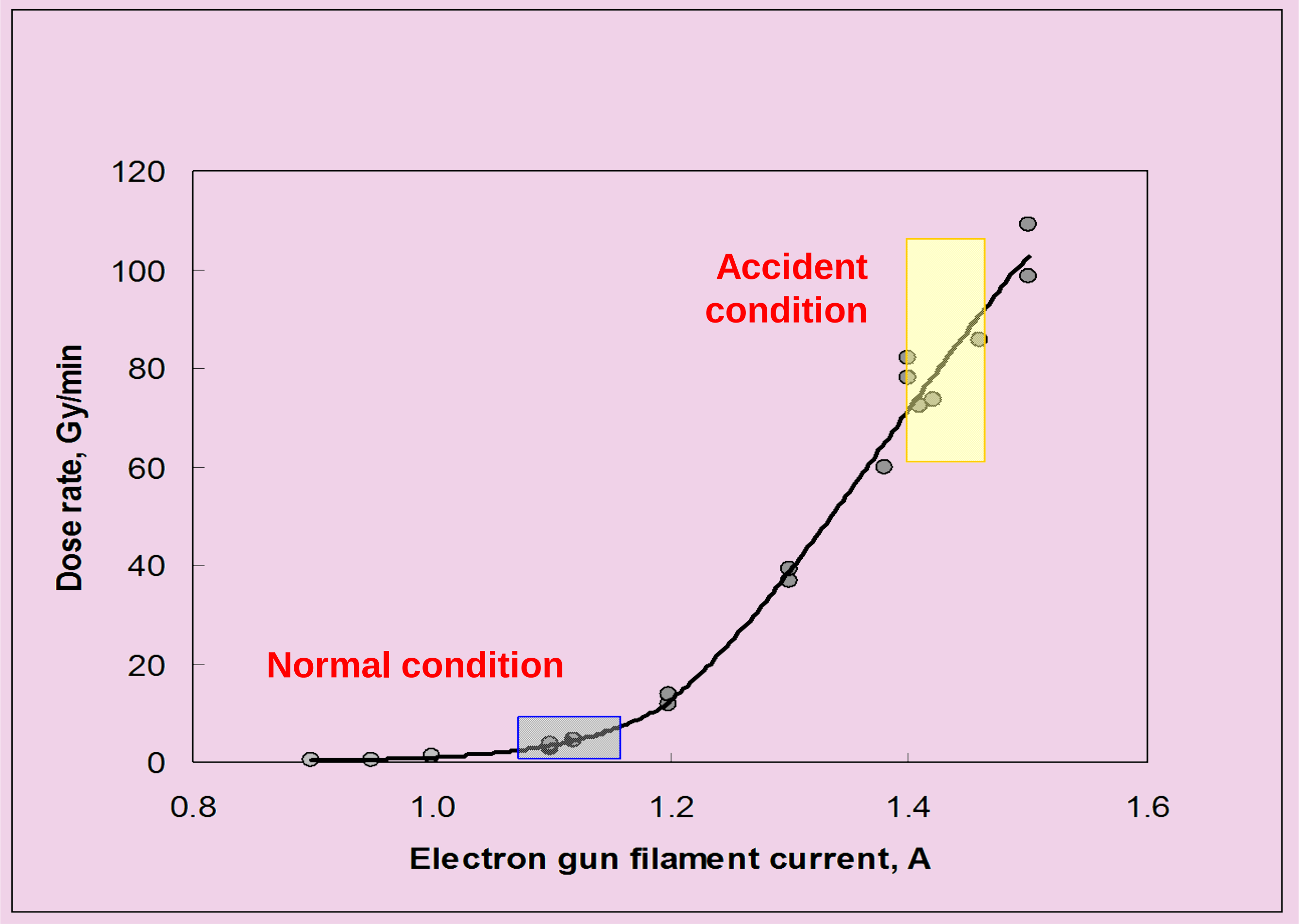


Function of diode D 29

A: Diode working properly
B: Diode disabled (open circuit)

- Sequence of steps to initiate irradiation includes a test of beam monitoring chambers, but …
- … the information about missing power supply can not pass through faulty diode …
- … interlock is not informed that monitoring chambers are missing
- … and gives green light to the next step in the sequence towards irradiation

Dose rate vs gun current



Lessons in short

- React and investigate when patients show unusual reactions
- QC program must include routines to check accelerator performance after power failure
- Equipment should be retrofitted or replaced when technology is out-dated
  - This is actually a very complicated process
    - who decides and when should it be done

Suspension levels
EU directive RP-162
C f national regulation

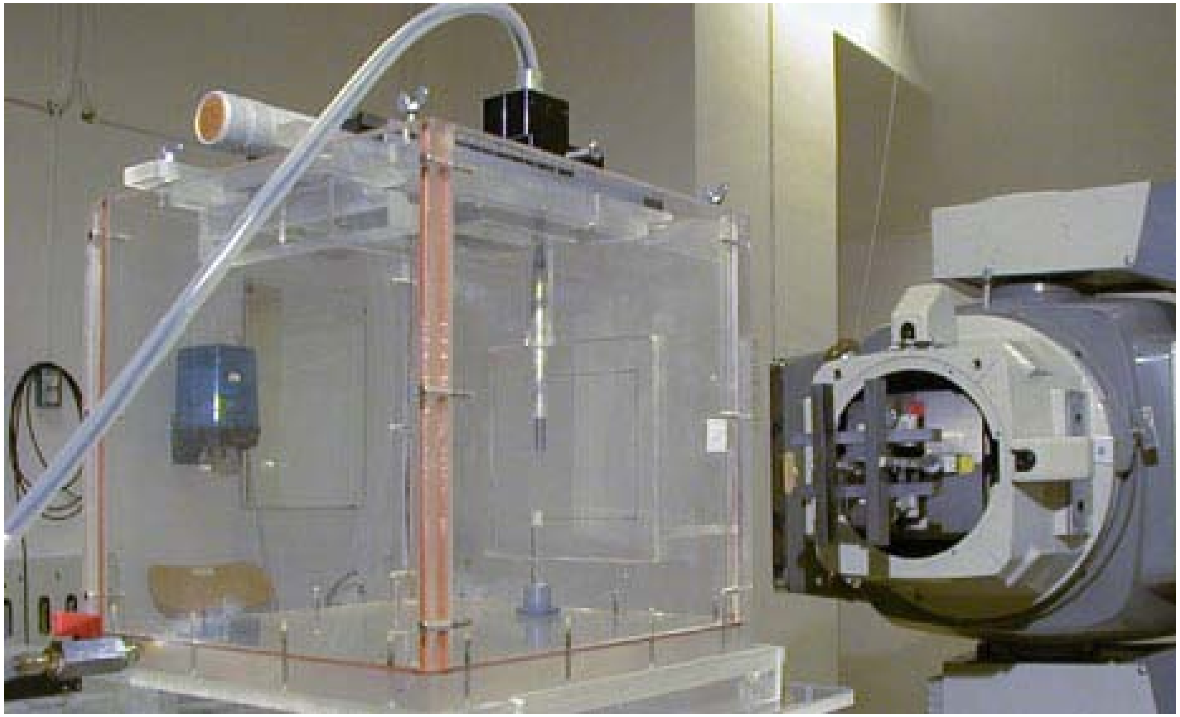
Menu

4 – Mis-calibration of beam

United Kingdom

Erroneous calibration, Exeter, UK, 1988

- Installation of a new cobalt source (a replacement source)
- A physicist calibrated the new source



2/2/88.

O/P calibration of New Source

Baldwin Farmer 2570 with probe, in water tank at depth 5.0c

Water tank outside dimensions (perspex): 32 × 32 × ~21 cm to water surf

T = 293   P = 760.3 .   SSD = 800 mm,   100 × 100 mm FIELD

Farmer left on for 45 mins before any measurements

Water tank filled and left to come to room temp overnight

Farmer readings (0.8 mins): 90.~~95~~, 90.92, 90.90, 90.90, 90.90 → 90.90_5

" " (0.4 mins) 46.47, 46.40, 46.40, 46.42, 46.42 → 46.42_2

Steady state 0.4 min reading 44.48_3

Steady State Doserate

at 800 mm, 100 × 100 $= 2 \times \frac{293.3}{293} \times \frac{760}{760.3} \times \underset{\text{absorbed dose Farmer factor}}{0.947} \times \frac{100}{79.0} \times 44.48$

= 106.7 cGy/min

"Dose effective Timer error" $= \frac{90.90_5 - 2 \times 44.48_3}{2 \times 44.48_3}$

= 0.0218 mins

1/0.4 = 2.5 not 2 !!!
Should have been
133.4 rtg/min

ESTRO School

What went wrong and how it was detected?

- The physicist may have multiplied by the wrong factor to achieve an equivalent exposure for one full minute. Tragically, this inaccuracy was not then recognised, possibly because the physicist was working on his own and his figures may not have been checked.
  - Or it was checked and what was noticed was what was expected
- Commonly only relative dosimetry may follow
- As a result of a calibration error, 205 patients were significantly overdosed (25%) with increased morbidity and possible deaths considered as a consequence.
- Institute of Physical Sciences in Medicine performed a National multicentre comparison of dosimetric consistency - External Audit

Lessons

- One clear lesson from this is that calibration of a new cobalt source/linac must be checked and rechecked (and rechecked...)
  - One may wish that a suppliers could specify the likely output of the source (compare brachytherapy)

- It is certainly possible to cross check a new installation in this way, and it might even be sensible to repeat the calibration of a new source a month after its first use in case of contamination with other isotopes which might have unexpected patterns of decay.

- External (internal) audit

Lessons to learn

- Carry out an investigation if the results of audit indicate a discrepancy
  - If possible, prior to clinical use of a new unit, an external audit should be performed
- If there is a high incidence and severity of acute effects it must be investigated
- Ensure a high level of training and competence in order to deal with potentially hazardous sources
- Specific training should be additional to basic education and not simply attending occasional short courses

Looking around

- **Copenhagen** – QC showed 5% deviation in output - was adjusted immedeatly
  - Linac OK but incorrect calibration factor for ion chamber – detected after several weeks even if in-vivo dosimetry was in placed (however, lack of comprehensive analysis)
  - No second physicist checked QC
- **Ottawa** – Recommissioning of unit after move – missed back scatter factors
  - No second physicist
  - Detected when annual QC was done
- **Touluse/Ohio** – Commissioning of SRT with unsuitable ion chamber
  - No second physicist
  - Detected by company
- …

Menu

5 – In-correct use of treatment planning system

UK

North Staffordshire Royal Infirmary, 1982-1991

- Until 1982, a hospital relied on manual calculations for the correct dose to be delivered to the tumour
  - Treatments were generally performed at standard SSD (100 cm) (very few SAD)
- A computerized treatment planning system was acquired in 1981- clinical use in autumn of 1982
  - Partly because TPS simplified the calculation procedures, the hospital began treating with isocentric techniques more frequently
  - It was assumed that correction factors for non-standard SSD should be applied
- In 1991 a new computer planning system was installed and a discrepancy was discovered between the new plans and those from the previous system
  - Further investigation revealed that the original TPS already contained within it the correction for calculations at non-standard SSD. The INVERSE SQUARE LAW
- During the 9-year period, 6% of patients treated in the department were treated with isocentric technique; for many of these patients it formed only part of their treatment
  - 1045 patients whose calculations were affected by the incorrect procedures, 492 developed local recurrences that could be attributed to the error
  - Under dosage varied between 5 and 35%

News when detected

THE GUARDIAN
Wednesday September 23 1992

Error by hospital over use of equipment went undetected for nine years ● Inquiry puts blame on lack of supervisory systems

1,000 cancer sufferers were under-treated

'If she had been run over by a negligent driver, he'd have had to pay a fortune . . . I was told that if she'd had full treatment, then she would have recovered'

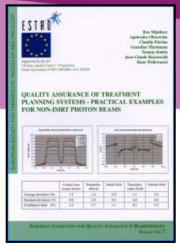
Memories . . . An embittered Paul Munslow with a drawing of his wife Chris, who died in July

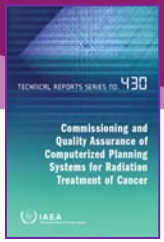
'She said: Those bloody people have killed me'

Erlend Clouston meets husband of 47-year-old who died after under-dosage was admitted

Why I quit over Keays

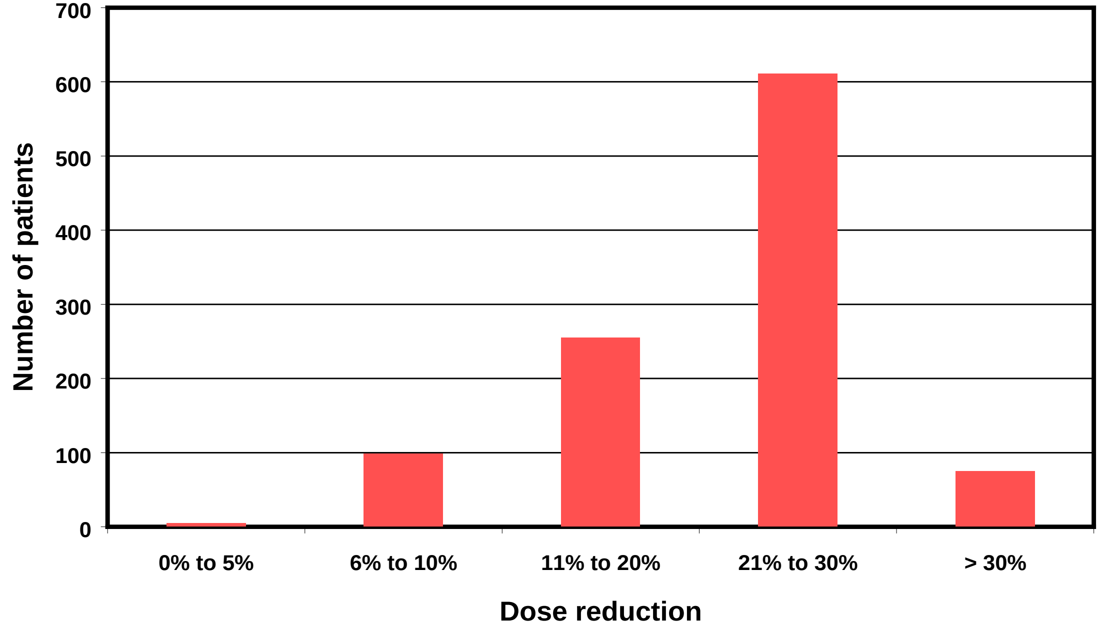
Lessons






- Ensure that staff are properly trained in the operation of the equipment
- Ensure that staff understand the operating procedures
- Include in the Quality Assurance Programme:
  - Procedures to perform complete commissioning of treatment planning equipment before first use
  - Procedures for independent checking of patient treatment time calculations

Dose reduction distribution for patients



Commissioning is also a learning period!

Looker further – Calibration of TPS – Australia

- The incident was discovered in 2006 when an independent measure of machine output, external to the linear accelerator quality assurance process, was performed to implement some new quality assurance software.
- These measurements highlighted that there was an under-dosing of 5% when they used data from TS3.
- Further investigation at the time of the detection of this anomaly was able to trace back to the TPS beam calibration ratio as the likely cause of the consistent 5% dose discrepancy.
- It involved 869 patients between 2004 and 2006.

Menu

6 – Non-updated data route

or

Erroneous use of treatment planning system and oncology information system

Incorrect manual parameter transfer

- Introduced a new common data base for linacs, TPS and R/V system in 2005.

- Thus all plan data are available among all modules
  - Incl TPS and treatment console at the linacs

- Previously all plans were calculated for
  1 Gy as prescribed dose
  - The MUs were scaled to correct dose manually

- Now all plans were made for the correct prescribed dose

What happened?

- 5th January 2006, Lisa Norris, 15 years old, started her whole CNS treatment at BOC
- The treatment plan was divided into head-fields and lower and upper spine-fields
- This is considered to be a complex treatment plan, performed about six times per year at the BOC.

What happened?

- Whole CNS plans still went by the "old system", where TPS calculates MU for 1 Gy with subsequent upscaling for dose per fx
- A "**medulla planning form**" was used, which is passed to treatment radiographers for final MU calculations
- HOWEVER – "Planner X" let the TPS calculate the MU for the full dose per fx – not for 1 Gy as intended
- Since the dose per fx to the head was 1.67 Gy, the MU's entered in the form were 67% too high for each of the head-fields

Output (MU/100cGy)

Annex 2: A blank copy of the first page of Medulla Planning FM.14.014 as used for Lisa Norris's treatment plan

BEATSON ONCOLOGY CENTRE - QA CONTROLLED DOCUMENT

MEDULLA PLANNING FORM FM.14.014
TWO SPINE FIELDS

Name:	Site:
B.O.C. No:	Unit:
Radiotherapist:	Date:
Physics:	

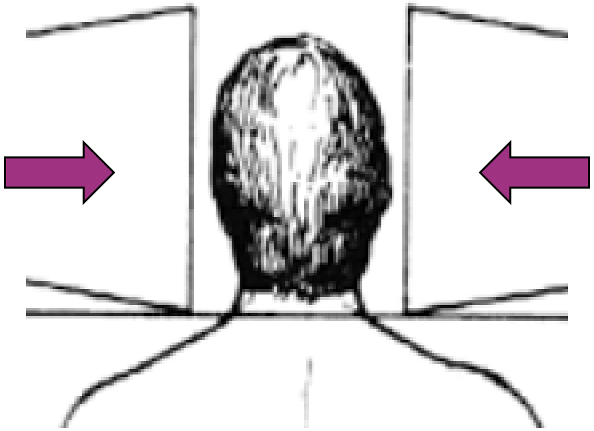
Setup	Head fields isocentric; asymmetric jaws; customised shielding trays. Physics to move junction after every .... fractions (see over).			
Site	Head (a)		Upper Spine (b)	Lower Spine (c)
Description	Right Lateral	Left Lateral	Posterior	Post / Sup
Field Size (approx for first .... fractions				
Jaw Settings	x_1 y_1 x_2 y_2	x_1 y_1 x_2 y_2		
F.S.D.	ISOCENTRIC		100 cm	100 cm
Gantry Angle	90°	270°	0°	.......° (i.e. ...... ° to sup)
Collimators	.......° (i.e. ....° Sup End Post)	.......° (i.e. ......° Sup End Post)	90°	90°
Floor Rotation	0°	0°	270°	270°
Beam Modifier	Shielding block tray code =	Shielding block tray code =	Wax compensator (a). tray code 17	Wax compensator (b). tray code 17

Beam Weight (%)	100% (a)	100% (a)	100% (b)	100% (c)
Output (MU/100cGy)				
Dose Information	T.A.D. mid brain = 100% Normalisation = ... %		spinal cord: ......% max subcut: .....%	spinal cord: ......% max subcut: .....%

File Name: FM14014	Page Number: 1 of: 1	Date: 11.8.98
Issue Number: 1	Authorised By:	Issued By:

How did it hit the patient

- This error was not found by the more senior planners who checked the plan
- The radiographer on the unit thus multiplied with the dose per fraction a second time



- **2.92 Gy per fx** to the head

Discovery of accident

- “Planner X” calculated another plan of the same kind and made the same mistake
- This time, the error was discovered by a senior checker (1st of Feb ‘’06)
- The same day, the error in calculations for Lisa Norris was also identified

- The total dose to Lisa Norris from the Right and Left Lateral head fields was 55.5 Gy (19 x 2.92 Gy)
- She died nine months after the accident

- Probably due to recurring disease

Latent threat

- #1 August 2005 – prescription dose not entered into system
- #2 November 2005 – prescription dose equal 1 Gy
- #3 December 2005 – This case
- #4 January 2006 – Planned and dose entered correctly (missed opportunity)
- # 5 February 2006 – The output from the planning process was questioned

Lessons to learn

- The experienced planner supervised and checked the plan (i.e. checking her/him self)
- No instructions for putting values into the form, Old form
- Could have been avoided by independent check of MU
- In-vivo dosimetry may have identified the erroneous dose
- Lack of staff (6-7000 patient annually)

Lessons to learn

- Ensure that all staff
  - Are properly trained in safety critical procedures
  - Are included in training programmes and has supervision as necessary, and that records of training are kept up-to-date
  - Understand their responsibilities

- Include in the Quality Assurance Program
  - Formal procedures for verifying the risks following the introduction of new technologies and procedures
  - Independent MU checking of ALL treatment plans

- Review staffing levels and competencies

Looking around

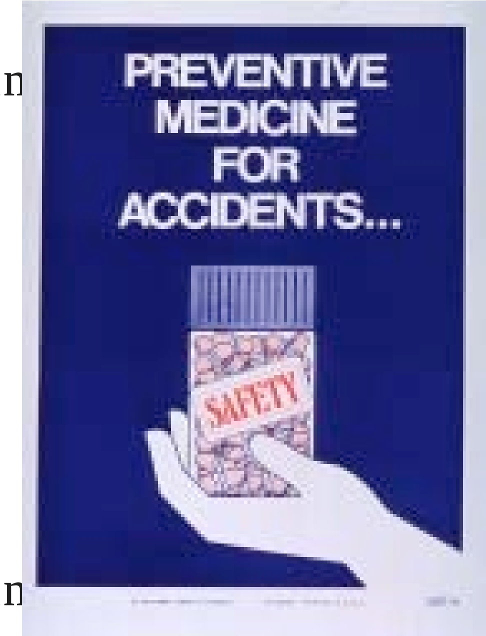
- Dynamic versus hard wedges in Epinal, France
  - Mixup between planning and delivery

- Correcting setup after imaging, Sweden
  - Mix up of +/- direction during review
  - Different in on-line vs off-line!!!

Menu

“Causes” of the accidents in this lecture

- Incorrect commissioning
  - Non-qualified physicist
  - Lack of internal/external audit after commissionin
- Incorrect repair of accelerator
  - Non-qualified repair and lack of reporting…
- Accelerator interlock failure
  - Outdated design…
- Miss-calibration of beam
  - Lack of understanding and education…
  - Lack of internal/external audit after commissionin
- In-correct use of TPS/RV system
  - Lack of understanding and education…
  - Missing one data route – risk analysis missing




Beer is proof that God
loves us and wants us to be happy
Benjamin Franklin 1706
2016-10-05

Autopsy of the Epinal accident

Pr. Eric F. LARTIGAU

Centre Oscar Lambret

59000 Lille, France

Accidents : Epinal & Toulouse

CENTRE
HOSPITALIER
JEAN MONNET
EPINAL

The RT department of Epinal

- 2 Clinac 600 et Clinac 2100
- Multi leaves
- 600-700 patients / y
- 2 radiation oncologists
- 1 physicist
- 10 technologists
- 2 secretaries
- 1 coordinator
- 1 technician

EPINAL

- 2000 : conformal Radiotherapy (prostate)

2001 : daily Matching not compensated = over dosage of 8%

- 2004 – 2005 : Error: dynamic Wedges

  - for 24 patients = overdosage of 20 %

Jan 2005: first clinical symptoms

Sept 2005 : internal declaration of the accident
July 2006 : declaration to the national authorities

Oct 2006: inspection IGAS/ASN and IRSN

19 months ?

Jan 2005: first clinical symptoms

Sept 2005 : internal declaration of the accident

July 2006 : declaration to the national authorities

Oct 2006: inspection IGAS/ASN and IRSN

Why ????

Why ?

- Sept 2005 : internal declaration of the accident
- **July 2006** : declaration to the national authorities

- Everybody knew

- RTT’s declared to the press….

The initial report IGAS/ASN feb 2007

- First actions
  - Information, work up and treatment of the patients
  - Discovery of other rectitis

  - Q. Assurance not developed and used in the dpt
  - No links to the administration
  - **<u>Follow up not organised</u>**

- Immediate proposals
  - Help to the victims
  - technical and organisational modifications
  - Management of the crisis
  - QA program in radiotherapy

Interruption of the treatments

- 5 march 2007 :
  - Report IGAS / ASN
  - declaration of the Ministry N°1
    - suspension
- 6 – 7 march 2007 :
  - Transfer of the treatments to CAV Nancy
  - Discovery of the « + 8% »
- 9 march : Declaration Ministry n° 2
- March 2007 : 2^{e} IRSN mission

Group I : the 24 victims

scale ASN / SFRO = 6+

- Prostate: 23+1 = 24 patients
- *From Mai 2004 to august 2005*
- Virtual wedges
  - + 20% (physical dose 80–112 Gy/7w)
  - +8% PI
- 5 death (currently 19)
- Grade IV tox
- Diagnosed and treated by IRSN

Groupe II:
the « 400» with excess of dose

scale ASN / SFRO = 4+ (or 5)

- Prostate: 397 + 12 = 411 patients
- *October 2000 to October 2006*
- Daily portal imaging
  - Over exposition 8 –10 %
- (1 died)
- Sequelaes :
  - Rectitis
  - Incontinency

Group III:
the « 5000 » with error of calculation

scale ASN / SFRO = not defined

- All localisations except breast (source Skin distance)
  - 312 patients + 7,1 %
  - 3500 pts + 5,5%
  - 1100 pts +3%
- *from 1987 to 2000 (July)*
- Error of calculation DSP / DSA
  - % fonction of the energy of RX
  - $((100 + Dmax)/100)^2$
- 3rd mission IRSN
- Sequellae : under investigation
- Long term follow up

Summary

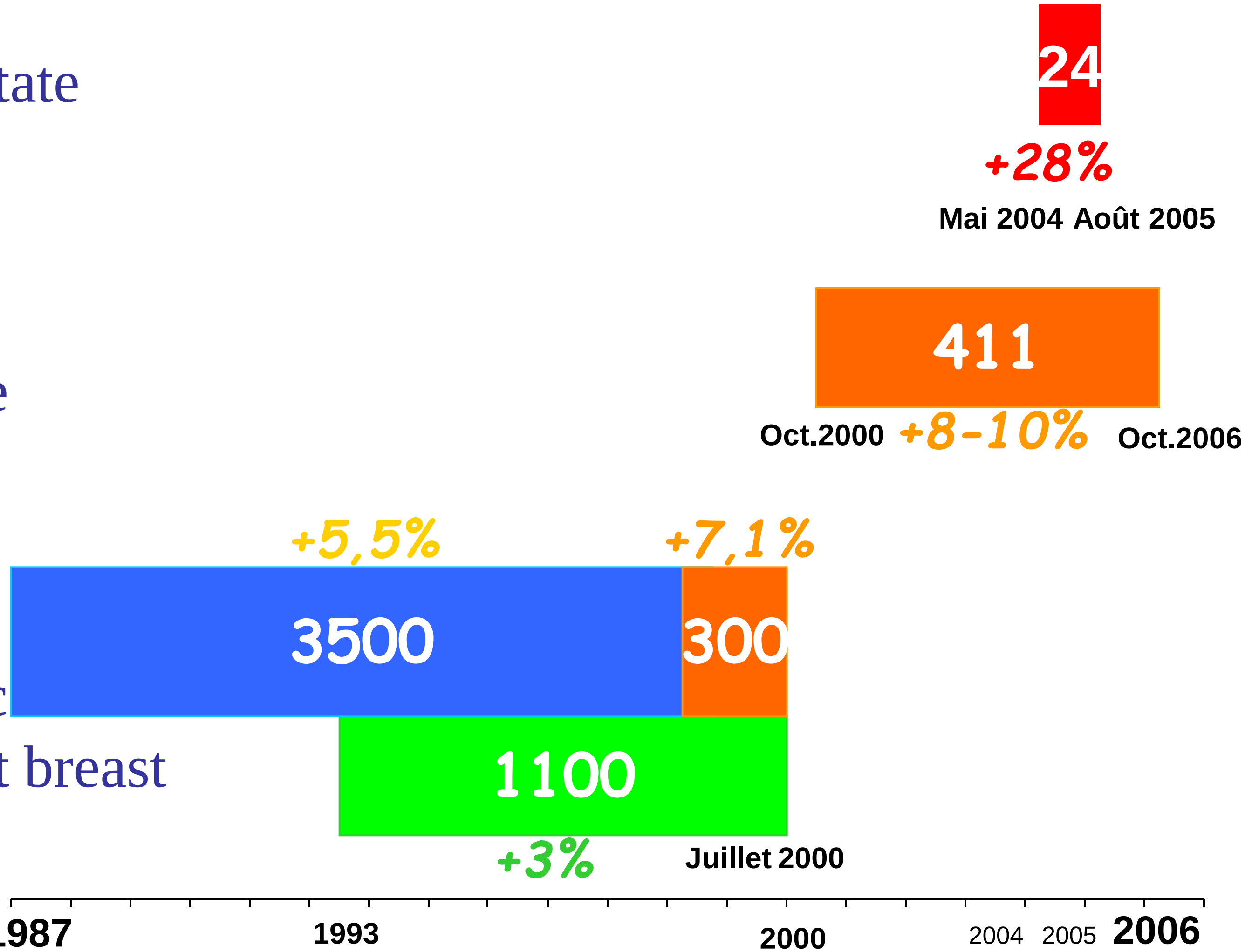
I *wedges* prostate

II *PI* prostate

III *Calcul error*

All loc

Except breast



Follow up of the patients

- To manage
  - the 24 victims
  - The « 400 »
  - Green telephone number
- OTHER Patients with symptoms
  - Diagnosis of severe rectitis in other patients (2000-2001)

Fees

- Epinal 1 :
  - 10 000 € SHAM
- Epinal 2 et 3 :
  - 5000 € for ONIAM
  - 5000 € SHAM
- Ollier’s comity :
  - Fast track
  - Trial

Insurance fees Sham

June 2009

Potential	**585**
Received	**470**
Experts	**346**
Diseagrement	**43**
SHAM	**247**
Accepted	**185**

Today’s all agreed

Starting the new treatments

- From 18/02/2008
  - Clinac 2100
  - Clinac 600 from June 2009
- Physicians from RCC CAV / j = 1,5 ETP
- Physicists : 1 phys CAV / j = 1,5 ETP
- RTT Epinal : 7,5 ETP

AUTORITÉ DE SÛRETÉ NUCLÉAIRE

asn

REPUBLIQUE FRANCAISE

Paris, le 18 février 2008

Note d'information

L'ASN autorise la reprise des activités du service de radiothérapie du centre hospitalier Jean Monnet à Épinal

Le 8 février 2008, l'ASN a autorisé le service de radiothérapie du centre hospitalier Jean Monnet à Épinal à reprendre ses activités.

The Trial

- January 30th, 2013:
- 2 physicians: 18 months, 20 000 euros and banned
- Physicist: same

Accident in Toulouse
April 2006- April 2007

- Stereotactic RT on Novalis
- Large chamber for small beam check
- 150 patients with overdosage

Single physicist without int/ext control

No death

Main differences

- Epinal : no declaration to authorities and patients
- Toulouse : straight forward declaration

Errare humanum est, sed perseverare diabolicum

Conclusion

A single person is at maximum risk !!!!!!

Communication is key

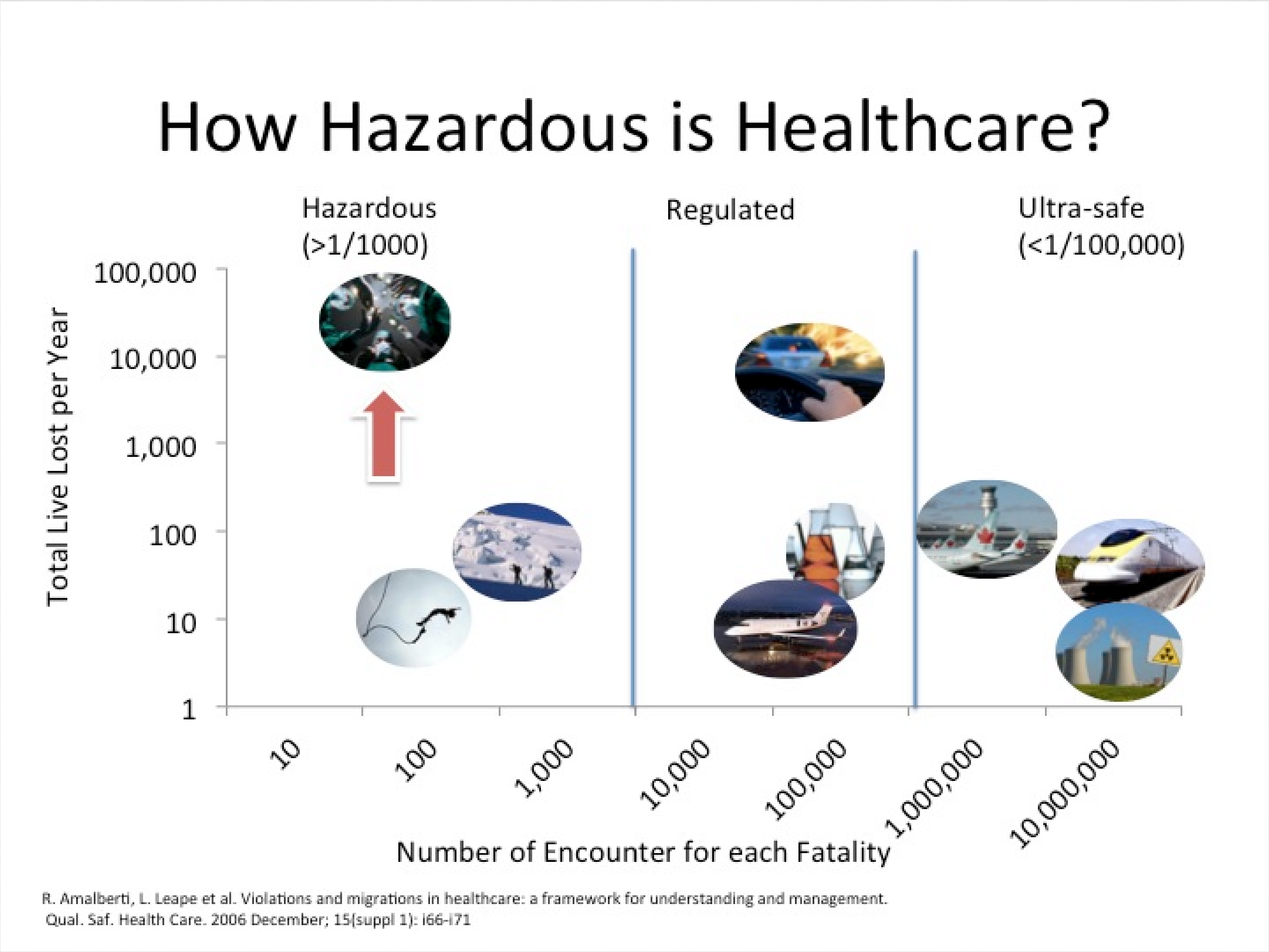
LESSONS LEARNED FROM RADIOTHERAPY ACCIDENTS

AUDE VAANDERING (RTT/QM)

LEARNING OBJECTIVES

- ✓ The risk of errors in RT
- ✓ The potential for accidents in RT
- ✓ The integration of risk management within the larger concept of quality management

ACCIDENTS IN A HEALTHCARE



ACCIDENTS IN RADIOTHERAPY

<0,1% error per treatment session
(>0,05-0,03%)

Consequences:

- Underdosage
  - Recurrence → Death

- Over-dosage
  - Increased side effects→ Death

- [Decreased patient satisfaction]

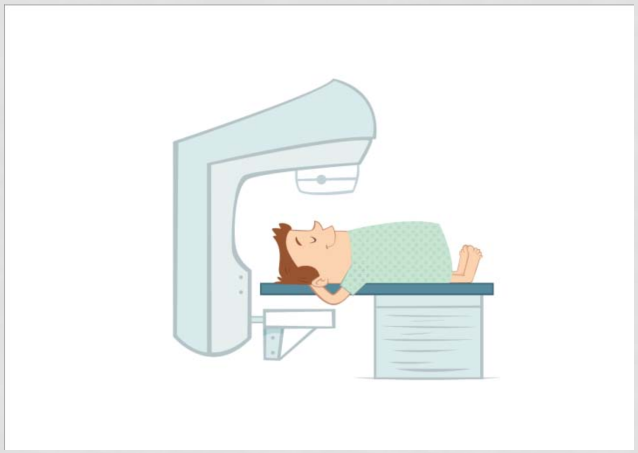
POTENTIEL FOR ACCIDENTS IN RADIOTHERAPY

- Patients are deliberately exposed to intense radiations beams

- Too much dose or not enough dose can have severe consequences

- Radiotherapy is a **complex** process

WHY THIS COMPLEXITY?

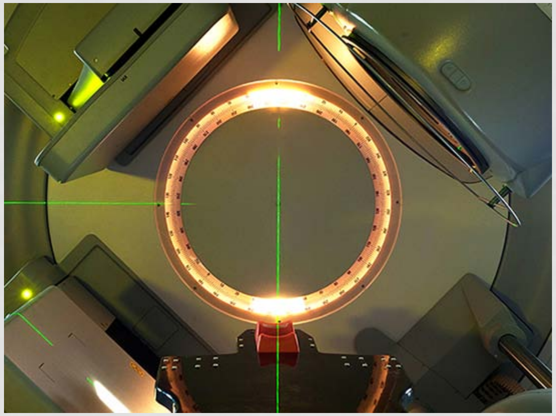


Patient

Teamwork

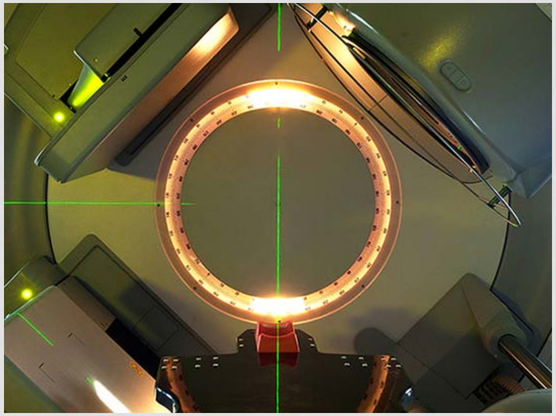
WHY THIS COMPLEXITY?

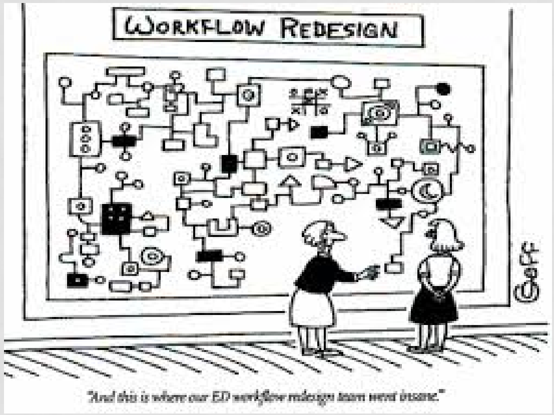
Technical complexity
Integration of R&V
Changes in treatment techniques (2D → 3D → IMRT →4D)
IGRT



WHY THIS COMPLEXITY?

Technical complexity	Process/Procedure complexity
Integration of R&V	IGRT workflows & Adaptive process
Changes in treatment techniques (2D → 3D → IMRT →4D)	Motion Management
IGRT	Other: Scan - plan - treat…





IMPACT OF COMPLEXITY ON ERRORS IN RADIOTHERAPY

Impact of complexity and computer control on errors in radiation therapy

B.A. Fraass

Department of Radiation Oncology, Cedars-Sinai Medical Center, 8700 Beverly Blvd., AC1085, Los Angeles, CA 90048, USA; e-mail: benedick.fraass@cshs.org

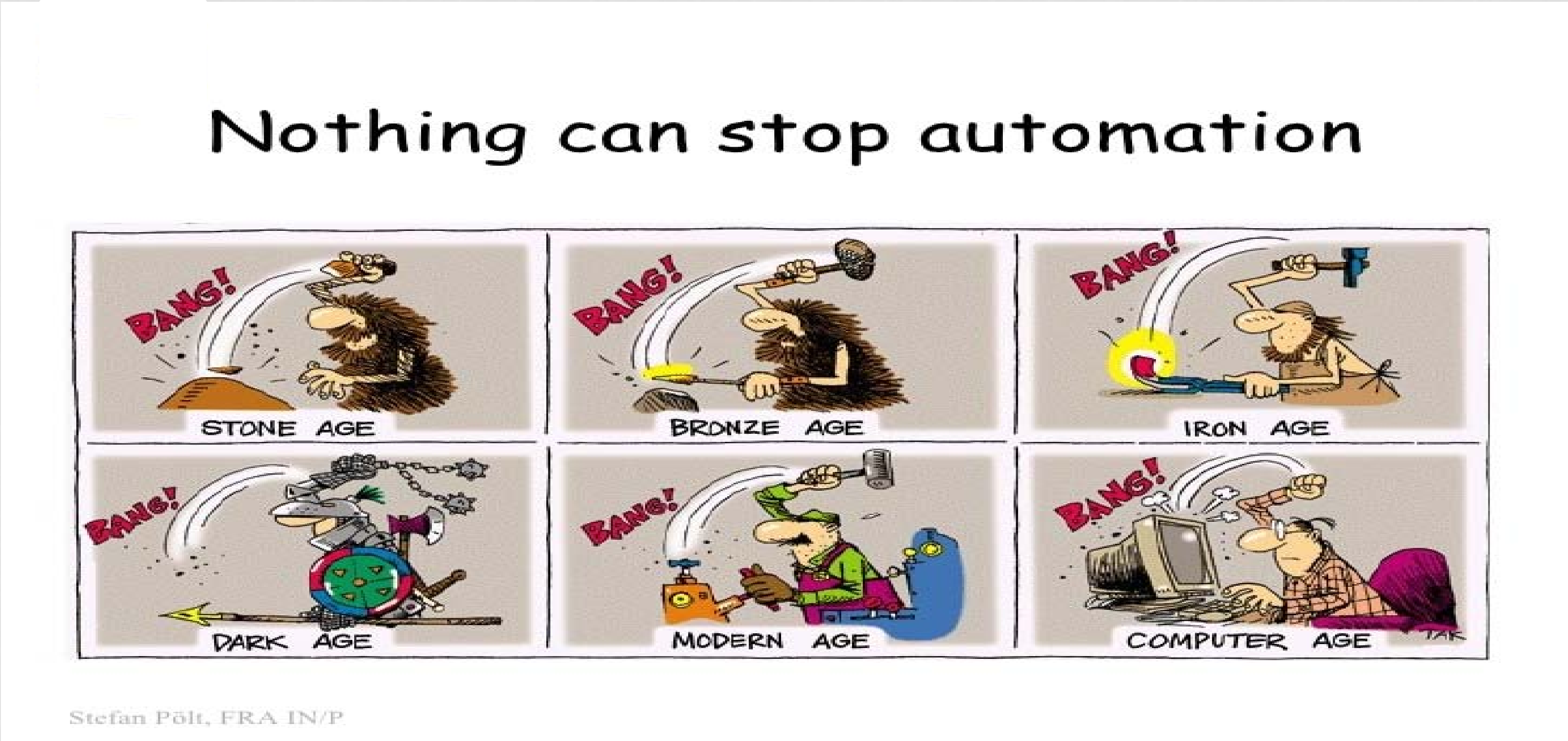
TYPES OF ERRORS

"With modern computer- controlled radiotherapy, [] an error is less likely to be a random event that only affects a single fraction, and is more likely to be somewhat systematic, so that it may affect many fractions or, in fact, a whole treatment course."

"New QA approaches are required to improve radiotherapy safety and quality in
the face of this dramatic change in the types of errors."

B.A Fraass
(2012)

COMPLEXITY AND AUTOMATION



Still a need for manual entries for important steps of the RT process:

- Commissioning of TPS
- Patient set up on <u>treatment</u> couch*

HUMAN COMPLEXITY

- “**WHO radiotherapy risk profile**” & “**US Regulatory Commission (NRC) data** (2008)
  - Estimation that +- 60% of radiotherapy incidents are due to human errors
- **Portaluri et al.** (2009)
  - 62,5 % of incidents due to attention failures

Ann Ist Super Sanità 2009 | Vol. 45, No. 2: 128-133

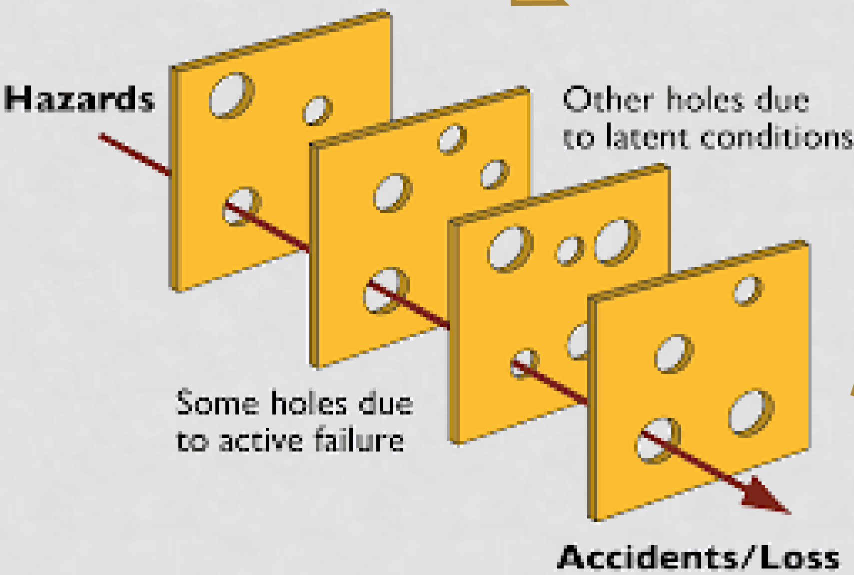
Incidents analysis in radiation therapy: application of the human factors analysis and classification system

Maurizio Portaluri[a], Fulvio I.M. Fucilli[b], Santa Bambace[c], Roberta Castagna[a], Maria Chiara De Luca[a], Giorgio Pili[d], Vittorio Didonna[e], Francesco Tramacere[a], Maria Carmen Francavilla[a], Angela Leone[a] and Maria Grazia Leo[b]

HUMAN COMPLEXITY

Human failures

Technical failures

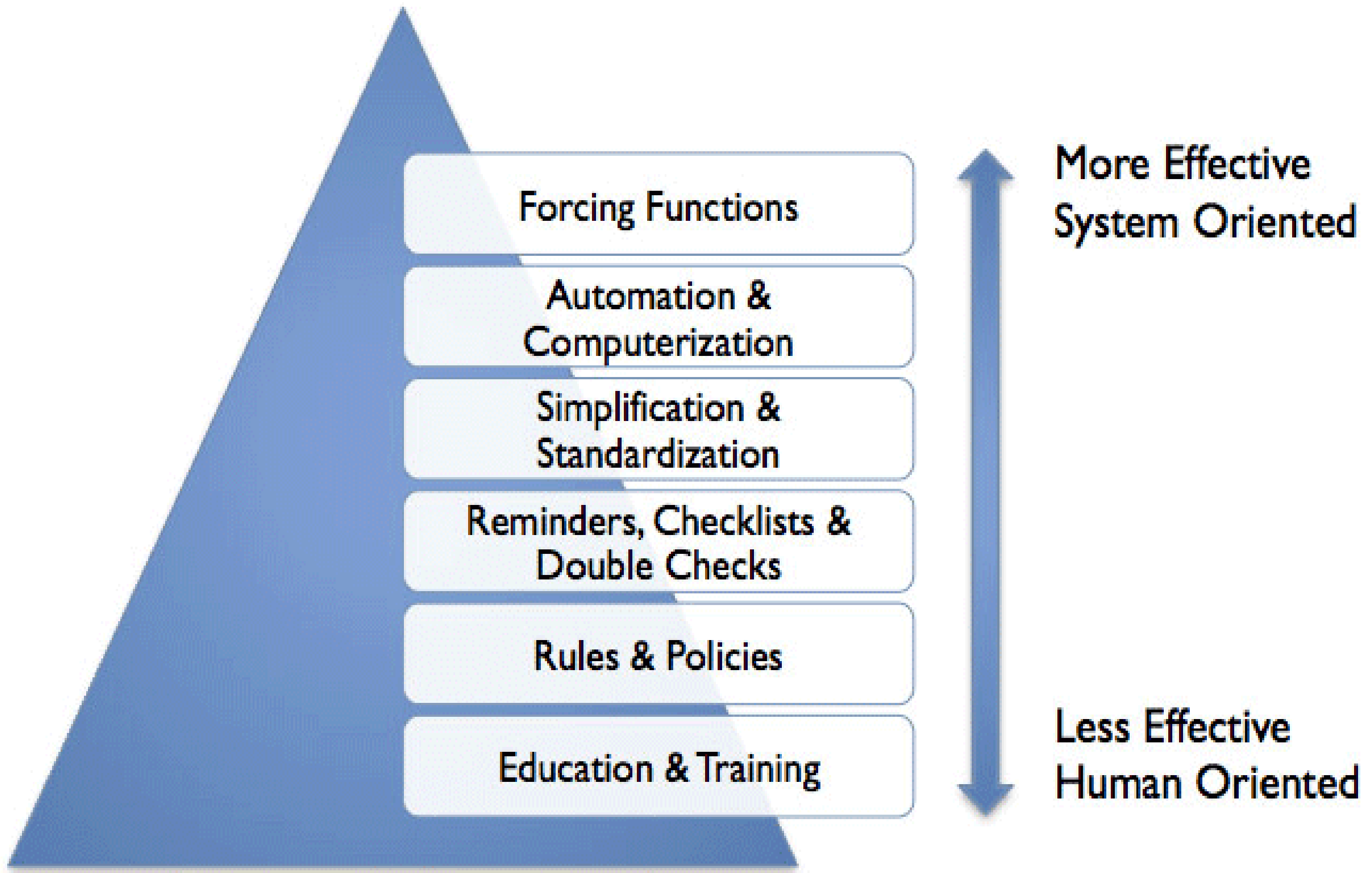


Organizational failures

Reason's model

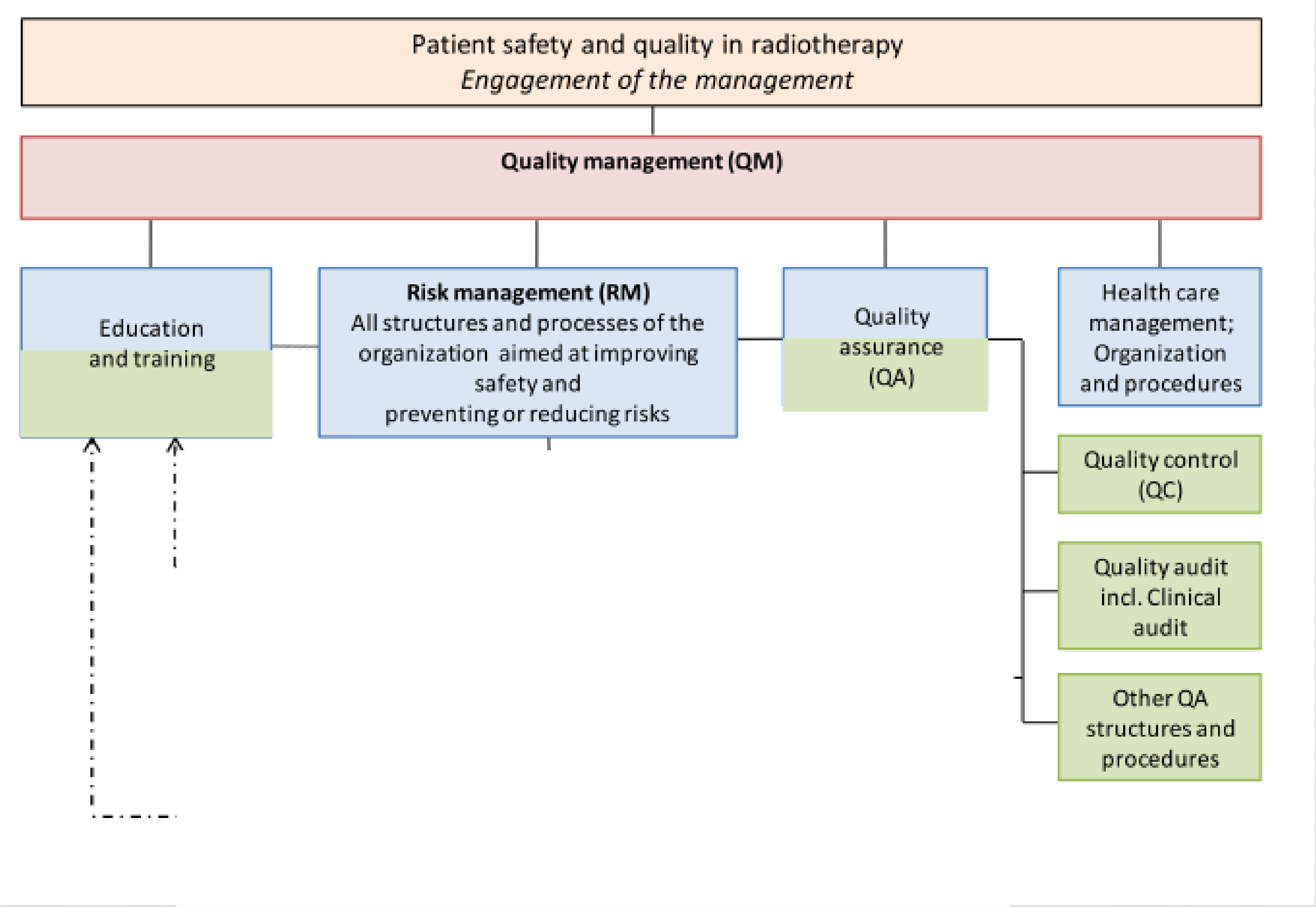
- Human errors: active failure
- Environment: latent failures

BARRIERS

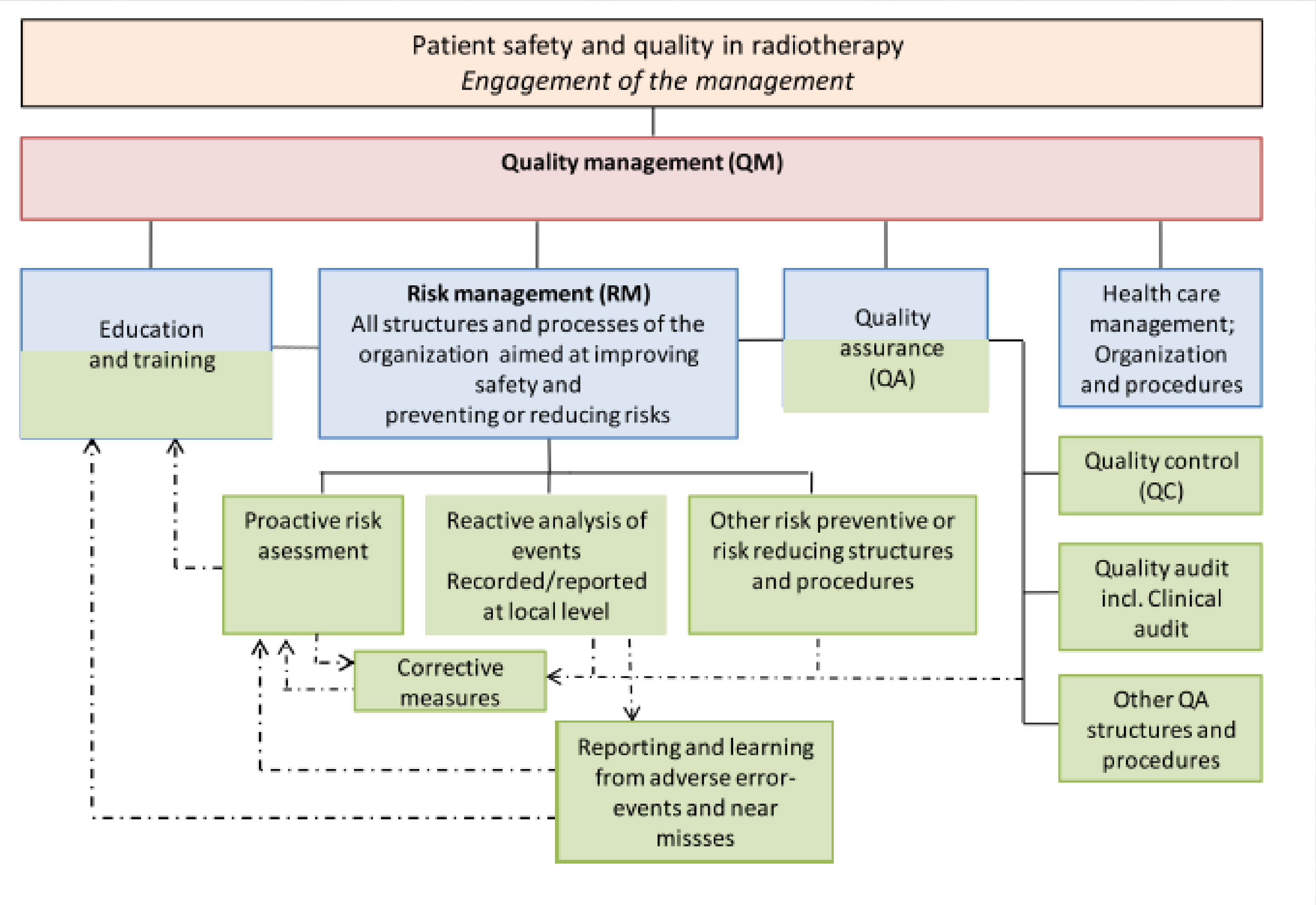


Institute for Safe Medical Medication practices. Medication error prevention "toolbox". Med Safe Alert 1999;4:1.

PATIENT SAFETY



PATIENT SAFETY

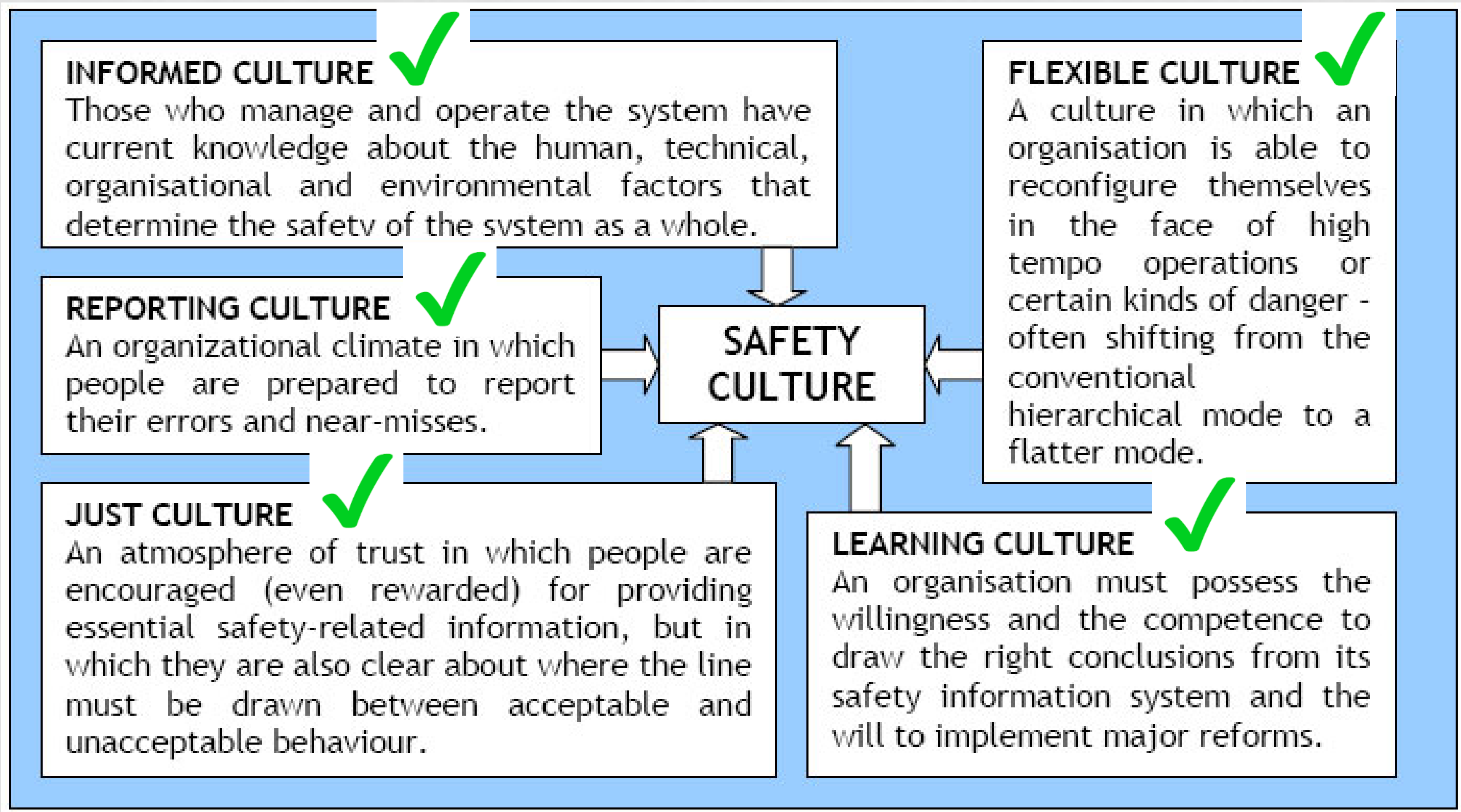


SAFETY CULTURE

"A patient safety culture is referred to as the employees' shared beliefs, values and attitudes regarding patient safety in an organization, which are reflected in the daily operational clinical practice"

Simons, P. A. M., Houben, R., Vlayen, A., Hellings, J., Pijls-Johannesma, M., Marneffe, W., & Vandijck, D. (2015). Does lean management improve patient safety culture? An extensive evaluation of safety culture in a radiotherapy institute. European Journal of Oncology Nursing. http://doi.org/10.1016/j.ejon.2014.08.001

SAFETY CULTURE



IMPORTANT POINTS TO REMEMBER

- ✓ There is a potential for accidents in radiotherapy
- ✓ Need for effective safety barriers
- ✓ Importance of a safety culture embedded within the organization/department

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The Genesis of an Accident

Tommy Knöös

Skåne University Hospital and Lund University

Sweden

Scott Jerome-Parks thought he was suffering from a nagging sinus infection. When he learned in early 2005 that a cancerous tumour had been growing on the back of his tongue, his doctors and family suspected a link with toxic dust formed in the collapse of the World Trade Center towers.

Mr. Jerome-Parks, a computer and systems analyst, had worked nearby and had volunteered at the site.

The New York Times

Mr. Scott Jerome-Parks with his wife, Carmen, on the day he received his diagnosis of tongue cancer. For his treatment, he chose St. Vincent's Hospital in Manhattan, which was promoting a new linear accelerator and a treatment called Intensity Modulated Radiation Therapy, which could more precisely shape and modulate the radiation beam. Treatment started March 8, 2005

Later his wife has mentioned that maybe they should have chosen the world known MSKCC, however, Jerome insisted on this new technology.

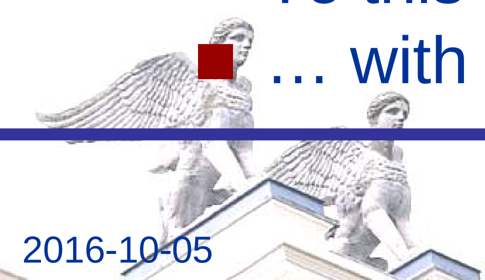
The New York Times

Radiotherapy process starts

- Tuesday - March 8, 2005
  - The patient begins an IMRT treatment at St Vincent's Hospital, Manhattan, NY.
  - The plan (1A Oropharyn) had passed the QC-process according to the local protocol
  - Verification images from the kV imaging system were checked (OBI)
  - The treatment is delivered correctly.
- Friday - March 11, 2005
  - The physician reviews the case after 4 treatments (either Friday or Monday morning)
    - Wants a modified dose distribution (Dr. Berson wanted the plan re-worked to give more protection to Mr. Jerome-Parks's teeth.)

Modified plan is created

- Monday - March 14, 2005
  - Tasked with carrying out Dr. Berson’s new plan was Ms. Nina Kalach, a medical physicist.
- On the morning of March 14, the medical physicist revised Mr. Jerome-Parks’s treatment plan using Varian software (Eclipse TPS).
    - Re-planning and re-optimization starts.
    - Fractionation is changed. Existing fluences are deleted and re-optimized. New optimal fluences are saved to database (DB).
  - Final calculations are started, where MLC motion control points for IMRT are generated.
- To this point – plan is fine (1B Oropharyn).
- … with the patient waiting in the wings…



Just occasionally???

- A few months before … New York State health officials reminded hospitals that I.M.R.T. required a “significant time commitment” on the part of their staffs.
- “Staffing levels should be evaluated carefully by each registrant,” the state warned, “to ensure that coverage is sufficient to prevent the occurrence of treatment errors and mis-administrations.”

Next step

- Shortly after 11 a.m., as Ms. Kalach was trying to save her work, the computer began seizing up, displaying an error message. *See next slide…*

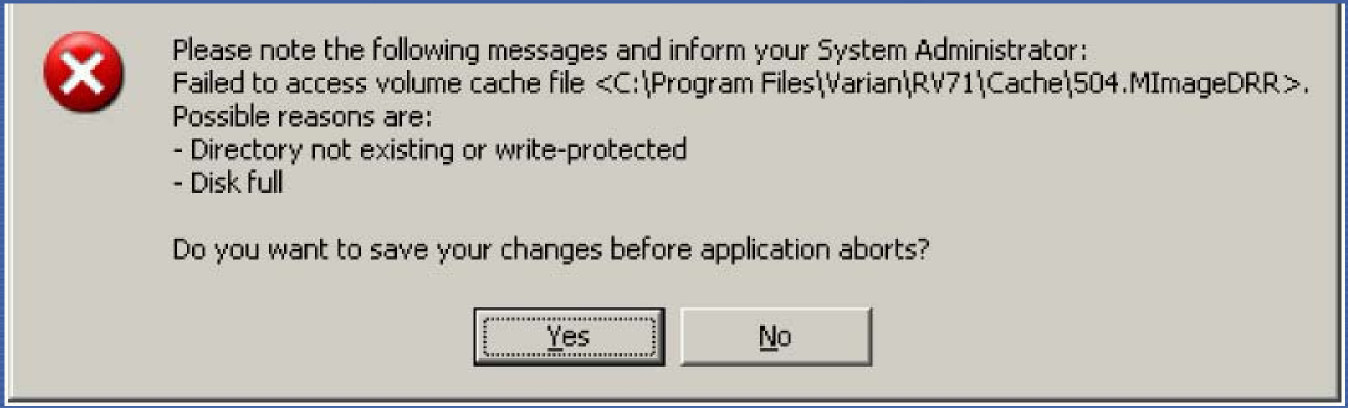
- The hospital would later say that similar system crashes "are not uncommon with the Varian software, and these issues have been communicated to Varian on numerous occasions."

Continue

- March 14, 2005, 11 a.m.
  - “Save all” is started. All new and modified data should be saved to the DB.
  - In this process, data is sent to a holding area on the server (cache), and not saved permanently until ALL data elements have been received.
  - In this case, data to be saved included: (1) actual fluence data, (2) a DRR and (3) the MLC control points
- The actual fluence data is saved normally.
  - Next in line is the DRR. The “Save all” process continues with this, but is not completed.
  - Saving of MLC control point data would be after the DRR, but will not start because of the above.

Continue

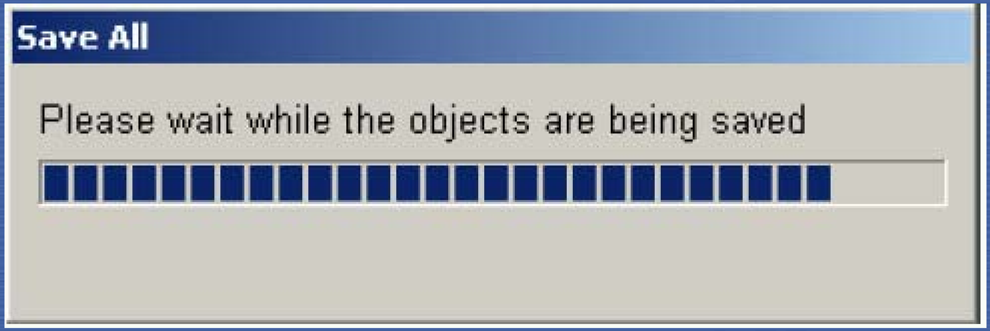
- March 14, 2005, 11 a.m.
  - An error message is displayed.
  - The user presses “Yes”, which begins a second, separate, save transaction.
  - MLC control point data is moved to the holding area.



The transaction error message displayed

Continue

- March 14, 2005, 11 a.m.
  - The DRR is, however, still locked into the faulty first attempt to save.
  - This means the second save won’t be able to complete.
  - The software would have appeared to be frozen.

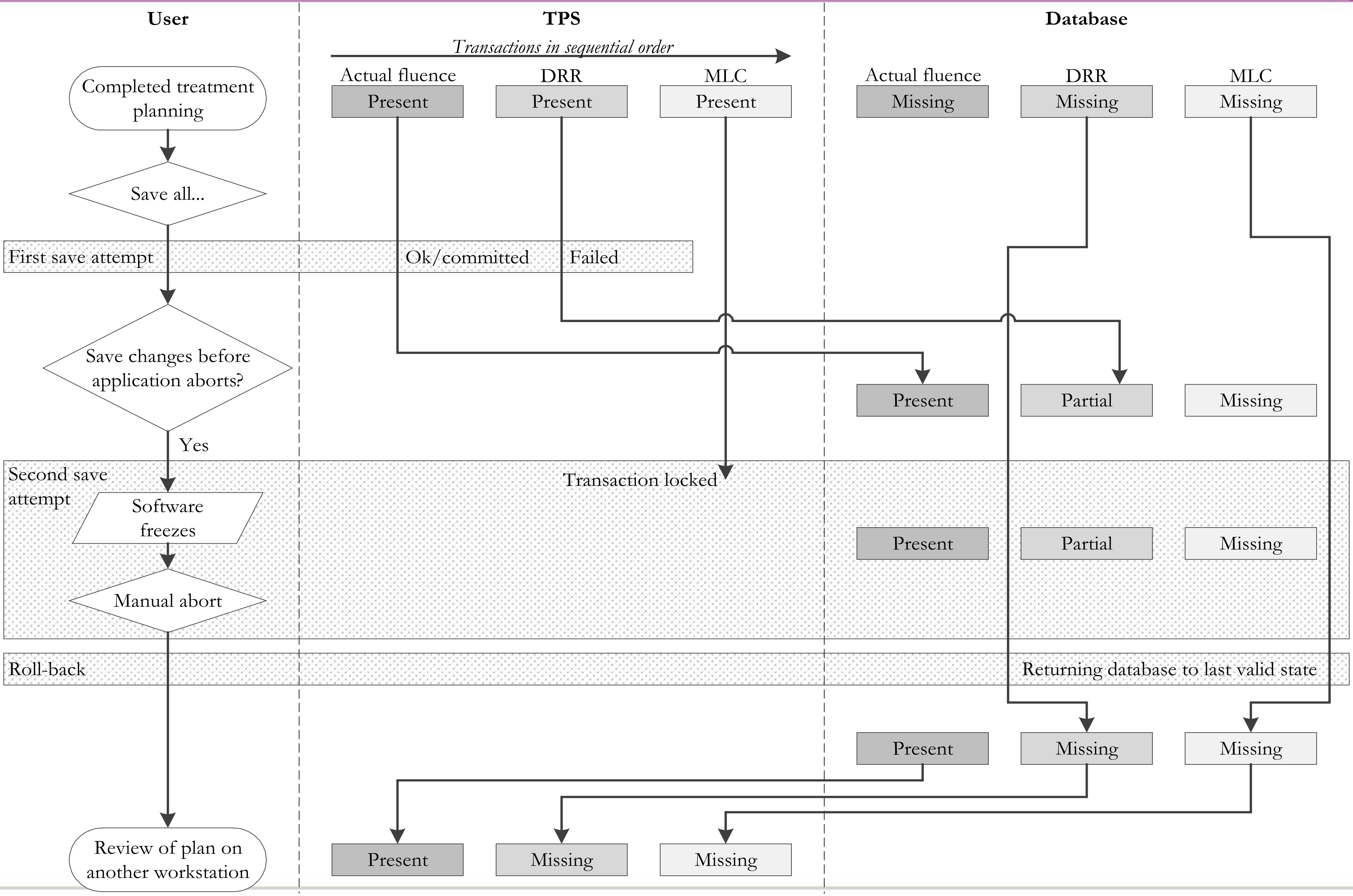


The frozen state of the second “Save All” progress indication

What happened?

- March 14, 2005, 11 a.m.
  - The user then terminated the TPS software manually, probably with Ctrl-Alt-Del or Windows Task Manager
  - At manual termination, the DB performs a "roll-back" to return the data in the holding area to its last known valid state
  - The treatment plan now contains (1) actual fluence data; (2) not the full DRR; (3) no MLC control point data

St. Vincent's Hospital, U.S.A. (2005)



Treatments continues with the altered/new plan

- Monday - March 14, 2005, 11 a.m.
  - No verification plan is generated or used - should be done according to local QA program
  - The plan is subsequently prepared for treatment (treatment scheduling, image scheduling, etc
- It is approved by a physician (Dr Berson) at 12:24 PM
- According to local QA program, a second physicist should then have reviewed the plan
  - Including an overview of the irradiated area outline
  - MLC shape
  - Etc

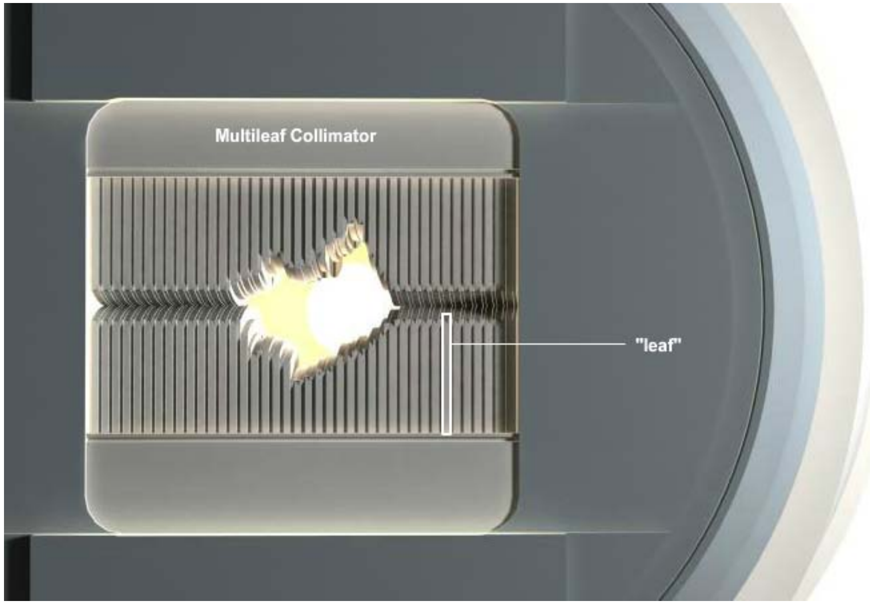
Treatment performed with the new plan

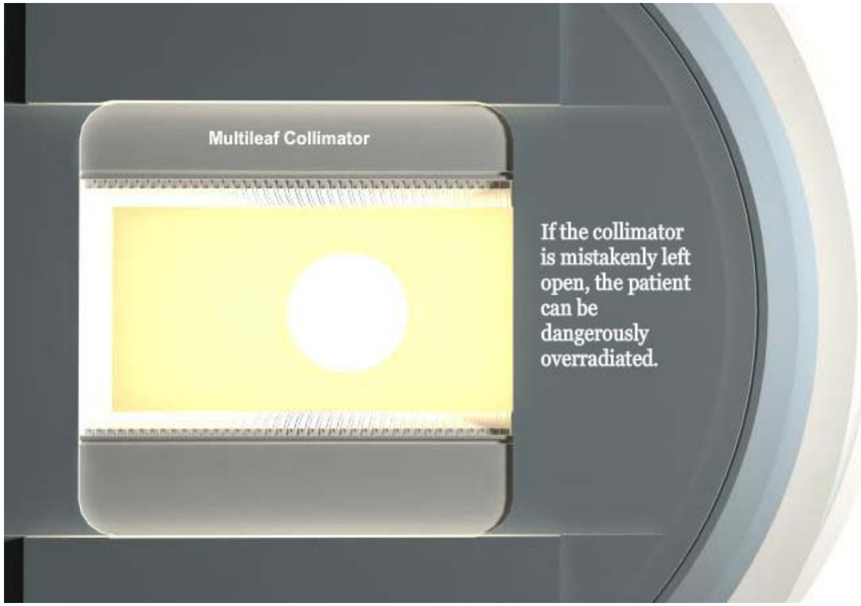
- Two therapists were preparing Mr. Jerome-Parks for his procedure, placing a moulded mask over his face to immobilize his head.
- At 12:57 p.m. — six minutes after yet another computer crash — the first of several Tx were given

According to Mr Parks Sr the staff were worried about the patient's nausea and were concentrated on the video monitors(!)

Discovery

- **Tuesday to Wednesday - March 15-16, 2005**
  - The patient is treated an additional two fractions
- **Wednesday - March 16, at 6:29 p.m** a **verification plan** is created and run on the treatment machine.
  - What she saw was horrifying: the multileaf collimator (MLC), which was supposed to focus the beam precisely on his tumour, was wide open.
  - A little more than a half-hour later, she tried again. Same result.
  - Finally, at 8:15 p.m., The medical physicist ran a third test. It was consistent with the first two.
- A frightful mistake had been made: the patient's entire neck, from the base of his skull to his larynx, had been exposed.
- The patient received 13 Gy per fraction for three fractions, i.e. 39 Gy in 3 fractions



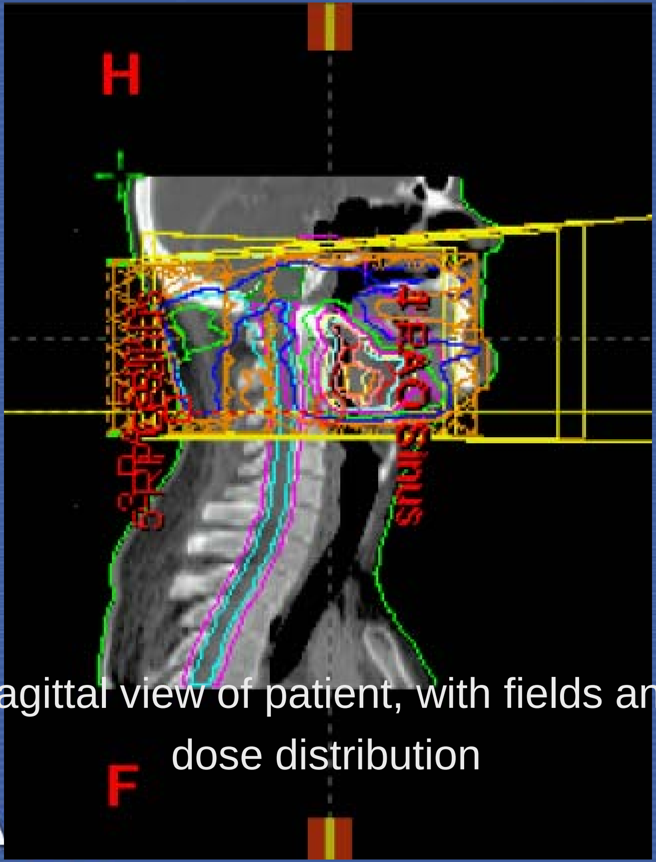


EXPLANATION OF THE ERRONEOUS DOSE

Graphics from NYT

What happened?

- March 14, 2005, 11.a.m.
  - Within 12 s, another workstation, WS1, is used to open the patients plan. The planner **would** have seen this:

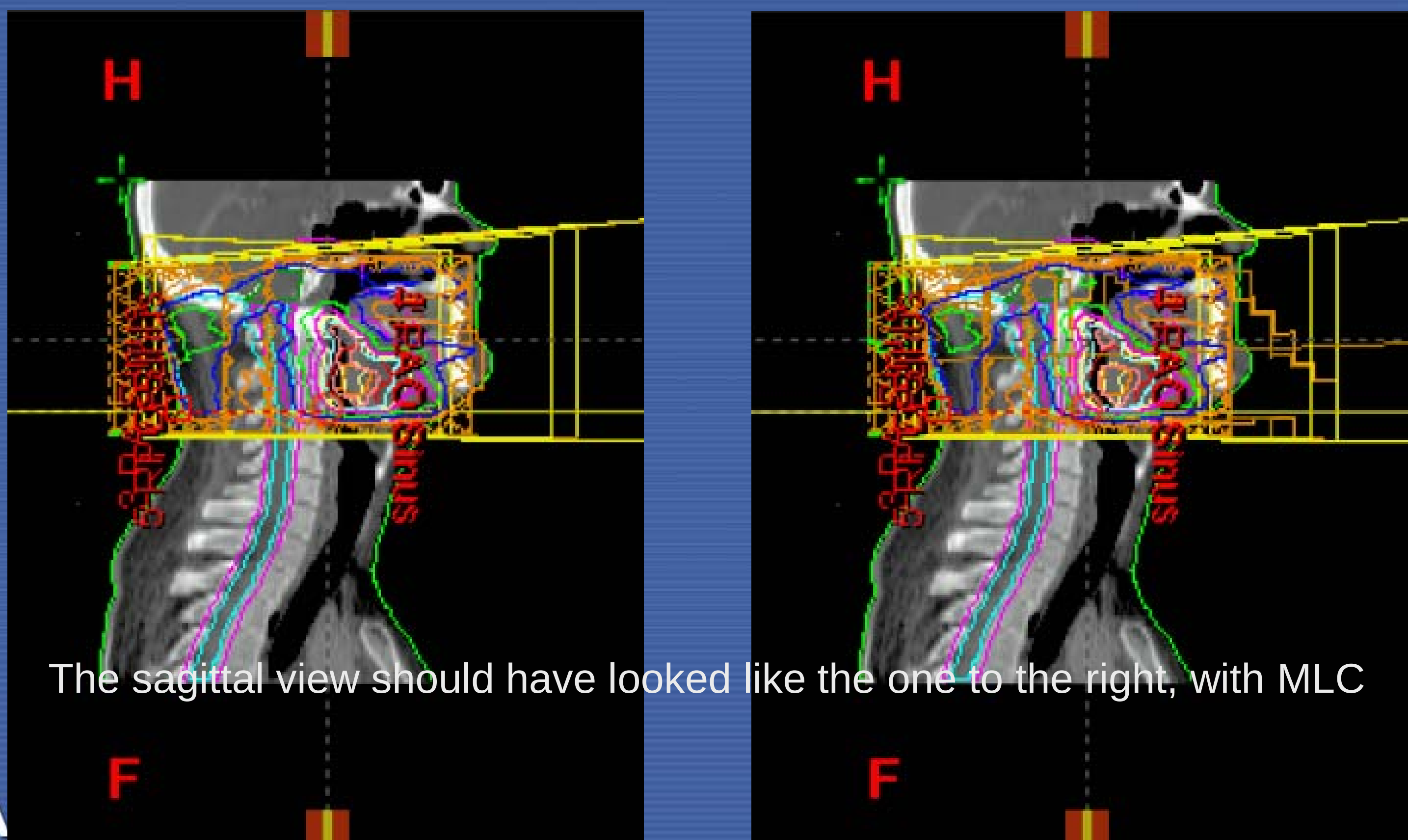


Sagittal view of patient, with fields and dose distribution

Valid fluences were already saved. Calculation of dose distribution is now done by the planner and saved. MLC control point data is not required for calculation of dose distribution.

What happened?

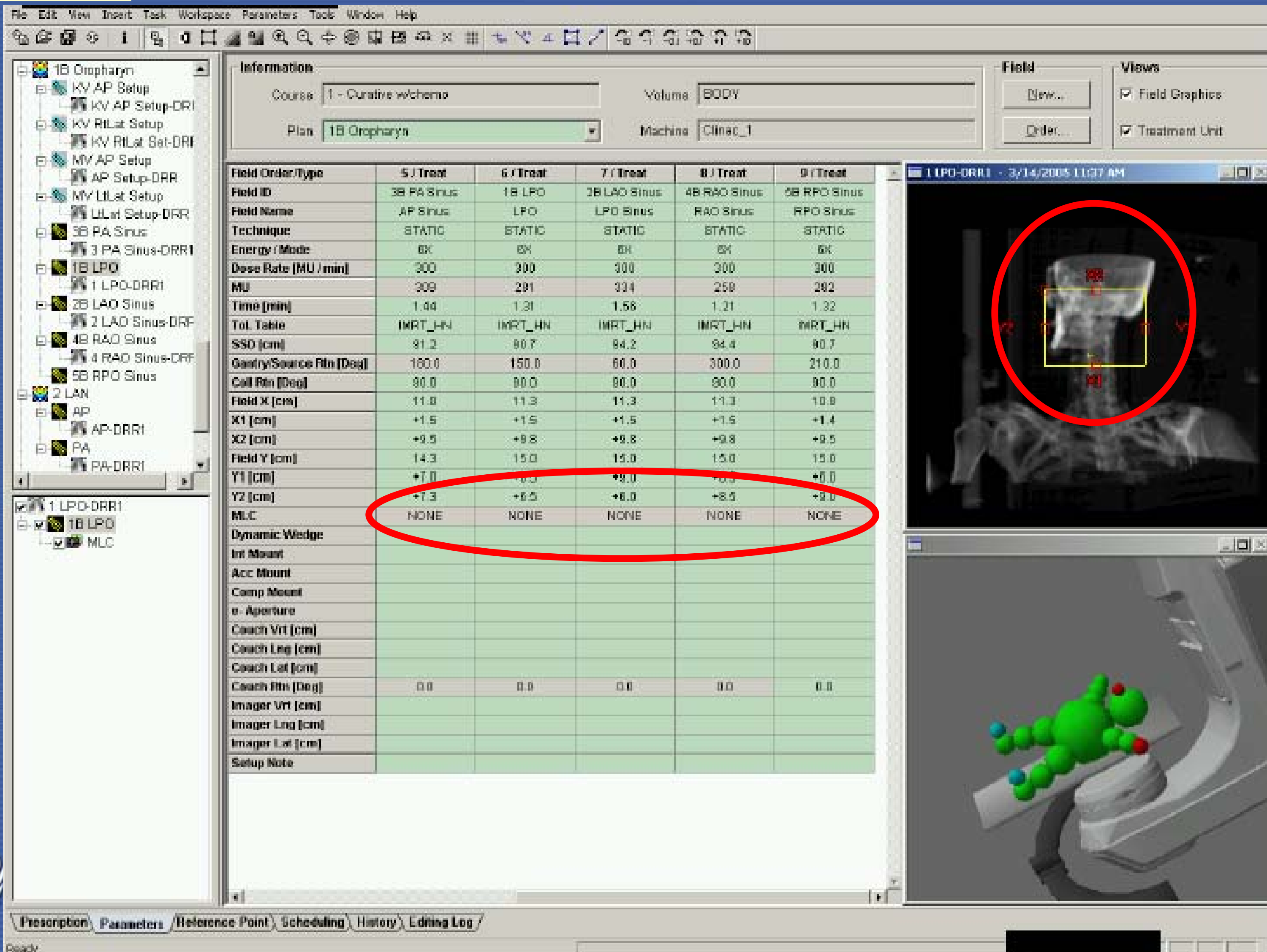
- March 14, 2005, 11.a.m.
  - Within 12 s, another workstation, WS1, is used to open the patients plan. The planner **should** have seen this:



The sagittal view should have looked like the one to the right, with MLC

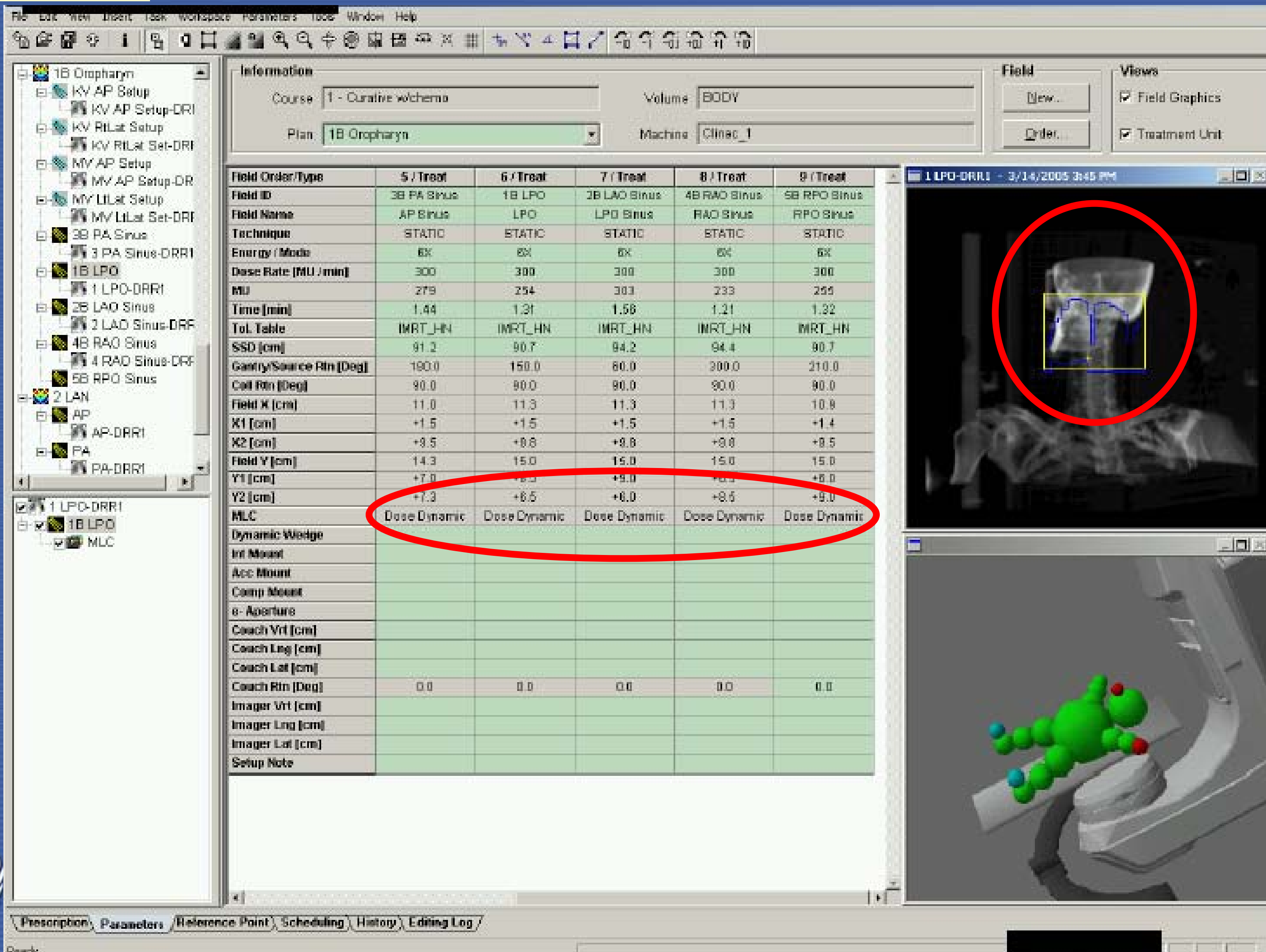
What happened?

- <u>Would</u> have been seen on verification:



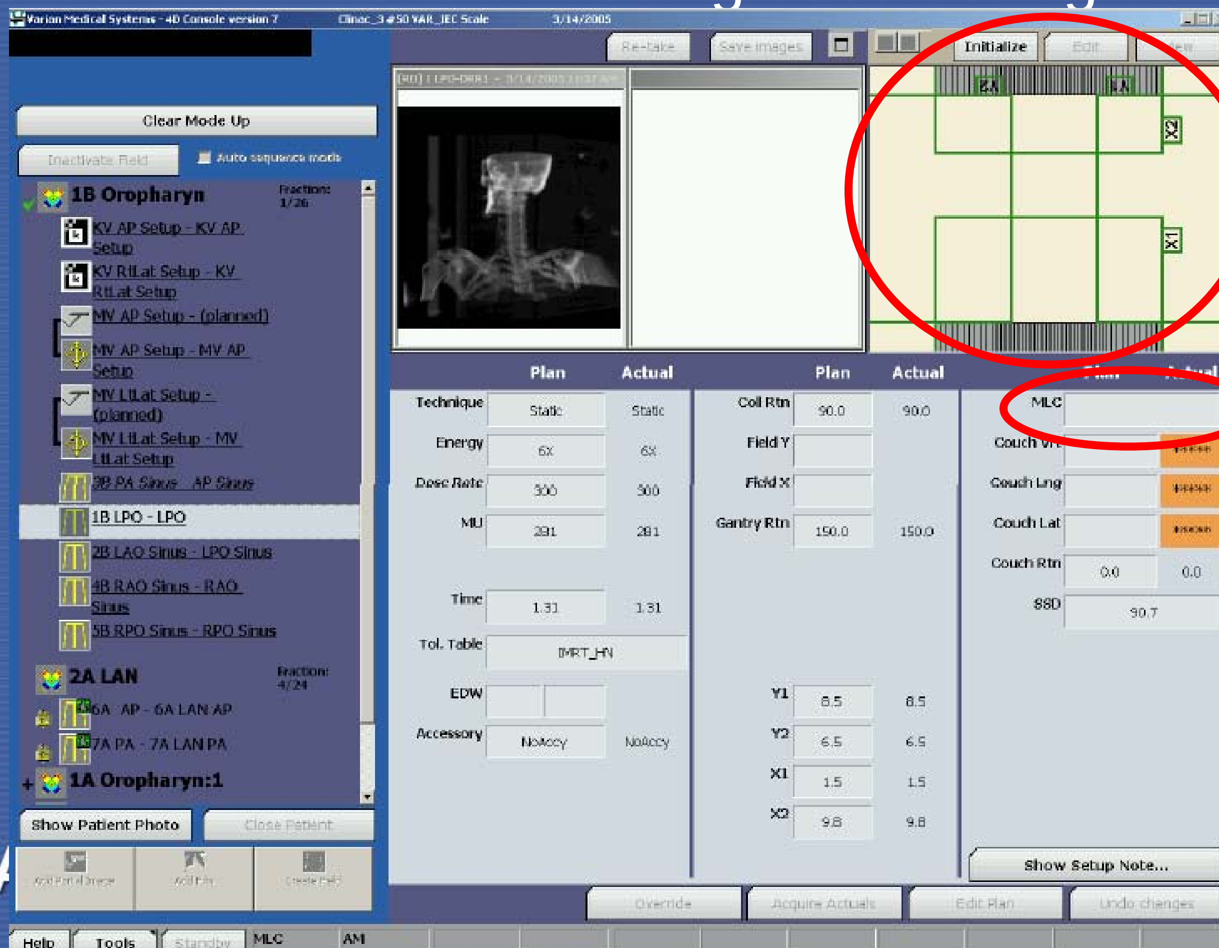
What happened?

- Should have been seen on verification:



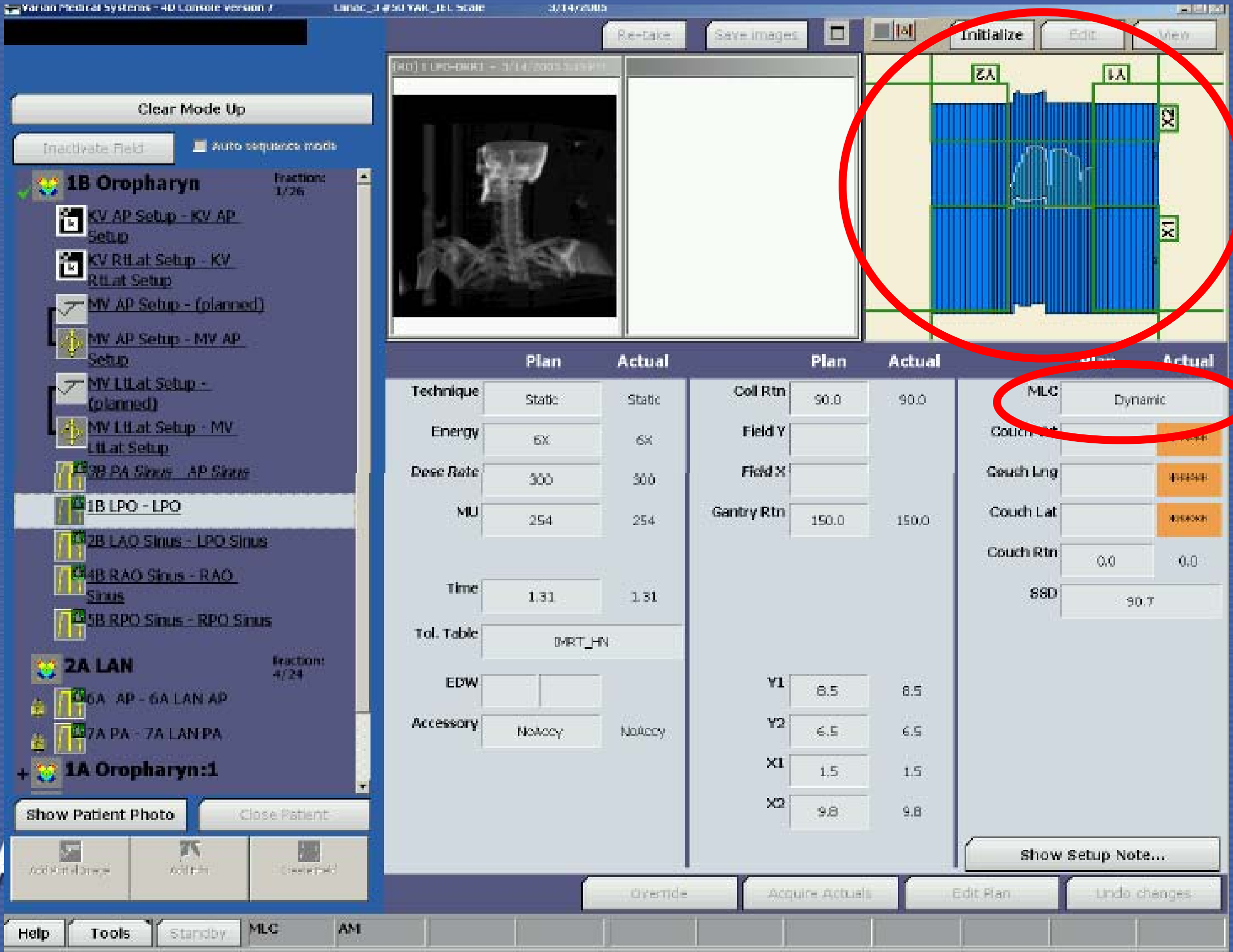
What happened?

- March 14, 2005, 1 p.m.
  - The patient is treated. The console screen <u>would</u> have indicated that MLC is not being used during treatment:



What happened?

- March 14, 2005, 1 p.m.
  - Should have seen this on the display:



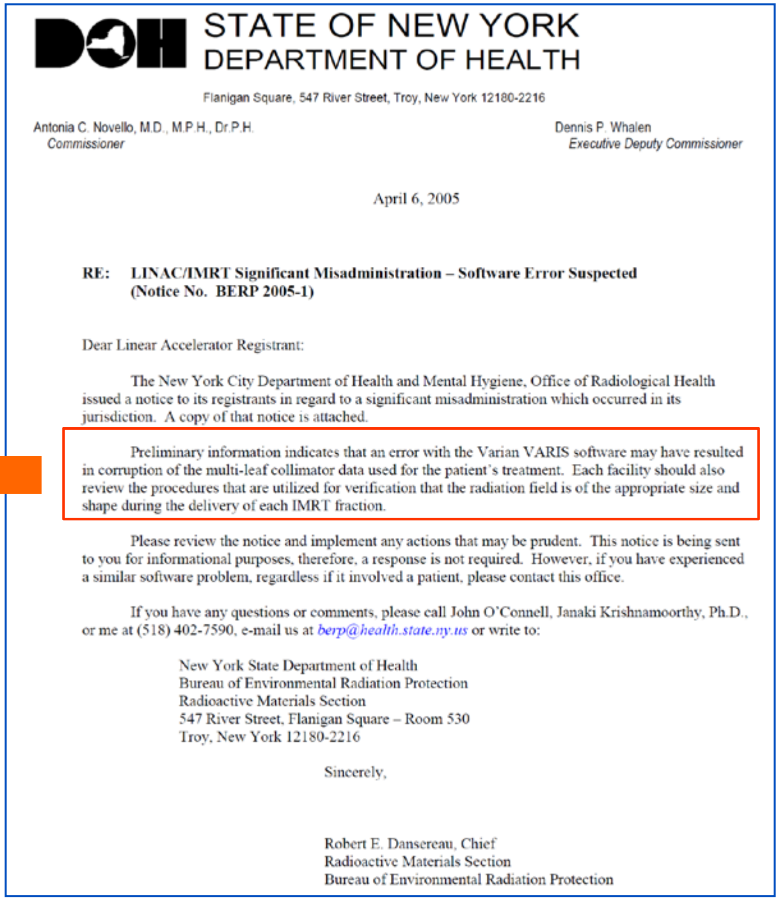
IAEA

Patient informed

- Early the next afternoon, as Mr. Jerome-Parks and his wife were waiting with friends for his fourth modified treatment,
- Dr. Berson unexpectedly appeared in the hospital room.
- There was something he had to tell them.
- For privacy, he took Mr. Jerome-Parks and his wife to a lounge on the 16th floor, where he explained that there would be no more radiation.
- Mr. Jerome-Parks had been seriously overdosed, they were told, and because of the mistake, his prognosis was dreadful.

From the files of DOH - NYC

Preliminary information indicates that an error with the Varian VARIS software may have resulted in corruption of the multi-leaf collimator data used for the patient's treatment. Each facility should also review the procedures that are utilized for verification that the radiation field is of the appropriate size and shape during the delivery of each IMRT fraction.


STATE OF NEW YORK
DEPARTMENT OF HEALTH

Flanigan Square, 547 River Street, Troy, New York 12180-2216

Antonia C. Novello, M.D., M.P.H., Dr.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

April 6, 2005

RE: LINAC/IMRT Significant Misadministration – Software Error Suspected (Notice No. BERP 2005-1)

Dear Linear Accelerator Registrant:

The New York City Department of Health and Mental Hygiene, Office of Radiological Health issued a notice to its registrants in regard to a significant misadministration which occurred in its jurisdiction. A copy of that notice is attached.

Preliminary information indicates that an error with the Varian VARIS software may have resulted in corruption of the multi-leaf collimator data used for the patient's treatment. Each facility should also review the procedures that are utilized for verification that the radiation field is of the appropriate size and shape during the delivery of each IMRT fraction.

Please review the notice and implement any actions that may be prudent. This notice is being sent to you for informational purposes, therefore, a response is not required. However, if you have experienced a similar software problem, regardless if it involved a patient, please contact this office.

If you have any questions or comments, please call John O'Connell, Janaki Krishnamoorthy, Ph.D., or me at (518) 402-7590, e-mail us at *berp@health.state.ny.us* or write to:

New York State Department of Health
Bureau of Environmental Radiation Protection
Radioactive Materials Section
547 River Street, Flanigan Square – Room 530
Troy, New York 12180-2216

Sincerely,

Robert E. Dansereau, Chief
Radioactive Materials Section
Bureau of Environmental Radiation Protection

DOH files cont… 25 March 2005

NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE
OFFICE OF RADIOLOGICAL HEALTH
2 LAFAYETTE ST, 11TH FLOOR
NEW YORK, NY 10007

March 25, 2005

ORH INFORMATION …

Addressees

All Holders of Therap…

Purpose

We are issuing this In… radiation LINAC units of a sig… the Varian VARIS oncology infor… estigation by Varian, but the circumstances of the … serious enough to warrant early notification. All Users of Varian treatment systems must be alert to the existence of a system flaw with the potential of leading to a very high overdose.

All Users of Varian treatment system must alert to the existence of a system flaw with the potential of leading to a very high overdose.

Description of Circumstances

On March 14, 15 and 16, 2005, a patient received fractionated treatments for base of the tongue cancer. Normal review protocols were followed. The Prescribed dose per fraction was 2 Gray, using a 5-field IMRT technique. A revised treatment plan was developed by a physicist and approved by a physician to reduce dose to the teeth. Analysis revealed that the dynamic multileaf collimators were wrongly in the open position during the three treatments. A dose calculation revealed that the patient received three fractionated treatments in the range of 13-14 Gy per treatment to a volume between the base of the skull and the larynx. Total dose received w… approximately 39-42 Gy.

Preliminary information in… re error resulted in corruption of the MLC data used for this patient… are shown co… Treatmen… was not. …

Varian n… Report to…

A dose calculation revealed that the patient received three fractionated treatments in the range of 13-14 Gy per treatment to a volumes between the base of the skull and the larynx. Total dose received was approximately 39-42 Gy.

Page 3 of 2

March 25, 2005

ORH INFORMATION NOTICE 2005-01 (cont'd)

Effects of Misadministration

The report of misadministration lists possible sequelae in 2 phases. These include a number of serious effects, although the report does not predict the likelihood or severity of each of the possible problems.

Action

Although treatment plans are entered which should cause multileaf collimators to be in place, the VARIS system may not properly actuate collimators. This has resulted in a serious radiation overexposure. All Users of Varian treatment systems utilizing the multifield IMRT technique must be aware of this defect with the multileaf collimators, and must be certain that their systems are not affected by this problem before scheduling further treatments.

All Users of Varian treatment system utilizing the multifield IMRT technique must be aware of this defect…

Page 2 of 2

DOH files cont .. 19 April 2005

STATE OF NEW YORK
DEPARTMENT OF HEALTH

Flanigan Square, 547 River Street, Troy, New York 12180-2216

Antonia C. Novello, M.D., M.P.H., Dr.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

April 19, 2005

RE: UPDATE: LINAC/IMRT Significant Misadministration – Software Error Suspected (Notice No. BERP 2005-2)

Dear Linear Accelerator Registrant:

On April 6, 2005, a Notice (BERP 2005-1) was sent to you with regard to a significant misadministration that occurred during the delivery of an IMRT treatment. The Notice indicated that an error might have occurred in the Varian VARIS software which resulted in corruption of the data used to control a multi-leaf collimator. The purpose of this notice is to provide updated information.

Varian Medical Systems representatives, including engineering, service, applications, education and quality personnel, conducted an investigation. Varian concluded that the Varian software performed as expected and was not the cause of this misadministration. Copies of Varian's summary analysis and open letter dated April 4, 2005 are enclosed. A complete analysis is available from Varian Medical Systems and can be obtained by contacting Kolleen T. Kennedy, Vice President, Oncology Division at (650) 424-6235 or e-mail at *kolleen.kennedy@us.varian.com*.

This event, along with others that have occurred, mandates that we remind facilities of the absolute necessity to verify that the radiation field is of the appropriate size and shape prior to the patient's first treatment. Facilities are also reminded of the need to perform a second check of the treatment plan, calculations, and/or data input into a Record and Verify System before treatment begins, and therapists must closely monitor the console/ visual indicators during treatment.

Please review the Notice, and implement any actions that may be prudent. This Notice is being sent to you for informational purposes, therefore, a response is not required.

Varian software performed as expected and was not the cause of this misadministration.

…therapists must closely monitor the console/visual indicators during treatment.

- 2 -

If you have any questions or comments, please call John O'Connell, Janaki Krishnamoorthy, Ph.D., or me at (518) 402-7590, e-mail us at *berp@health.state.ny.us* or write to:

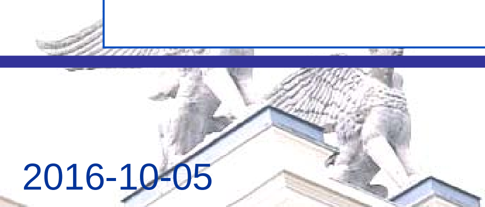
New York State Department of Health
Bureau of Environmental Radiation Protection
Radioactive Materials Section
547 River Street, Flanigan Square – Room 530
Troy, New York 12180-2216

Sincerely,

Robert E. Dansereau, Chief
Radioactive Materials Section
Bureau of Environmental Radiation Protection

RD/JO:ks

Attachments



Varian's Response

- Three page long letter
- Addressed as

An Open Letter to Our Customers

- Includes a lot of references to their manuals
- NOT a WORD referring to what went wrong at St Vincents???

Excerpt from a Varian letter to all customers

Dow R. Wilson
PRESIDENT, ONCOLOGY SYSTEMS

VARIAN medical systems

August 3, 2005

> So, as one example, if a save process were to appear to freeze and you were to press Ctrl+Alt+Delete then Shutdown to end the computer session or use Task Manager to end the program, then you must verify that all plan data were saved fully and correctly before using that plan to treat a patient (*not just the data entered immediately prior to starting the save*).

Lessons to learn

- Do what you should be doing according to your QA program – do not override barriers
  - The error could have been found through verification plan (normal QA procedure at the facility) or independent review or…
- Be alert when computer crashes or freezes, when the data worked on is safety critical
- Work with awareness at treatment unit, and keep an eye out for unexpected behaviour of machine

Sensing that death was near, Mr. Scott Jerome-Parks and his wife summoned his family for a final Christmas together.

Friends sent buckets of sand from the beach in Gulfport, Miss., where they had played together, so that he could sink his feet in it and remember happy times. Two month later in Febr. 2007 he died from his injuries.

The New York Times

It was important to Scott Jerome-Parks that his fatal radiation overdose be studied and talked about publicly, so that others could learn from his misfortune. He died in February 2007. He was 43 years old.

The New York Times

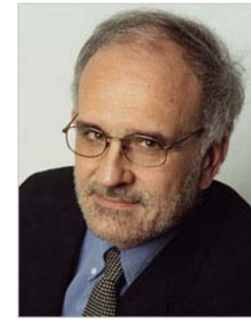
T Knöös

ESTRO School

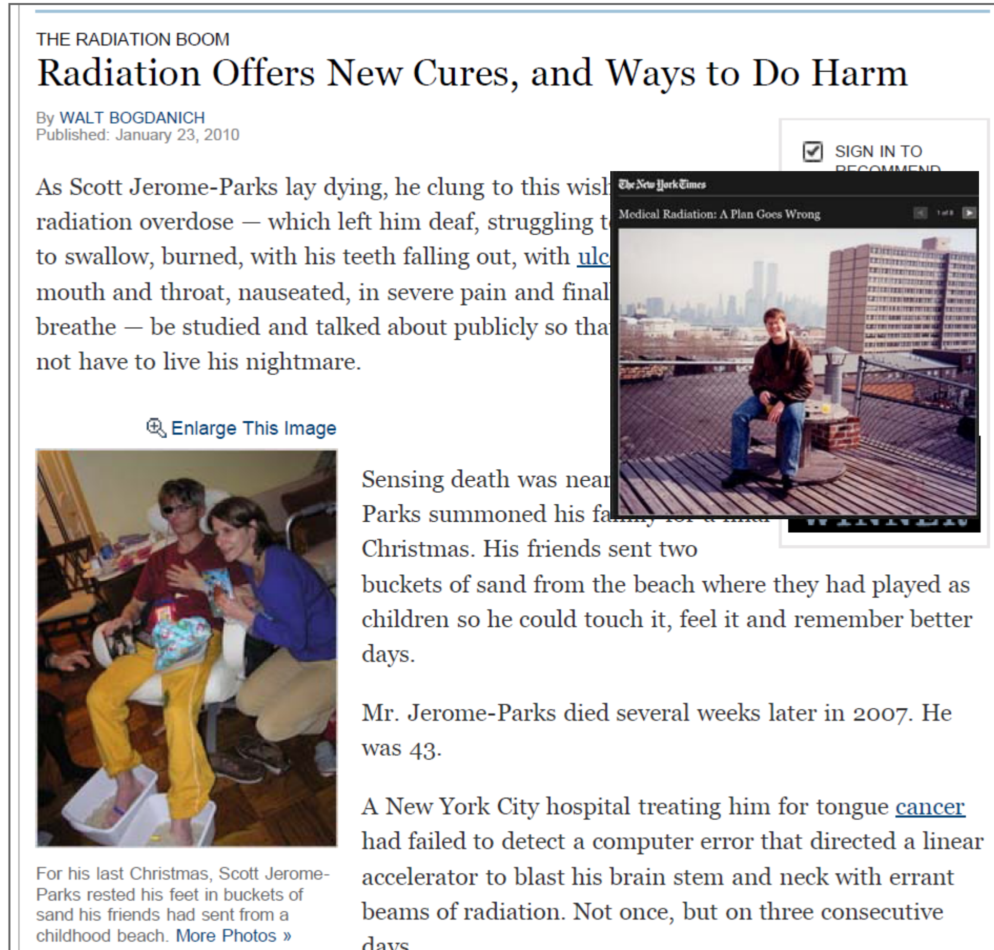
Questions

- Why does not Varian inform us more detailed?
- How about the DOH/NY?
- How about our colleagues/professionals?
- Did we lack awareness of risks?
- Punishments?

The New York Times Jan 2010



- Several articles in NYT early 2010
- Lot's of fuss in the community
- Hearing in US
- Meetings etc…



THE RADIATION BOOM

Radiation Offers New Cures, and Ways to Do Harm

By WALT BOGDANICH
Published: January 23, 2010

SIGN IN TO RECOMMEND

As Scott Jerome-Parks lay dying, he clung to this wish radiation overdose — which left him deaf, struggling to swallow, burned, with his teeth falling out, with ulc mouth and throat, nauseated, in severe pain and final breathe — be studied and talked about publicly so tha not have to live his nightmare.

Enlarge This Image

For his last Christmas, Scott Jerome-Parks rested his feet in buckets of sand his friends had sent from a childhood beach. More Photos »

Sensing death was near Parks summoned his fa Christmas. His friends sent two buckets of sand from the beach where they had played as children so he could touch it, feel it and remember better days.

Mr. Jerome-Parks died several weeks later in 2007. He was 43.

A New York City hospital treating him for tongue cancer had failed to detect a computer error that directed a linear accelerator to blast his brain stem and neck with errant beams of radiation. Not once, but on three consecutive days.

Energy and Commerce - Subcommittee on Health held a hearing entitled "Medical Radiation: An Overview of the Issues" on Friday, February 26, 2010

Panel I
Mr. James Parks
Dr. Rebecca Smith-Bindman M.D.
Mr. Eric E. Klein Ph.D.
Ms. Cynthia H. McCollough Ph.D.
Ms. Suzanne Lindley

Panel II
Mr. Michael G. Herman Ph.D.
Ms. Sandra Hayden B.S.
Dr. E. Stephan Amis Jr.
Dr. Tim Williams
Mr. David N. Fisher
Mr. Kenneth Mizrach

Chairman Mr Pallone, NJ

Available at: http://www.youtube.com/watch?v=NcqRgVqeQSg

http://www.youtube.com/watch?v=L_IzTqhghMs

Mr Park's Testimony Pt 1

References

- [Treatment Facility] Incident Evaluation Summary, CP-2005-049 VMS. 1-12 (2005)
- ORH Information Notice 2005-01. Office of Radiological Health, NYC Department of Health and Mental Hygien (2005)
- New York Times series of articles by Walt Bogdanich 2010

Thanks for listening

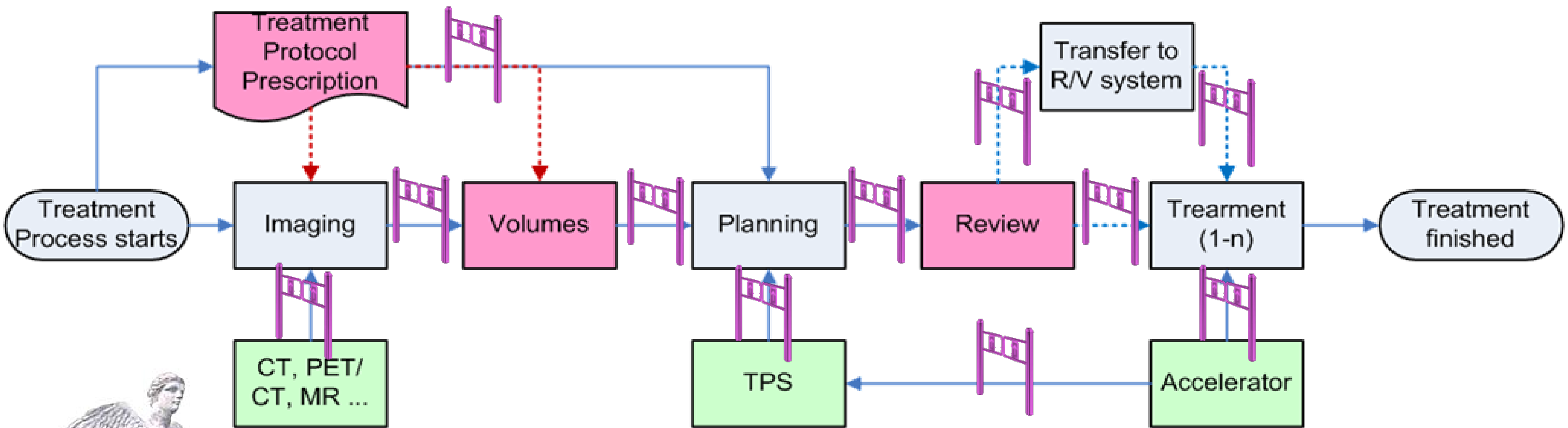
- Poland 2001, interlock failure linac
- Spain 1990, wrong repair linac
- Panama 2000, TPS
- US 2007, reversal of images
- France 2006, wrong detector choice
- France 2004, Dynamic wedges
- France 2007, repeated MV imaging
- France 2007, error in inhouse TPS
- Denmark, 2001, miscalibration linac
- Australia, 2005 miscalibration linac
- US, 2005 miscalibration SRT(not much known)
- Canada, 2008 miscalibration ortovoltage
- US, 2009 miscalibration of SRT
- US, 2010, seeds mispositioned
- US, 2010 missing wedge filter

And...

Picture taken from One World Trade Center

Next session

- Five groups
- Discuss barriers in the process
  - Which failed or not?
  - Missing barriers?



The New York Times

Sunday, January 24, 2010

The Radiation Boom
Radiation Offers New Cures, and Ways to Do Harm

Scott Jerome-Parks

- MD requests tweak of plan to spare teeth
- Data transfer software crashes; allows corrupted data to be sent to machine
  - But gave a warning and allowed a choice
- Physicist made the wrong choice
  - No QA checks were done
- Times article : rush to treat
  - Therapists inattention
- Patient received 13 Gy/fx; 3 fx; in 3 days
  - Patient was in agony after first Tx. Nurses and physicians ignored this symptom

2012 | State of the Art Techniques
in IMRT, IGRT, SBRT, PROTON and BRACHYTHERAPY: *Emphasis on Quality and Safety*
ASTRO

IHE-RO Solution

Automation of quality assurance (AQuA) in radiation oncology process.

- Allow treatment unit to verify plan parameters against the plan stored in treatment planning system immediately prior to treatment.
- Allow treatment management system to verify and store QA measurements acquired from IMRT QA.
- Automating the acquisition and storage of independent MU checks (dose *versus* MU) during RT plan transfer from TPS to management system and delivery system.

2012 | **State of the Art Techniques**
in IMRT, IGRT, SBRT, PROTON and BRACHYTHERAPY: *Emphasis on Quality and Safety*
ASTRO

Do Accidents Still Happens?

- Have we learnt from history?
- Are the machines/systems fool-proof today?
- Have we implemented defence in depth i.e. errors are trapped before they reach the patient?
- Are we well educated and trained and never making any mistakes?

Aftermath

- St. Vincent's Hospital closed in 2010
  - No one knows if it is due to the articles in NYT
  - Sold to be replaced by a luxurious apartment complex…

WHY REPORTING INCIDENTS ?

ESTRO – AVIGNON OCT 1-4TH, 2016

QUALITY & SAFETY MANAGEMENT

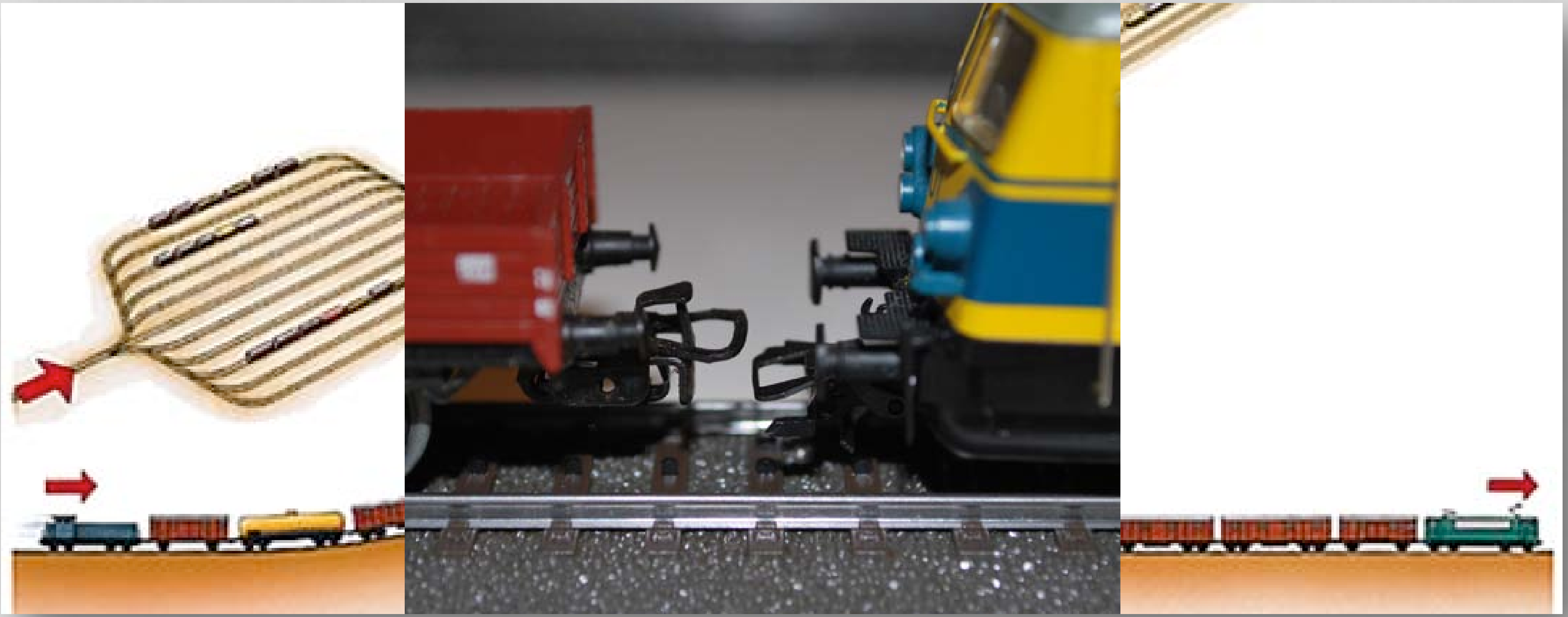
- Primary prevention
  - TQM
- Secondary prevention
  - Incident registration and analysis.
  - Return on experience (REX)
- Accident management
  - Attitude toward patient(s)
  - Attitude toward organisation
  - Attitude toward media/authorities/regulatory

HEINRICH TRIANGLE

1931
HW Heinrich

HEINRICH INVESTIGATION

- Heinrich was asked by the railway managers to investigate on the too frequent injuries (or event death) of railway workers observed on the yards where trains were being assembled.



HEINRICH INVESTIGATION

- Usually it is not too bad.
- Sometimes it is severe.
- Rarely it is lethal.

HEINRICH INVESTIGATION

1. Procedures are clear.
2. Procedures are not enforced.
3. Violations are frequent.
4. With time, violations become the rule.
5. Workers are killed despite clear and sound rules.

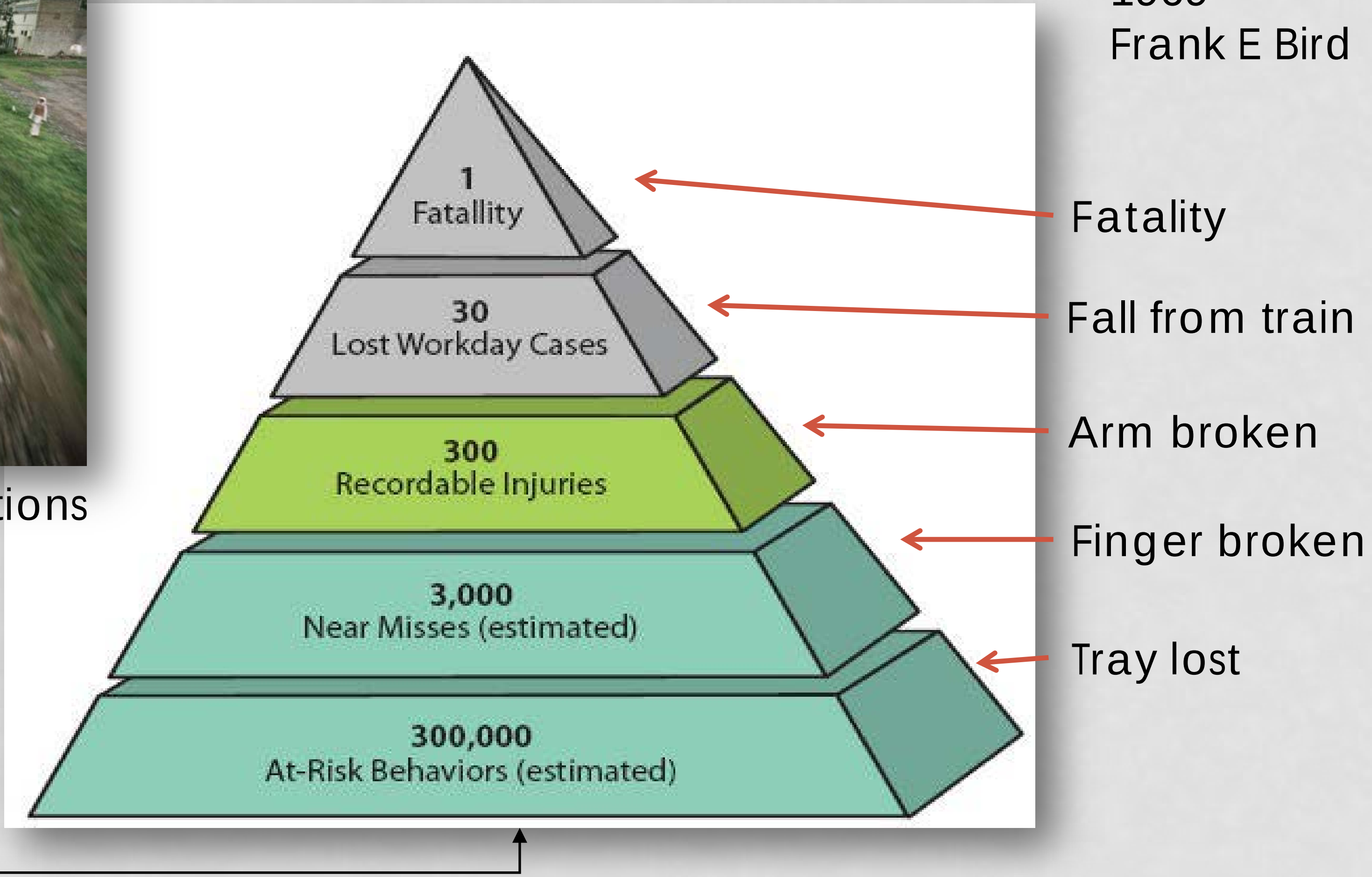
VIOLATION

- This is clearly dangerous.
- This is frequently done.
- This is strictly forbidden.

HEINRICH TRIANGLE

Role of violations

1969
Frank E Bird



CAUSES ?

- Repetitive tasks.
- Boring job.
- Inadequate working condition.
- Insufficient staff.
- Long shifts.
- Lack of supervision.
- Etc…

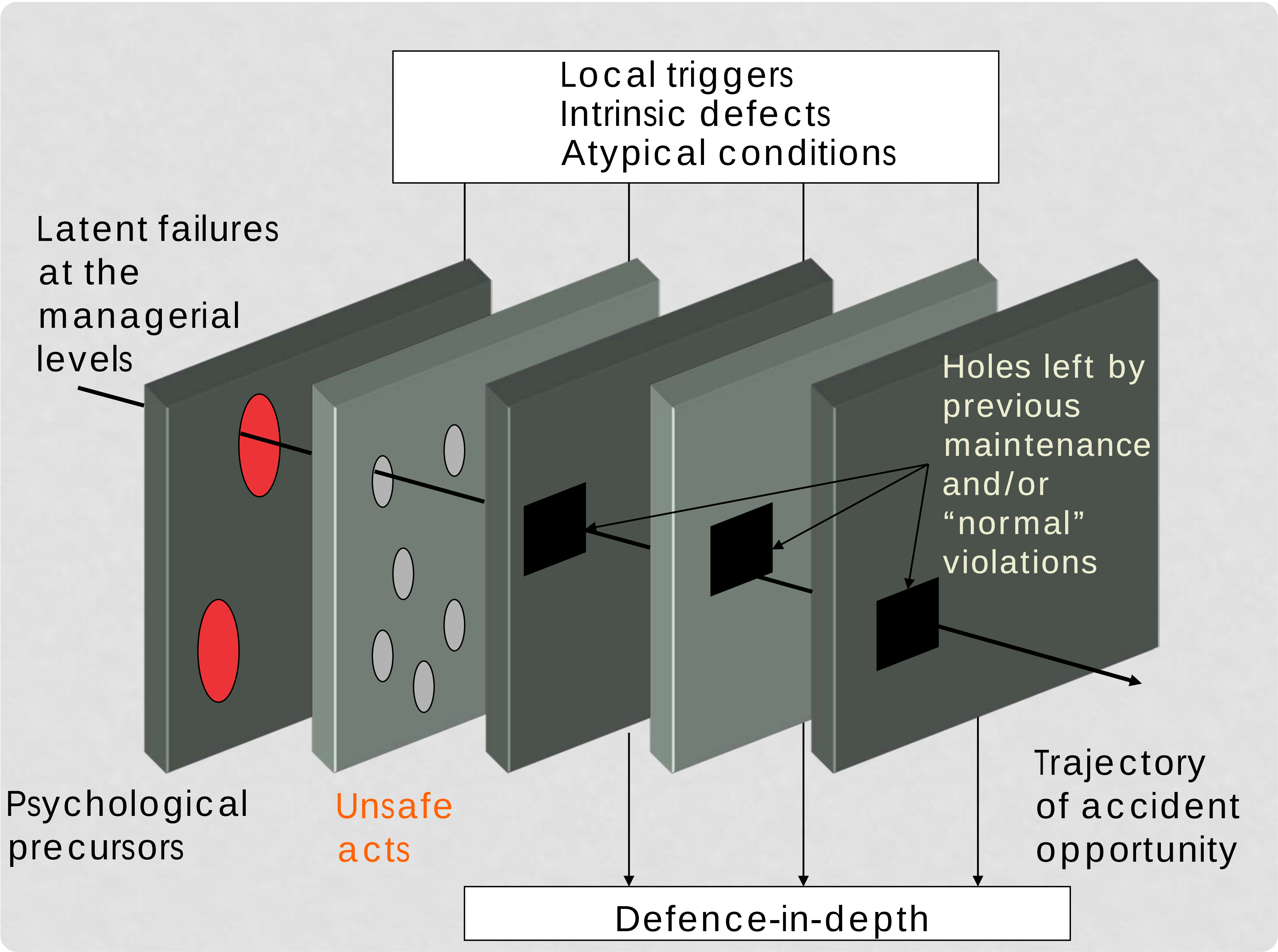




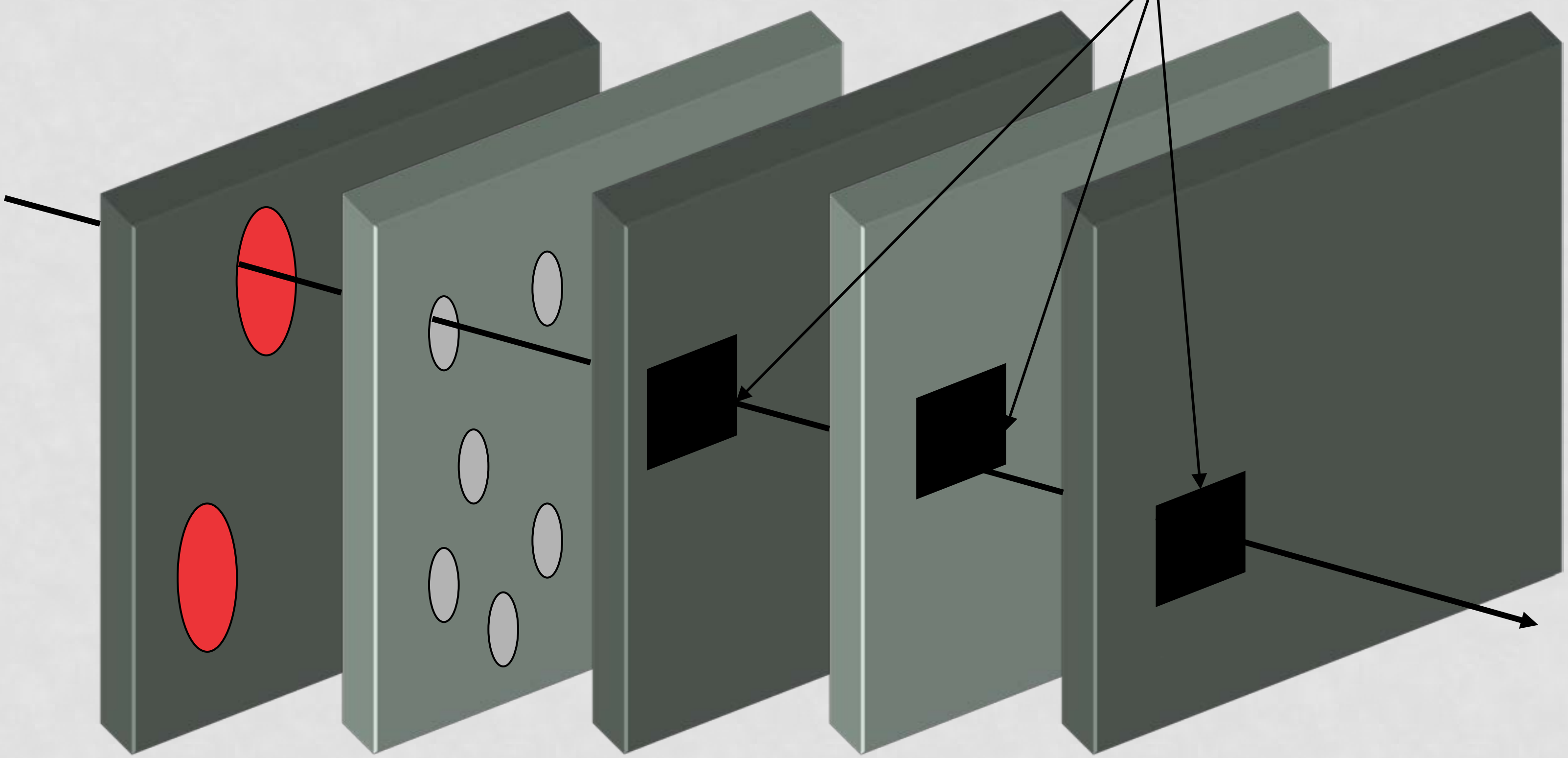
ONE EXAMPLE (BRINDISI)

- Distraction frequent at the linac command station (*) (7 h/d of a highly repetitive activity).
- 3 RTT per linac
- Work divided in 3 tasks:
  - Patient positioning
  - Data programmation
  - Treatment check-list
- Rotation every 60 minutes

(*) Human Factor Analysis and Classification System HFACS


Local triggers
Intrinsic defects
Atypical conditions
Latent failures at the managerial levels
Holes left by previous maintenance and/or “normal” violations
Psychological precursors
Unsafe acts
Trajectory of accident opportunity
Defence-in-depth

The existence of “holes” is revealed by incidents. Whenever an incident occurs, it “teaches” something about the overall safety level of the system.



Incidents are “free lessons”,
learn from them and patch holes

This is not an option...

VIOLATIONS

- Romans said that a law that is not widely accepted is probably a bad law.
- A procedure frequently violated, is it a bad procedure?

EDUCATION AND TRAINING

- Operators that do not have a deep understanding of the consequence of their actions are unlikely to understand the benefit of strict procedures.
- Education, education, education…
- Training, training, training…
- AND review procedures with operators…
- AND supervision!

INCIDENT REPORTING

AUDE VAANDERING (RTT/QM)

ESTRO – Avignon October 1st – 4th

LEARNING OBJECTIVES

- ✓Definition of an incident reporting and learning system (IRLS)
- ✓The workflow of an incident reporting and learning system
- ✓The prerequisites of an IRLS
- ✓The types of IRSL - *SAFRON and ROSIS as examples*

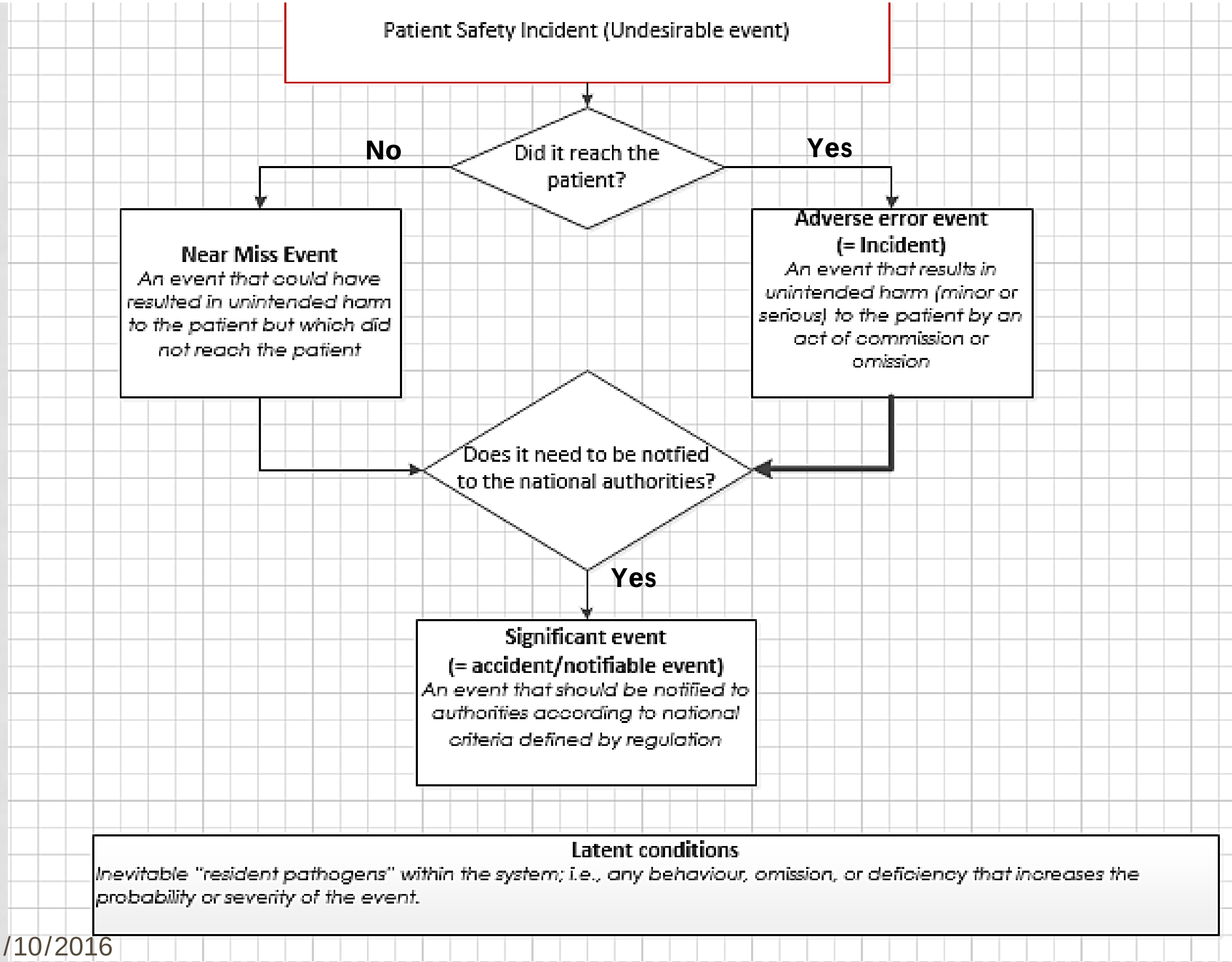
INCIDENT REPORTING SYSTEMS

« Mistakes are a fact of life. It's the response to the error that counts »

- Nikki Giovanni

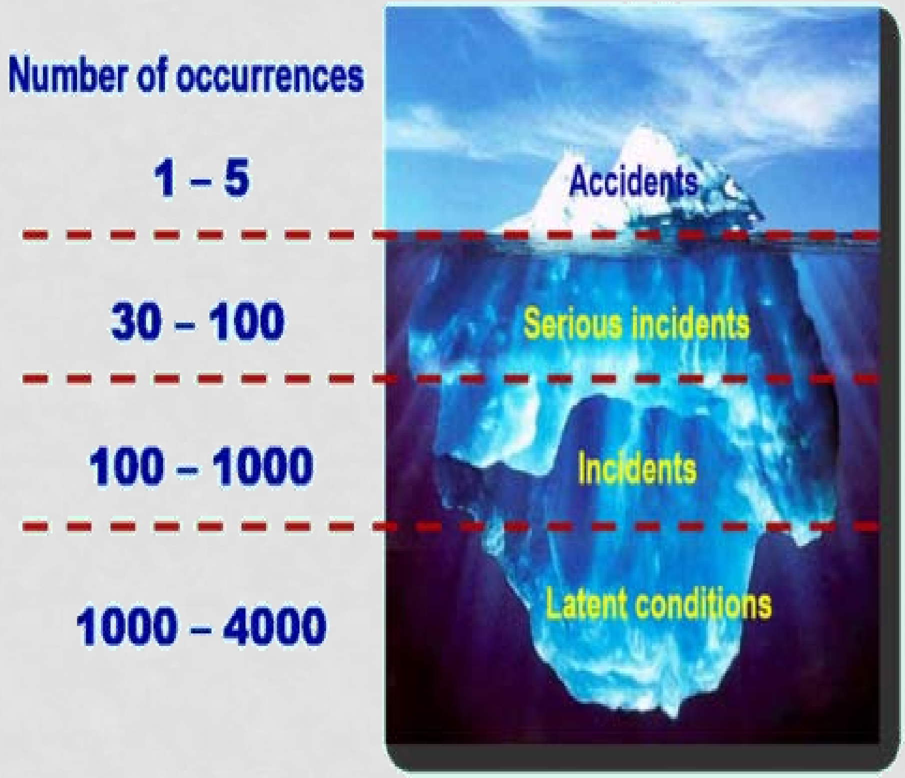
« Errare humanum est, perseverare diabolicum »

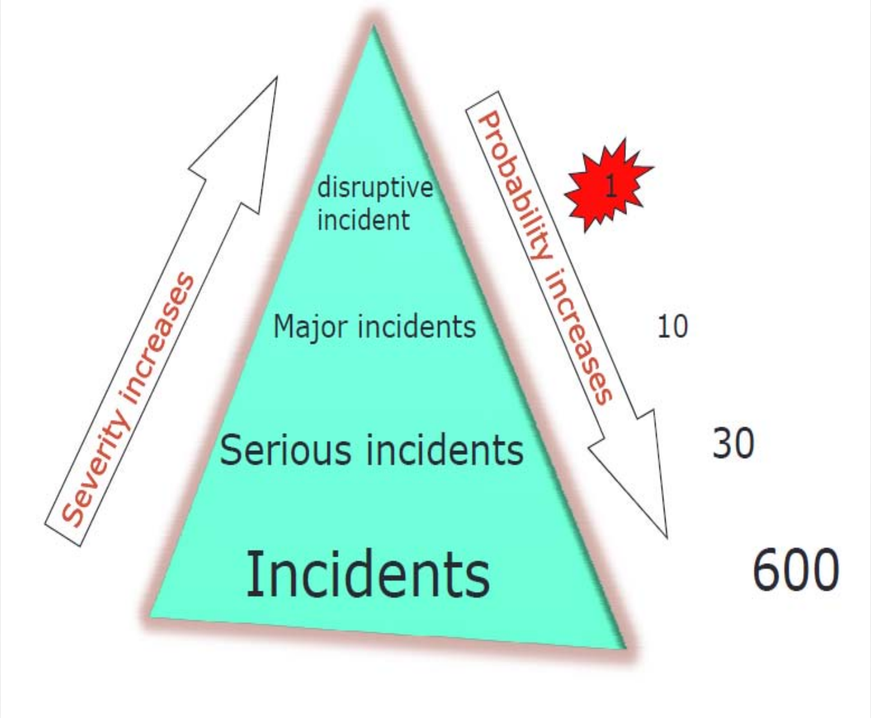
TERMS AND DEFINITIONS



INCIDENT REPORTING SYSTEMS

Heinrich triangle





Bird, Frank E., Germain, George L., (1992). Practical Loss Control Leadership. Loganville, Georgia: International Loss Control Institute, Inc.

INCIDENT REPORTING AND **LEARNING** SYSTEMS

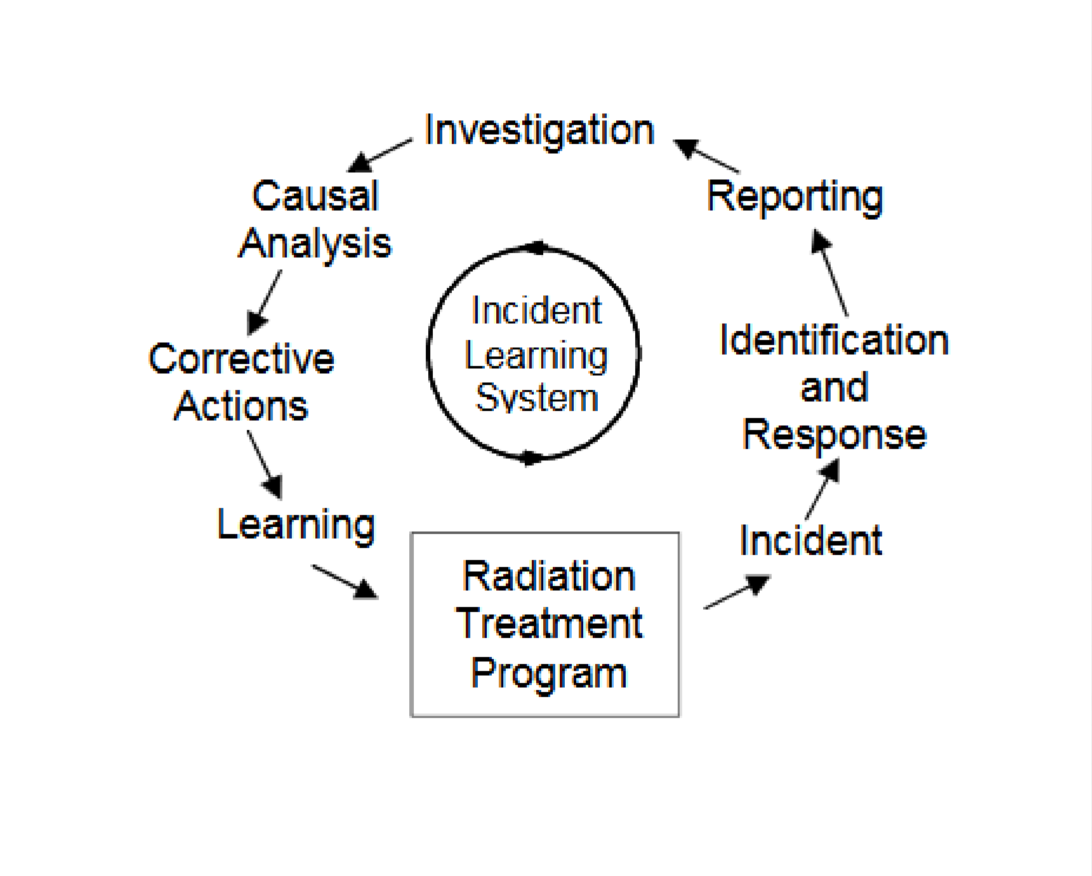
- Tool that allows:
  - for a user to declare an undesired event

REPORTING

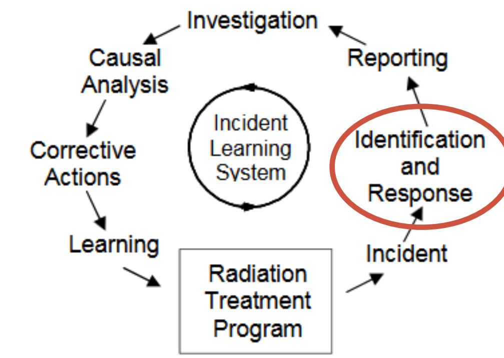
  - for the organization to identify hazards, risks and opportunities to improve patient safety

LEARNING

INCIDENT REPORTING AND **LEARNING** SYSTEMS (IRLS)



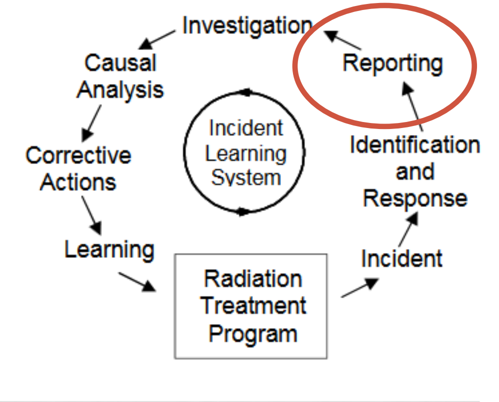
1. IDENTIFYING THE EVENT



- What am I detecting?
  - Accident? Incident? near-miss? Quality breach?

- Do I need to take immediate action?
  - Immediate corrective action? Injury? Hazards?

2. REPORTING THE EVENT



- =Completing a report

Employee Incident Report

Date

Employee
Name
Title/position

Manager
Name
Title/position

Incident
Date
Time
Location

Description of incident

Employee explanation

Witnesses

Action to be taken
❑ Verbal warning ❑ Probation ❑ Dismissal
❑ Written warning ❑ Suspension ❑ Other

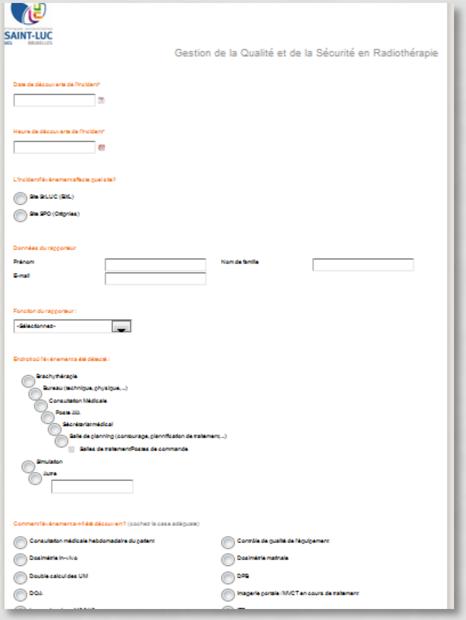
Explain

By signing this document, you acknowledge that you have read and understood the information contained herein

Employee Manager

Date Date

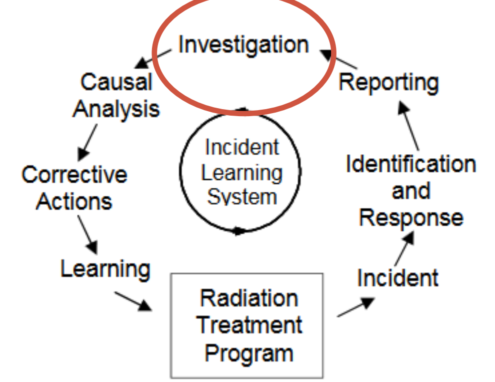
www.BusinessFormTemplate.com

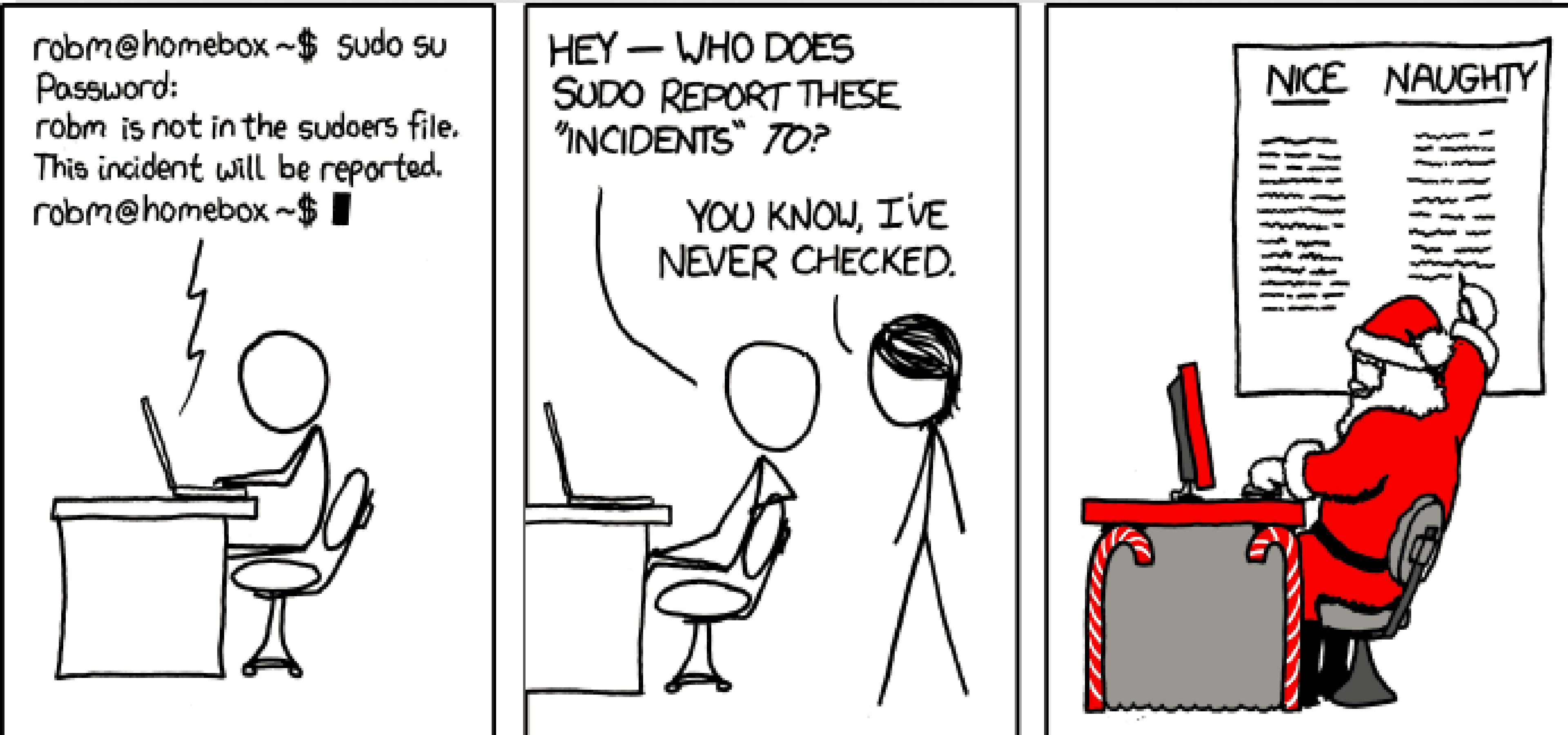


SAINT-LUC

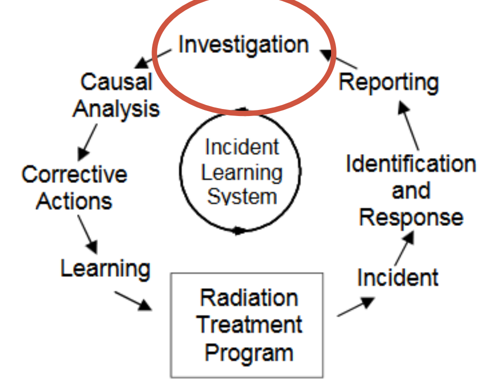
Gestion de la Qualité et de la Sécurité en Radiothérapie

3. INVESTIGATING THE EVENT



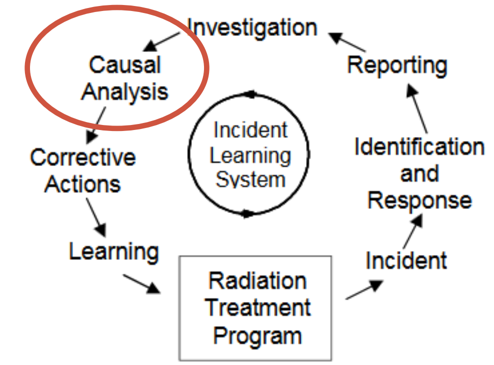


3. INVESTIGATING THE EVENT

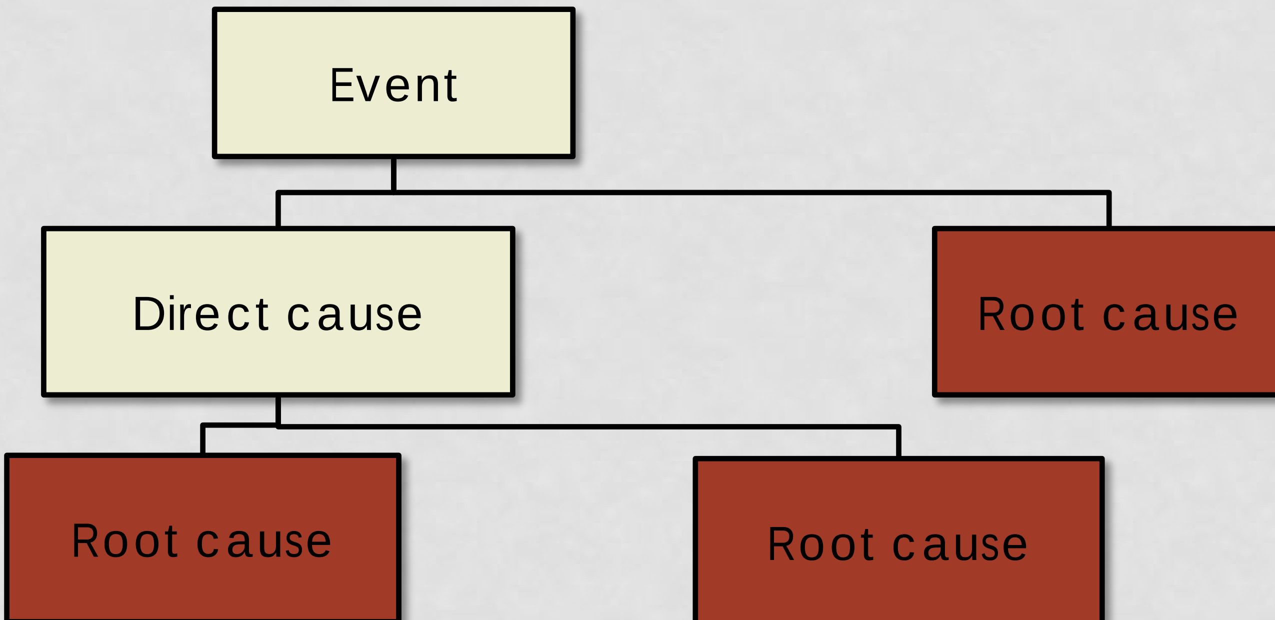


- Setting the time-line
- Completing the information
  - Interviews
  - Consulting documents/logs
  - Use of objectivity

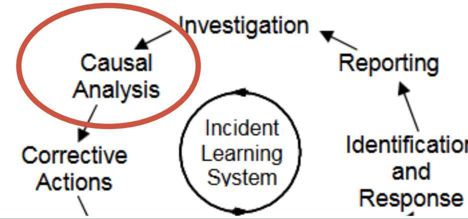
4. CAUSAL ANALYSIS



- Analyzing the facts and determining the causes (Why?)
- Various methodologies

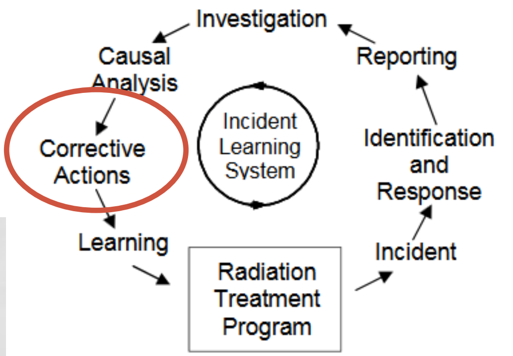


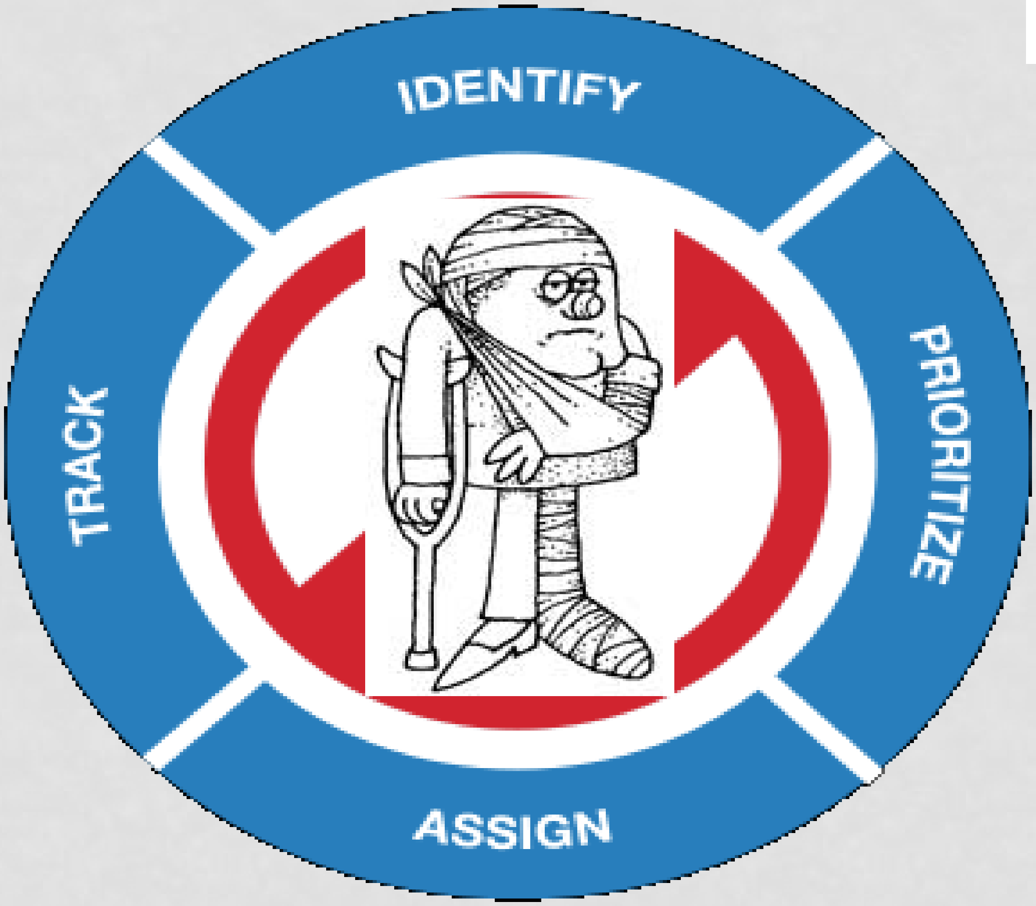
4. CAUSAL ANALYSIS



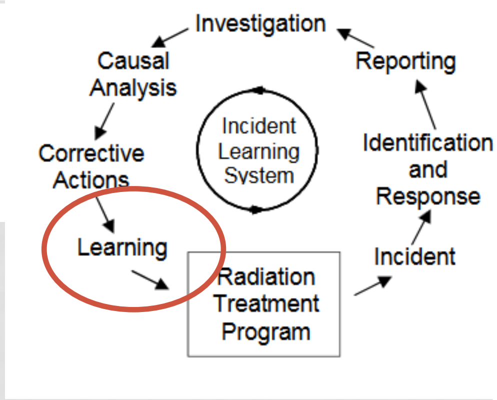
Methodologies	Advantages	Disadvantages
Root Cause Analysis (RCA) 5 Whys? methods	= systematic questioning to identify the main causes • Schematic description • Easy to implement	• Partial analysis due to the focus on identifying links between the event's causes • No chronology
Root Cause Analysis (RCA) Ishikawa diagram	= focus on five to seven aspects: materials, method, manpower, environment, etc	No representation of logical relationships • No chronology
Root Cause Analysis (RCA) HFACTS	= Method based on systematic questioning to identify the main causes (Includes supervision failures)	• No representation of logical relationships • No chronology
ALARM	= Method designed for a hospital's clinical activities -steered towards finding latent errors in organisation and governance	• The actions to be taken are more complicated (addressing latent errors)
Causal/fault Tree Analysis	= Schematic description and reconstruction of the chronology of the facts	Factors not ranked
ORION®	= Systemic method of analysis and recreates the context surrounding the event (=ALARM + fault tree)	Initial analysis require support

5. CORRECTIVE ACTIONS



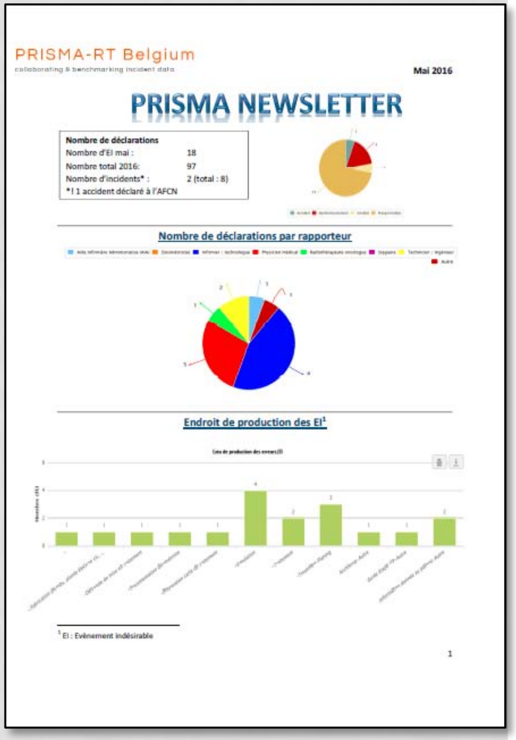


6. LEARNING



= Organizational learning → **safety culture**

- Communication of "**lessons learned**" to individuals involved + teams + (wider audience)
- Review of the **effectiveness** of the actions taken (+communication)



PRISMA-RT Belgium

Mai 2016

PRISMA NEWSLETTER

Nombre de déclarations
Nombre d'EI mai : 18
Nombre total 2016: 97
Nombre d'incidents* : 2 (total : 8)
* 1 accident déclaré à l'AFCN

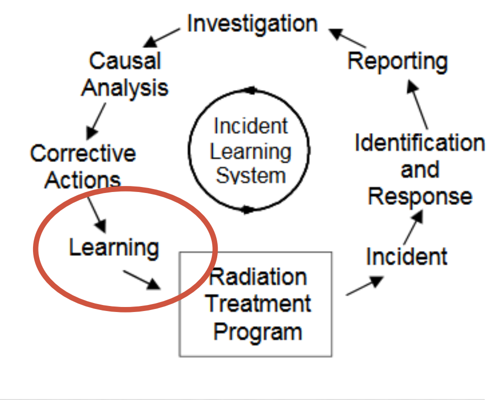
Nombre de déclarations par rapporteur

Endroit de production des EI[1]

[1] EI : Evènement indésirable

1

6. LEARNING



= Organizational learning → **safety culture**

- Periodic review of "lessons learned" and effectiveness of corrective actions to identify system-wide improvements

PREREQUISITES OF IRLS

Prerequisite	Reason
Non punitive	Reporters should be free of fear of retaliation or punishment from others as a result of reporting

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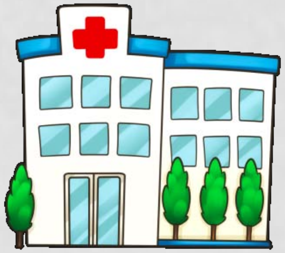
Systems oriented	Recommendations focuses on changes in systems, processes or products rather than individual performances
Responsive	Recommendations are disseminated

TYPES OF IRLS

- Internal versus external systems

- Mandatory versus voluntary

- Specialization-specific versus institutional



INTERNAL VERSUS EXTERNAL SYSTEMS

Internal	External
= Reporting of incidents **within** an organisation	= Reporting of incidents **outside** an organisation
→ "Lessons to learn" are more direct and explicit → Specific in relation to the organisation (procedures/ equipment/characteristics...) ...	→ Context of benchmarking → "Lessons to learn" become part bigger pool of events → Identification of safety-critical steps

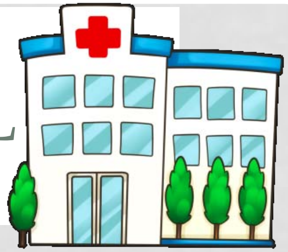
Courtesy of Mary Coffey – ESTRO Risk Management course

COMPULSORY VERSUS VOLUNTARY

Compulsory	Voluntary
= Required reporting of an event	= Encouraged reporting
→ Provide public with minimum level of protection (investigation of serious events) → Provide an incentive to hospitals to improve patient safety → Require hospitals to invest in patient safety (comparable care)	→ Effective sharing of information and lessons learned → Analysis of events to select most effective means for improving safety → Facilitate speedy investigation and action

Courtesy of Mary Coffey – ESTRO Risk Management course

SPECIALIZED VERSUS INSTITUTIONAL



Specialized	Institutional
= Reporting and analysis within a radiotherapy specific platform	= Reporting and analysis within an institutional/hospital platform
Advantages - RDTH specific view - Ease of understanding the undesirable event - Close link between the RDTH department and the "analysts" - Adaptability	**Advantages** - Integration of the RDTH events within a greater context
Disadvantages: - Might miss the "bigger picture" - Loss of integration with the hospital setting	**Disadvantages**: - Loss of specificities linked to RDTH

INCIDENT REPORTING AND LEARNING SYSTEMS

- SAFRON
- ROSIS

Welcome:

ROSIS

Radiation Oncology Safety Information System

ROSIS

Radiation Oncology Safety Information System

HOME | ABOUT ROSIS | REGISTER CLINIC | SUBMIT REPORT | ROSIS DATA | SPOTLIGHT CASES | RESOURCES | LINKS

+ Radiation Oncology Safety Information System

Welcome to ROSIS

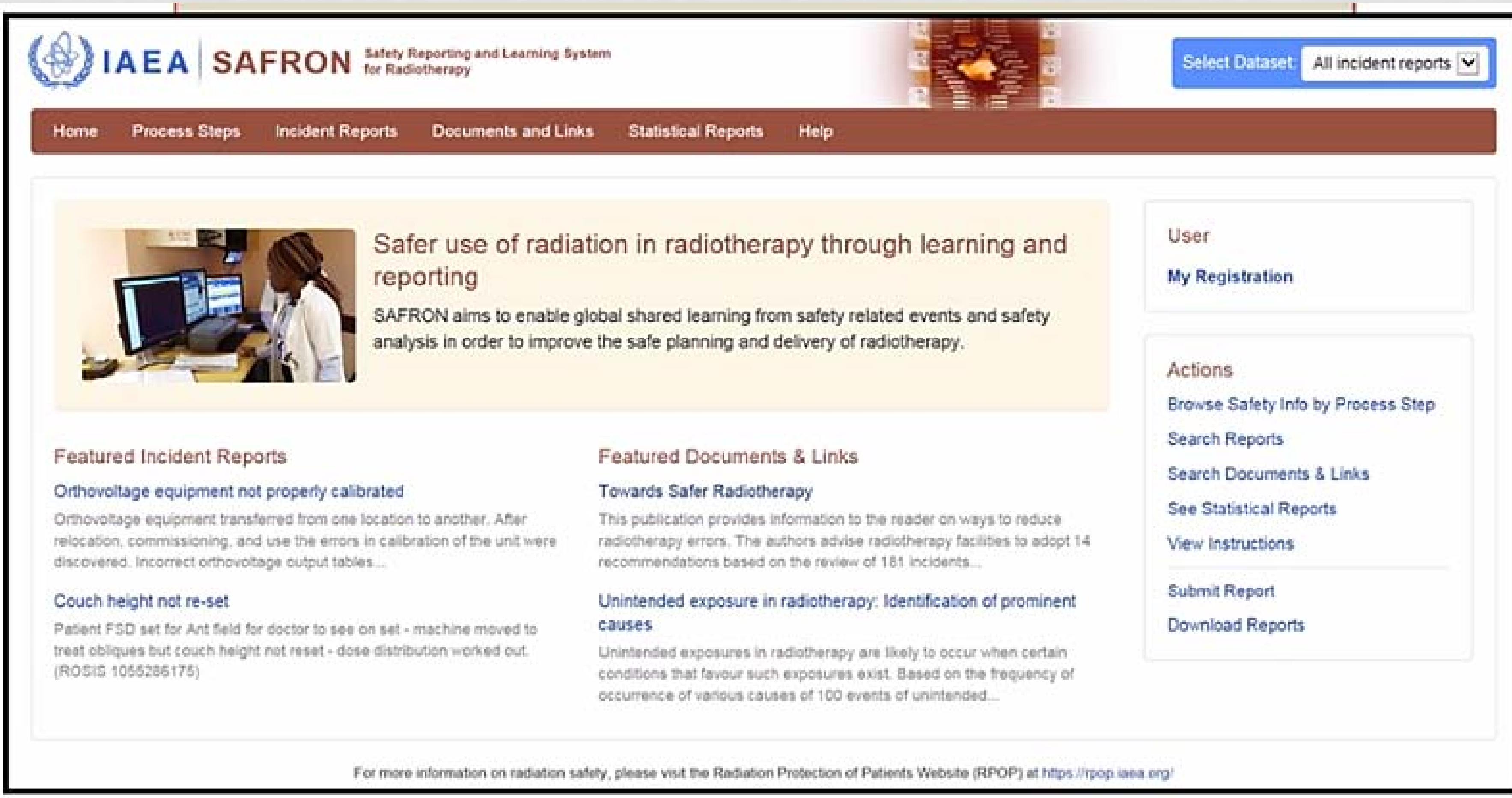
a voluntary safety reporting system for Radiation Oncology

ROSIS is short for "Radiation Oncology Safety Information System" and it is a voluntary web-based safety information database for Radiotherapy. The system is based on professional front-line staff in radiotherapy clinics reporting incidents and corrective actions over the Internet to a database.

NEWS

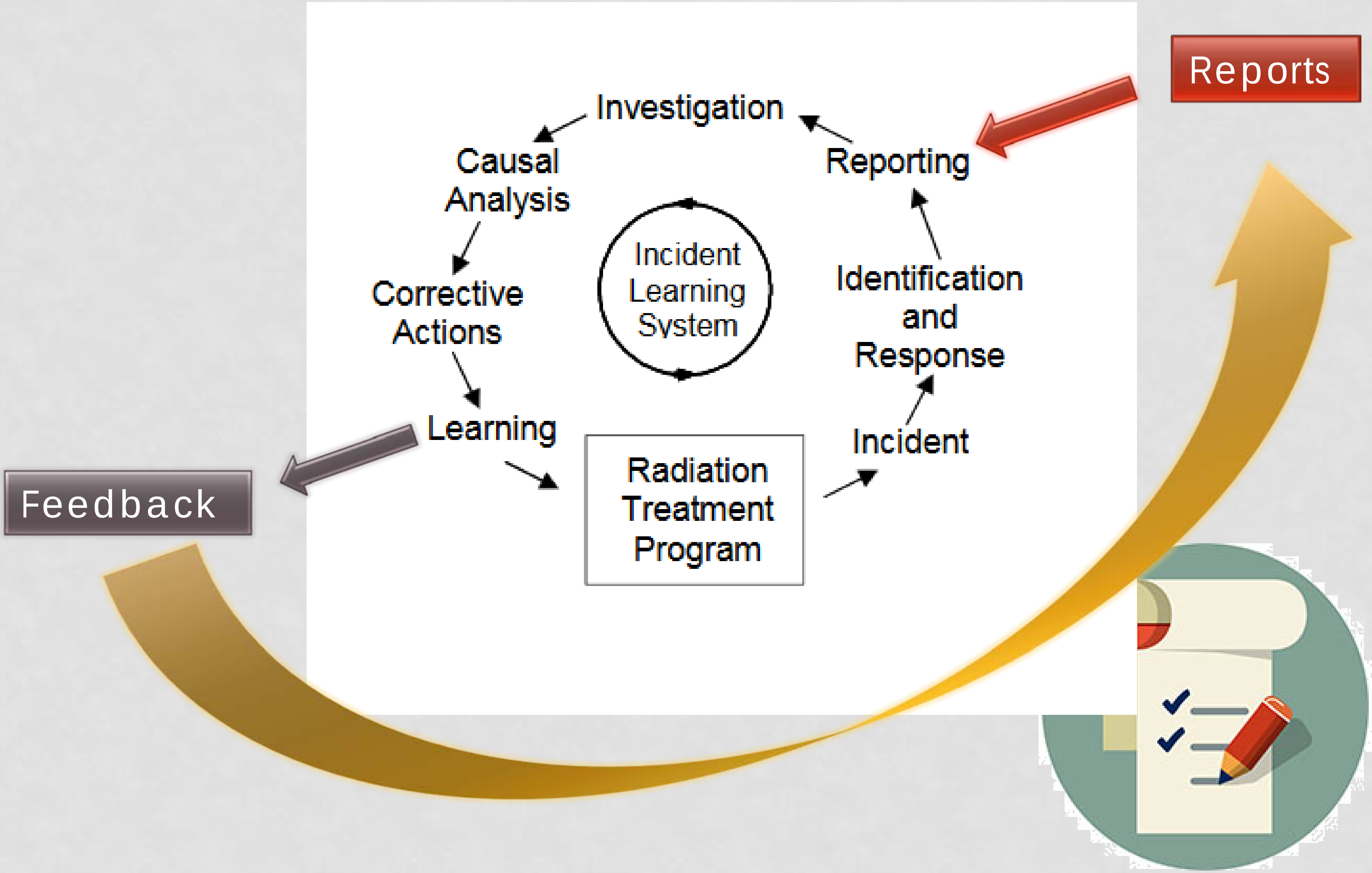
Working Towards Safer Health Care Delivery - minimising the impact of incidents in radiotherapy" May 2007.

IAEA | SAFRON Safety Reporting and Learning System for Radiotherapy



https://rpop.iaea.org/RPOP/RPoP/Modules/login/safron-register.htm

IMPORTANT POINTS TO REMEMBER



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How to react to a radiotherapy accident:
Communication to the media

Pr Eric F. LARTIGAU

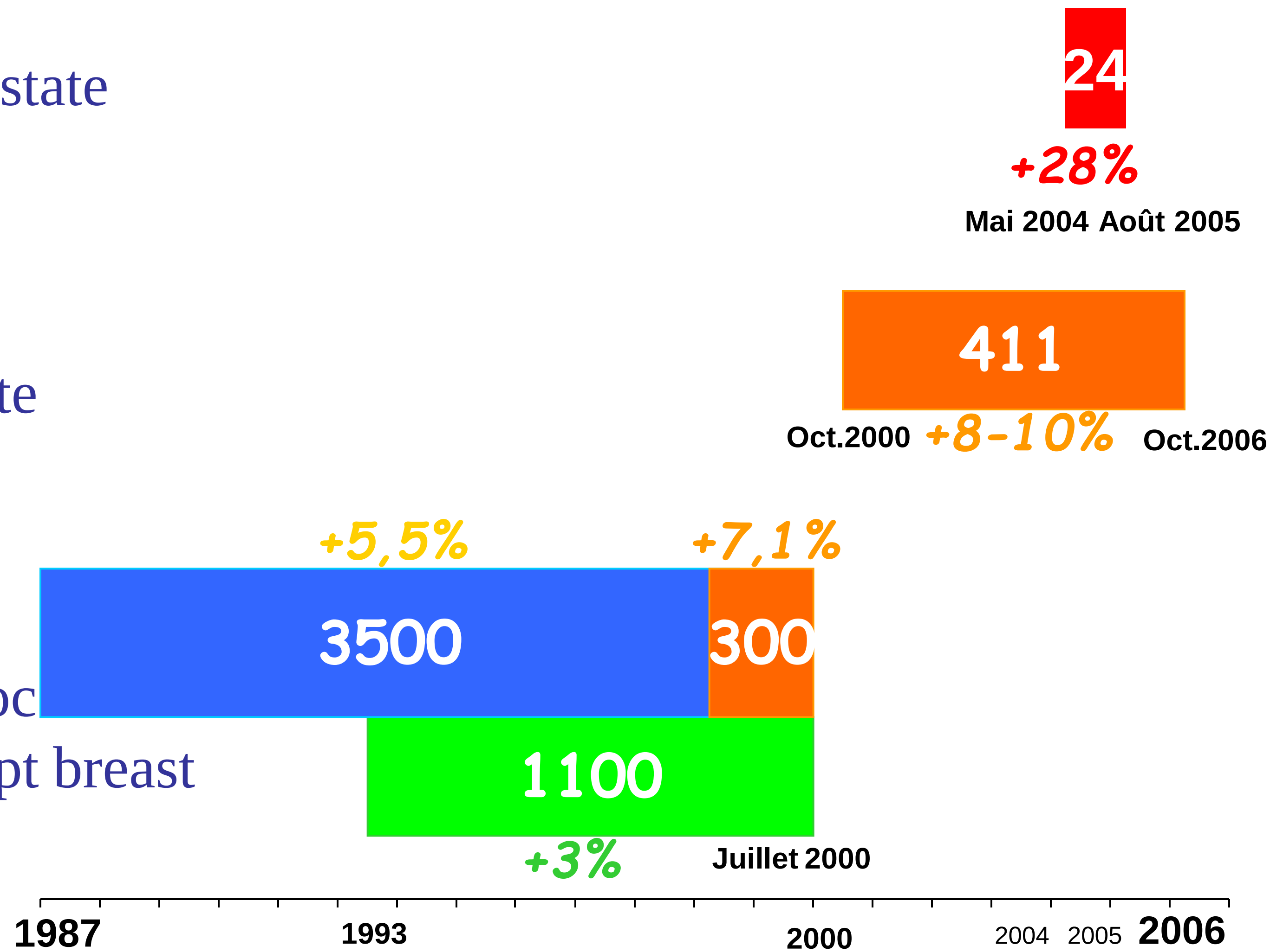
Centre Oscar Lambret
Lille, France

Summary

I *wedges* prostate

II *IP* prostate

III *error of calcul* All loc Except breast



19 months ?

Jan 2005: first clinical symptoms

Sept 2005 : internal declaration of the accident

July 2006 : declaration to the national authority

Oct 2006: inspection IGAS/ASN and IRSN

Why ????

Main differences

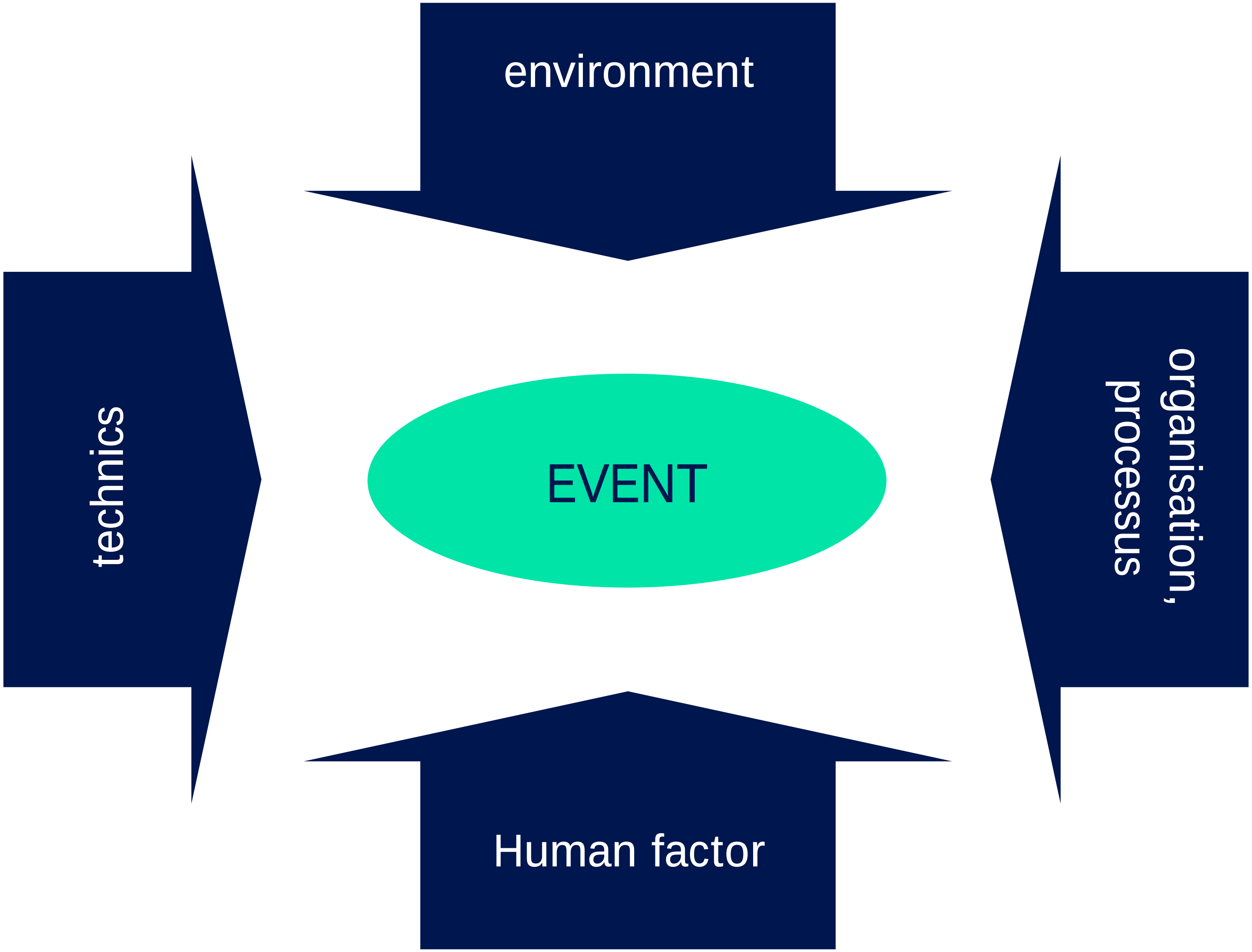
- Epinal : no declaration to authorities and patients
- Toulouse : straight forward declaration

Errare humanum est, sed perseverare diabolicum

Safety basics

If you think safety is expensive,
think about an accident (Epinal).

4 families of risk factors



IMPORTANCE OF HUMAN FACTORS

> 2/3 of all incidents result from failures in human performance due to :

- inadequate or misunderstood procedures, improper training,
- insufficient situation awareness,
- difficulty in understanding displayed information
- …

Total with known causes	134
Unknown or awaiting reports	49
Total	183

Accidents by primary cause

*As determined by the investigating authority, percent of accidents with known causes.

Safety/security in medecine

- Yearly in France : **> 12 000 deaths related to medical activities** (*Ministery of Health 2006)*
- In radiotherapy : some recorded (Rosis...)
- Most :
  - **not described**
  - **not analysed**
  - **not corrected**

Problems

In 2005 :

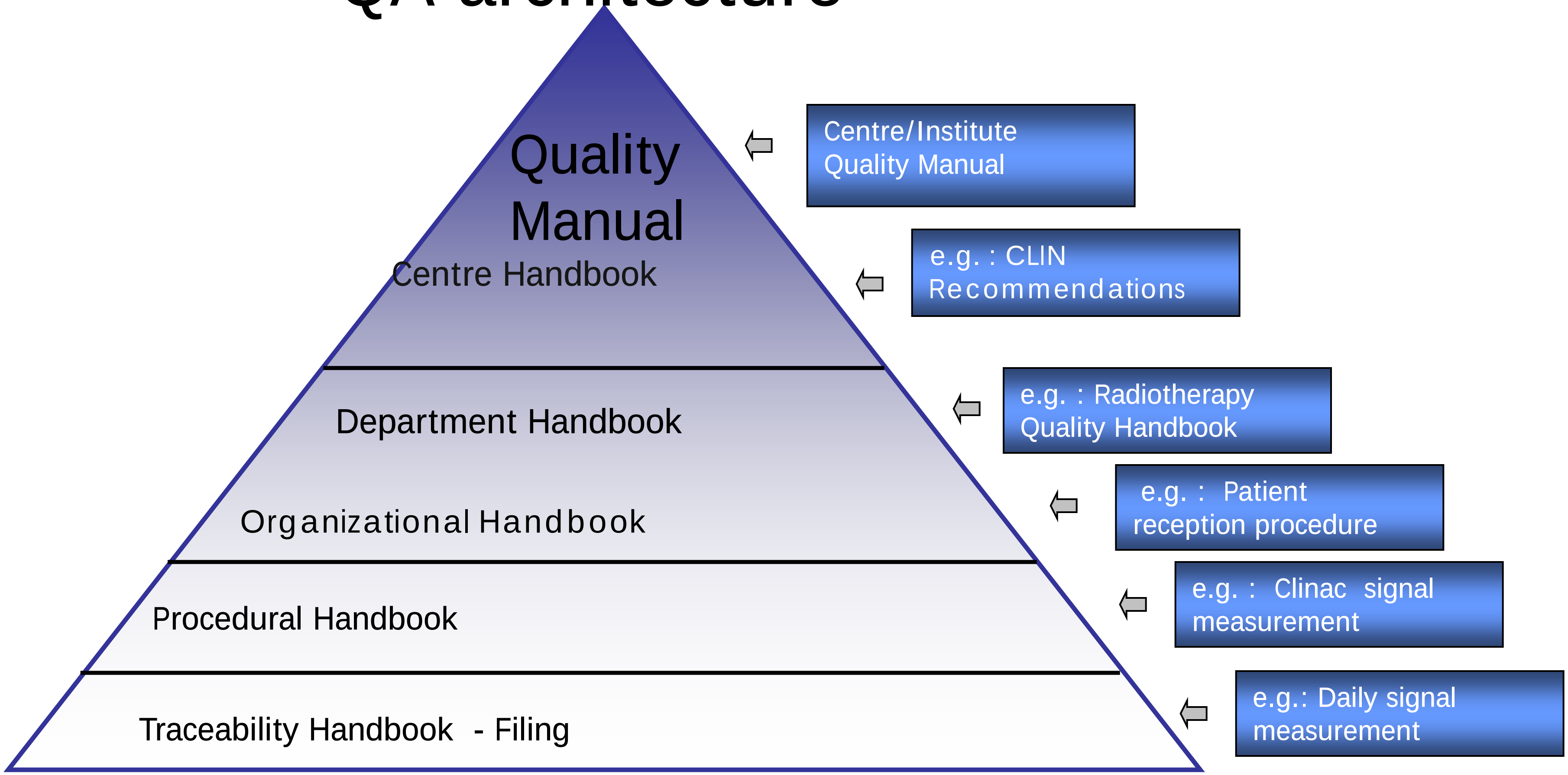
All professionals were aware of the existence of errors, but very fews declarations were registered

and analysed + + + + + + +

- **management solution : "non punishment" commitment**
- **confidence** to increase declaration numbers
- **2016**: natural trend

SOP :The best practices handbook :
The book !

QA architecture



Roles and responsibilities

Safety is everybody's business

- Authorities;
- Industry
- Management;
- Operators;
- Professional associations (ESTRO...)

Communication is not !!!!

What’s a crisis ?

An unexpected event that may damage your organization reputation (or more...)

Before a crisis

- Prepare
- Simulate
- Repeat

In one world:

anticipate, you will get one !!!

During: ACTION

- Speak first
- Transparency: in/out

AFTER

- Follow up: social network
- e reputation: be pro active

Which event to communicate on?

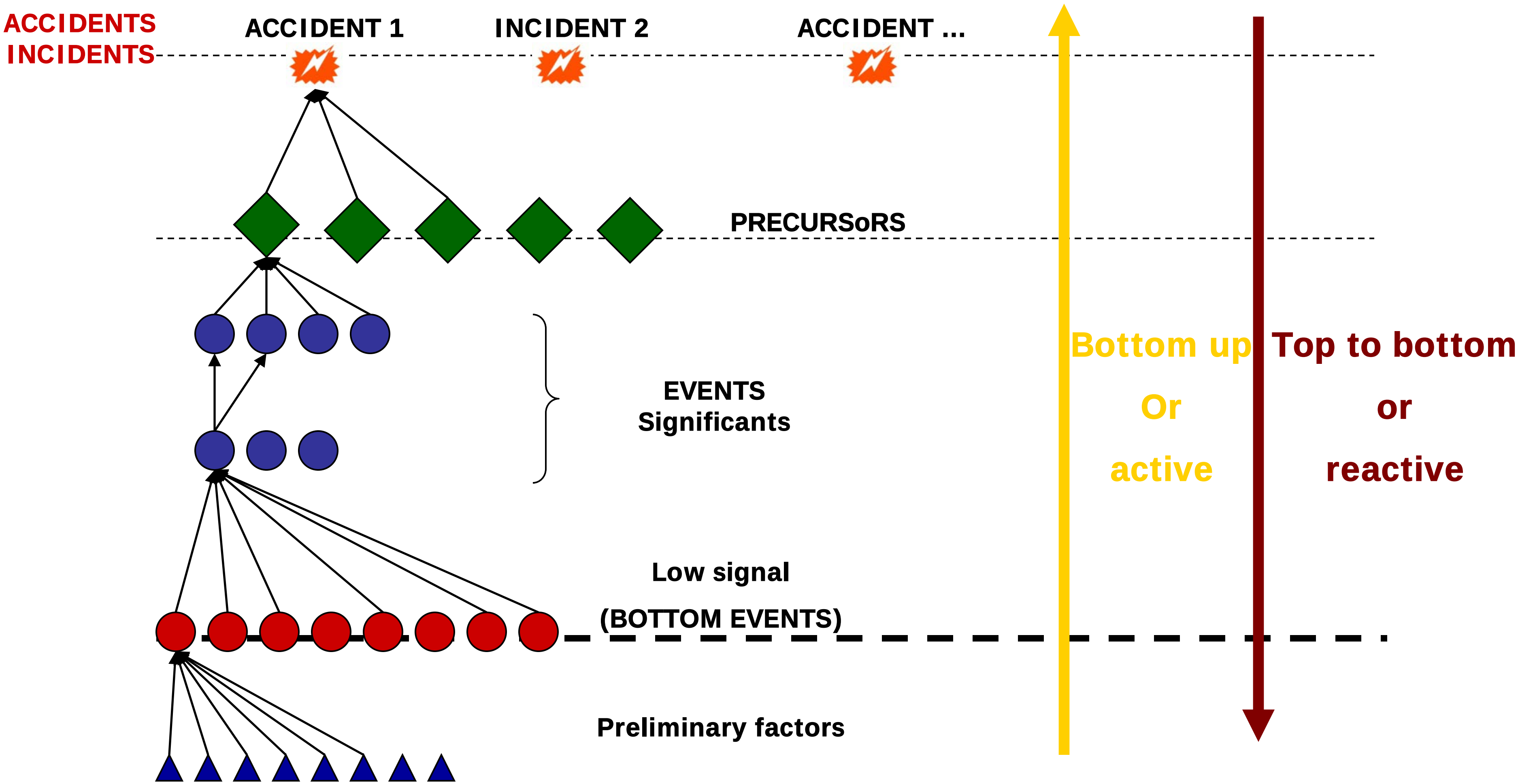
News on :

- accidents
  - Epinal
- incidents
  - Centre Hospitalier Universitaire de Rangueil – Toulouse

But most of the events are corrected before hand:

- Precursors
  - Dosimetry
  - Patient identity
  - ….

Hierarchy



ACCIDENTS
INCIDENTS
ACCIDENT 1
INCIDENT 2
ACCIDENT ...
PRECURSoRS
EVENTS
Significants
Low signal
(BOTTOM EVENTS)
Preliminary factors
Bottom up
Or
active
Top to bottom
or
reactive

Why getting the precursor events ?

Because the reasons of any accident, incident or precursor event are the same !!!!!

Communicate on your recording +++

- In: management
- Out: transparency

But consequences are very different !!!!!!

When you get the accident :

- ✓ Patient/family information/follow up
- ✓ Declaration to the health authority
- ✓ Declaration to the hospital management
- ✓ Analysis and correction of causes

Lille

- 2 level 2 in 5 years : patients potential consequences

- 2007 : spine reduction (52 Gy)
  - All media (national +international....)
  - 1 negative paper: communication not controled !!!!

- 2009 : dosimetry error : no news

In between : active communication on safety procedures

Pro active communication is good for you !!!!

When accident is known:

- Always make a medical answer towards the patients
- Do not leave the official bodies to do so (regulatory authorities)
- Communication has to be strongly organised within the hospital

Basic

Only a few well identified people must communicate

You communicate on everything but trough well identified channels

Get press people to help you (agency)

Not to get it again (the crisis):

= training, training, training, training …

Conclusion

- **Safety/security is a never ending process**
- **Human factor is the only issue !**
- **Everything else can be corrected**
- **Communication is <u>professional job</u>**

Thanks to F Debouck, AF cs, M. Valéro et C. Rousse, ASN

Taxonomies and Severity Scales

Peter Dunscombe

UNIVERSITY OF CALGARY

Disclosures

- Occasional Consultant to Varian
- Occasional Consultant to the IAEA
- Director, TreatSafely, LLC
- Director, Center for the Assessment of the Radiological Sciences.

Taxonomies and Severity Scales

Taxonomies

Drop down

Yes, more than 1 patient
Yes, one patient
Other, e.g. staff
No, but someone could have been; potential incident
No information provided
Prescribed dose per fraction (Gy):

Table

What safety barrier	failed to identified the incident?	identified the incident?	might have identified it?
Verification of patient ID	☐	☐	☐
Verification that pretreatment condition have been taken into account	☐	☐	☐
Verification of imaging data for planning (CT scan, fusion, imaging modality, correct data set)	☐	☐	☐

List

2. Policies, Procedures, Regulations

- 2.1 Relevant policy nonexistent
- 2.2 Policy not implemented
- 2.3 Policy inadequate
- 2.4 Policy not followed
- 2.5 External regulation not followed
- 2.6 Conflicting policies

ESTRO school

Learning Objectives

- To review the structure of a generic Incident Learning System.
- To place taxonomies in the context of SAFRON and the AAPM structure.
- To review some current taxonomies in radiotherapy incident learning.

Exercises

- After each taxonomy we'll do a short Exercise
- You can work on your own or in a group
- There's no "wrong" answer!
- Later in the School we'll look at your anonymized and aggregated answers.

Outline

•Incident Learning Systems

To review the structure of a generic Incident Learning System.

•SAFRON and AAPM

To place taxonomies in the context of SAFRON and the AAPM structure.

•Taxonomy Review

To review some current taxonomies in radiotherapy incident learning.

Taxonomies and Severity Scales

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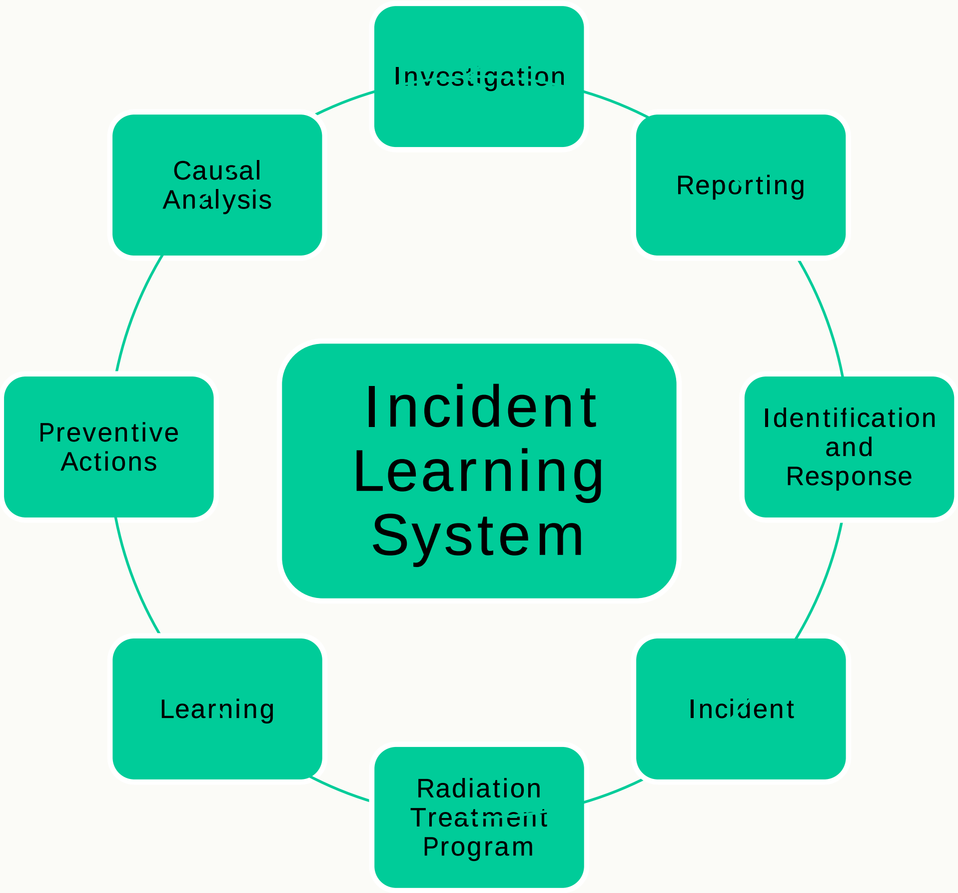
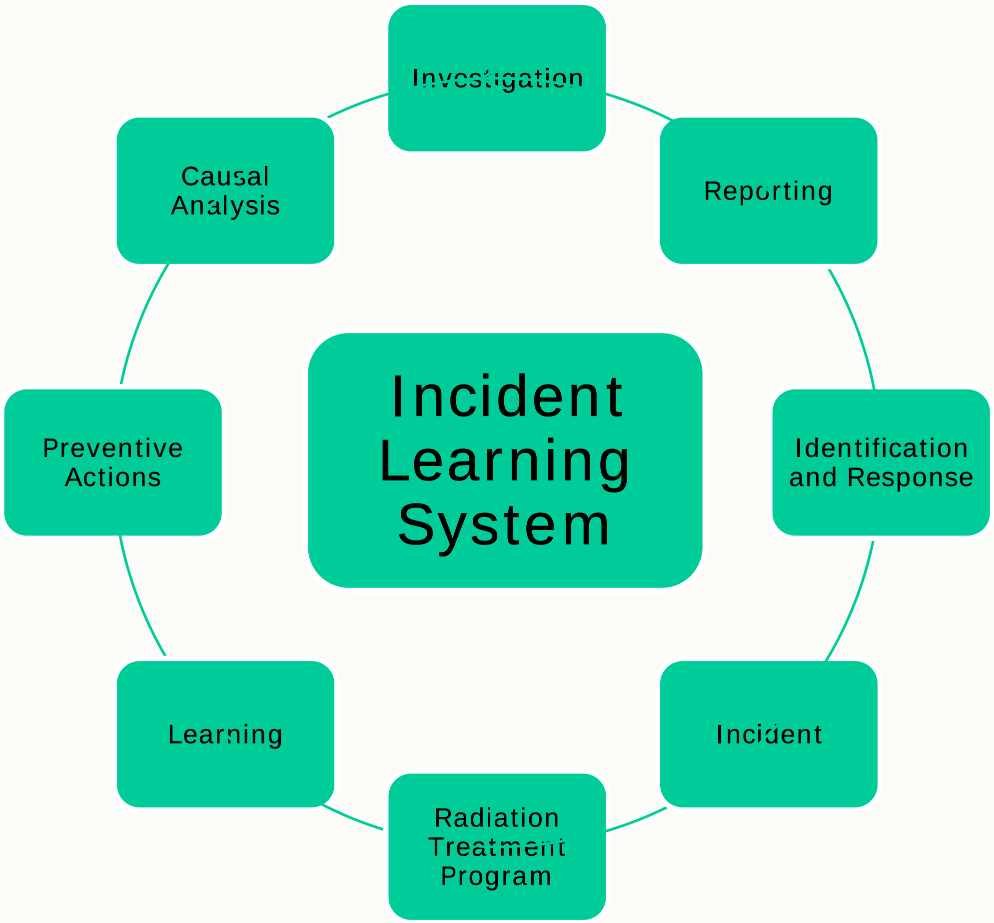
Taxonomies and Severity Scales



http://www.ihe.ca/publications/library/archived/a-reference-guide-for-learning-from-incidents-in-radiation-treatment

Taxonomies and Severity Scales

A major challenge in the use of an Incident Learning System is the transfer of information between the boxes

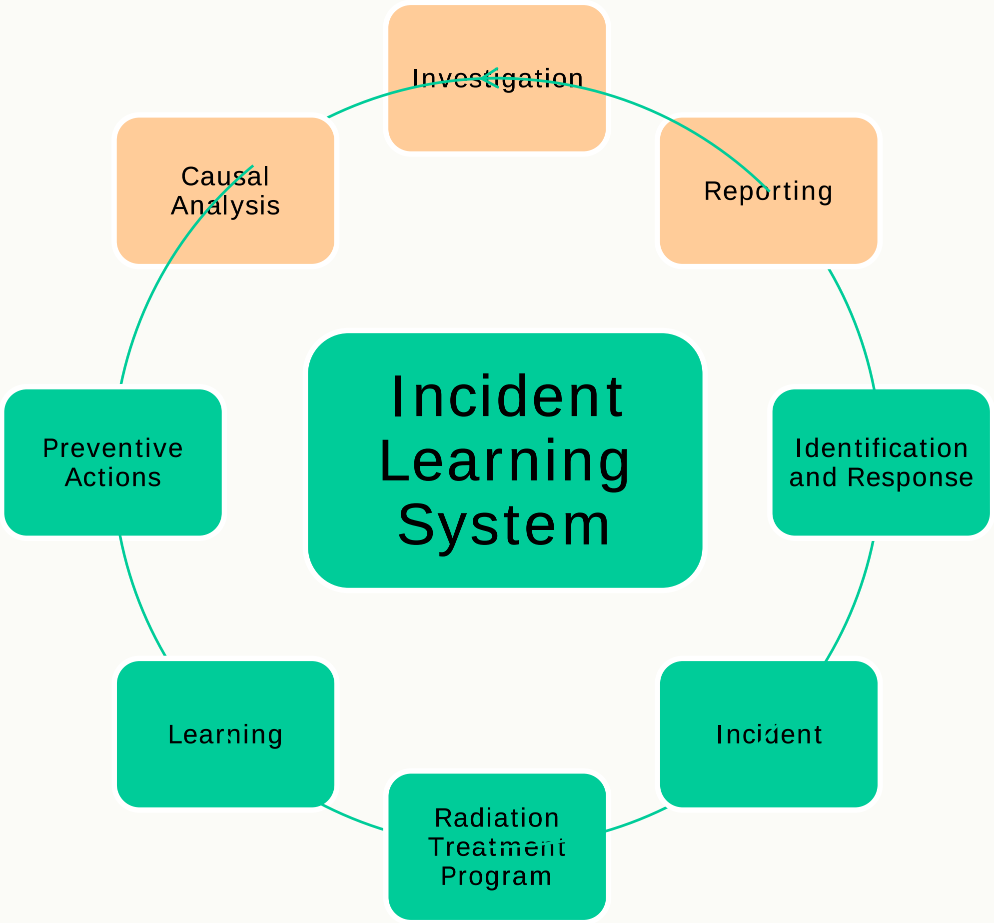


Taxonomies and Severity Scales

If the information transferred between the top boxes is:

a. Incomplete
b. Ambiguous

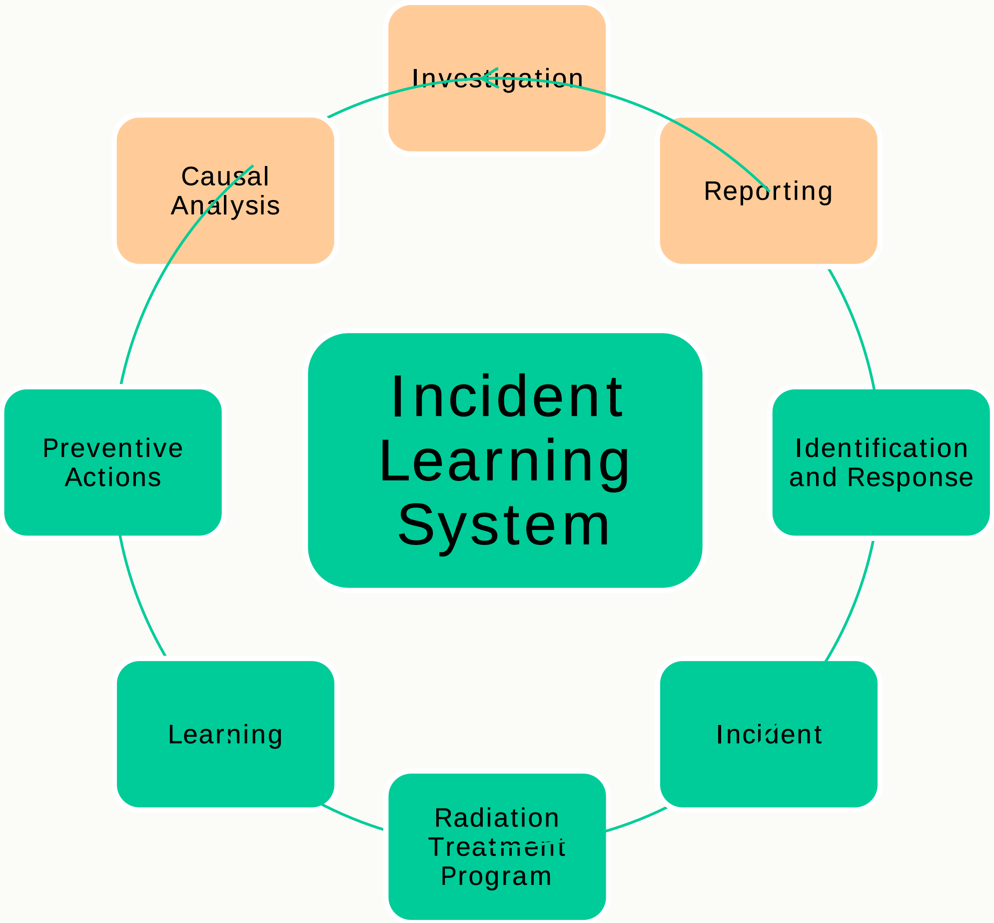
The exercise will be at best useless and at worst misleading



Taxonomies and Severity Scales

Synoptic reporting and Taxonomies are intended to ensure that information within the Incident Learning System is both

a. **Complete**
b. **Unambiguous**



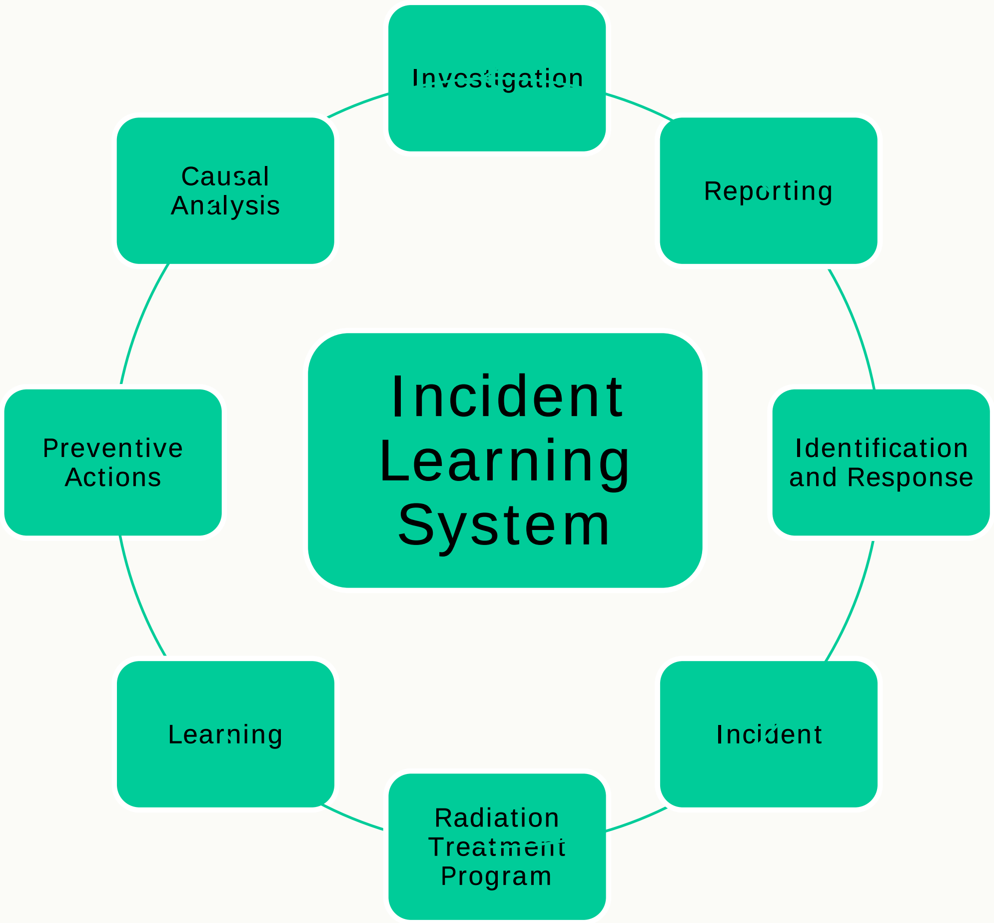
ESTRO school

Taxonomies and Severity Scales

Synoptic reporting describes the approach of requiring certain key information to be provided in the description of an Incident.

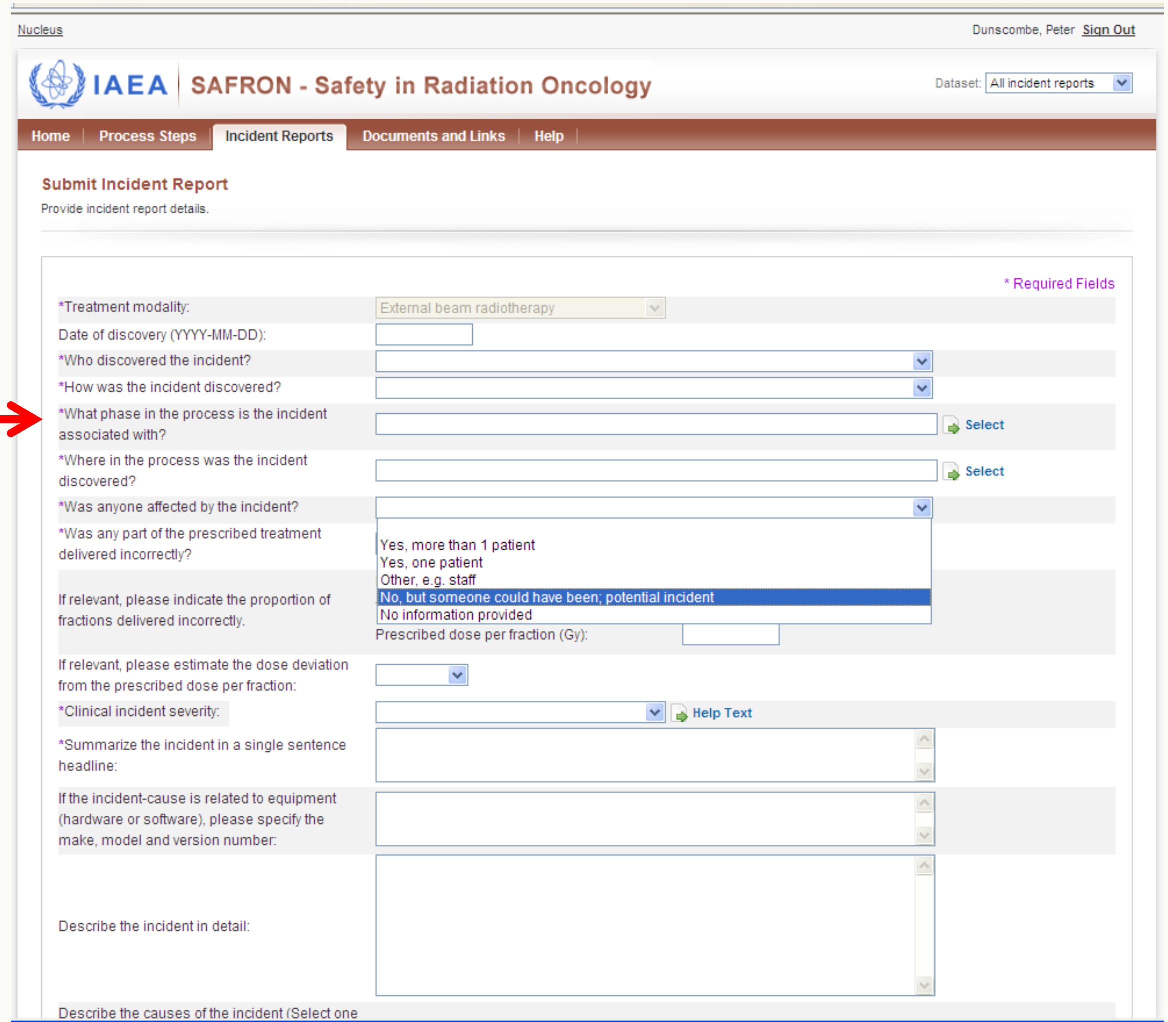
A synopsis is a summary of the key information about an incident.

It is intended to address the issue of **completeness**.



Taxonomies and Severity Scales

Key information is requested through mandatory data entry fields.

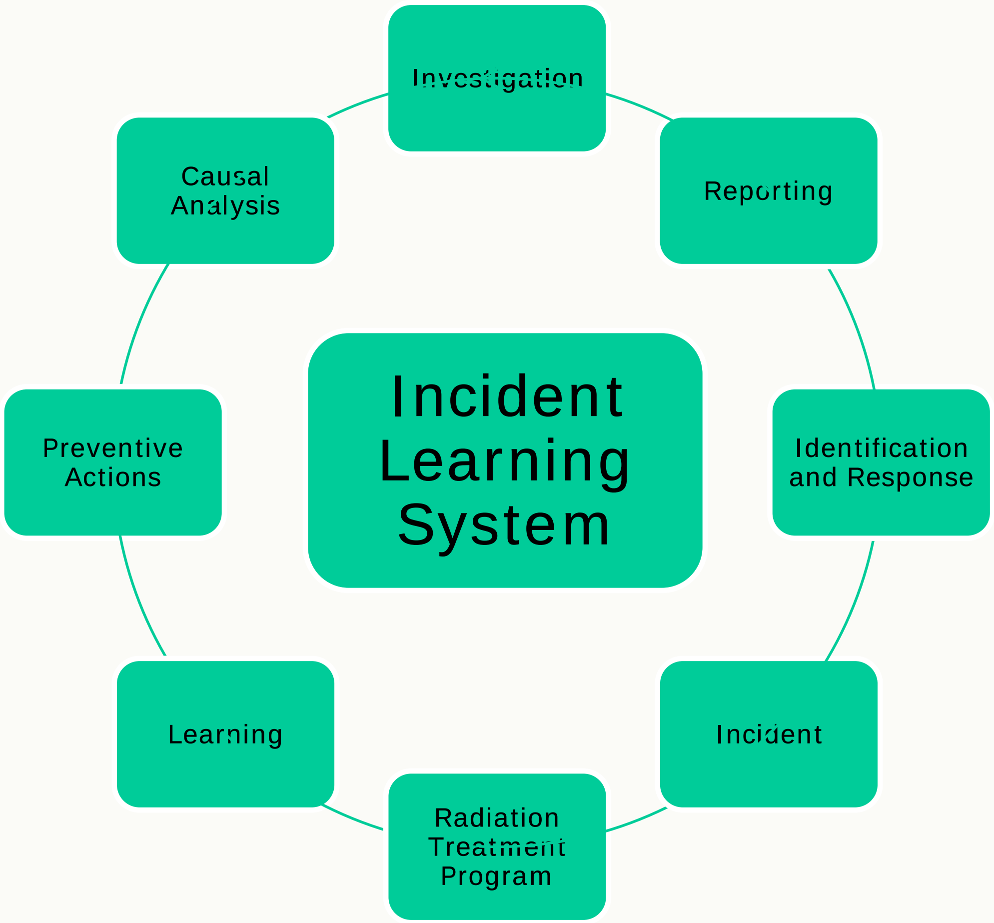


Taxonomies and Severity Scales

Taxonomies (i.e. classification schemes) limit the choices of incident descriptions to a specified vocabulary.

A taxonomy is a classification of something

Taxonomies are intended to address the issue of **ambiguity**.



Taxonomies and Severity Scales

Taxonomies

Drop down

- Yes, more than 1 patient
- Yes, one patient
- Other, e.g. staff
- No, but someone could have been; potential incident
- No information provided

Prescribed dose per fraction (Gy):

Table

What safety barrier	failed to identified the incident?	identified the incident?	might have identified it?
Verification of patient ID	☐	☐	☐
Verification that pretreatment condition have been taken into account	☐	☐	☐
Verification of imaging data for planning (CT scan, fusion, imaging modality, correct data set)	☐	☐	☐

List

2. Policies, Procedures, Regulations
- 2.1 Relevant policy nonexistent
- 2.2 Policy not implemented
- 2.3 Policy inadequate
- 2.4 Policy not followed
- 2.5 External regulation not followed
- 2.6 Conflicting policies

ESTRO school

Outline

•Incident Learning Systems

To review the structure of a generic Incident Learning System.

•SAFRON and AAPM

To place taxonomies in the context of SAFRON and the AAPM structure.

•Taxonomy Review

To review some current taxonomies in radiotherapy incident learning.

Taxonomies and Severity Scales

Nucleus

Dunscombe, Peter Sign Out

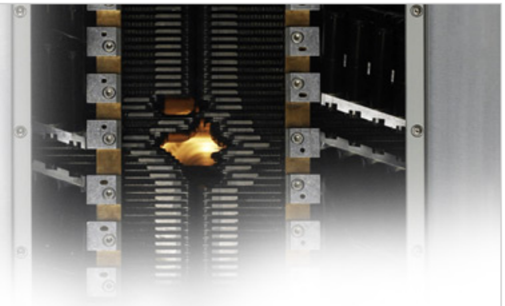
IAEA | SAFRON - Safety in Radiation Oncology

Dataset: All incident reports

Home | Process Steps | Incident Reports | Documents and Links | Help

Safety Reporting and Learning System for Radiotherapy

SAFRON is voluntary and aims to enable global shared learning from safety related events and safety analysis in order to improve the safe planning and delivery of radiotherapy. SAFRON is provided by the IAEA.



Actions

Browse Safety Info by Process Step >

Search for Incident Reports >

Submit Incident Report >

Search for Documents & Links >

View My Registration >

View Instructions >

Featured Incident Reports

Incorrect calibration of machine output
Electron beams of 7 and 11 MeV were calibrated incorrectly, resulting in underdosage of 17-18%. On the same machine, a photon beam was calibrated incorrectly, resulting in overdosage of 5%. In...

Misapplication of distance correction
An institution treated most patients with a constant source-skin distance (SSD) technique, although some patients were treated with a constant source-axis distance (SAD) or isocentric technique....

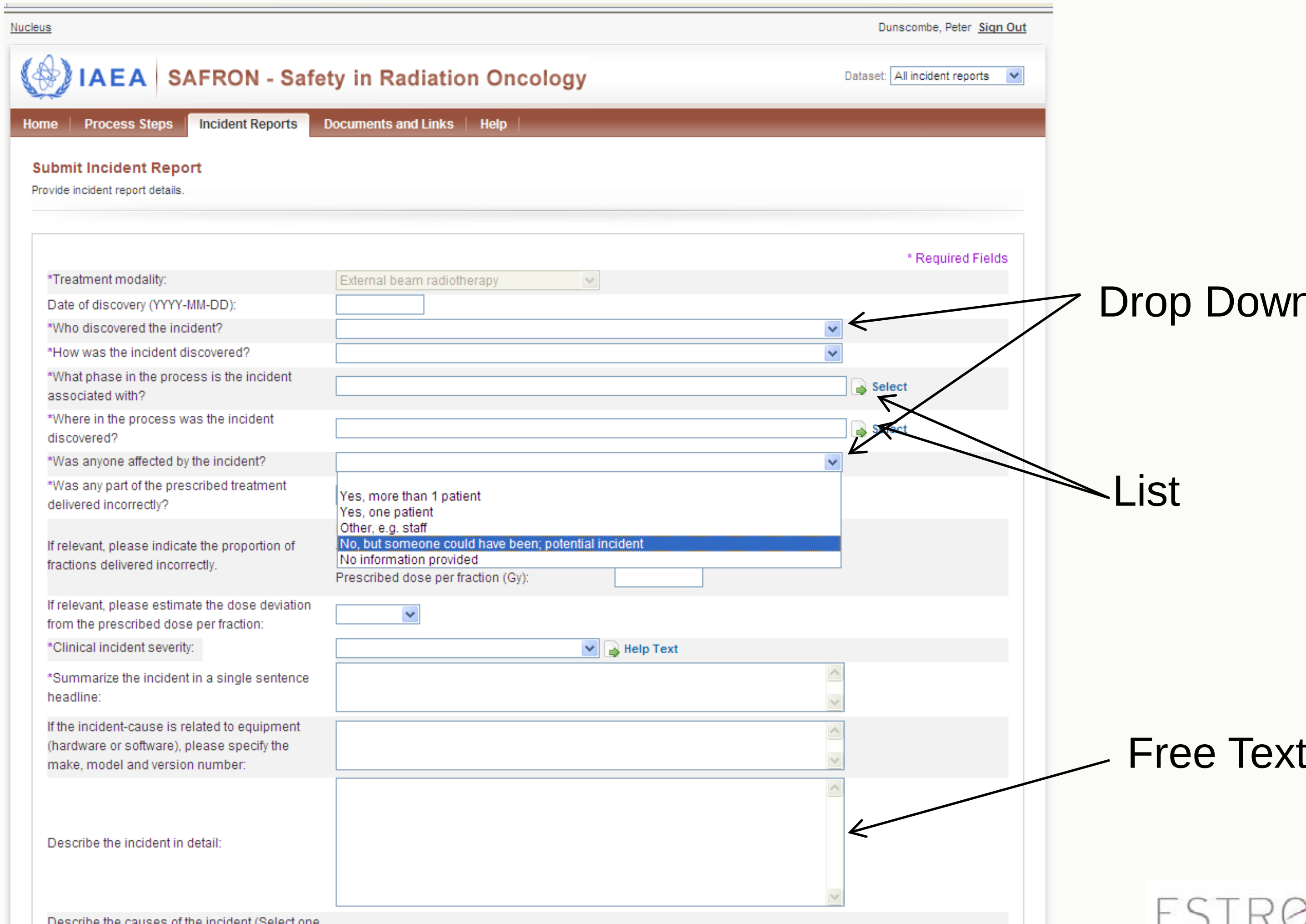
Featured Documents & Links

Task Group 142 report: Quality assurance of medical accelerators
This is an AAPM report on quality assurance of medical accelerators. It provides the reader with information on up-to-date recommendations of Table II of the AAPM TG-40 report on quality assurance...

Acceptance Testing and Commissioning of Linear Accelerators
This Report gives guidance for the acceptance testing and commissioning of radiotherapy linear accelerators and comprises a comprehensive account, including some of the most recent clinical...

https://rpop.iaea.org/SAFRON/Default.aspx

Taxonomies and Severity Scales


Nucleus

Dunscombe, Peter Sign Out

IAEA SAFRON - Safety in Radiation Oncology

Dataset: All incident reports

Home | Process Steps | Incident Reports | Documents and Links | Help

Submit Incident Report

Provide incident report details.

* Required Fields

*Treatment modality: External beam radiotherapy

Date of discovery (YYYY-MM-DD):

*Who discovered the incident?

*How was the incident discovered?

*What phase in the process is the incident associated with? Select

*Where in the process was the incident discovered? Select

*Was anyone affected by the incident?

- Yes, more than 1 patient
- Yes, one patient
- Other, e.g. staff
- No, but someone could have been; potential incident
- No information provided

*Was any part of the prescribed treatment delivered incorrectly?

If relevant, please indicate the proportion of fractions delivered incorrectly.

Prescribed dose per fraction (Gy):

If relevant, please estimate the dose deviation from the prescribed dose per fraction:

*Clinical incident severity: Help Text

*Summarize the incident in a single sentence headline:

If the incident-cause is related to equipment (hardware or software), please specify the make, model and version number:

Describe the incident in detail:

Describe the causes of the incident (Select one

Taxonomies and Severity Scales

Consensus recommendations for incident learning database structures in radiation oncology

E.C. Ford, L. Fong de Los Santos,
T. Pawlicki, S. Sutlief, and P. Dunscombe

Medical Physics 39, 7272-7290. 2012

Taxonomies and Severity Scales

RO•ILS
RADIATION ONCOLOGY
INCIDENT LEARNING SYSTEM
Sponsored by ASTRO and AAPM

Features
- Voluntary.
- Initially free to users.
- Detailed reports not discoverable.
- Released on 19th June 2014.

ESTRO school

Exercise 1: Roles

An error was discovered just as the patient was being set-up. Who should be reporting (R)/analyzing (A) what?

	RO	MP	RTT	T
Who discovered the Incident?				
How was the Incident discovered?				
What phase in the process is the Incident associated with?				
Where in the process was the Incident discovered?				
Was anyone affected by the Incident?				
Was any part of the prescribed treatment delivered incorrectly				
If relevant please estimate the dose deviation from the prescribed dose per fraction.				
Clinical Incident Severity (actual or potential)				
Describe the causes of the Incident.				
What safety barrier failed to identify the incident?				

Exercise 1: Roles

An error was discovered just as the patient was being set-up. Who should be reporting (R)/analyzing (A) what?

	RO	MP	RTT	T
Who discovered the Incident?	R			
How was the Incident discovered?				
What phase in the process is the Incident associated with?				A
Where in the process was the Incident discovered?				
Was anyone affected by the Incident?				
Was any part of the prescribed treatment delivered incorrectly				
If relevant please estimate the dose deviation from the prescribed dose per fraction.				
Clinical Incident Severity (actual or potential)				
Describe the causes of the Incident.				
What safety barrier failed to identify the incident?				

Taxonomies and Severity Scales

Outline

- **Incident Learning Systems**

To review the structure of a generic Incident Learning System.

- **SAFRON and the AAPM**

To place taxonomies in the context of SAFRON and the AAPM structure.

- **Taxonomy Review**

To review some current taxonomies in radiotherapy incident learning.

Taxonomies and Severity Scales

IAEA | SAFRON - Safety in Radiation Oncology

The drop downs, tables and lists that SAFRON uses:

1. Who discovered the Incident?
2. How was the Incident discovered?
3. What phase in the **process** is the Incident associated with?
4. Where in the **process** was the Incident discovered?
5. Was anyone affected by the Incident?
6. Was any part of the prescribed treatment delivered incorrectly?
7. If relevant please estimate the dose deviation from the prescribed dose per fraction.
8. Clinical Incident **severity**
9. Describe the **causes** of the Incident.
10. What **safety barrier** failed to identify the incident……..

ESTRO school

A few taxonomies

- Process Maps
- Severity
- Causes
- Barriers

Taxonomies and Severity Scales

A few taxonomies

- **Process Maps**
- **Severity**
- **Causes**
- **Barriers**

Taxonomies and Severity Scales

What's the difference between a process map and a process tree?

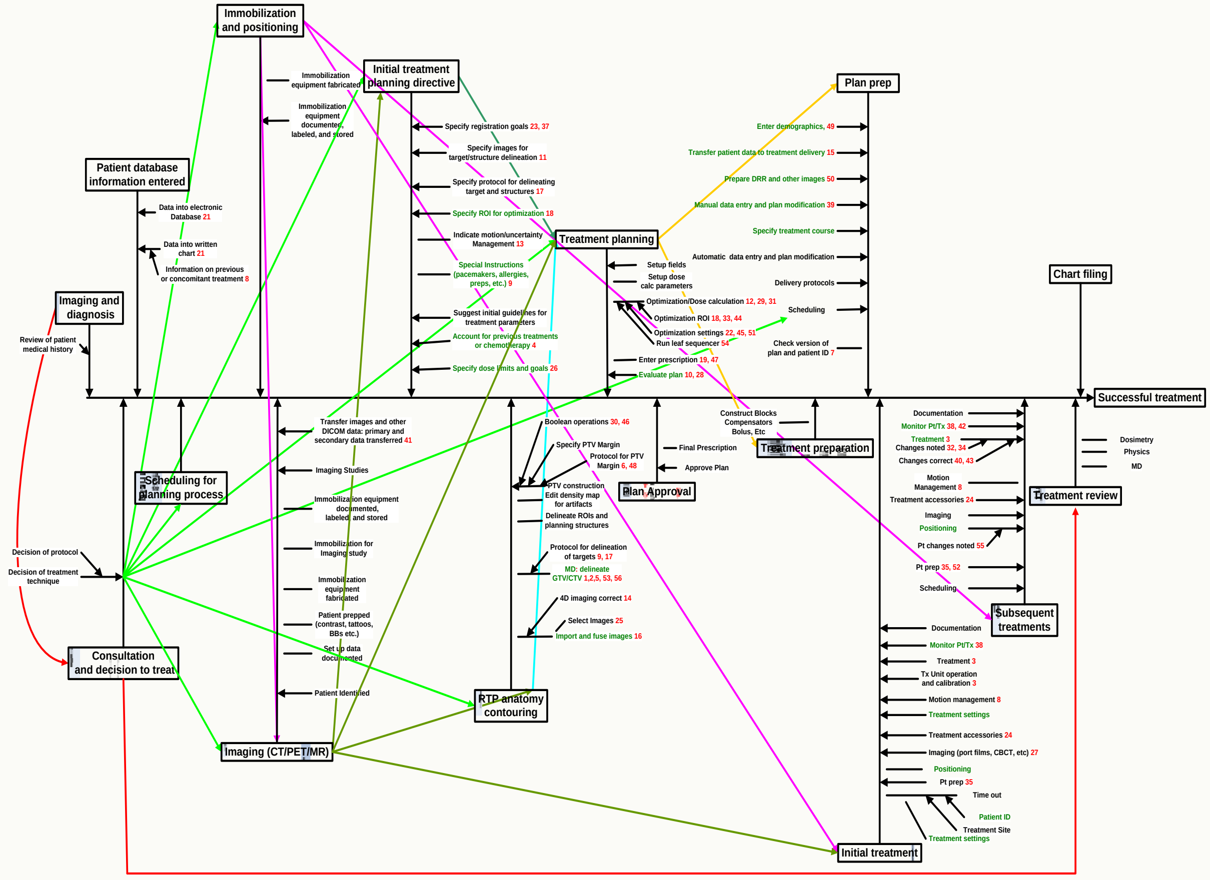
A map is presented as a linear chronological journey through the whole process with (conditional) return loops as necessary.

A tree is presented as groups of sub-processes feeding into the main process.

ESTRO school

Taxonomies and Severity Scales

TG 100's Process Tree



Huq MS, Fraass BA, Dunscombe P, et al. The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management. Medical Physics 43, 4209 – 4262. 2016.

Taxonomies and Severity Scales

Ford's Process Map

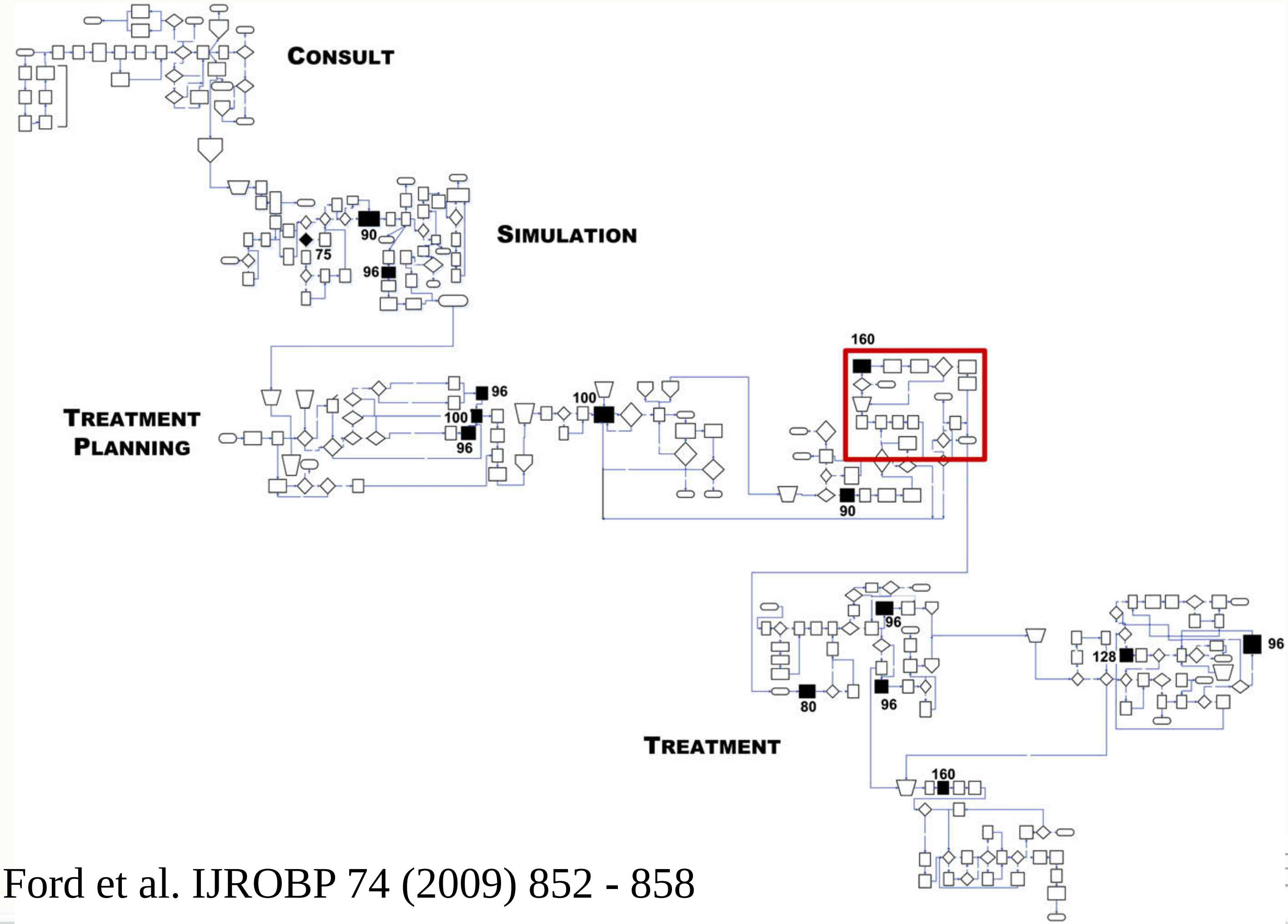
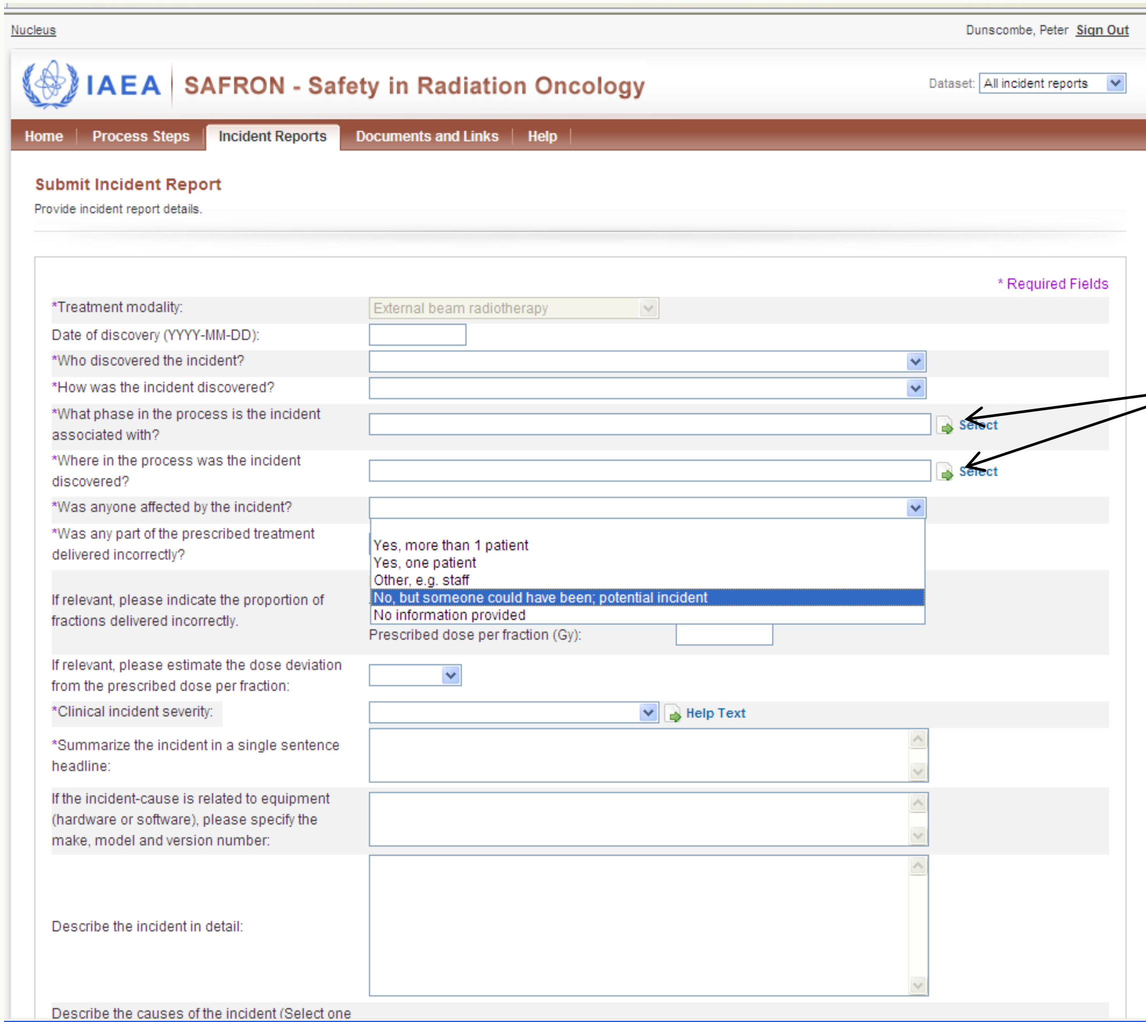


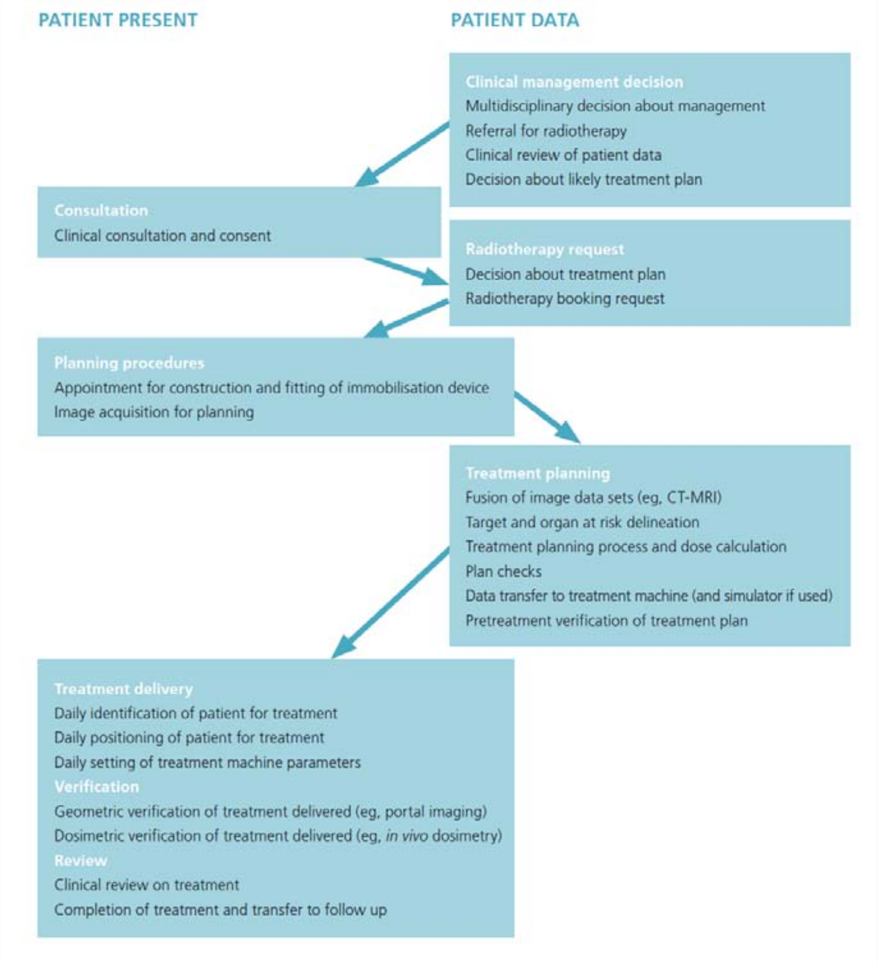
Figure 1. Ford et al. IJROBP 74 (2009) 852 - 858

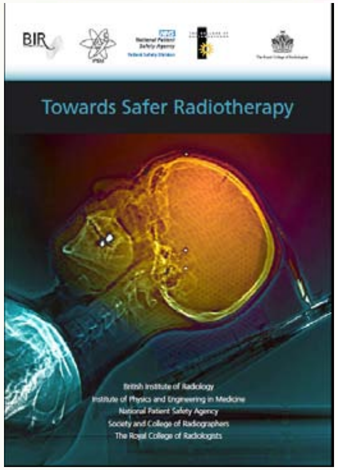
Taxonomies and Severity Scales



Process Maps

Taxonomies and Severity Scales





From "Towards Safer Radiotherapy"

Taxonomies and Severity Scales

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Select a Associated Process Step

- 2.4.1. Confirmation of ID
- 2.4.2. Production of immobilization devices
- 2.4.3. Production of other accessories/personalized beam shaping device
- 2.4.4. Recording of information in patient record
- 2.4.5. Instructions to patient
- 2.4.6. Other

⊟ 2.5. Simulation, imaging and volume determination

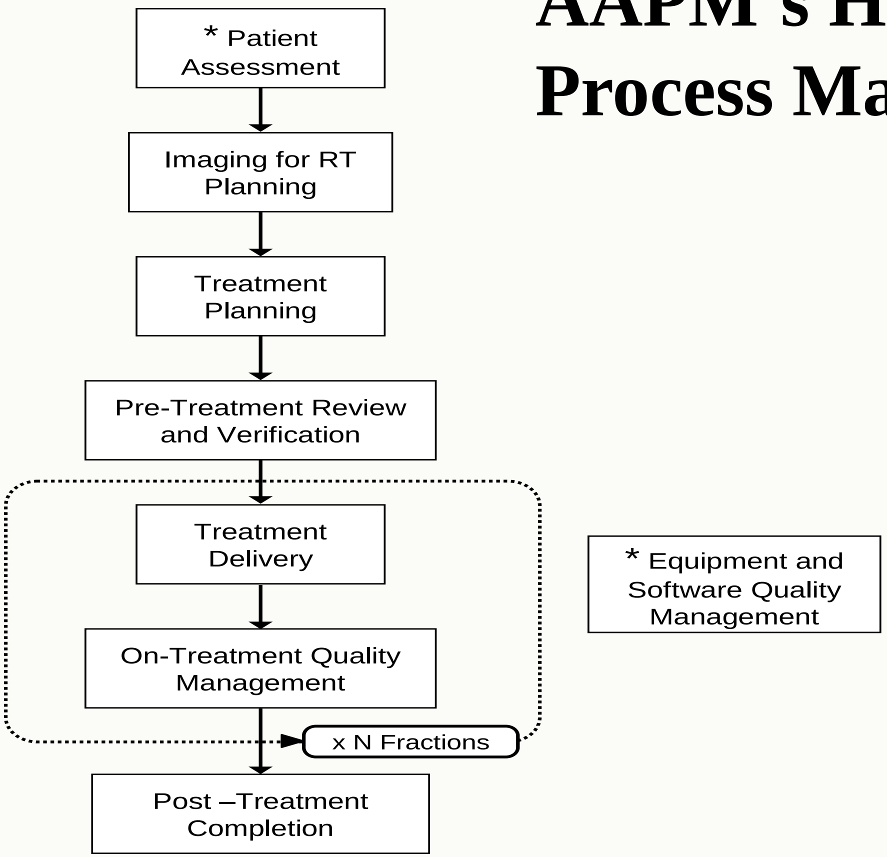
- 2.5.1. Confirmation of ID
- 2.5.2. Positioning of patient
- 2.5.3. Localization of intended volume
- 2.5.4. Production of images
- 2.5.5. Labelling of images
- 2.5.6. Saving and recording of data
- 2.5.7. Other

⊟ 2.6. Treatment planning

- 2.6.1. Verification of patient ID
- 2.6.2. Importing of data from external data sources

Taxonomies and Severity Scales

AAPM's High Level Process Map



E Ford, L Fong de los Santos, T Pawlicki, S Sutlief, P Dunscombe. Consensus recommendations for incident learning database structures in radiation oncology. Medical Physics 39, 7272-7290. 2012

AAPM Proposed Process Map

2. Imaging for RT Planning ☺		
SB	2.1	Verification of patient ID
	2.2	Imaging decision (type and technique)
	2.3	Physician directive for imaging technique and immobilization
	2.4	Patient Positioning
	2.5	Construction of immobilization and ancillary devices
	2.6	Documentation of patient positioning and immobilization and ancillary devices
	2.7	Contrast administration
	2.8	Primary image acquisition (CT)
	2.9	Marking reference point on patient and/or localization device and in software.
	2.10	Utilization of other imaging modalities (i.e. MRI, US, PET)
	2.11	Transfer of images to treatment planning system
	2.12	Transfer of images to archiving system
	2.13	Other

Exercise 2: Discoverability

How likely are errors in these steps to be discovered later in the process?

	Very likely	Perhaps	Very unlikely
Patient Assessment			
Imaging for RT Planning			
Treatment Planning			
Pre-treatment review and verification			
Treatment delivery			
On-treatment Quality Management			
Post-treatment Completion			
Equipment and software quality management			

Exercise 2: Discoverability

How likely are errors in these steps to be discovered later in the process?

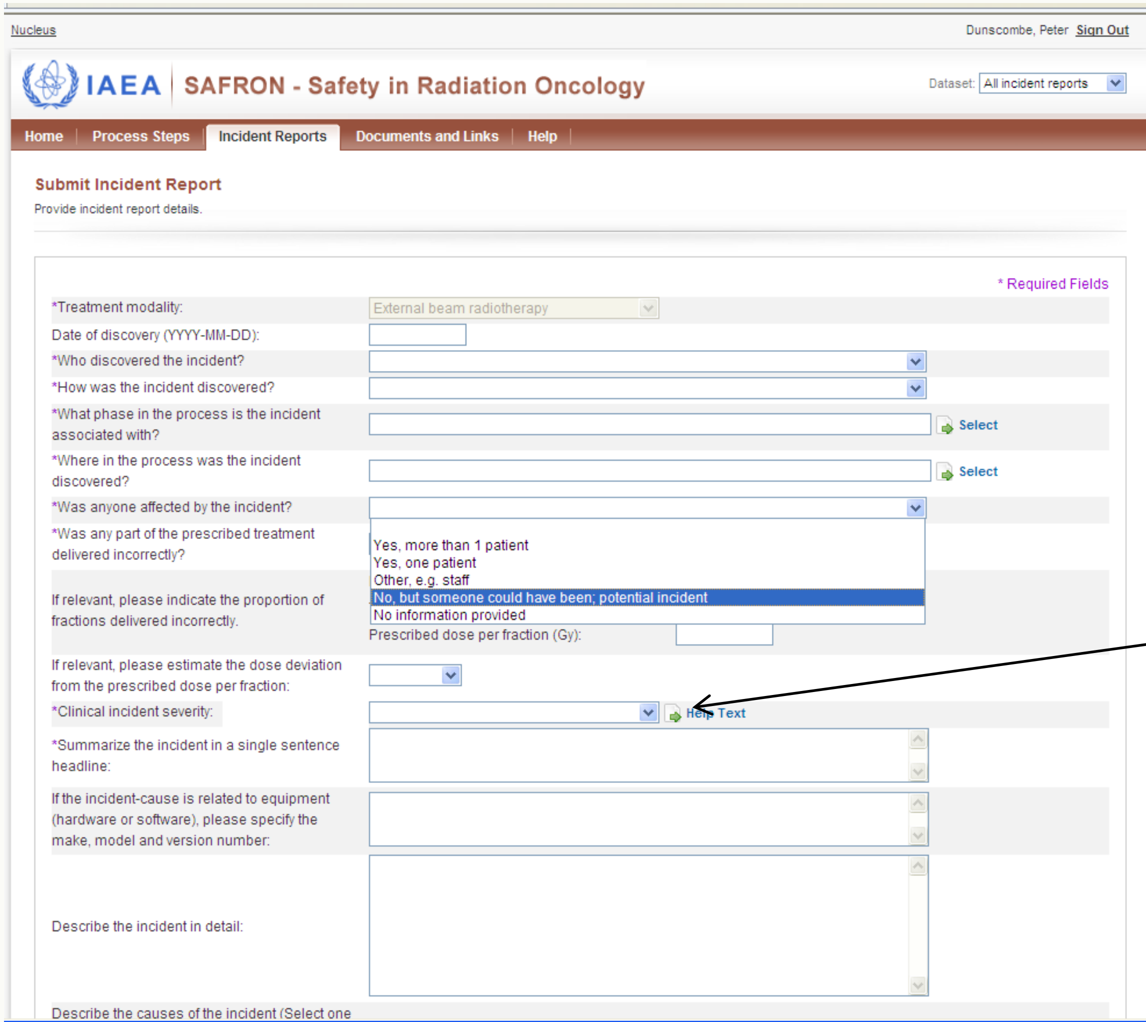
	Very likely	Perhaps	Very unlikely
Patient Assessment	✔		
Imaging for RT Planning			
Treatment Planning			
Pre-treatment review and verification			✔
Treatment delivery			
On-treatment Quality Management			
Post-treatment Completion			
Equipment and software quality management			

Example

A few taxonomies

- Process Maps
- **Severity**
- Causes
- Barriers

Taxonomies and Severity Scales



Severity

Taxonomy Review: Process maps »Severity »Causes »Barriers

Taxonomies and Severity Scales

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Incident Severity Help

- **Minor Incident**
  - Dose variation from prescribed total dose of <5%
  - Near miss or unsafe condition which could potentially cause a treatment error
  - Patient complaint
- **Potential Serious Incident**
  - A near miss that could have been a serious incident
- **Serious Incident**
  - Dose variation from prescribed total dose of 5 - 10%
  - Radiation dose or medication error causing side effects requiring minor treatment or ongoing monitoring and assessment
  - Set up variation > 1cm - no critical structures included
- **Potential Major Incident**
  - A near miss that could have been a major incident
- **Major Incident**
  - Dose variation from prescribed total dose of 10 - 20%
  - Radiation dose or medication error causing side effects requiring major treatment and intervention or hospitalization
  - Set up variation that will/could impact on normal tissue (e.g. heart, lung, eyes, kidney etc.)
- **Critical Incident**
  - Radiation dose or medication error causing death or disability
  - Dose variation from prescribed total dose of >20%
  - Completely incorrect volume

ESTRO school

Taxonomies and Severity Scales

ASN-SFRO SCALE APPLICATION

	Events (unpredicted, unexpected)	Causes	Consequences (CTCAE V3.0 grade)
5 to 7* ACCIDENT	Death	Dose (or irradiated volume) much greater than normal resulting in complications or sequelae incompatible with life	Death
4** ACCIDENT	Serious life-threatening event, disabling complication or sequela	Dose or irradiated volume much greater than the tolerable doses or volumes	Serious unexpected or unpredictable acute or delayed effect, grade 4
3** INCIDENT	Event resulting in severe alteration of one or more organs or functions	Dose or irradiated volume greater than the tolerable doses or volumes	Severe unexpected or unpredictable acute or delayed effect, grade 3
2** INCIDENT	Event resulting in or likely to result in moderate alteration of an organ or function	Dose greater than the recommended doses, or irradiation of a volume that may lead to unexpected but moderate complications	Moderate unexpected or unpredictable acute or delayed effect, grade 2, minimal or absence of alteration of quality of life
1 EVENT	Event with dosimetric consequences but no expected clinical consequences	Dose or volume error (e.g. dose error or target error in a session not compensable over the treatment as a whole)	No symptoms expected
0 EVENT	Event with no consequences for the patient	Dose error (number of monitor units, filter, etc.) compensated over the treatment as a whole. Error of identification of a patient treated for the same pathology (compensable)	

* *In the case of deaths of several patients:*
- *the minimum level 5 is raised to 6 if the number of patients is greater than 1 but less than or equal to 10;*
- *the minimum level 5 is raised to 7 if the number of patients is greater than 10.*

** *If the number of patients is greater than 1, a + sign is added to the assigned level (example: 3 become 3+).*

Taxonomies and Severity Scales

Severity Metric: medical score.

Score	Consequences (actual or predicted)
10	Premature death
8/9	Life threatening – intervention essential
7	Permanent major disability (or grade 3/4 permanent toxicity)
5/6	Permanent minor disability (or grade 1/2 permanent toxicity)
3/4	Temporary side effects – major treatment/hospitalization
2	Temporary side effects – intervention indicated
1	Temporary side effects – intervention not indicated
0	No harm
--	Unknown

Severity Metric: dosimetric score.

Score	Dose deviation per course or per fraction
9/10	> 100% absolute dose deviation from the total prescription for any structure
7/8	> 25-100% absolute dose deviation from the total prescription for any structure
5/6	> 10-25% absolute dose deviation from the total prescription for any structure
3/4	> 5-10% absolute dose deviation from the total prescription for any structure
1/2	< 5% absolute dose deviation from the total prescription for any structure
--	Not applicable

Exercise 3: Severity

Medical and dosimetric scores do not directly address the issue of geometric misses? How would you report a geometric miss?

	Yes	No
Ignore geometric misses – they are too difficult to quantify		
Record the largest dose deviation in the PTV or Organ at Risk		
Only record if an OAR dose limit were exceeded		
Error in mm in the position of the field central ray with respect to patient anatomy		
Error in mm of any field edge		
Use a metric which combines dose and volume information such as EUD		

Exercise 3: Severity

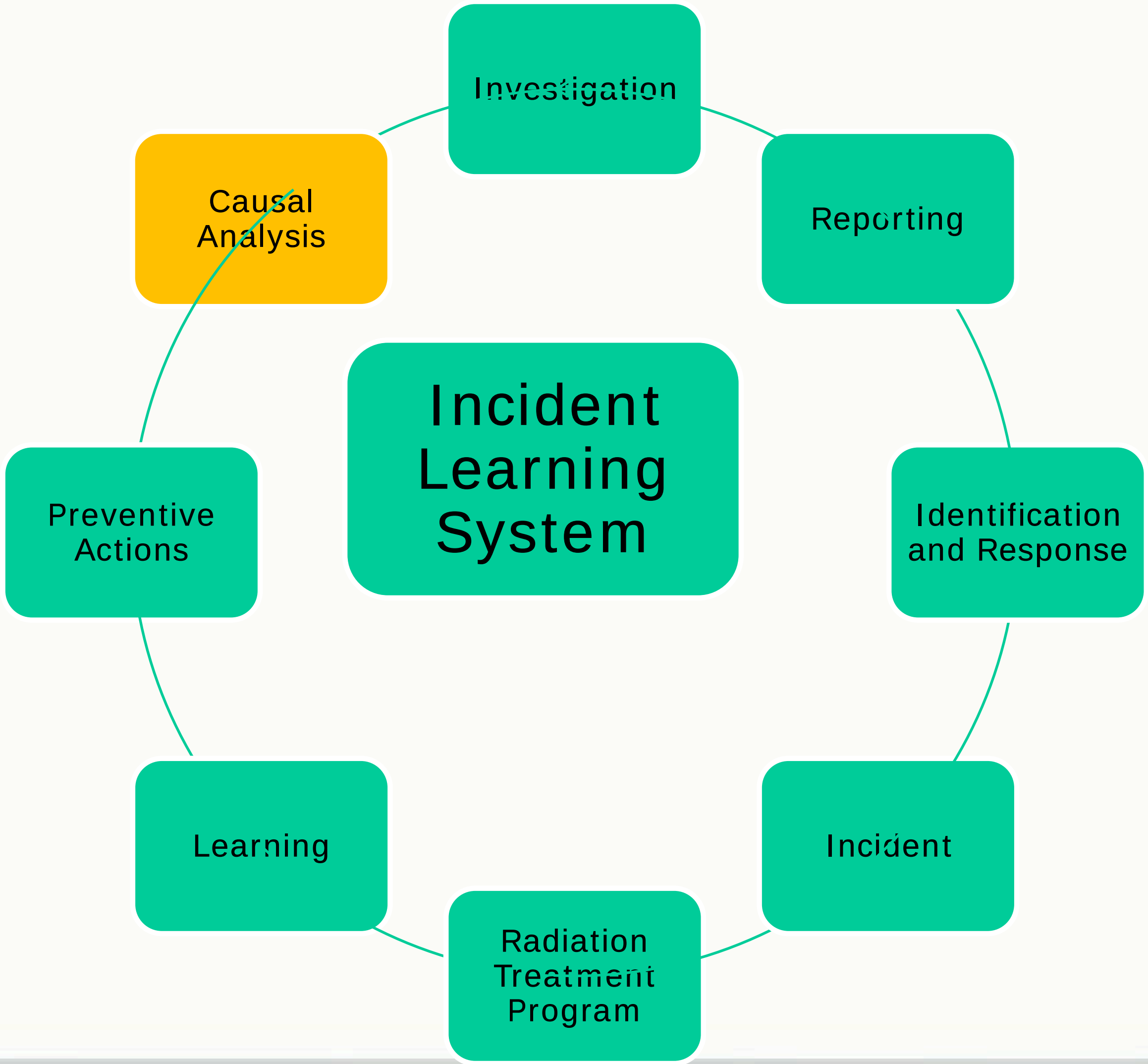
Medical and dosimetric scores do not directly address the issue of geometric misses? How would you report a geometric miss?

	Yes	No
Ignore geometric misses – they are too difficult to quantify		✔
Record the largest dose deviation in the PTV or Organ at Risk	✔	
Only record if an OAR dose limit were exceeded	✔	
Error in mm in the position of the field central ray with respect to patient anatomy		✔
Error in mm of any field edge		✔
Use a metric which combines dose and volume information such as EUD		✔

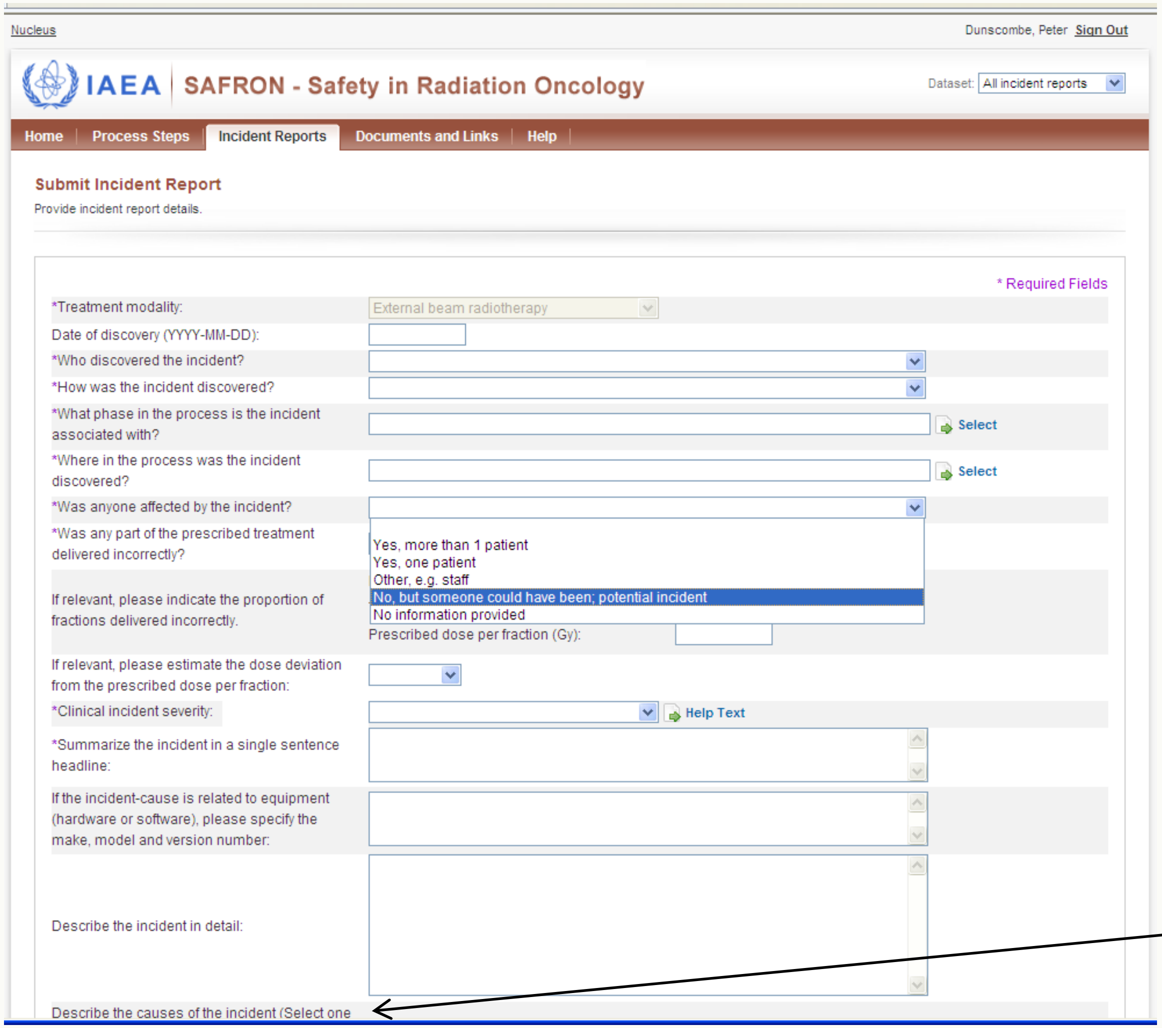
A few taxonomies

- Process Maps
- Severity
- **Causes**
- Barriers

Taxonomies and Severity Scales



Taxonomies and Severity Scales



Causes

Taxonomy Review: Process maps »Severity »Causes »Barriers

Taxonomies and Severity Scales

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Select multiple Incident causes from tree view

- Job Factors
  - Standards/Procedures/Practices
    - 1.1 Not developed
    - 1.2 Inadequate standard/procedure/practice
    - 1.3 Standard/Procedure/Practice not followed
    - 1.4 Inadequate communication of procedure
    - 1.5 Inadequate assessment of risk
    - 1.6 Not implemented
  - Materials/Tools/Equipment
    - 2.1 Availability
    - 2.2 Defective
    - 2.3 Inadequate maintenance
    - 2.4 Inspection
    - 2.5 Used incorrectly
    - 2.6 Inadequate assessment of materials/tools/equipment for task
  - 3. Design
    - 3.1 Inadequate hazard assessment

Submit

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Taxonomies and Severity Scales

Classification of Basic Cause

Facility Management/Planning

1 Inadequate Human Resources
- 1.1 Inconsistent with prof. recommendations
- 1.2 Inconsistent with vendor specs
- 1.3 Inconsistent with regulations
- 1.4 No provision for increase in activities
- 1.5 Personnel availability

2 Inadequate Capital Resources
- 2.1. Inadequate budget for equipment
- 2.2. Inadequate support/service contracts
- 2.3. Inadequate training support
- 2.4. Insufficient IT infrastructure
- 2.5. Inappropriate or inadequate equipment

3 Policies, Procedures, Regulations
- 3.1. Relevant policy nonexistent
- 3.2. Policy not implemented
- 3.3. Policy inadequate
- 3.4. Policy not followed
- 3.5. External regulation not followed
- 3.6. Conflicting policies

4 Training
- 4.1. Facility training inadequate
- 4.2. Vendor training inadequate
- 4.3. Training needs not identified
- 4.4. Inadequate assessment of staff competencies
- 4.5. Lack of continuing education

5 Communication
- 5.1. Poor/incomplete/unclear/missing documentation
- 5.2. Inadequate communication patterns designed
- 5.3. Inappropriate or misdirected communication
- 5.4. Failure to request needed information
- 5.5. Medical records incorrect/incomplete/absent
- 5.6. Lack of timeliness
- 5.7. Verbal instruction inconsistent w documentation

6 Physical Environment
- 6.1. Physical environment inadequate
- 6.2. Distracting environment
- 6.3. Interruptions
- 6.4. Conflicting demands/priorities

7 Leadership and External Issues
- 7.1. Inadequate safety culture
- 7.2. Failure to remedy past known shortcomings
- 7.3. Environment not conducive to safety
- 7.4. Hostile work environment
- 7.5. Inadequate supervision
- 7.6. Lack of peer review
- 7.7. Leaders not fluent in the discipline
- 7.8. Outdated practices

Clinical Infrastructure

8 Materials/Tools/Equipment
- 8.1. Availability
- 8.2. Defective
- 8.3. Used incorrectly
- 8.4. Inadequate assessment of material/tool/equipment for the task

9 Acceptance Testing & Commissioning
- 9.1. Not following best-practice documents
- 9.2. Lack of independent review
- 9.3. Lack of review of pre-existing reports
- 9.4. Lack of effective documentation

10 Equipment Design and Construction
- 10.1. Inadequate P&Ps for QA and QC
- 10.2. Inadequate hazard assessment
- 10.3. Inadequate design specification
- 10.4. Inadequate assessment of operational capabilities
- 10.5. Poor human factors engineering
- 10.6. Interoperability problems
- 10.7. Networking problems (IT)
- 10.8. Software operation failure
- 10.9. Poor construction (physical)

11 Equipment Maintenance
- 11.1. Failure to report problems to vendor
- 11.2. Failure to follow vendor field change orders
- 11.3. Failure to provide adequate preventive maintenance
- 11.4. Failure by vendor to share failure/safety issues
- 11.5. Unavailability of local and field support

12 Environment (within the facility)
- 12.1. Ergonomics (room layout, equipment setup)
- 12.2. Machine collision issues (room specific)
- 12.3. Environment (water, HVAC, electrical, gas)
- 12.4. IT infrastructure and networking issues
- 12.5. Delay in corrective actions for facility problems

13 External Factors (beyond Facility Control)
- 13.1. Natural environment
- 13.2. Hazards

Clinical Process

14 Failure to detect a developing problem
- 14.1. Environmental masking
- 14.2. Distraction
- 14.3. Loss of attention
- 14.4. Lack of information

15 Failure to interpret a developing problem
- 15.1. Inadequate search
- 15.2. Missing information
- 15.3. Incorrect information
- 15.4. Expectation Bias

16 Failure to select the correct rule
- 16.1. Incomplete or faulty rule
- 16.2. Old or invalid rule
- 16.3. Misapplication of a rule

17 Failure to develop an effective plan
- 17.1. Information not seen or sought
- 17.2. Inappropriate assumptions
- 17.3. Failure to recognize a hazard
- 17.4. Information misinterpreted
- 17.5. Inadequate management of change
- 17.6. Inadequate assessment of needs & risks
- 17.7. Side effects not adequately considered
- 17.8. Mistaken options

18 Failure to execute the planned action
- 18.1. Stereotype take-over/faulty triggering
- 18.2. Plan forgotten in progress
- 18.3. Plan misinterpreted
- 18.4. Plan too complicated (bounded reality)

19 Patient-Related Circumstances
- 19.1. Misleading representation
- 19.2. Cognitive performance issues
- 19.3. Non-compliance
- 19.4. Language issues and comprehension
- 19.5. Patient condition, eg, physical capabilities, inability to remain still

20 Human Behavior Involving Staff
- 20.1. Unclear roles, responsibilities & accountabilities
- 20.2. Acting outside one's scope of practice
- 20.3. Slip causing physical error
- 20.4. Poor judgment
- 20.5. Language and comprehension issues
- 20.6. Intentional rules violation
- 20.7. Negligence

21 Other

Exercise 4: Basic Causes

What do you think are the most reported Basic Causes in radiotherapy? Please rank.

Issues to do with	Rank
Workers' knowledge/skill	
Standards and procedures	
Personal judgment	
Communication	
Work planning	
Equipment and materials.	

Exercise 4: Basic Causes

What do you think are the most reported Basic Causes in radiotherapy? Please rank.

Example

Issues to do with	Rank
Workers' knowledge/skill	5
Standards and procedures	4
Personal judgment	3
Communication	6
Work planning	1
Equipment and materials.	2

ESTRO school

Taxonomies and Severity Scales

A few taxonomies

- Process Maps
- Severity
- Causes
- **Barriers**

Taxonomies and Severity Scales

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*What phase in the process is the incident associated with? Select

*Where in the process was the incident discovered? Select

*Was anyone affected by the incident?

*Was any part of the prescribed treatment delivered incorrectly?

If relevant, please indicate the proportion of fractions delivered incorrectly.
- How many fractions were delivered incorrectly?
- Total number of fractions prescribed:
- Prescribed dose per fraction (Gy):

If relevant, please estimate the dose deviation from the prescribed dose per fraction:

*Clinical incident severity: Help Text

*Summarize the incident in a single sentence headline:

If the incident-cause is related to equipment (hardware or software), please specify the make, model and version number:

Describe the incident in detail:

Describe the causes of the incident (Select one or several reasons): Select Incident Causes

*Did the incident reach the patient? ☐Yes ☐No

What safety barrier	failed to identified the incident?	identified the incident?	might have identified it?
Verification of patient ID	☐	☐	☐
Verification that pretreatment condition have been taken into account	☐	☐	☐
Verification of imaging data for planning (CT scan, fusion, imaging modality, correct data set)	☐	☐	☐
Verification reference points	☐	☐	☐
Physician peer review	☐	☐	☐
Review of treatment plan	☐	☐	☐
Independent confirmation of dose	☐	☐	☐

ESTRO school

Taxonomies and Severity Scales

IAEA | SAFRON - Safety in Radiation Oncology

What safety barrier	failed to identified the incident?	identified the incident?	might have identified it?
Verification of patient ID	☐	☐	☐
Verification that pretreatment condition have been taken into account	☐	☐	☐
Verification of imaging data for planning (CT scan, fusion, imaging modality, correct data set)	☐	☐	☐
Verification reference points	☐	☐	☐
Physician peer review	☐	☐	☐
Review of treatment plan	☐	☐	☐
Independent confirmation of dose	☐	☐	☐
Time out	☐	☐	☐
Use of record and verifying system	☐	☐	☐
Verification of treatment accessories	☐	☐	☐
Image based position verification	☐	☐	☐
In vivo dosimetry	☐	☐	☐
Intra-treatment monitoring	☐	☐	☐
Regular independent chart checks	☐	☐	☐
Regular clinic patient assessment	☐	☐	☐
Post treatment evaluations (evaluation of clinical and process)	☐	☐	☐
Independent review of commissioning	☐	☐	☐

Taxonomies and Severity Scales

The US system is based on a structure in which safety barriers are explicitly identified

4. Pre-Treatment Review and Verification		
SB	4.1	Physics plan review
SB	4.2	Independent dose calculation
	4.3	Plan data transfer to treatment unit
SB	4.4	Verification of parameters at treatment unit
SB	4.5	Pretreatment patient specific plan measurement (e.g. IMRT QA)
SB	4.6	Physics verification/approval
SB	4.7	Physician plan peer review (e.g. chart rounds)
SB	4.8	Therapists chart check
	4.9	Other

Exercise 5: Barriers

Please rank the following safety barriers in order of effectiveness at intercepting errors.

Barrier	Rank
Radiation therapist time out	
Physics plan review	
SSD checks	
Portal imaging	
Physician plan review	
Checklists	

Exercise 5: Barriers

Please rank the following safety barriers in order of effectiveness at intercepting errors.

Barrier	Rank
Radiation therapist time out	4
Physics plan review	5
SSD checks	1
Portal imaging	6
Physician plan review	2
Checklists	3

Summary

- We have reviewed the structure of a generic Incident Learning System.
- We have placed taxonomies in the context of SAFRON and the AAPM structure.
- We have reviewed some current taxonomies in radiotherapy incident learning.

Prisma model & PRISMA-RT

Petra Reijnders-Thijssen M.A.
manager quality & patient safety

Content

part 1: PRISMA in MAASTRO

part 2: PRISMA explanation

part 3: PRISMA-RT collaboration

Part 4: Benchmark

(part 1) PRISMA in MAASTRO

- Why systematic data analyses?
- Reporting committee
- Operation procedure in MAASTRO
- Database
- Results/examples

What do we want from the reports?

- Goal: analysis-results and effective improvements
- More insight on root causes of the failures which result in systematic deviations
- Looking for trends instead of intervening on one incident

PRISMA - model

Prevention and
Recovery
Information
System for
Monitoring and
Analysis

developed by
prof. T.W.v.d Schaaf

PRISMA-model

1. Collecting all (near)incidents
2. Incident Production Tree
3. Classification of base causes
4. Database
5. Analysis
6. Feedback to the organization
7. Action on the basis of the analysis

Advantages of the PRISMA-model

- Instrument for Quality Assurance
- Analysis improvement
- Statistical support of the analysis
- Monitoring the effect of management measures to reduce the number of incidents
- Possibility to benchmark with other RT-departments

example :

wrong patient treatment

MAASTRO

Datum melding:

31-01-2012

Gegevens melder:

inlognaam citrix		e-mailadres	
voornaam		achternaam	
functie			

Initialen betrokken:

Datum voorval:

(formaat dd-mm-yyyy, bijvoorbeeld: 25-11-2007)

Tijdstip voorval:

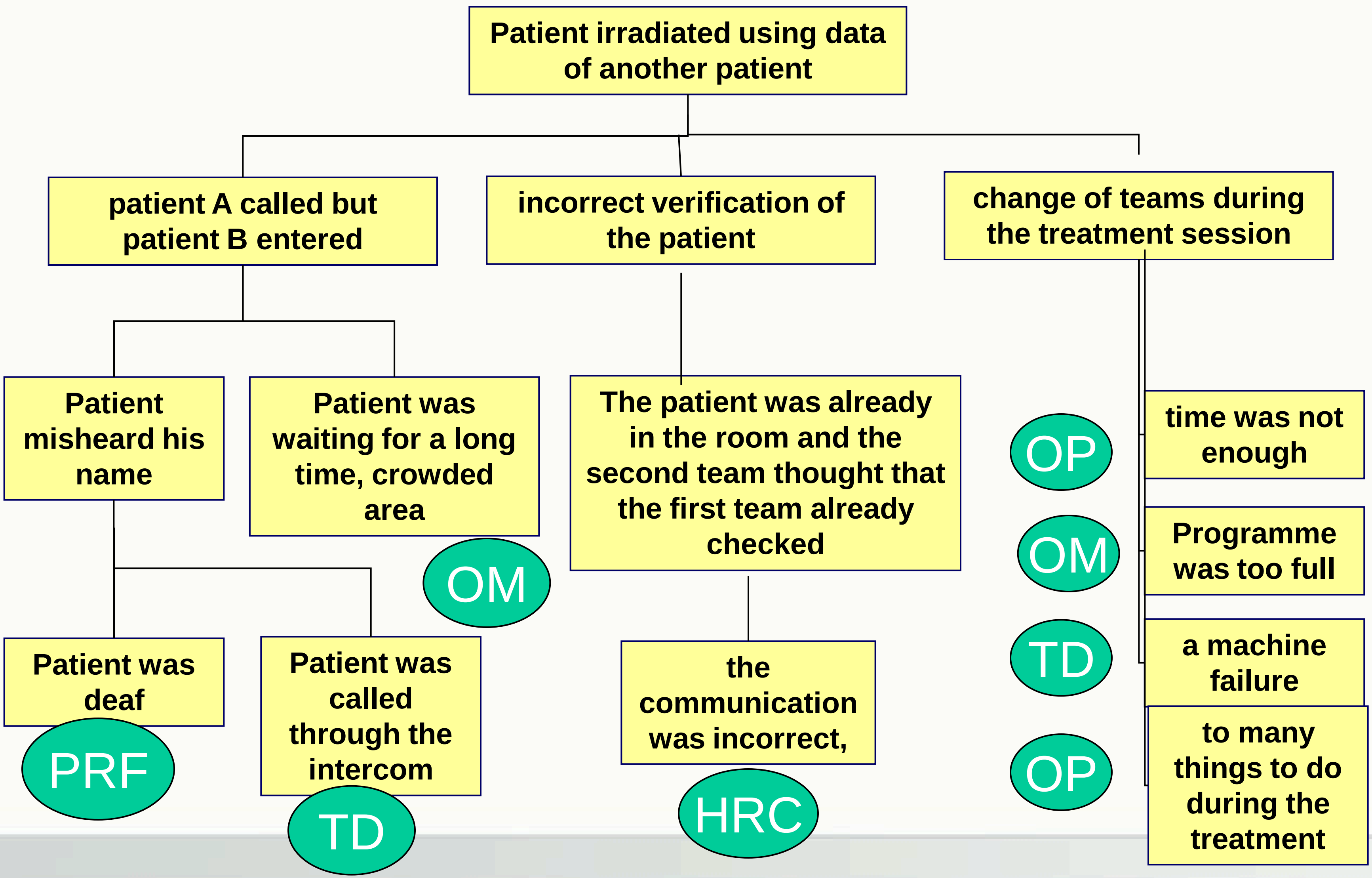
(formaat hh:mm, bijvoorbeeld: 13:00)

Melding heeft betrekking op de volgende groep

-- Selecteer -- | -- Selecteer --

Patisnummer (bij geen patisnummer vul '0' in)

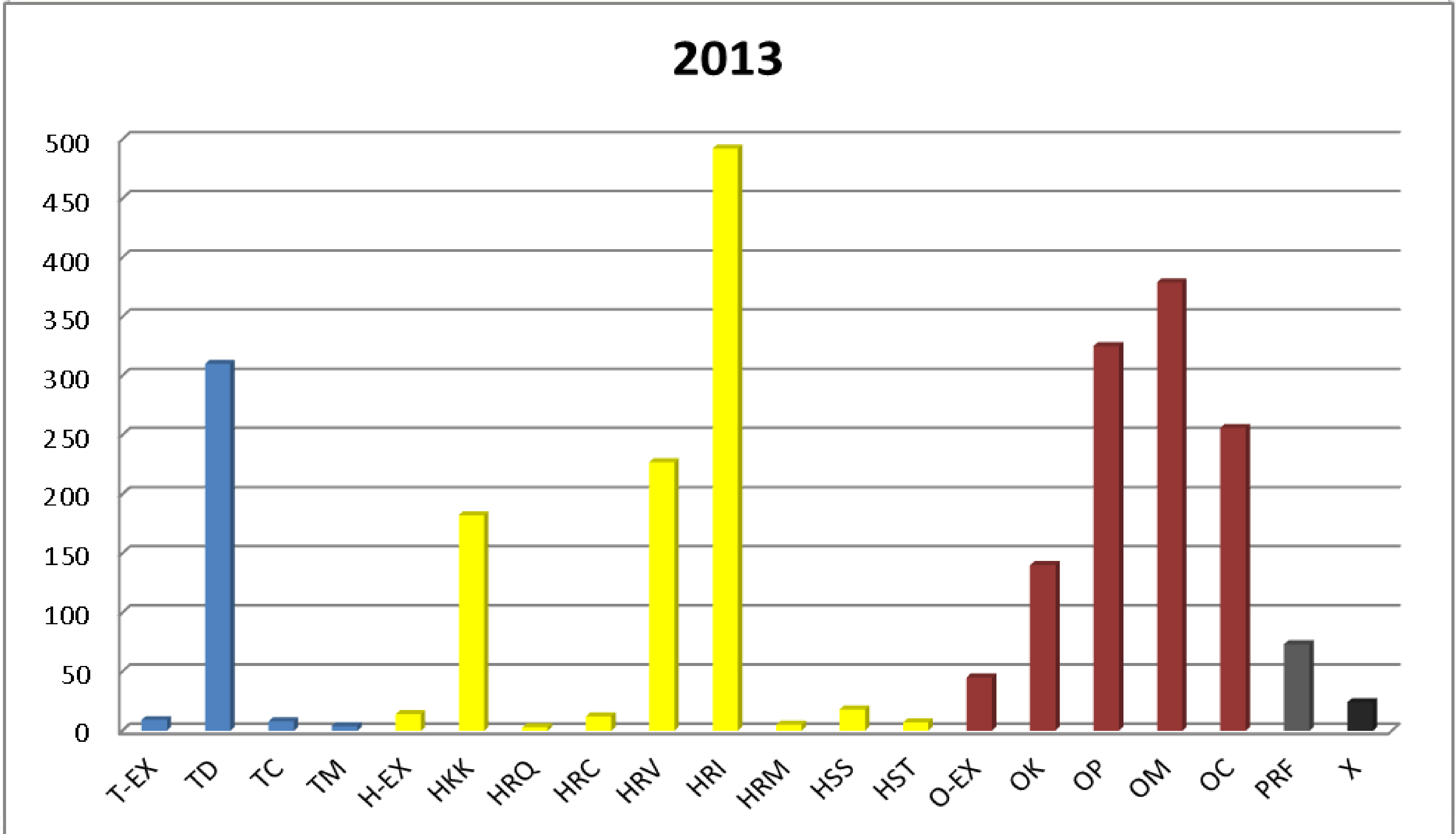
patient data exchange



classifications codes of rootcauses

- Technical failure (T): T-ex, TD,TC,TM
- Organisational failure (O): O-ex OK,OP,OM,OC
- Human failure (H): H-ex,HKK, HRQ,HRC,HRV,HRI,HRM, HSS,HST
- Patient Related factor: PRF
- Not possible to classify : X

what data is generated from the database



management actions

Action / Classification Matrix

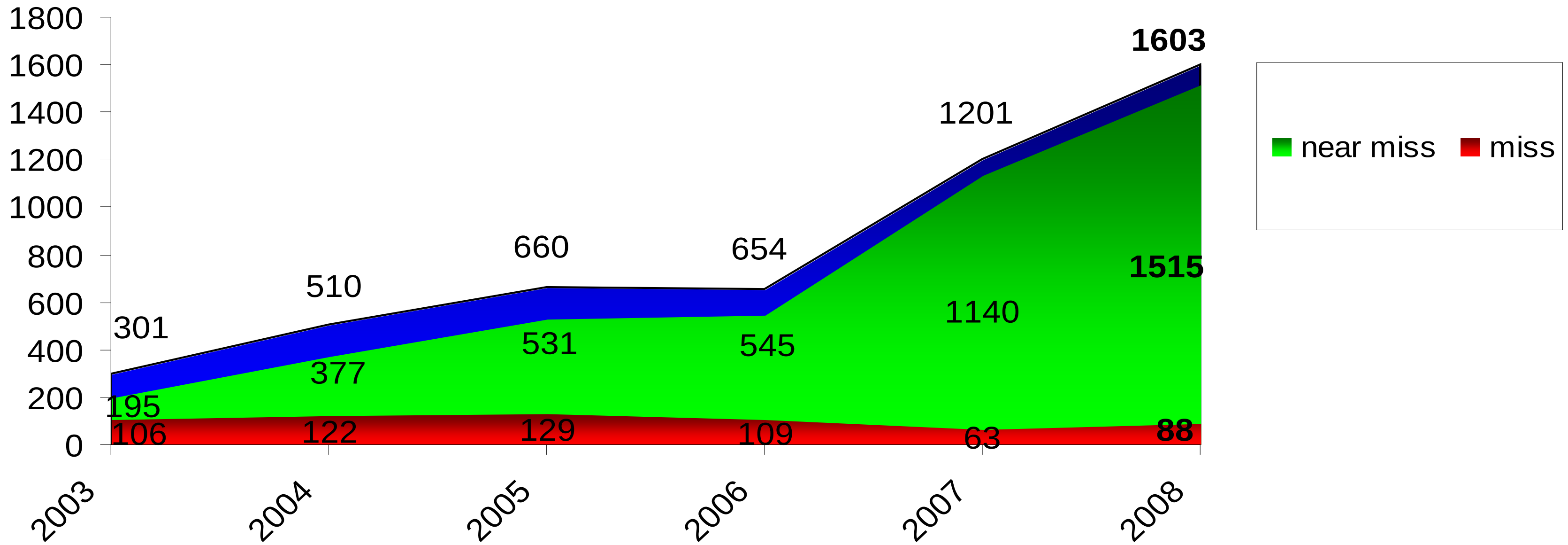
Classification Code	Technical	Procedure	Information & Communication	Training	Motivation
TD	X				
TC	X				
TM	X				
OK		X			
OP		X			
OM		X			
OC		X	(X)		
HKK			X		No
HRQ			X		No
HRC			(X)	X	
HRV				X	
HRI				X	
HRM				X	
HSS	X				No
HST	X				No

example of data analyse

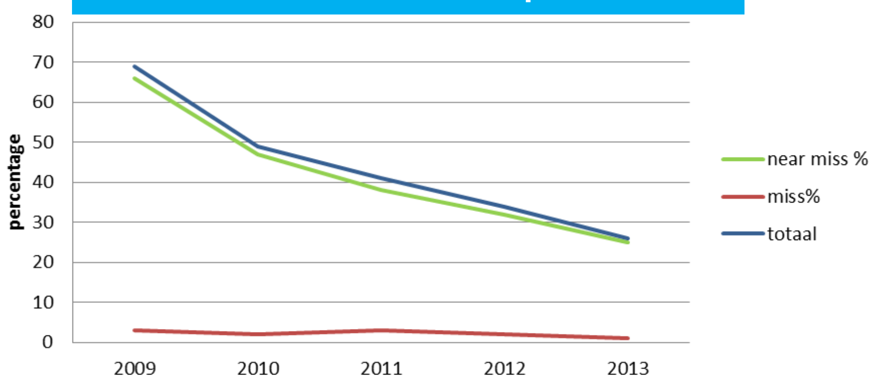
- high score OP (organisational produre) in relation to treatment process and newly qualified RTs
- conclusion: newly qualified staff didn’t know how to act when a linac stopped.
- action: add the procedure into the introduction program

Examples of grafics

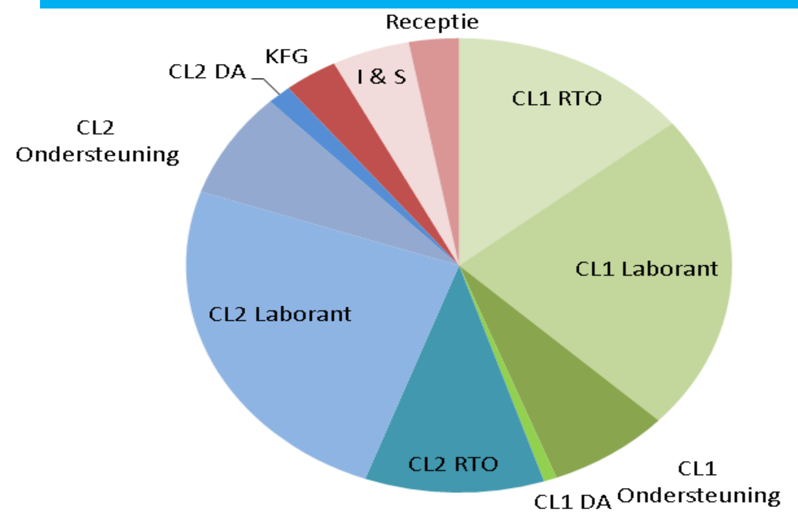
Trend amount of reports



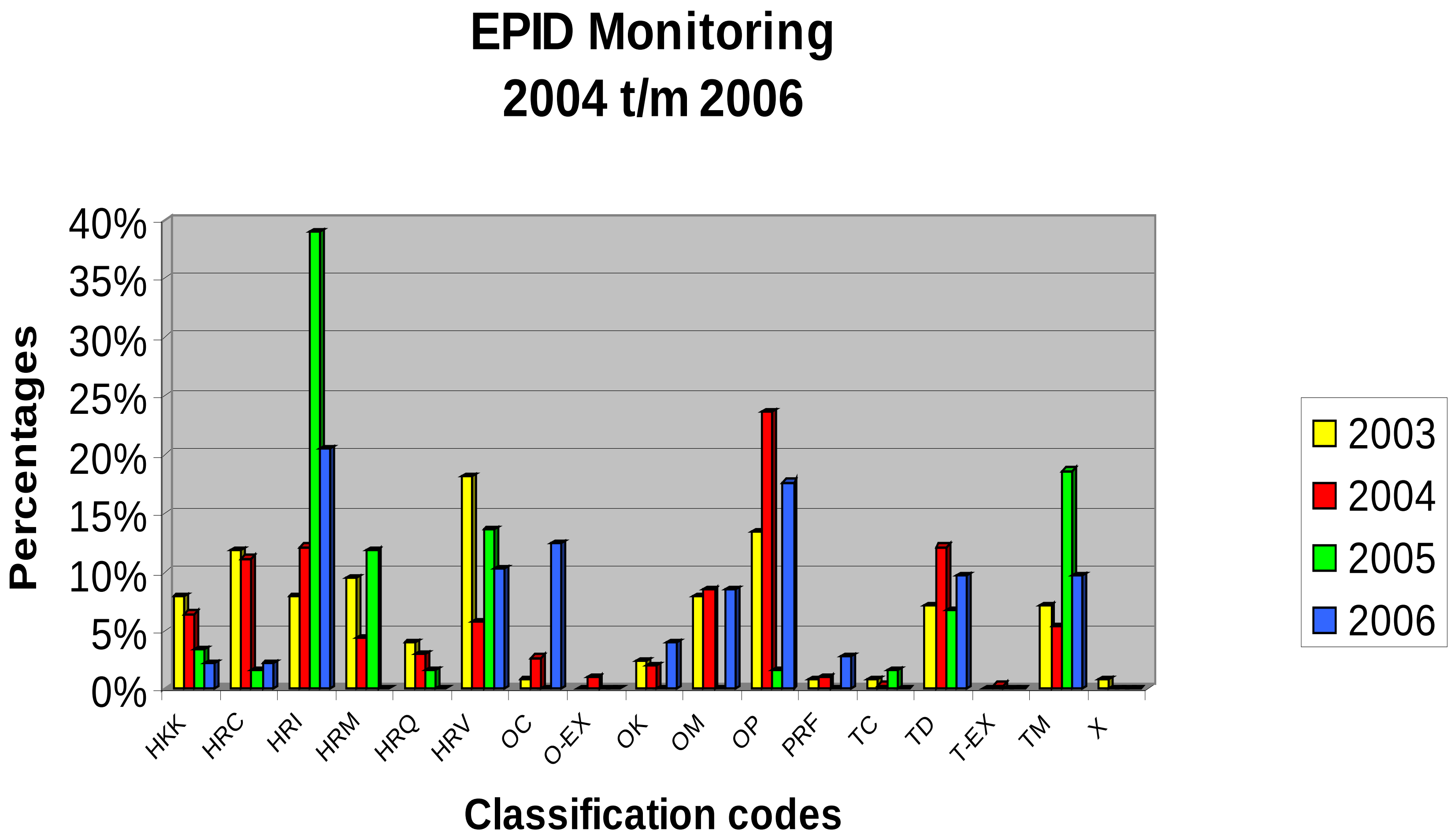
reports devided by the amount of treated patients



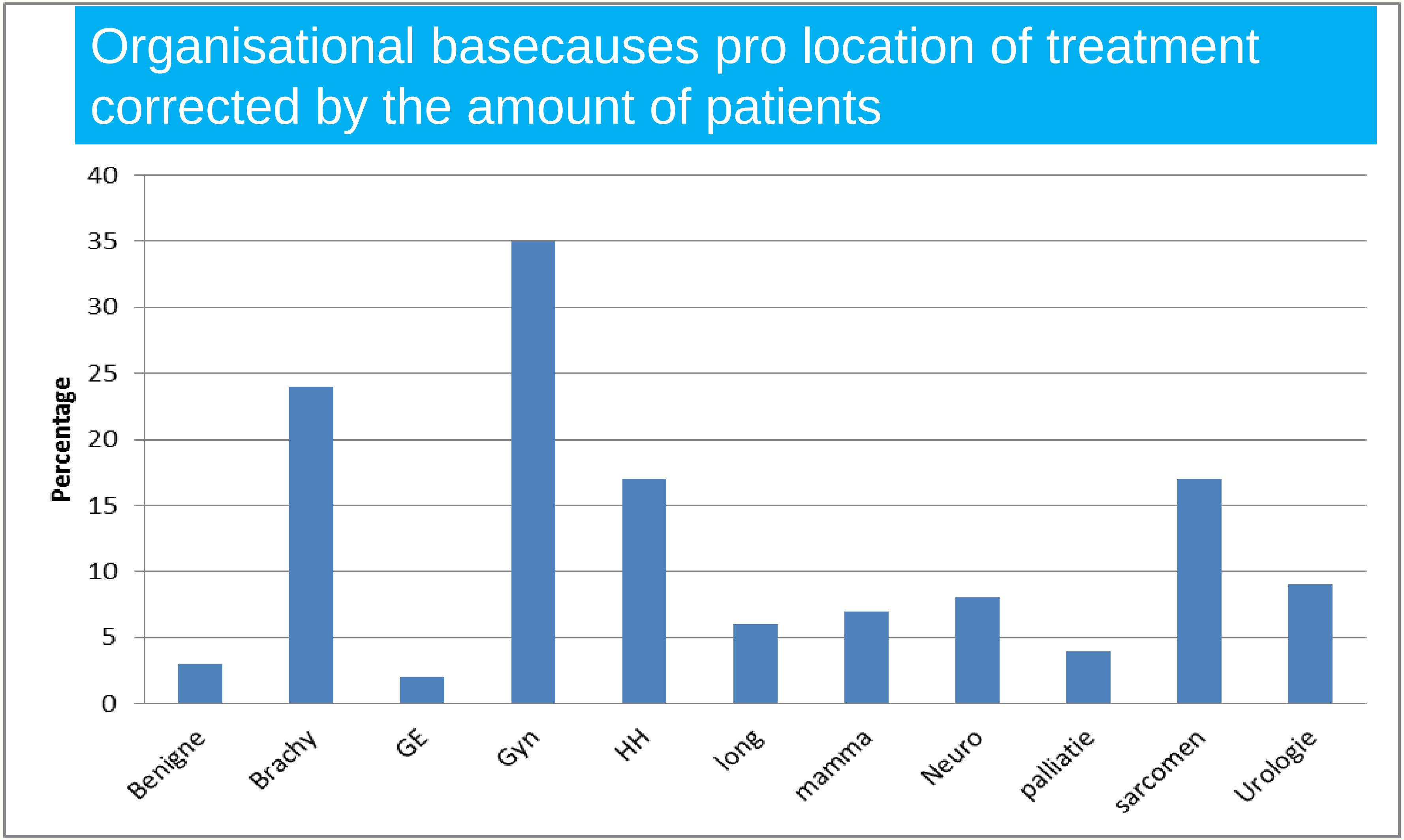
Reports pro functional group



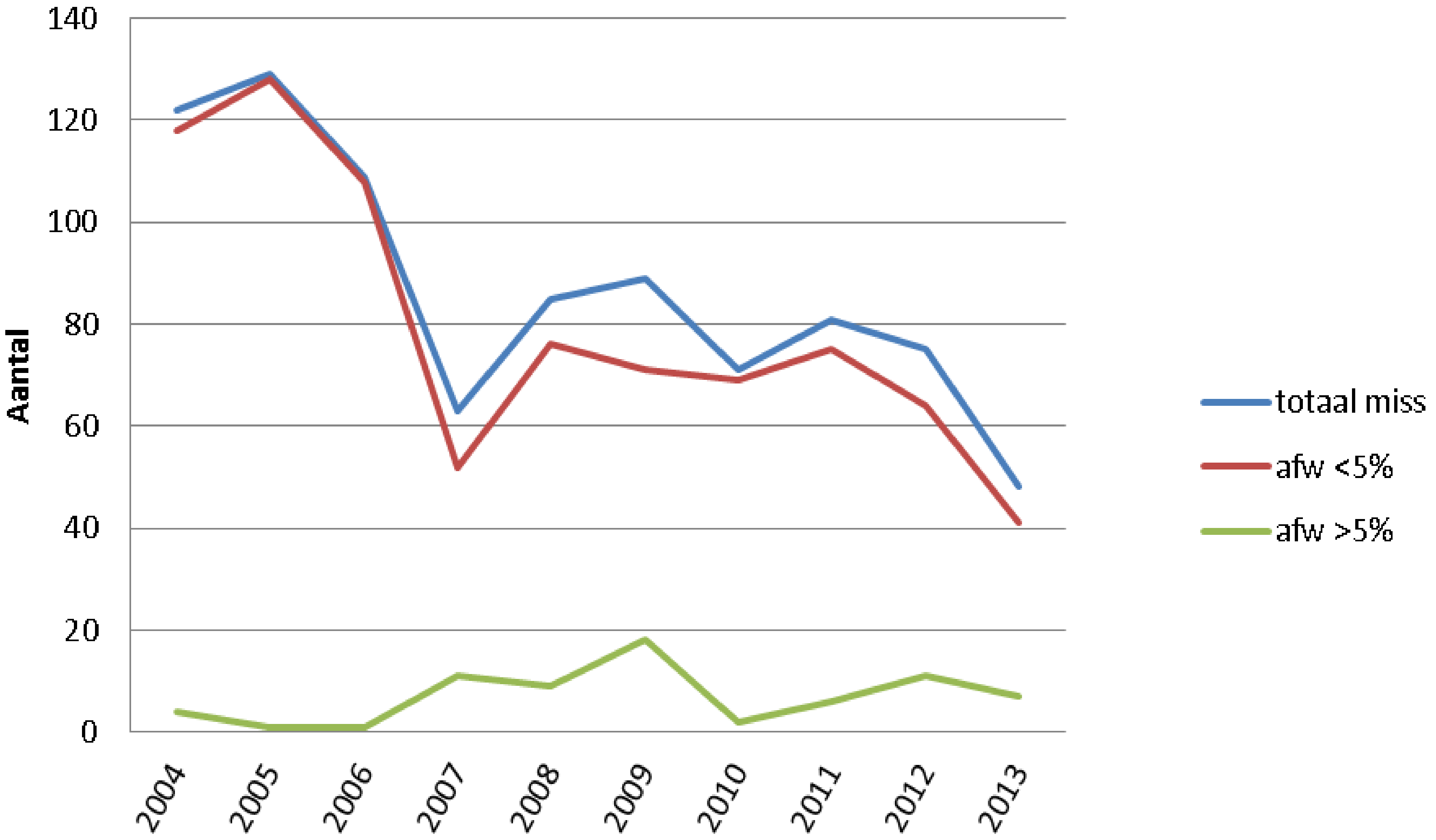
Monitoring d.m.v. PRISMA



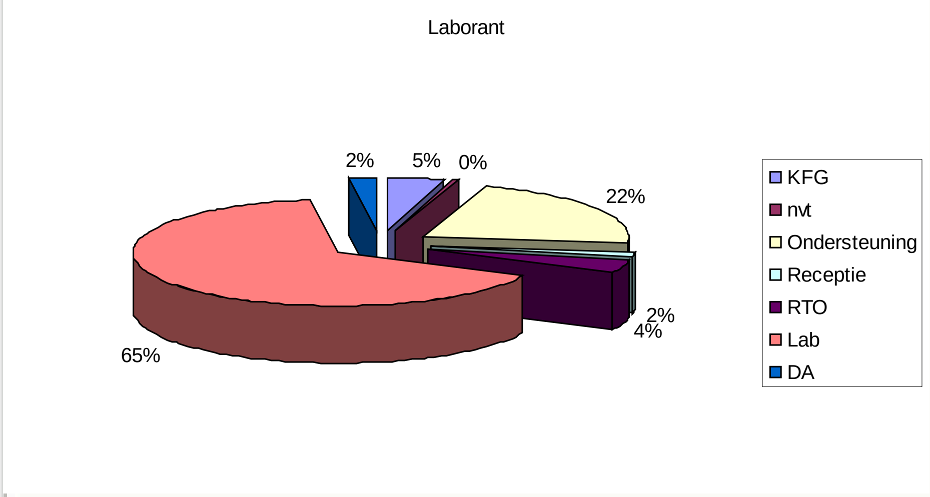
deviation between location of treatment

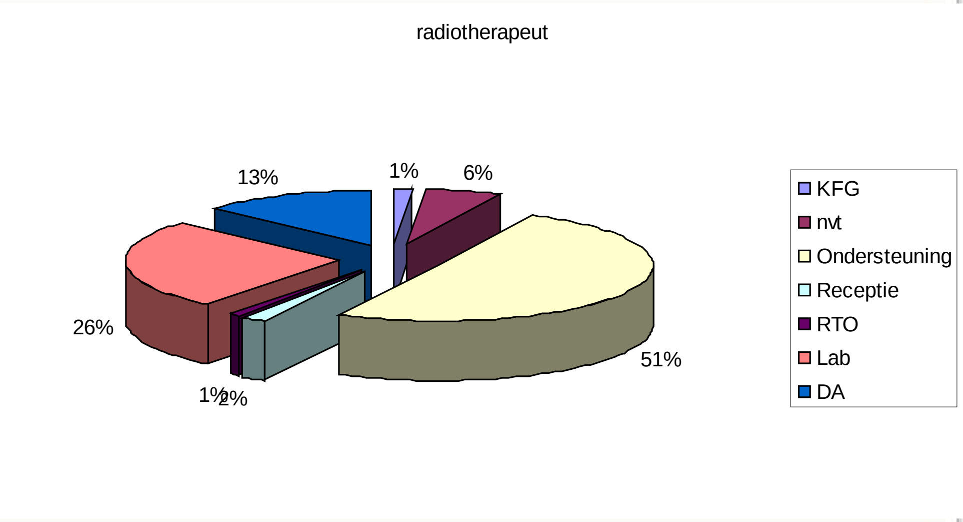


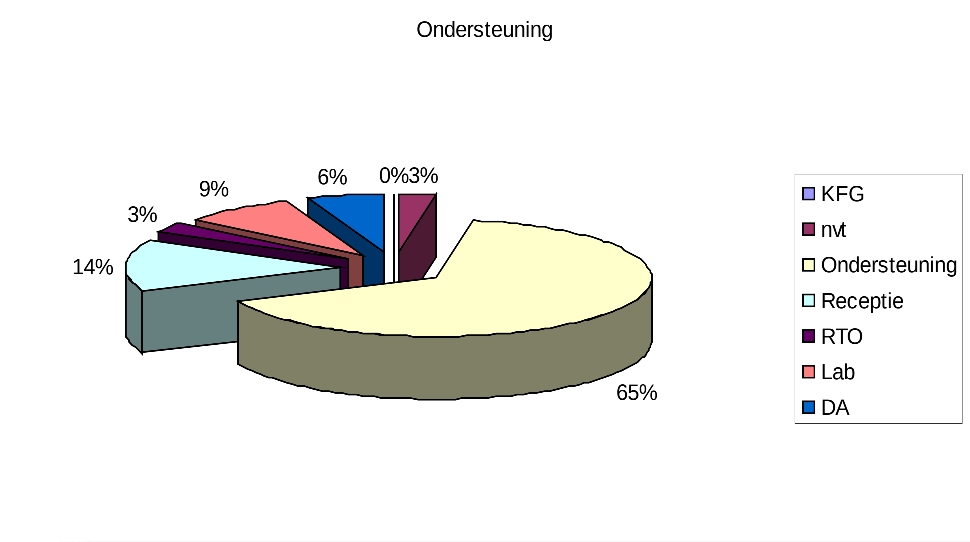
Trend miss <5% / >5% dosisafwijking

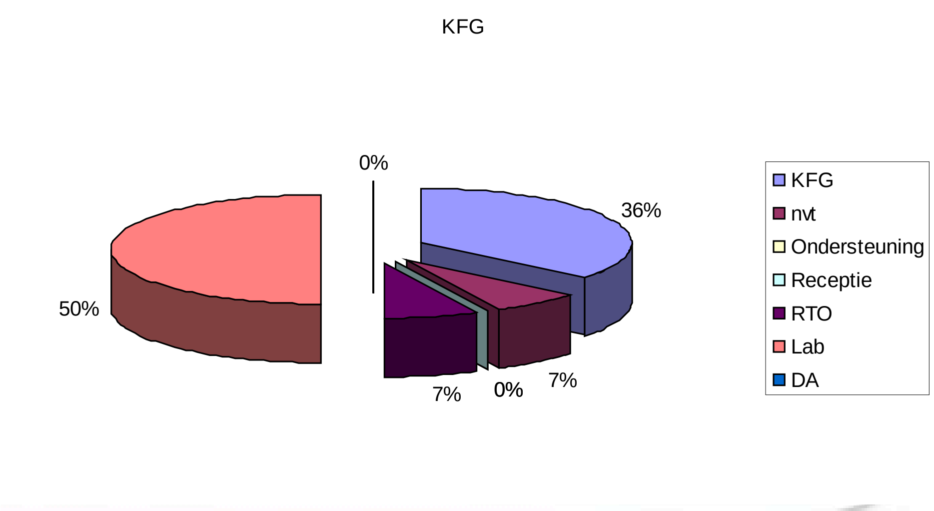


who report over who?

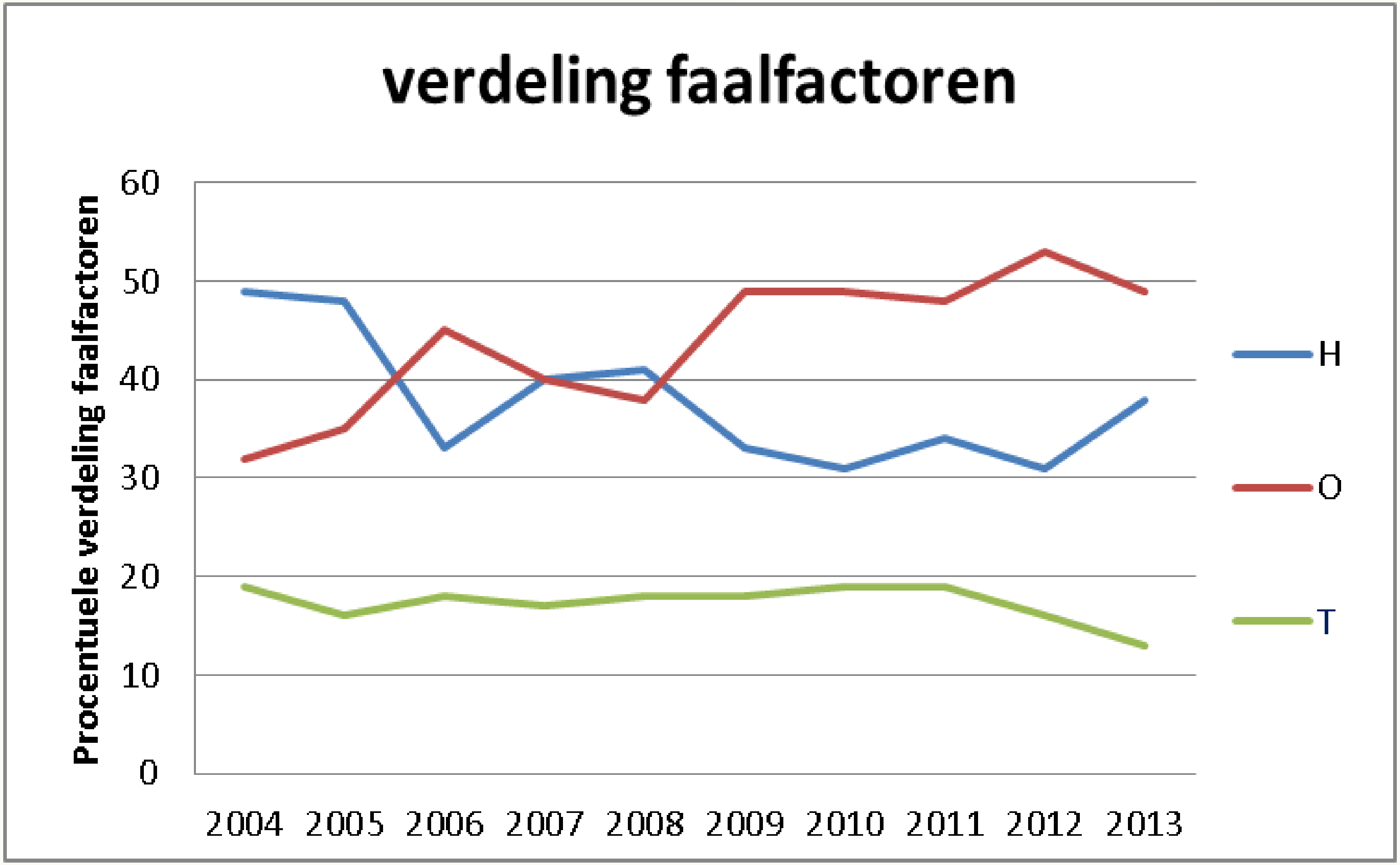








trends in H / T / O



reporting committee

1. Physicist
2. RTTs (prisma-analysts)
3. Administrative staff
4. Physician
5. (This year: opened for newcomers to create more awareness and involvement)

Meeting: every second week, one hour

Prisma-analyses: 4 hours every week

Input : report of miss and near-miss incidents

reporting committee

- Analyze the reports and generates data analyses
- The committee meets every 2 weeks
- A trend analysis is carried out every 3 months
- There is a management meeting every month

Conclusions

- PRISMA-model is a feasible system for routine use in a radiotherapy department
- Enables the organization to analyse causes and context variables of incidents
- Analysis useful for management to reduce causes of incidents
- Analysis useful for monitoring the effect of actions taken to reduce incidents.

(part 2) PRISMA explanation

- Why?
- Basic principle in PRISMA
- Insight on human limitations
- correlation with basic causes

Humans in complex situation

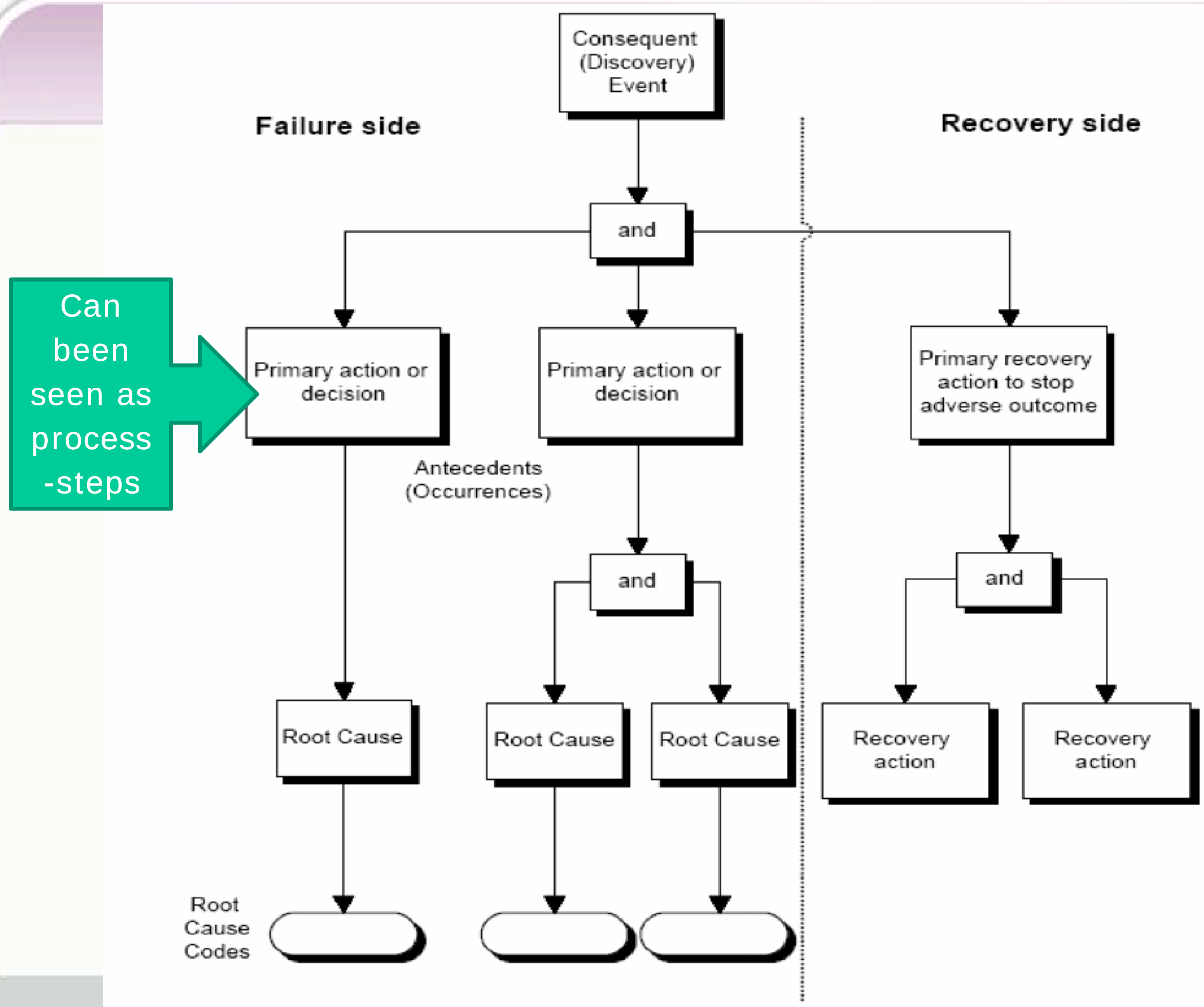
- They make mistakes no matter how highly trained, experienced or motivated they are
- The goal is to keep the inevitable mistakes from becoming consequential
- Simple rules are most effective
- Reliable systems combined with effective communication is the best approach

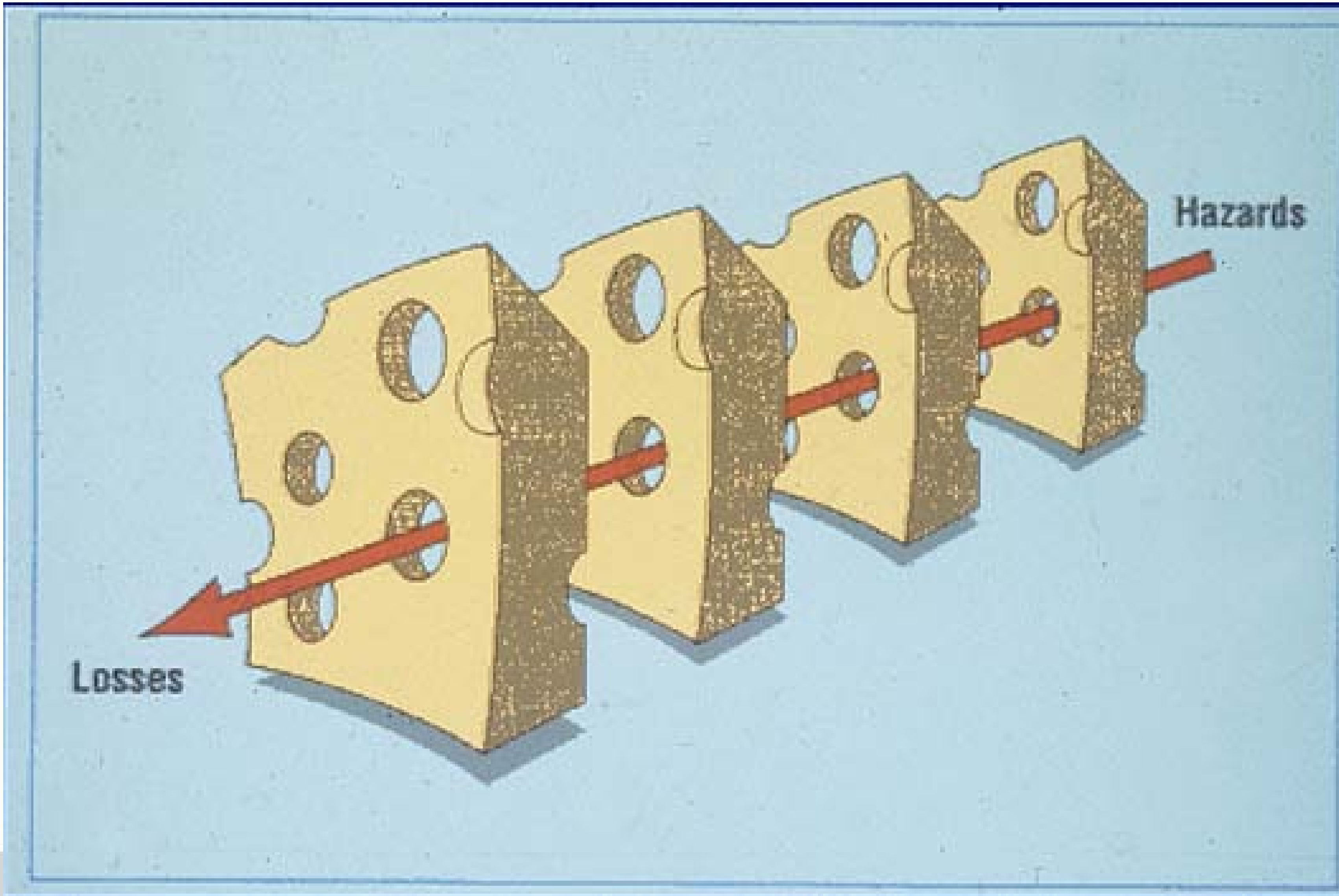
Error is Inevitable Because of Human Limitations

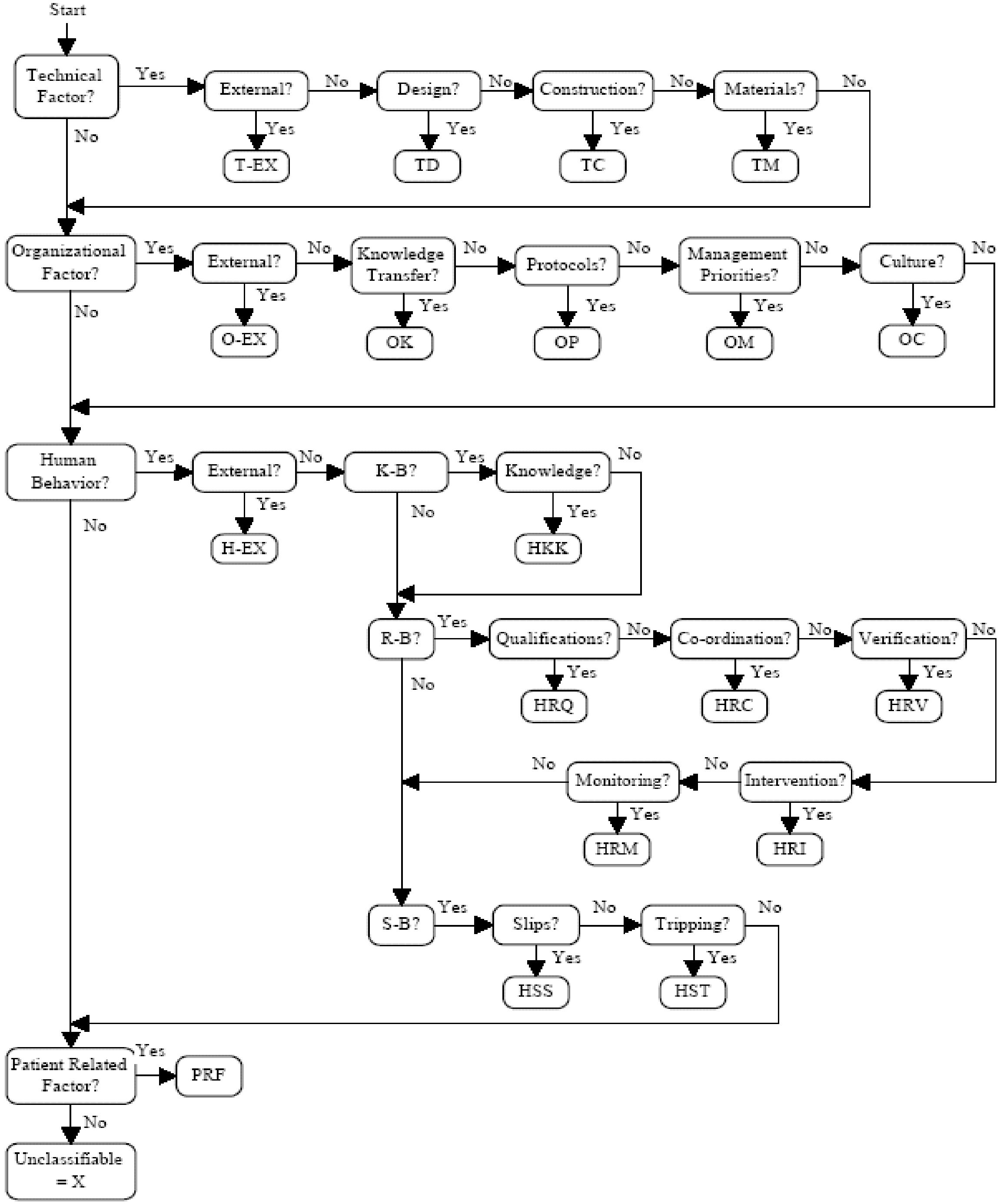
- Limited memory capacity – 5 to 7 pieces of information in short term memory
- Negative effects of stress – error rates
  - Tunnel vision
- Negative influence of fatigue and other physiological factors
- Limited ability to multitask – cell phones and driving
- Flawed judgment

(part 3): PRISMA-explanation

- Incident prescription
- **Tree analyses**
  - Top event,
  - Failure and recovery part
  - Direct causes oorzaken
  - Base causes
- Mind the stop-rules


Consequent (Discovery) Event
Failure side
Recovery side
and
Can been seen as process -steps
Primary action or decision
Primary action or decision
Primary recovery action to stop adverse outcome
Antecedents (Occurrences)
and
and
Root Cause
Root Cause
Root Cause
Recovery action
Recovery action
Root Cause Codes


Hazards
Losses



Start
Technical Factor?
Yes
External?
No
Design?
No
Construction?
No
Materials?
No
Yes
T-EX
Yes
TD
Yes
TC
Yes
TM
No
Organizational Factor?
Yes
External?
No
Knowledge Transfer?
No
Protocols?
No
Management Priorities?
No
Culture?
No
Yes
O-EX
Yes
OK
Yes
OP
Yes
OM
Yes
OC
No
Human Behavior?
Yes
External?
No
K-B?
Yes
Knowledge?
No
Yes
H-EX
No
Yes
HKK
No
R-B?
Yes
Qualifications?
No
Co-ordination?
No
Verification?
No
Yes
HRQ
Yes
HRC
Yes
HRV
No
No
Monitoring?
No
Intervention?
Yes
HRM
Yes
HRI
S-B?
Yes
Slips?
No
Tripping?
No
Yes
HSS
Yes
HST
Patient Related Factor?
Yes
PRF
No
Unclassifiable = X

recovery factors

	planned	Non planned
Human	P-H	NP-H
Technical	P-T	NP-T
Organisational	P-O	NP-O
Patient related	(P-PRF)	NP-PRF
rest		NP-X

Contextvariable MAASTRO

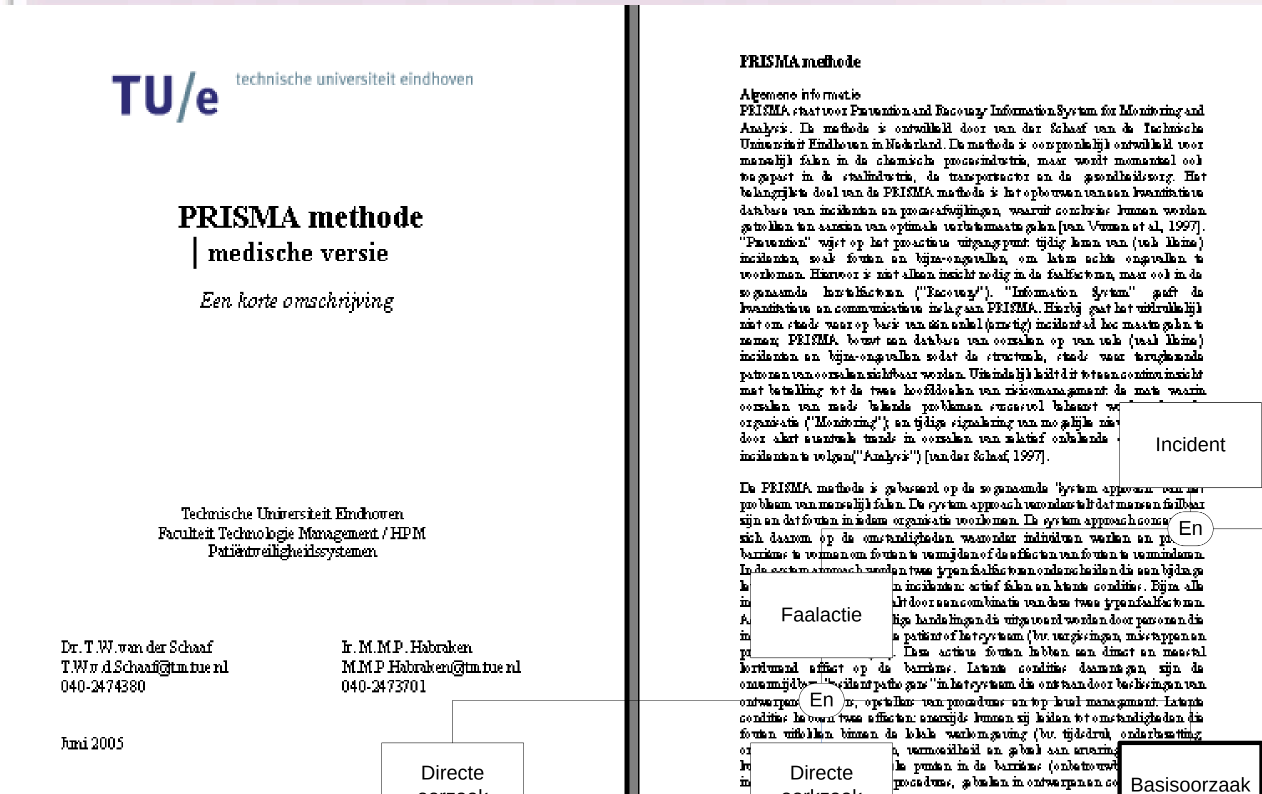
<u>Organization characteristics</u>: treatment urgency, redesign days, working methods, work unit

<u>Human characteristics:</u> duty time experience, experiential moments

<u>Technique characteristics:</u> origin equipment, how long experience is with the equipment

<u>Special circumstances</u>: emotional patient, transfer, change

PRISMA manual



technische universiteit eindhoven

PRISMA methode

medische versie

Een korte omschrijving

Technische Universiteit Eindhoven
Faculteit Technologie Management / HPM
Patiëntveiligheidssystemen

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T.W.v.d.Schaaf@tm.tue.nl
040-2474380

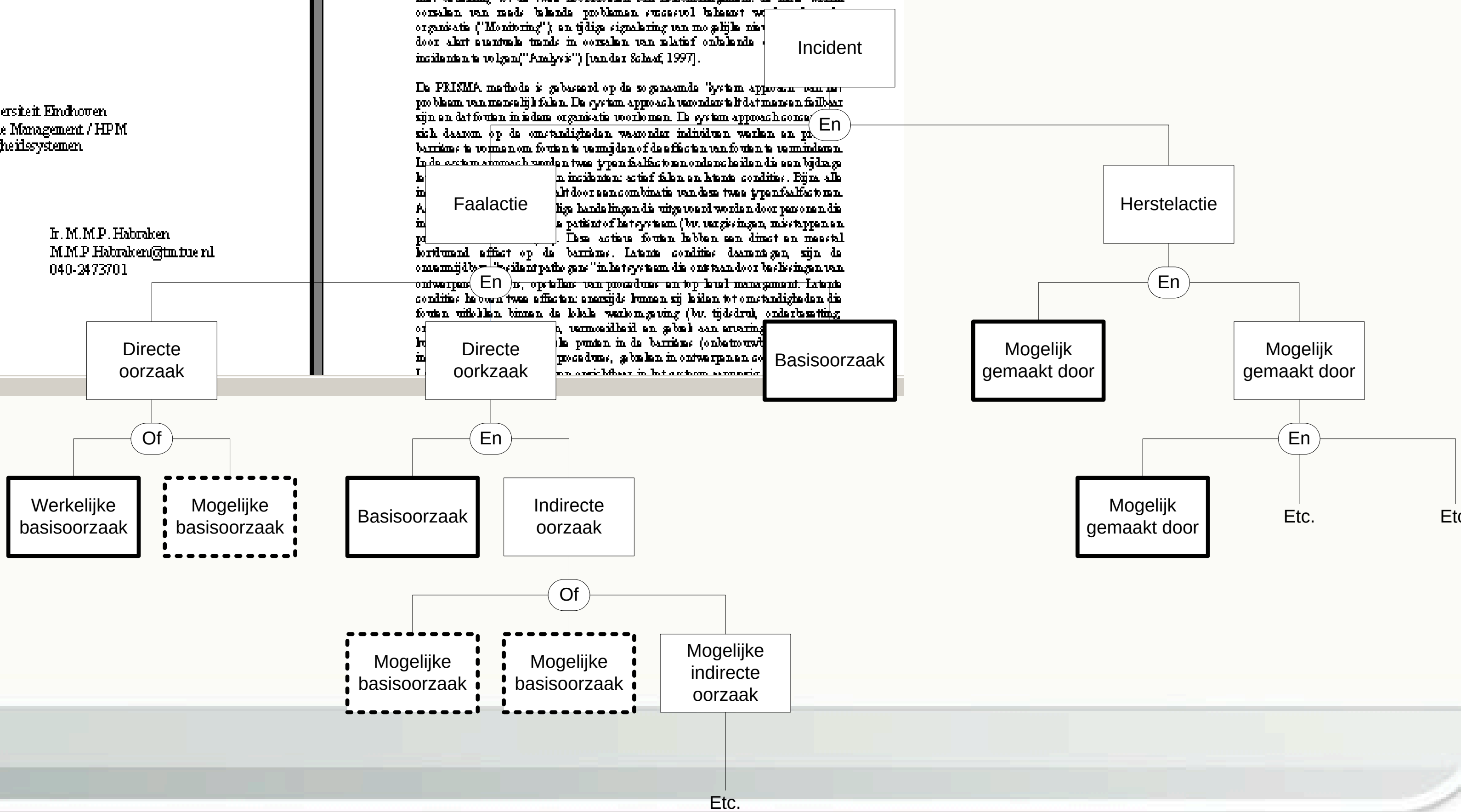
Ir. M.M.P. Habraken
M.M.P.Habraken@tm.tue.nl
040-2473701

Juni 2005

PRISMA methode

Algemene informatie
PRISMA staat voor Prevention and Recovery Information System for Monitoring and Analysis. De methode is ontwikkeld door van der Schaaf van de Technische Universiteit Eindhoven in Nederland. De methode is oorspronkelijk ontwikkeld voor menselijk falen in de chemische procesindustrie, maar wordt momenteel ook toegepast in de staalindustrie, de transportsector en de gezondheidszorg. Het belangrijkste doel van de PRISMA methode is het opbouwen van een kwantitatieve database van incidenten en procesafwijkingen, waaruit conclusies kunnen worden getrokken ten aanzien van optimale verbetermaatregelen [van Vuuren et al, 1997]. "Prevention" wijst op het proactieve uitgangspunt: tijdig leren van (vele kleine) incidenten, zoals fouten en bijna-ongevallen, om latere echte ongevallen te voorkomen. Hiervoor is niet alleen inzicht nodig in de faalfactoren, maar ook in de zogenaamde herstelfactoren ("Recovery"). "Information System" geeft de kwantitatieve en communicatieve inslag aan PRISMA. Hierbij gaat het uitdrukkelijk niet om steeds weer op basis van één enkel (ernstig) incident ad hoc maatregelen te nemen; PRISMA bouwt een database van oorzaken op van vele (vaak kleine) incidenten en bijna-ongevallen zodat de structurele, steeds weer terugkerende patronen van oorzaken zichtbaar worden. Uiteindelijk leidt dit tot een continu inzicht met betrekking tot de twee hoofddoelen van risicomanagement: de mate waarin oorzaken van reeds bekende problemen succesvol beheerst wo[...] organisatie ("Monitoring"); en tijdige signalering van mogelijke nie[...] door alert eventuele trends in oorzaken van relatief onbekende [...] incidenten te volgen ("Analysis") [van der Schaaf, 1997].

De PRISMA methode is gebaseerd op de zogenaamde "system approach" [...]



(part 3) PRISMA –rt collaboration

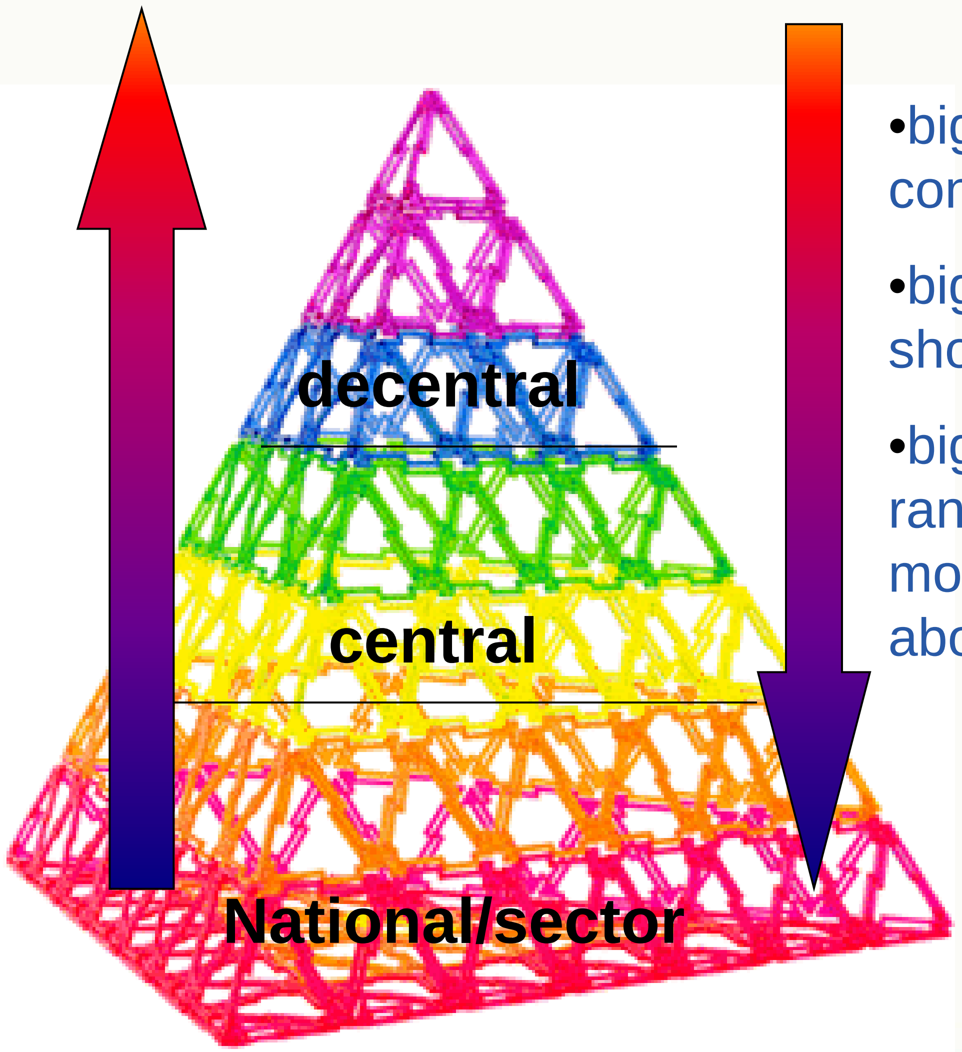
scientific projects about datamining:

master projects on

- costs effecitivity TUE : based on recovery of incidents
- Transition reseach risico effect of machinery Electa -> Siemens
- communication research Siemens (TUE)
- Collaboration Cath/ZRTI: patient identification and datatransfer
- OZRC : EPID proces PRISMA

Advantages of a national system

- confidence
- more individual input
- more specific organisational improvements



- bigger amount of contributors
- big database in shorter time period
- bigger and faster range of learning moments (incl insight about new risks)

Figuur: T.W.v.d. Schaaf 4-11-2004

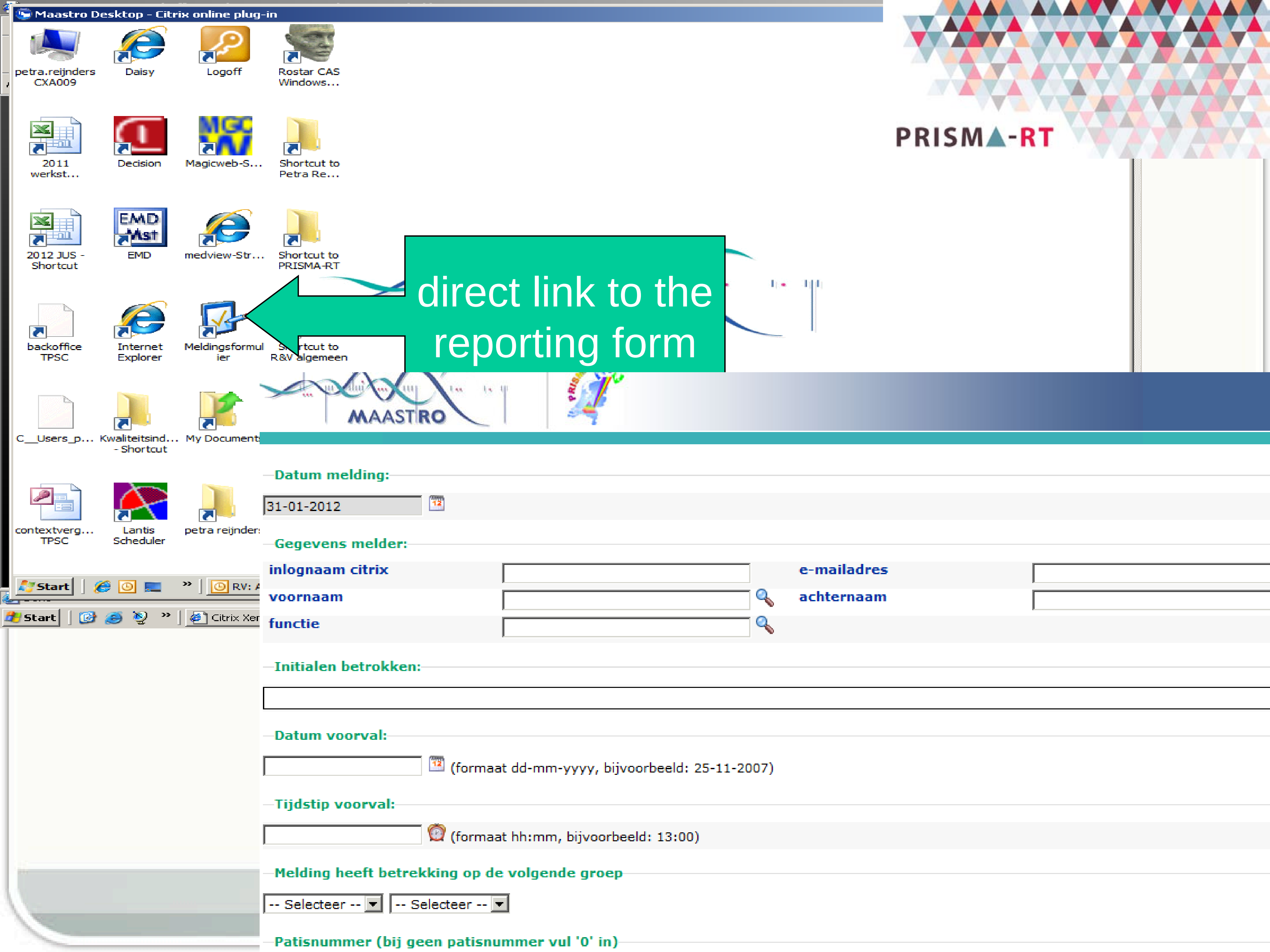
association between of 17 Dutch radiotherapy departments

PRISMA-RT

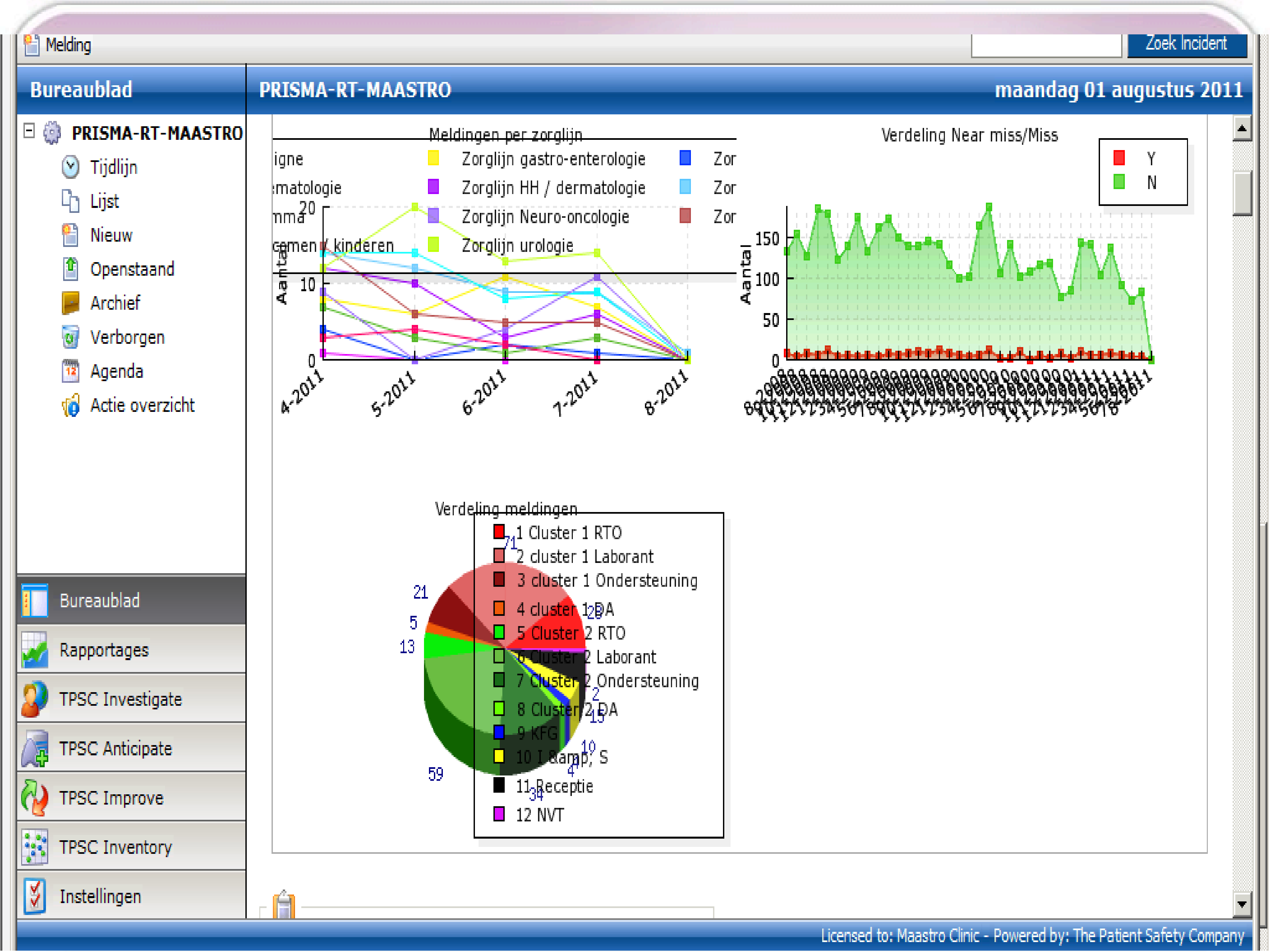
www.prisma-rt.nl

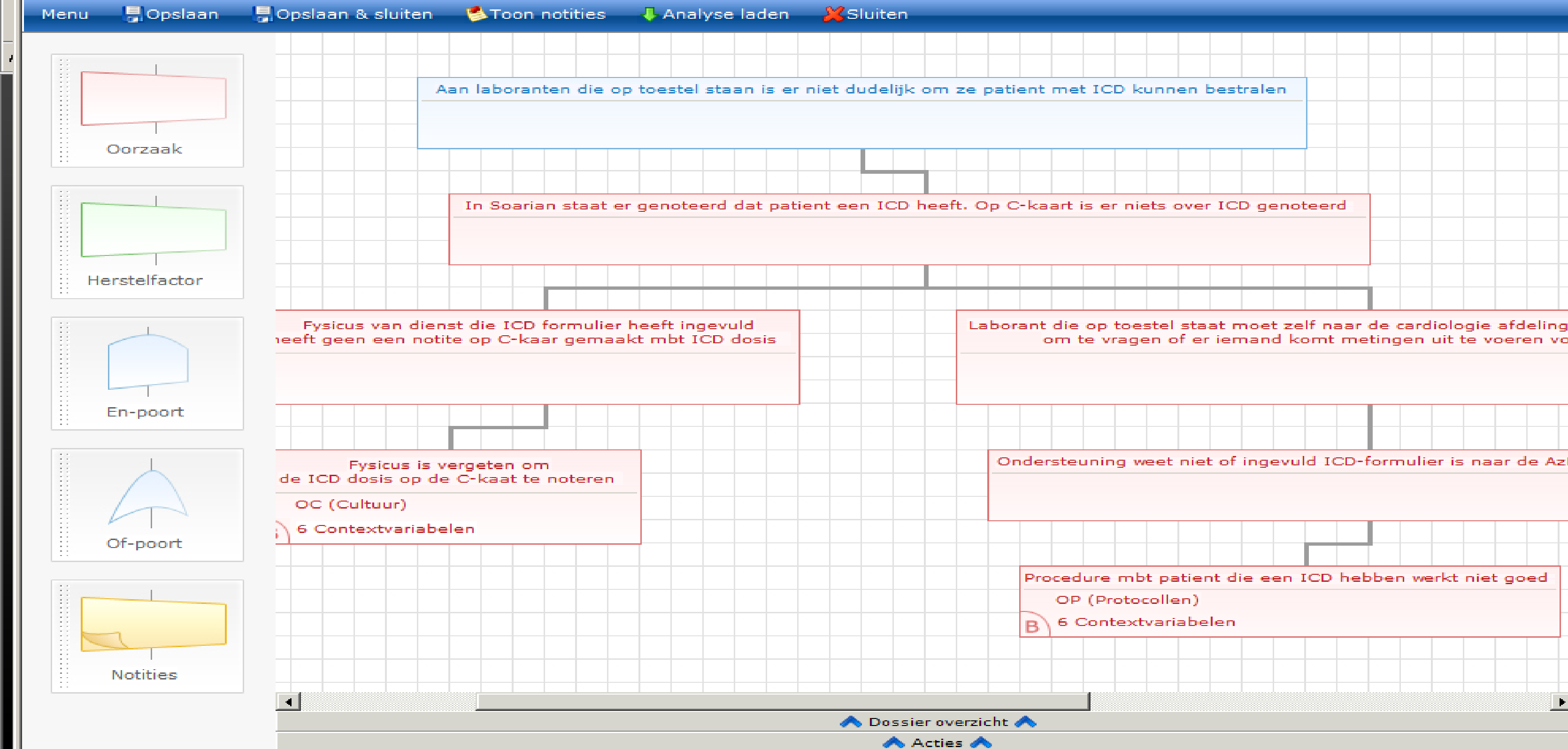
1. content of the local part of database

- Every RT department has a local protected environment
- No information on the reports content is shared
- Data analyses are done within the organisation on local data



Maastro Desktop - Citrix online plug-in
petra.reijnders CXA009
Daisy
Logoff
Rostar CAS Windows...
2011 werkst...
Decision
Magicweb-S...
Shortcut to Petra Re...
2012 JUS - Shortcut
EMD
medview-Str...
Shortcut to PRISMA-RT
backoffice TPSC
Internet Explorer
Meldingsformulier
Shortcut to R&V algemeen
C__Users_p...
Kwaliteitsind... - Shortcut
My Documents
contextverg... TPSC
Lantis Scheduler
petra reijnders
Start
Citrix Xen
PRISMA-RT
direct link to the reporting form
MAASTRO
Datum melding:
31-01-2012
Gegevens melder:
inlognaam citrix
e-mailadres
voornaam
achternaam
functie
Initialen betrokken:
Datum voorval:
(formaat dd-mm-yyyy, bijvoorbeeld: 25-11-2007)
Tijdstip voorval:
(formaat hh:mm, bijvoorbeeld: 13:00)
Melding heeft betrekking op de volgende groep
-- Selecteer --
-- Selecteer --
Patisnummer (bij geen patisnummer vul '0' in)


Melding
Zoek Incident
Bureaublad
PRISMA-RT-MAASTRO
maandag 01 augustus 2011
PRISMA-RT-MAASTRO
Tijdlijn
Lijst
Nieuw
Openstaand
Archief
Verborgen
Agenda
Actie overzicht
Meldingen per zorglijn
Zorglijn gastro-enterologie
Zorglijn HH / dermatologie
Zorglijn Neuro-oncologie
Zorglijn urologie
Aantal
4-2011
5-2011
6-2011
7-2011
8-2011
Verdeling Near miss/Miss
Y
N
Aantal
150
100
50
0
Verdeling meldingen
1 Cluster 1 RTO
2 cluster 1 Laborant
3 cluster 1 Ondersteuning
4 cluster 1 DA
5 Cluster 2 RTO
6 Cluster 2 Laborant
7 Cluster 2 Ondersteuning
8 Cluster 2 DA
9 KFG
10 I & S
11 Receptie
12 NVT
Bureaublad
Rapportages
TPSC Investigate
TPSC Anticipate
TPSC Improve
TPSC Inventory
Instellingen
Licensed to: Maastro Clinic - Powered by: The Patient Safety Company



- Activiteiten
- Verzonden e-mails
- Uitnodigingen
- Aanvullingen
- Statuspagina

Analyse

- PRISMA
- Analyse (SIRE)
- Visgraat diagram
- Tijdsreconstructie
- Procesanalyse
- Barrièreanalyse

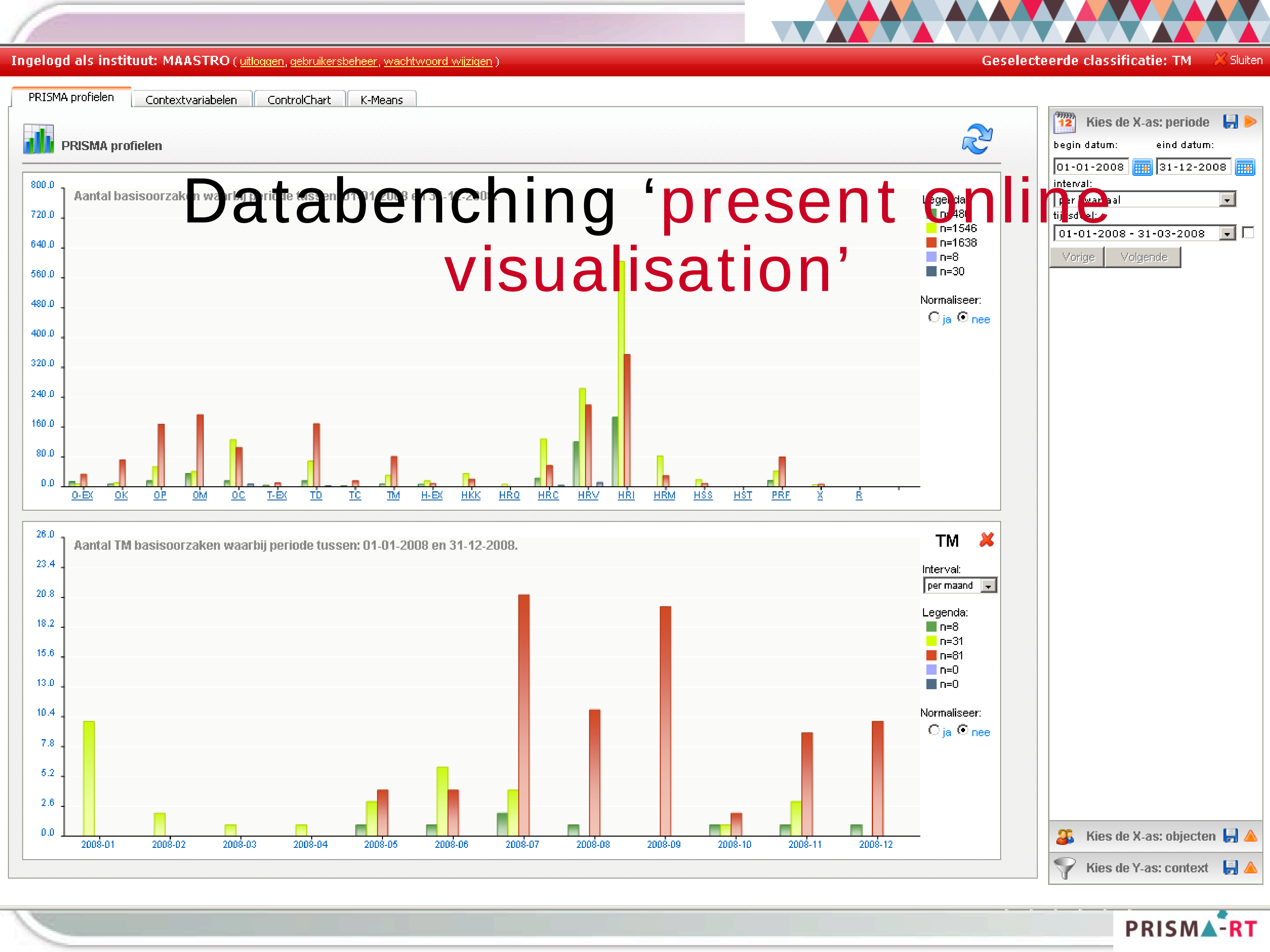
Prisma

Basisoorzaak:	Classificatie:	Contextvariabelen:
Procedure mbt patient die een ICD hebben werkt niet goed	OP (Protocollen)	Administratieve ondersteuning Treatment planning Ondersteuning Gastro-enterologie regulier > 1 jaar bestaande procedure
Fysicus is vergeten om de ICD dosis op de C-kaat te noteren	OC (Cultuur)	Fysische ondersteuning Treatment planning KFG Gastro-enterologie regulier > 1 jaar bestaande procedure

2. content of the benchmark

- grafics for comparison
- comparison of contextvariables
- comparison of base causes PRISMA
- comparison of normalised and not-normalised data

Databenching ‘present online visualisation’



example: Benchmark information used in a department

results:
5 actions taken in MAASTRO based on benchmarkanalyses

alyse lineaire versneller van de PRISMA-RT vereniging dd 14-4-10

ijving:

Aanvulling op dokument Benchmark analyse lineaire versneller dd 14-4-10

De invulling van de basisoorzaken beschrijvingen die behoren bij de analyse hoog OP bij proces linac icm contextvariabale " niet beschreven procedure" zijn alleen terug te halen uit de eigen lokale database. Zie hieronder de relevante data voor MAASTRO clinic waarbij de nummer van de melding en beschrijving behorende bij proces linac identiek is aan die van de beschrijving behorende bij de context "niet beschreven procedure".

OP (kwaliteit in procedure) mbt proces lineaire versneller en context "niet beschreven procedure" periode kwartaal 4 2009

Acties nav van bovenstaande issues(na intern overleg):

Nr melding	Beschrijving basisoorzaak OP	Actie Maastro specifiek	Navraag PRISMA-RT	Beschrijving actie
09-2629	Er is geen controle procedure voor de LO (lab. Omloop)	√		LO wordt niet gecontroleerd op uitvoering. Risico inschatting hiervan verrichten!

Annual meetings PRISMA-RT

4 meetings of expert-team and board

2 meetings with the members of PRISMA-RT

1 educational meeting with prisma-analysts

NB: Expert-team is responsible for the support and data analyses of the benchmark.

Board is responsible for the relationship

Method LIBB
(interobserver variability research)

PRISMA-RT

started in 2009 (yearly) :

50 ad random base cause prescriptions

=> Percentages agreement between observers/analysts

=> Comparing with gold standard of classification codes

PRISMA-RT

Results LIBB,

	Beschrijving basisoorzaak	Gouden standaard	Frequentie gouden standaard in %	Modus / Modale codering	Frequentie van de modus in %
1	Bij controle van gegevens, is automatisch aangenomen dat gegevens correct zijn omdat iemand anders gegevens afgetekend heeft	oc	24	hrv	58
2	Behandelend arts vergeet door te geven aan administratie dat patient opgenomen ligt en dus niet voor CT en bestraling komt	hrc	20	hri	65
3	Administratie geeft patient niet door dat zijn tijdstip van bestraling is veranderd	h-ex	16	prf	69
4	epid-beelden hebben een zeer slechte beeldkwaliteit, moeilijk te matchen	tm	34	td	42
5	Fysicus schat situatie op versneller verkeerd in	hri	8	oc	30
	Patientgegevens onterecht opgeborgen zonder dat er boostplan van patient gemaakt is	tm	29	td	37

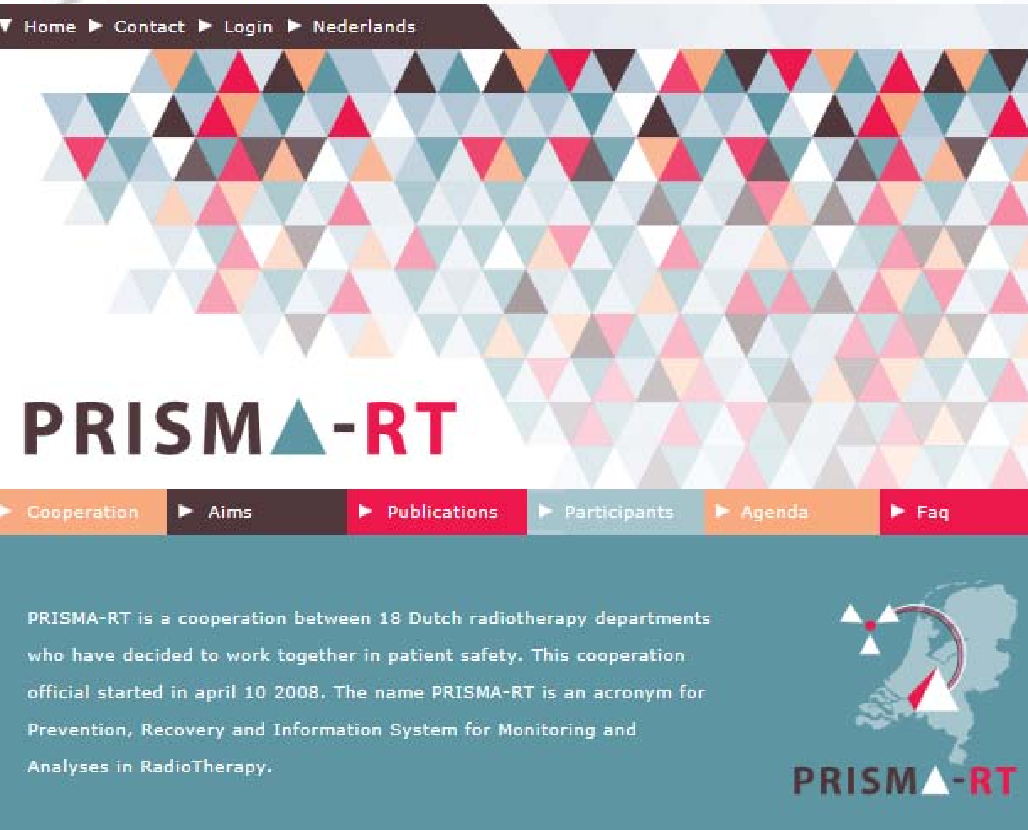
PRISMA-RT

Results PRISMA-RT NL

- >14 benchmark reports on different radiotherapy processes
- Meeting with vendors radiotherapy
- Several presentations, publications and abstracts
- 8 LIBB
- yearly educational meetings for the analysts
- Document about the vision
- Collaboration university on themes breathhold, MVI/EPD and alert-blindness

Website Belgium

www.prisma-rt.be



Website Netherlands
www.prisma-rt.nl

Futur ?

- Extend the collaborations in Radiotherapy
- Collaborate with other databases (f.e. ROSIS/SAFRON)
- Extend research activity based on PRISMA-data
- Fine-tuning the PRISMA database/method

Questions ??????

Petra.reijnders@maastro.nl

PRISMA workshop guide Lines

Learning objectives

To provide insight into the analysis system PRISMA for the reports of incidents and near-incidents.

To learn how to perform a root cause analyses using the PRISMA method.

To learn how to classify the root causes.

PRISMA-tree development

- Incident prescription
- **Tree analyses**

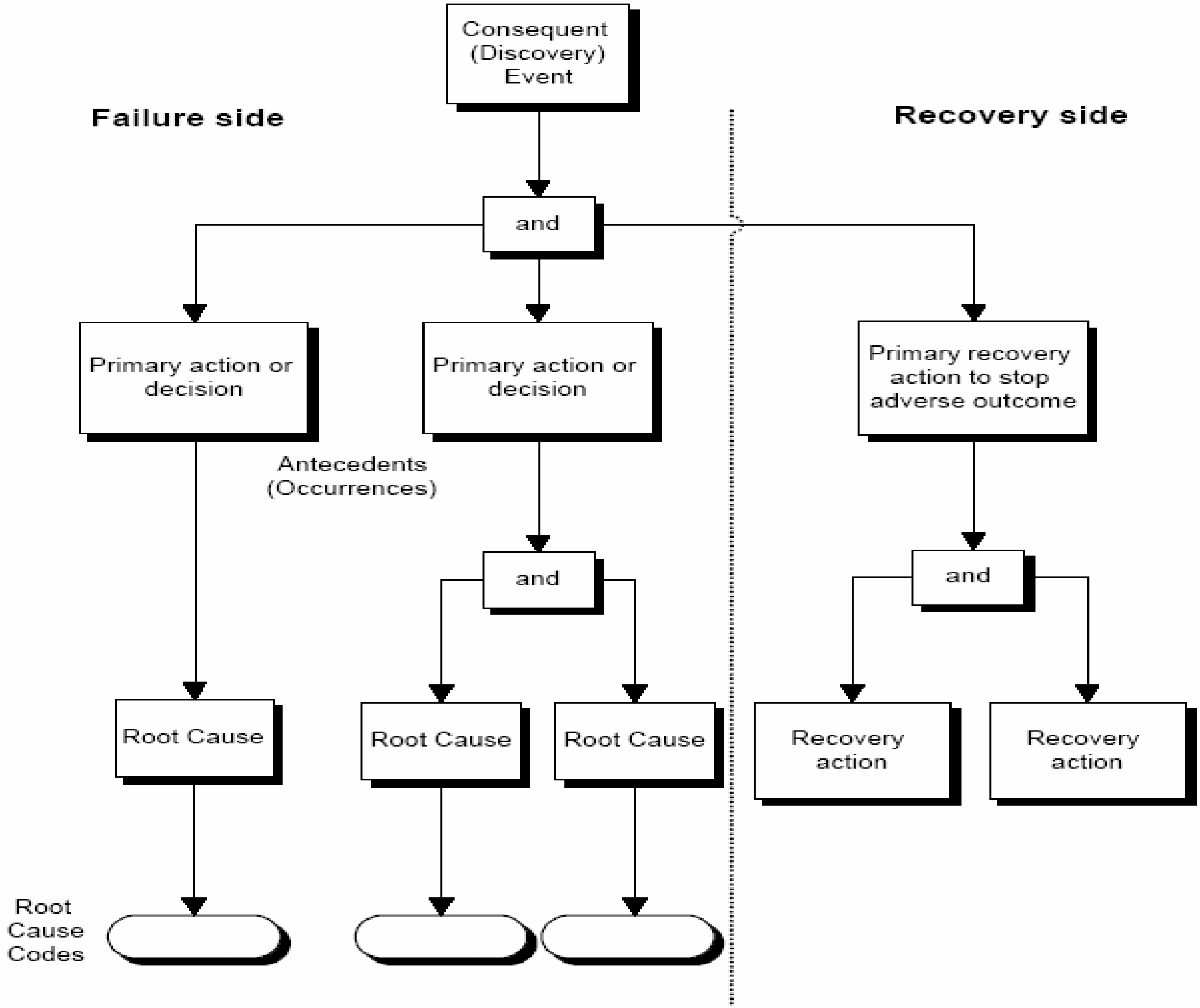
Top event,

Failure and recovery part

Direct causes

Base/Root causes

- Mind the stop-rules


Consequent (Discovery) Event
Failure side
Recovery side
and
Primary action or decision
Primary action or decision
Primary recovery action to stop adverse outcome
Antecedents (Occurrences)
and
and
Root Cause
Root Cause
Root Cause
Recovery action
Recovery action
Root Cause Codes

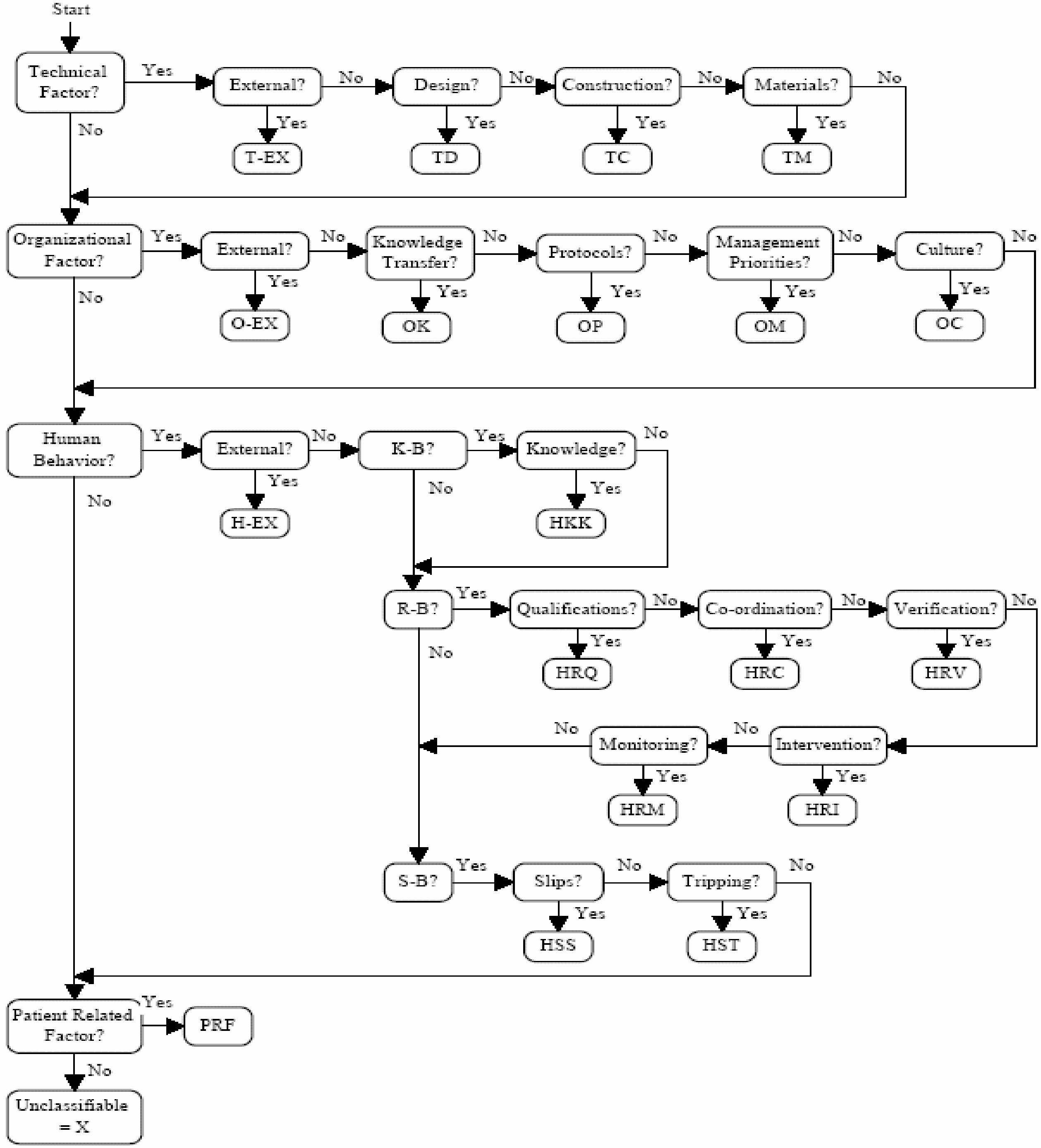
Steps of a PRISMA analyse

1. Define Top event: the consequence of discovery event (i.e the system) as the visible reason for the analyses.
2. Describe the 2 sides of the three, the failure and discovery
3. Define the direct causes= primary action of decision
4. Use the why questions to chronological define the root causes related to the direct cause
5. Select the classification codes for the defined root causes

Stopping rules

1. Stop extending the tree when no objective facts can be put forward anymore.

2. Stop extending the tree when the system boundery is passed, that is when the accompanying measures are outside the range of the influence of the organisation.

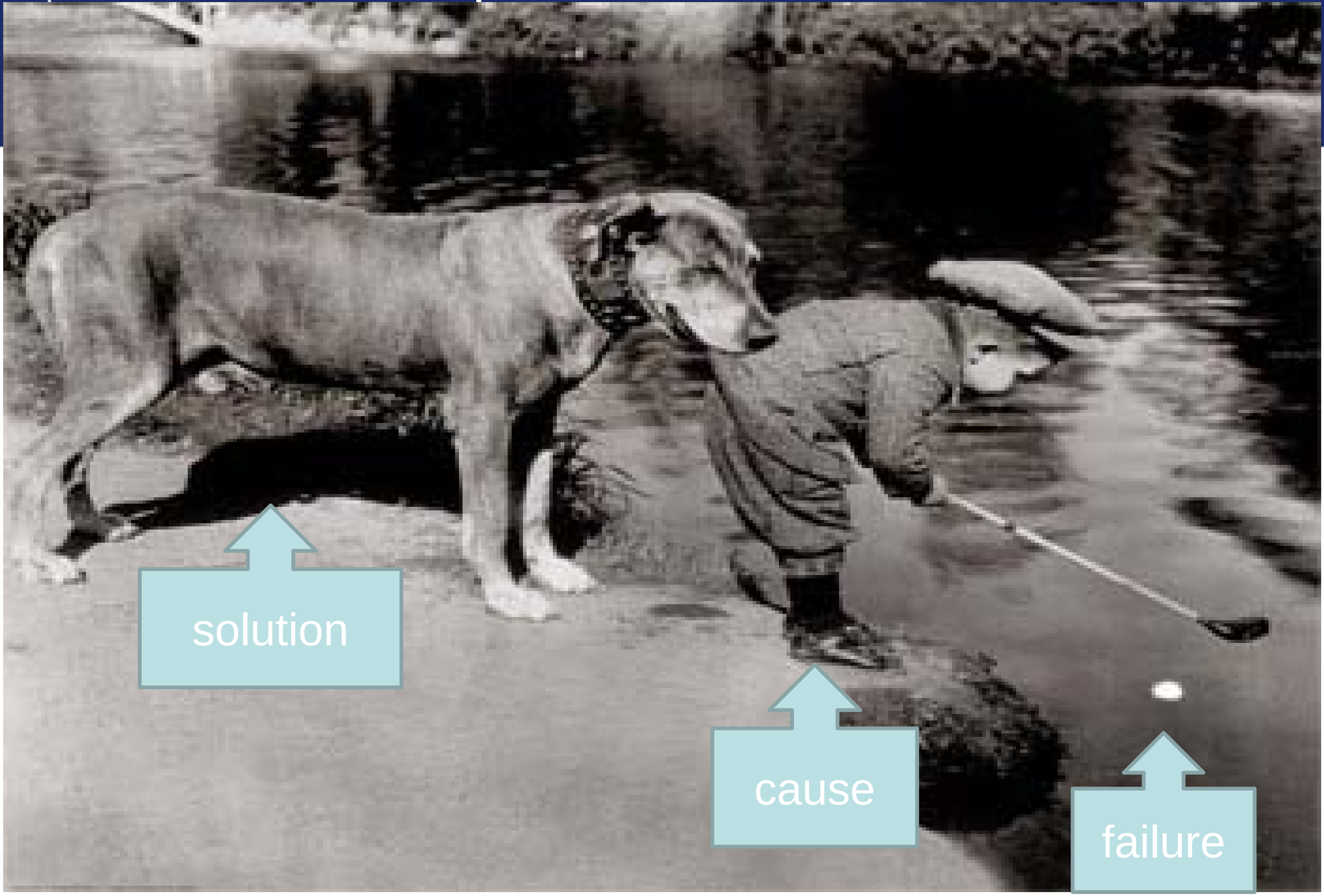


Start
Technical Factor?
Yes
External?
No
Design?
No
Construction?
No
Materials?
No
Yes
T-EX
Yes
TD
Yes
TC
Yes
TM
No
Organizational Factor?
Yes
External?
No
Knowledge Transfer?
No
Protocols?
No
Management Priorities?
No
Culture?
No
Yes
O-EX
Yes
OK
Yes
OP
Yes
OM
Yes
OC
No
Human Behavior?
Yes
External?
No
K-B?
Yes
Knowledge?
No
Yes
H-EX
No
Yes
HKK
No
R-B?
Yes
Qualifications?
No
Co-ordination?
No
Verification?
No
Yes
HRQ
Yes
HRC
Yes
HRV
No
No
Monitoring?
No
Intervention?
Yes
HRM
Yes
HRI
S-B?
Yes
Slips?
No
Tripping?
No
Yes
HSS
Yes
HST
Patient Related Factor?
Yes
PRF
No
Unclassifiable = X

Group exercise (1 hour)

- Read the case information of NY incident
- Create the PRISMA tree
- Define the classification codes to the rootcauses
- What questions should be asked to prefect the tree more in detail?
- Plenairy presentation of experience

questions!!!!



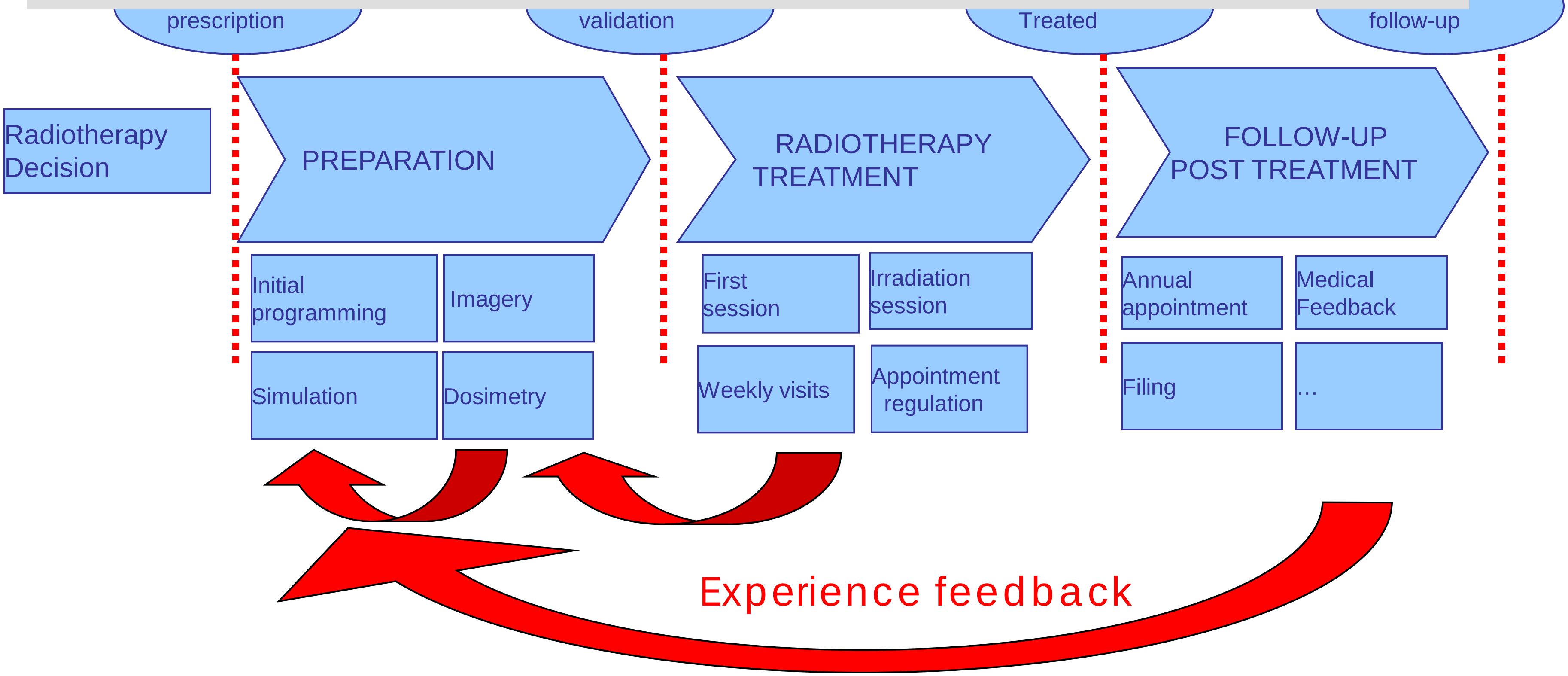
Legal aspects of incident reporting:

From INES SCALE to ASN/SFRO

Eric F. Lartigau
Centre Oscar Lambret
59000 Lille
France

Thanks to Carole ROUSSE, Nuclear Safety Authority ASN, Health Department

To apply robust and validated systems on safety



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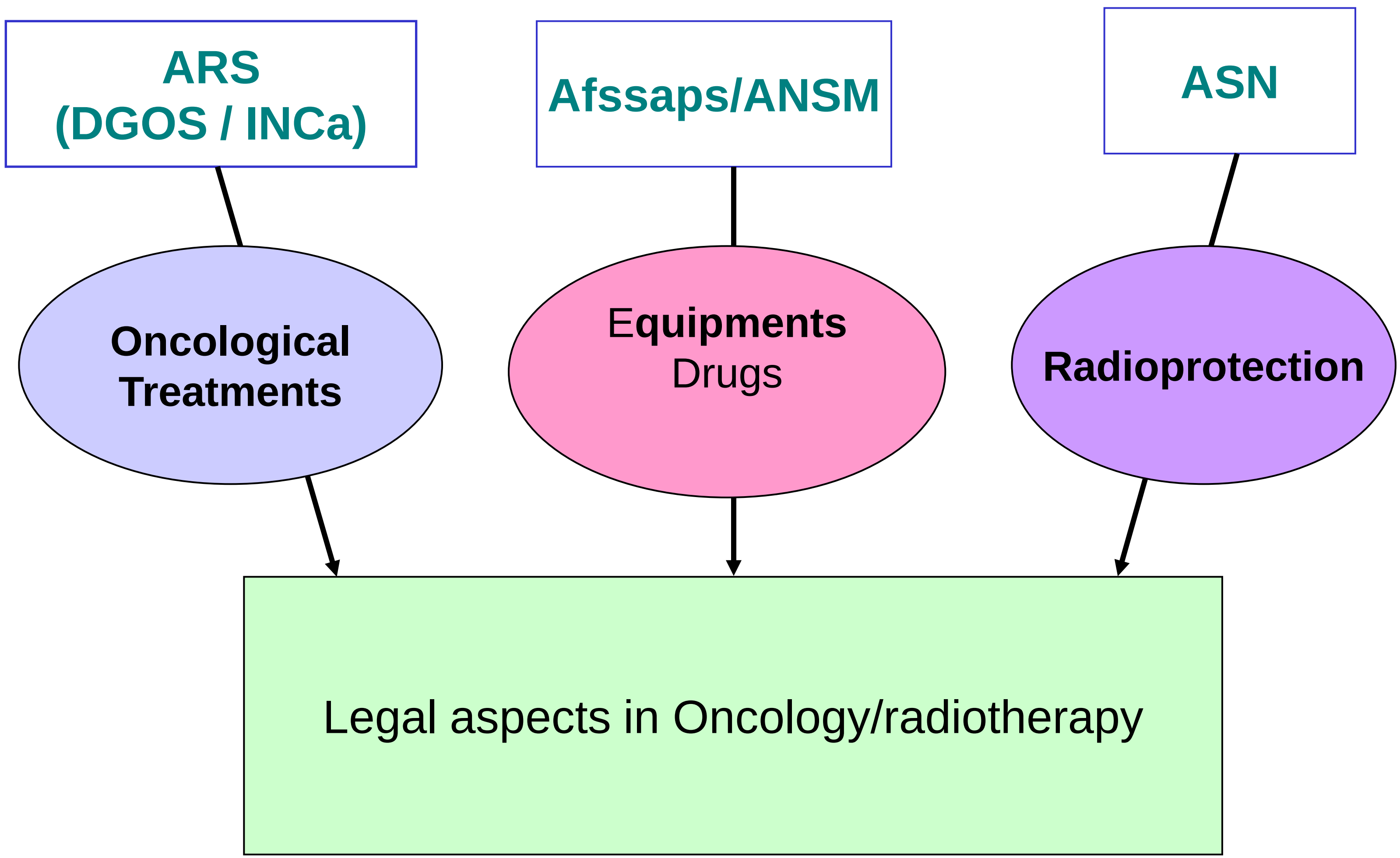

ARS
(DGOS / INCa)
Afssaps/ANSM
ASN
Oncological Treatments
Equipments
Drugs
Radioprotection
Legal aspects in Oncology/radiotherapy

1. Reporting
   – ASN-SFRO scale
   – Communication
2. Some figures
3. Difficulties encountered and recommandations

•**A legal obligation for ASN: the TSN Act recalls and confirms the role of ASN**

EXTRACTS FROM PART III OF ACT 2006-686 OF 13 JUNE 2006 ON TRANSPARENCY AND SECURITY IN THE NUCLEAR FIELD, CONCERNING INFORMATION OF THE PUBLIC ABOUT NUCLEAR SAFETY

Chapter I
Right of information concerning nuclear safety and radiation protection

Article 18
The State is responsible for informing the public about nuclear safety and radiation protection regulation measures and results. It provides the public with information on the consequences in France of nuclear activities conducted outside the country, in particular in the event of an incident or accident.

- INES scale does not cover events concerning persons exposed intentionally in the context of medical procedures (patients)
- Needed after a severe accident (Epinal accident) to provide the public with accessible information and to facilitate the understanding of the severity of an event

ASN-SFRO Scale

- Elaborated in July, 2007 by ASN with SFRO (French society of radiation oncologists) and tested for a 12-month period
- Evaluated with professionals (SFRO and SFPM, French society of medical physicists) in June, 2008

Final scale was published on ASN website in July, 2008

ASN-SFRO Scale

- The events are rated on an **8-level** severity scale (from 0 to 7, as INES)

- The scale **refers to an international clinical classification** and incorporate clinical grading tables already used by practitioners (CTCAE-Cancer Therapy Evaluation Program)

  - Grade 1 (mild effects)
  - Grade 2 (moderate effects)
  - Grade 3 (severe effects)
  - Grade 4 (serious or life-threatening effects)
  - Grade 5 (death)

1. Public information – ASN-SFRO Scale

	EVENTS (UNPREDICTED, UNEXPECTED)	CAUSES	CONSEQUENCES (CTCAE V3.0 GRADE)
5 to 7* ACCIDENT	Death	Dose (or irradiated volume) much greater than normal resulting in complications or sequelae incompatible with life	Death
4** ACCIDENT	Serious life-threatening event, disabling complication or sequela	Dose or irradiated volume much greater than the tolerable doses or volumes	Serious unexpected or unpredictable acute or delayed effect, grade 4
3** INCIDENT	Event resulting in severe alteration of one or more organs or functions	Dose or irradiated volume greater than the tolerable doses or volumes	Severe unexpedted or unpredictable acute or delayed effect, grade 3
2** INCIDENT	Event resulting in or likely to result in moderate alteration of an organ or fuction	Dose greater than the recommended doses, or irradiation of a volume that may lead to unexpected but moderate complications	Moderate unexpedted or unpredictable acute or delayed effect, grade 2, minimal or absence of alteration of quality of life
1 EVENT	Event with dosimetric consequences but no expected clinical consequence	Dose or volume error (e.g. dose error or target error in a session not compensable over the treatment as a whole)	No symptom expected
0 EVENT	Event with no consequence for the patient	Dose error (number of monitor units, filter, etc.) compensated over the treatment as a whole. Error of identification of a patient treated for the same pathology (compensable)	

* *In the case of deaths of several patients:*
- *the minimum level 5 is raised to 6 if the number of patients is greater than 1 but less than or equal to 10;*
- *the minimum level 5 is raised to 7 if the number of patients is greater than 10.*

** *If the number of patients is greater than 1, a + sign is added to the assigned level (example: 3 become 3+).*

ASN-SFRO Scale

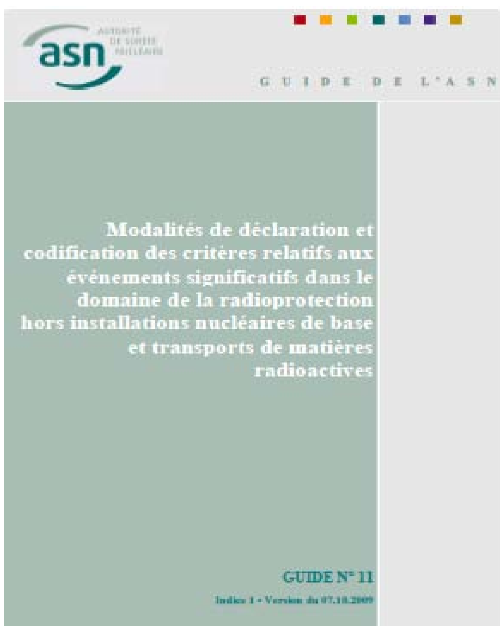
- Taking into account the expected effects due to overexposure (overdose or inappropriate volume)

- For confirmed effects, over-rating will be used to take into account the number of patients concerned

- 8/10/2010: ASN/SFRO

Notification system

- 2 Draft guidance for notification of significant events **in radiation protection (guidance n°11 and n°16) with operational criteria (www.asn.fr) published by ASN on June 2007 and November 2010**



Notification system

- Legal obligations:

  Significant events must be notified as specified in the public health code (CSP) :

L. 1333-3 modified by law n°2009-879 of July 21st, 2009 – art. 106 (V)

The licensee and the health professionals involved in the treatment or in the follow up of exposed patients must notify without delay to ASN any accident or incident likely to affect human health through exposure to ionizing radiation

R. 1333-109 modification expected in that terms:

The licensee and the health professionals involved in the treatment or in the follow up of exposed patients have to notify to ASN any events or incidents likely to have consequences for the health of person exposed to ionizing radiation as part of a medical procedure

Notification system

Criteria 2.1:
Patient exposure as part of a therapeutical procedure:

Any unexpected situation or any organizational, material or human malfunction occurring during radiation treatment of a patient resulting in:

- **improper treatment regarding the prescribed dose**

or

- the **occurrence of unpredictable deterministic effects**

given the therapeutic strategy decided with full-inform consent of the patient.

Notification system

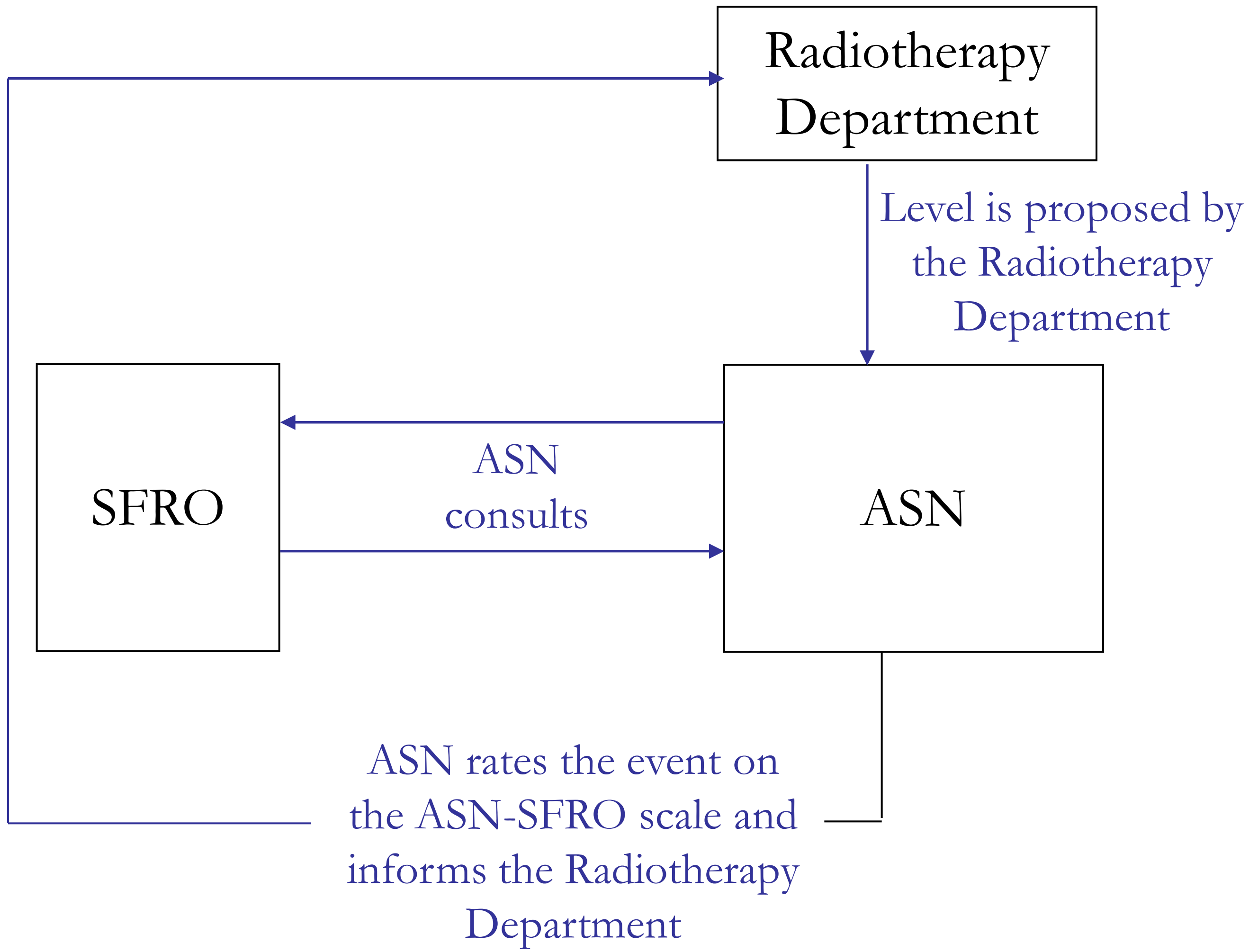
Criteria 2.1:
Patient exposure as part of a therapeutical procedure:

The conformity of the dose includes:

- for radiotherapy and brachytherapy, compliance with a **tolerance of +/- 5% of the total prescribed dose** + compliance with the planned schedule and/or fractionation, taking into account any clinical or technical constraints for the patient treatment;
- **non-systematic dose error likely to affect several patients, regardless of the value of the error.**

+ any incorrect identification of patient must be declared

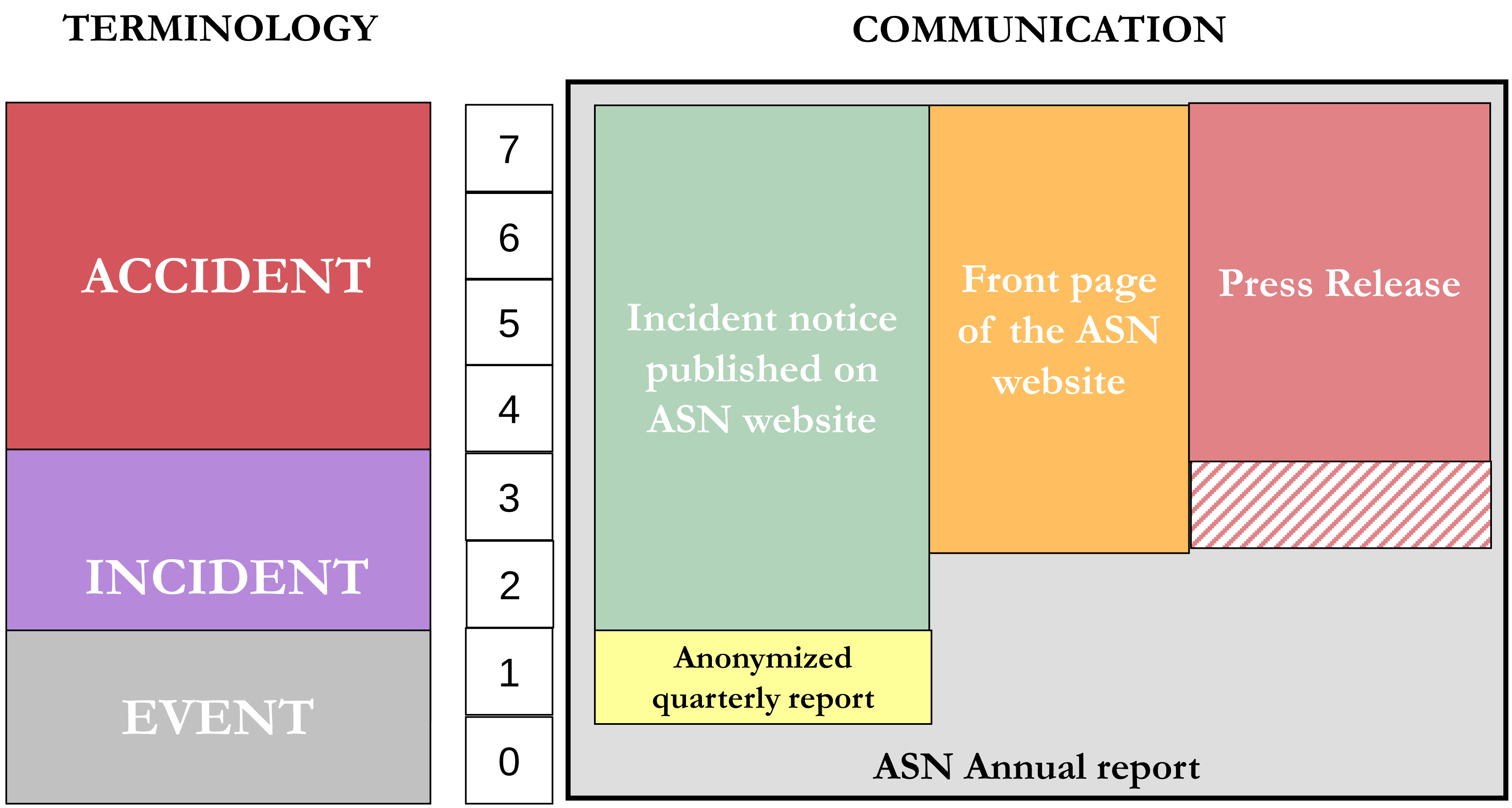
ASN-SFRO Scale



ASN-SFRO Scale

- The radiotherapy department is responsible for its own communication
- ASN information gives the rating of the event on the ASN-SFRO scale and is mainly focused on the steps taken by ASN to assess the situation and draw out the necessary safety conclusions
- **The physician must have informed the patient within the maximum legal period of 15 days (L. 1142-4 of the Public Health Code)**

ASN-SFRO Scale



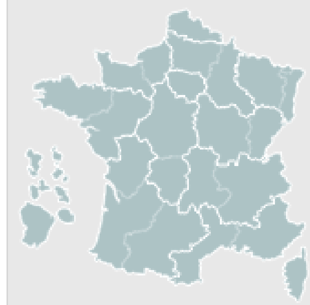
ASN WEB SITE

L'ASN | LA RÉGLEMENTATION | LE CONTRÔLE | LES APPUIS TECHNIQUES | INTERNATIONAL | ACTUALITÉS | AGENDA | DOSSIERS | PUBLICATIONS

Les activités contrôlées

- PRODUCTION D'ÉLECTRICITÉ
- AUTRES ACTIVITÉS INDUSTRIELLES
- ACTIVITÉS DE RECHERCHE
- UTILISATIONS MÉDICALES
- TRANSPORTS DE MATIÈRES RADIOACTIVES
- DÉCHETS / INSTALLATIONS EN DÉMANTÈLEMENT

L'ASN dans votre région



Accueil > Les activités contrôlées par l'ASN > Utilisations médicales > Avis d'incidents affectant un patient en radiothérapie

- La radiothérapie
- La curiethérapie
- La médecine nucléaire
- La radiologie et scanographie
- La radiologie interventionnelle
- L'irradiation de produits sanguins
- Guide n°11 de déclaration des événements significatifs en radioprotection hors INB et TMR
- Formulaires
- Avis d'incidents dans le domaine médical
- Avis d'incidents affectant un patient en radiothérapie

Avis d'incidents affectant un patient en radiothérapie

Mis à jour le 05 Octobre 2010

1 - 2 - 3 Suivant

Erreur de positionnement d'un patient lors d'une radiothérapie externe

CHR Metz-Thionville - Hôpital Notre Dame de Bon Secours - Metz (57)

Le 05 octobre 2010, le Centre Hospitalier Régional de Metz-Thionville à Metz a déclaré à l'ASN un incident relatif à un mauvais positionnement d'un patient lors de son traitement par radiothérapie.

Publié le 21/02/2011 - Avis d'incident

Incident lors d'une curiethérapie interstitielle cutanée

Institut Claudius Regaud - Toulouse (31)

Le 7 janvier 2011, l'ASN a été informée par le département de radiothérapie de l'Institut Claudius Régaud, à Toulouse, d'un incident détecté le jour même, survenu lors d'une curiethérapie interstitielle[1] cutanée.

Publié le 02/02/2011 - Avis d'incident

Erreur de traitement d'un patient en radiothérapie externe

Centre hospitalier de Cornouaille - Hôpital Laennec - Quimper (29)

Le 16 décembre 2010, le Centre hospitalier intercommunal de Cornouaille à Quimper a déclaré à la division de Nantes de l'ASN une erreur d'exposition d'un patient traité par radiothérapie externe pour un cancer pulmonaire.

Publié le 25/01/2011 - Avis d'incident

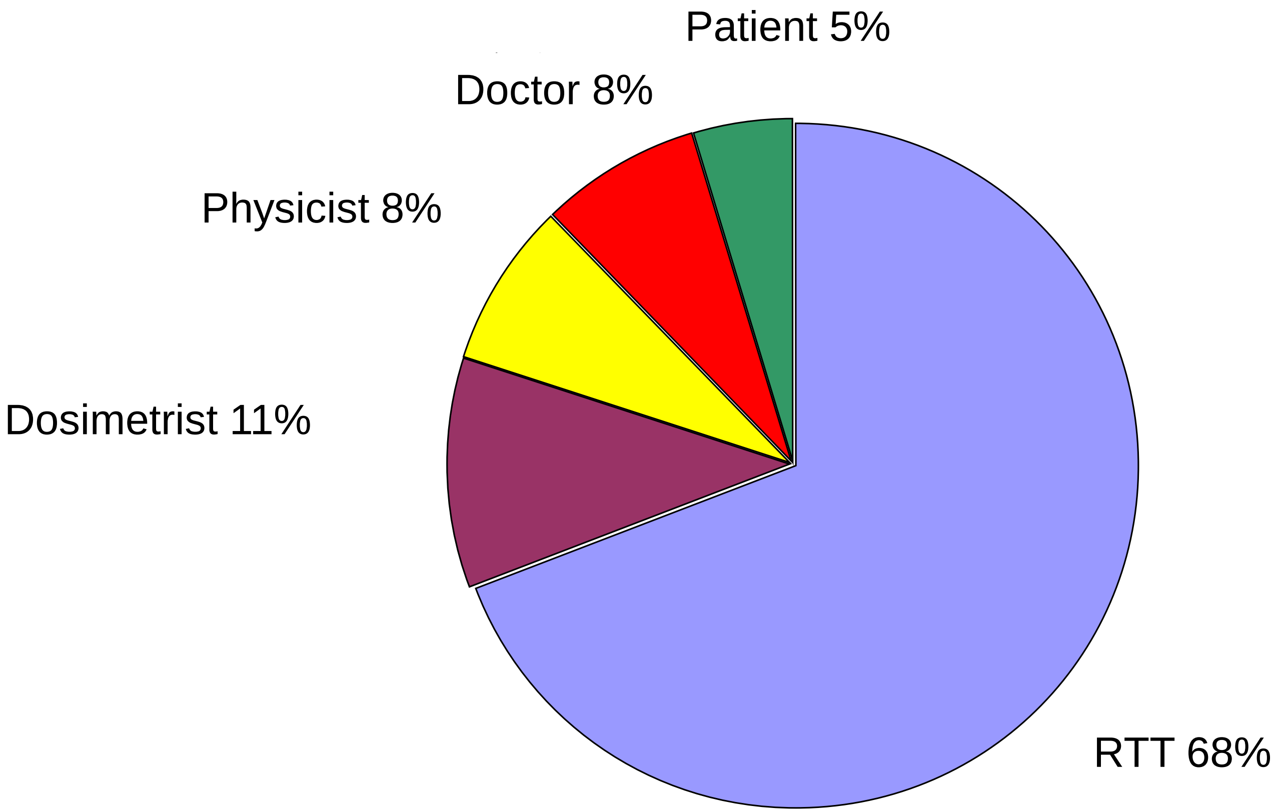
Voir aussi

Échelle ASN-SFRO pour la prise en compte des évènements de radioprotection affectant des patients dans le cadre d'une procédure de radiothérapie (PDF - 268,18 Ko)

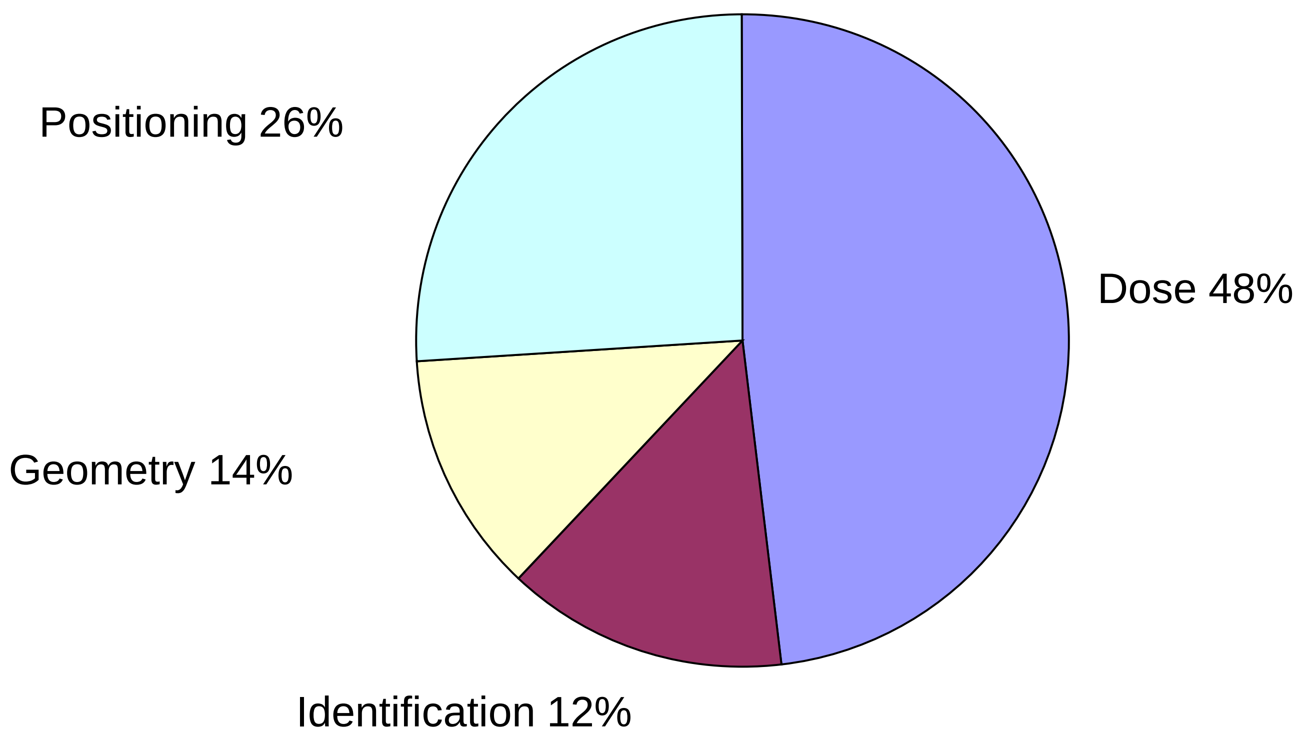
CONTENT

1. Public information on patients events
   - ASN-SFRO scale
   - Communication
2. **Some figures**
3. Difficulties encountered and recommandations

Declaring



Type



Causes

- **Human : +++**
- **Technics : ergonomy**
- **11 dual (ESR/material)**

  - 4 TPS
  - 4 R&V
  - 1 linac
  - 1 CBCT
  - 1 TPS/CBCT/R&V

Duals are software related

2014 **ASN-SFRO**

- **4 level 2**
- **117 level1**

YEARLY CONTROL ON SITE !!!

CONTENT

1. Public information on patients events
   - ASN-SFRO scale
   - Communication
2. Some figures
3. **Difficulties encountered and recommandations**

3. Difficulties encountered

A good rating tool and useful communication tool that helps media and public understanding on the significance of an event

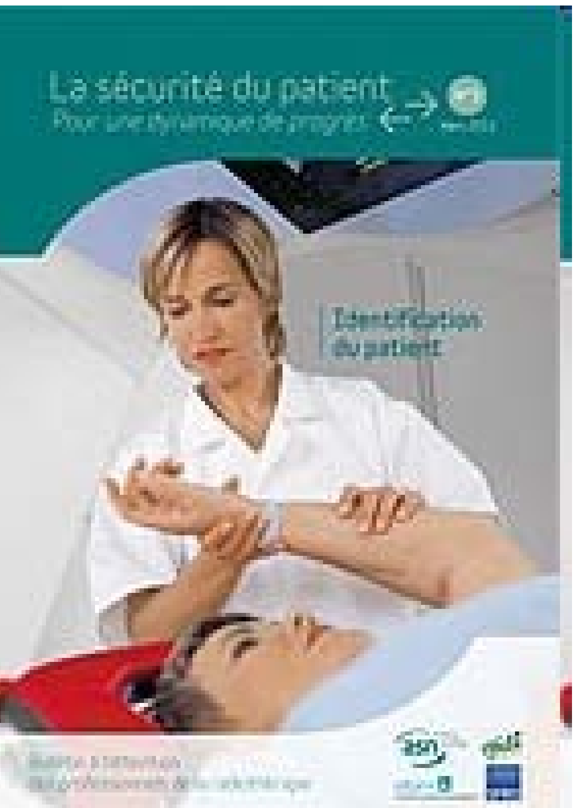
RATING PROBLEMS

- **Rating of some level 2 events (potential effects)**
- **Level 1 event are always without clinical consequence (while CTCAE grade 1 event are included in level 1)**
- **Difficulties to follow the evolution of the rating (late clinical consequence)**

3. Difficulties encountered

COMMUNICATION PROBLEMS

- **Disagreement of physicians about nominative incident notice for event without clinical effect (level 1) and consequence on patients anxiety => quaterly report for level 1 events without the name of the center**
- **Quaterly report not satisfying for public information => thought in progress**
- **Ethical questions (level 2 event for palliative treatment) => no incident notice**



2011: Patients identification
2011: First fraction
2012: Events to declare
2013: Dosi in vivo
2014: Side errors
2015: R& V recording defaults
2015: HDR/PDR brachy
2016: SBRT

Equipments/drugs AFSSAPS/ANSM

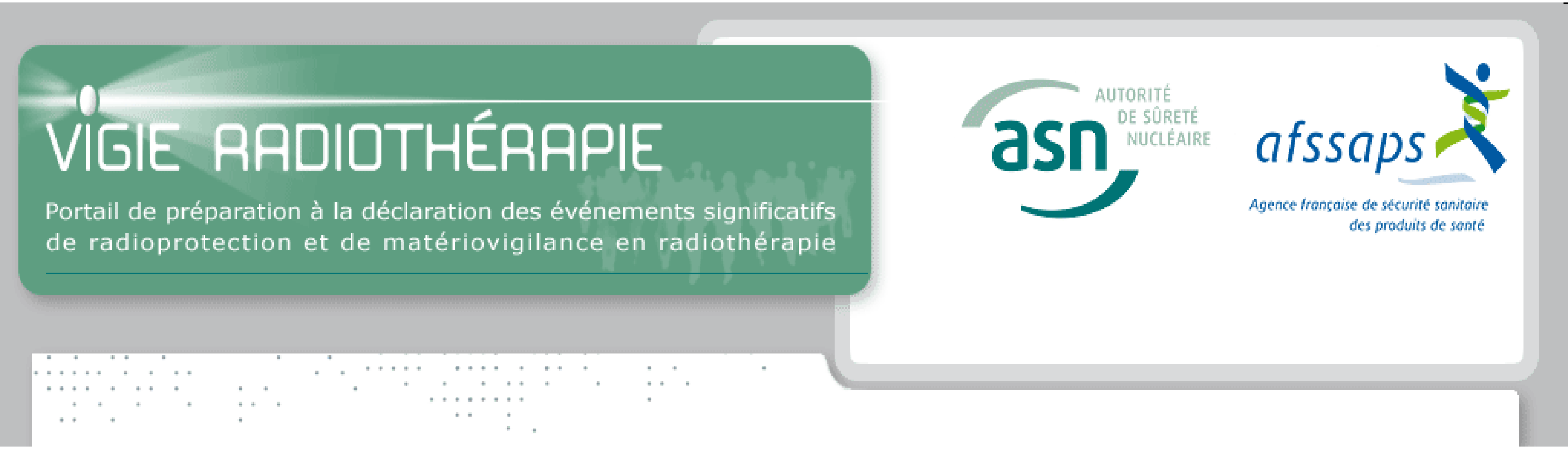
161 declarations in 2008-2009 :

- 16 (10 %) on treatment
- 50 (30 %) related to manufacturers: 40 % modifications in concept

- 32 **investigations ASN + Afssaps:**

22 linked to the system (19 software)

WEB SITE FOR DECLARATIONS



Opened on July 7th 2011

Outside of France

- Many recommendations…
- AIEA on good practice, ICRP86, WHO…
- Audits by professionals (clinical audits) : nordic countries
- Professional bodies : UK, US…
- National bodies: Spain…

29

UK recommendations

- **36. A specialty-specific voluntary system of reporting, analysis and learning from radiation incidents and near misses should be established. All radiotherapy centres should participate in this to enable national learning from safety learning**

- **37. Research into the optimal methods of feeding back lessons learnt from radiotherapy errors should be constructed.**

International Conference on Modern Radiotherapy

Advances and Challenges in Radiation Protection of Patients

Versailles, France, 2-4 December, 2009

Conclusion n° 5

« **Events/precursors likely to have possible effects on patients**: need to improve notification by radiotherapy centres and to develop error reporting and learning systems at national and international level (ROSIS, SAFRAD) for analysis and feedback experience. Need to further international efforts to harmonize classification of events (taxonomy) to facilitate translation of reporting into learning. »

Conclusion n°4

« **Responsibilities of manufacturers and suppliers :** regulators have to clearly define the responsibilities of manufacturers and suppliers on the commissioning of new devices and on the integration of the user's feedback experience. Regulatory and standardisation bodies must pay a specific attention to software associated to accelerators »

Conclusion n°6

« **Accidents** : Lessons learned from past accidents are well analysed (ICRP, IAEA) and actions to progress, under the responsibility of operators, are well identified, developing:

- Safety culture and safety tools;
- Quality assurance program and risk analysis;
- Adequate staffing and training »

Conclusion n° 7

« **Responsibilities of authorities** : on the basis of best national practices, regulatory bodies and health authorities have to provide more efforts to promote actions on adequate regulations, on quality assurance, on risk analysis, on clinical audits, on good clinical practices, etc »

Conclusion n° 8

« **Patient involvement :** A new challenge: to get the patient's voice in the dialogue through involvement of patients and their associations (e.g. International Network of Patients for Patient Safety) on advocacy, assessment of the quality and safety of treatments, risk acceptance and communication »

CONCLUSION

- Safety / security = crucial
- need to internal and external audits
- Mix : clinical and radioprotection audits

« an improvement anywhere is an improvement everywhere »

- ***Next step : patients participation***

34

Ethics for
Radiation Medicine Professionals

Peter Dunscombe

UNIVERSITY OF CALGARY

ESTRO school

Disclosures

- Occasional Consultant to Varian
- Occasional Consultant to the IAEA
- Director, TreatSafely, LLC
- Director, Center for the Assessment of the Radiological Sciences.

Why?

- **Ethics** is the foundation of everything we do, whether it's our clinical work, interaction with colleagues and students or our personal lives.

- **Ethics** is starting to appear in curricula for the education and training of people like us.

Learning Objectives

- To try to figure out what Ethics actually is.
- To discuss selected streams of ethical thought.
- To explore some of the key developments in medical ethics.
- To suggest a practical stepwise approach to situations with an ethical dimension.

Outline

- **What is Ethics?**

To try to figure out what Ethics actually is.

- **Ethical Thought.**

To discuss selected streams of ethical thought.

- **History of Medical Ethics.**

To explore some of the key developments in medical ethics.

- **Practical Ethics**

To suggest a practical stepwise approach to situations with an ethical dimension.

Exercises

- **After the discussion of each stream of ethical thought we'll do a short Exercise**
- **You can work on your own or in a group**
- **There's no "right" answer!**

Exercise

Scenario 1: Your institution has an error reporting system and a policy that says you must report errors. However, you've reported errors before and nothing has ever changed. Furthermore, there has never been any feedback. Do you continue to report errors?

Scenario 2: An error was made and a patient was underdosed by 2%. Do you tell the patient and/or their family?

Outline

- **What is Ethics?**

To try to figure out what Ethics actually is.

- **Ethical Thought.**

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- **Practical Ethics**

To suggest a practical stepwise approach to situations with an ethical dimension.

Ethics

A popular, but not very informative, definition of ethical behaviour:

Ethical behaviour shows respect for the dignity of man.

Ethics

=

Moral philosophy

Moral Philosophy

is about understanding and distinguishing between **good and bad, right and wrong,** or **good and evil,** in relation to the actions, volitions, or character of responsible beings; ethical.

A working definition of Moral Philosophy:

The enquiry into why we ought to behave in certain ways and what those behaviours are.

Note: We can consider behaviour in general or in specific situations.

Two classes of philosophical approach:

What ought I to do?

(What should my behaviour be in a specific situation?)

How should I live?

(What should my behaviour be in general?)

What ought I to do?

(What should my behaviour be in a specific situation?)

- maximize benefit to society (utilitarianism)
- do my duty (duty ethics)
- conform to prevailing values (values-based ethics)

How should I live?

(What should my behaviour be in general?)

Aristotle would say behave virtuously and you will flourish. (Virtue ethics)

ESTRO school

Outline

- **What is Ethics?**

To try to figure out what Ethics actually is.

- **Ethical Thought.**

To discuss selected streams of ethical thought.

- **History of Medical Ethics.**

To explore some of the key developments in medical ethics.

- **Practical Ethics**

To suggest a practical stepwise approach to situations with an ethical dimension.

Selected streams of ethical enquiry:

- Utilitarianism.
- Duty ethics.
- Virtue ethics
- Values-based ethics

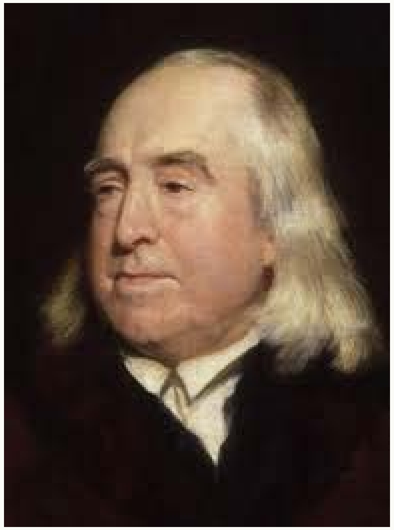
Selected streams of ethical enquiry:

- Utilitarianism.
- Duty ethics.
- Virtue ethics
- Values-based ethics

Utilitarianism:

The greatest good for the greatest number.

In its simplest form utilitarianism ignores social justice.



Exercise

Scenario 1: Your institution has an error reporting system and a policy that says you must report errors. However, you've reported errors before and nothing has ever changed. Furthermore, there has never been any feedback. Do you continue to report errors?

Scenario 2: An error was made and a patient was underdosed by 2%. Do you tell the patient and/or their family?

Which of the four possible courses of action for each scenario represents a utilitarian (consequentialist) approach?

Ethics for Radiation Medicine Professionals

Ethics Exercise. Scenario 1: Error Reporting

Your institution has an error reporting system and a policy that says you must report errors. However, you've reported errors before and nothing has ever changed. Furthermore, there has never been any feedback. Do you continue to report errors?

Ethics	Action
	While I'm reporting to a system that is obviously dysfunctional I could be spending more time with patients, which is far more beneficial. I'm not going to bother reporting any more errors – it's a complete waste of time. The consequences for all concerned are better if I just carry on treating patients.
	The rules say I have to report so I'm going to. It's my duty to report whether or not anything is done with the information.
	Reporting errors is the right thing to do. The system may not have worked in the past but, maybe, if we keep trying to support the initiative it will eventually become effective. I'll carry on reporting errors. My mentor, whom I really admire, would do that.
	Nobody round here seems to bother so I won't either. If I get dinged for it I'm just going to say "Why pick on me: no-one else is reporting". Such an action doesn't reflect my values but it seems to reflect the values of my institution.

Ethics for Radiation Medicine Professionals

Ethics Exercise. Scenario 1: Error Reporting

Your institution has an error reporting system and a policy that says you must report errors. However, you've reported errors before and nothing has ever changed. Furthermore, there has never been any feedback. Do you continue to report errors?

Ethics	Action
	While I'm reporting to a system that is obviously dysfunctional I could be spending more time with patients, which is far more beneficial. I'm not going to bother reporting any more errors – it's a complete waste of time. The consequences for all concerned are better if I just carry on treating patients.
Duty	The rules say I have to report so I'm going to. It's my duty to report whether or not anything is done with the information.
	Reporting errors is the right thing to do. The system may not have worked in the past but, maybe, if we keep trying to support the initiative it will eventually become effective. I'll carry on reporting errors. My mentor, whom I really admire, would do that.
	Nobody round here seems to bother so I won't either. If I get dinged for it I'm just going to say "Why pick on me: no-one else is reporting". Such an action doesn't reflect my values but it seems to reflect the values of my institution.

Ethics Exercise. Scenario 2: Disclosure

An error was made and a patient was underdosed by 2%. Do you tell the patient and/or their family?

Ethics	Action
	It’s always best to be honest. If I were the patient I would appreciate being told what happened to me, whether it will really affect my treatment and how the clinic will make sure it doesn’t happen again.
	This error is well within the normal variability of dose delivery so why worry the patient with information of no consequence.
	This clinic prides itself on being open with patients on all matters so I’ll take the time to tell the patient and answer any questions they have.
	The policy says the patient must be informed if the dose error is greater than 3%. This error was less than 3% so I don’t need to tell them.

Which of the four possible courses of action for each scenario represents a utilitarian (consequentialist) approach?

Ethics for Radiation Medicine Professionals

Selected streams of ethical enquiry:

- Utilitarianism.
- Duty ethics.
- Virtue ethics
- Values-based ethics

Duty ethics (deontology):

Do whatever your duty requires of you irrespective of the possible consequences.

•*Duties may be maxims laid down by an authority we acknowledge, for example a religion or a professional Code of Ethics.*

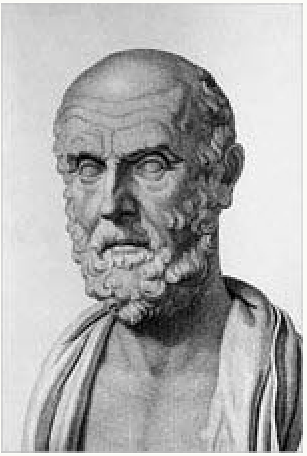
•*Duties may be derived by a process of reasoning.*

Hippocrates 460-370 BC

Hippocrates statements are maxims – they are not derived from “first principles” or the subject of philosophical analysis

Some of Hippocrates’ maxims:

- Very high respect for teachers
- Prescribe according to ability and judgement
- Never harm anyone
- No euthanasia or abortions
- Function within realm of ability
- No sexual relations with patients



Ethics for Radiation Medicine Professionals

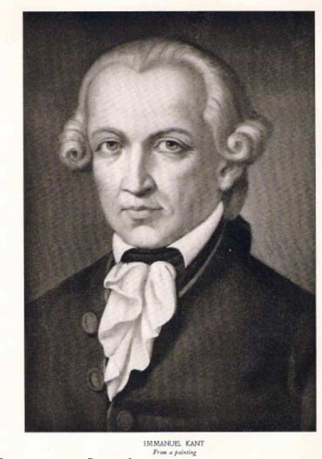
Kant 1724-1804

Kant proposed that we could use reason alone to determine what (not) to do.

The categorical imperative is

an instruction that is generalizable

from an individual to society.



Example: **We have a duty not to steal.** Without this duty anyone could steal. Thus effectively no-one would own anything. If no-one owns anything then nothing can be stolen.

Exercise

Scenario 1: Your institution has an error reporting system and a policy that says you must report errors. However, you've reported errors before and nothing has ever changed. Furthermore, there has never been any feedback. Do you continue to report errors?

Scenario 2: An error was made and a patient was underdosed by 2%. Do you tell the patient and/or their family?

Which of the four possible courses of action for each scenario represents a duty ethics (deontological) approach?

Selected streams of ethical enquiry:

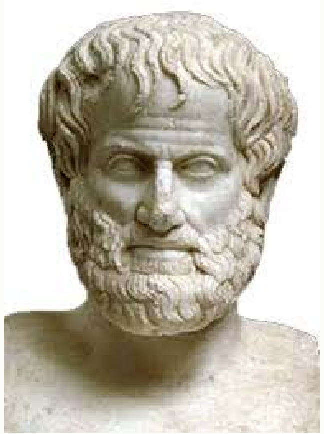
- Utilitarianism.
- Duty ethics..
- Virtue ethics
- Values-based ethics

Virtue ethics:

We will achieve happiness and flourish in our roles if we practice the virtues associated with those roles.

Aristotle 384-322 BC

the development of reason as the supreme goal of human existence to achieve happiness (and flourish) through the pursuit of moral (and intellectual) excellence.



Aristotle 384-322 BC

- "Man is a social/political animal" –famous quote.
- *Aristotle took a more observational approach to the elucidation of ethics and ethical behaviour.*
- *Identifies good (the characteristic of virtues) with happiness.*
- *We exhibit rationality in thinking (intellectual virtues) and in actions (moral virtues).*
- *We are not born as virtuous but we can be trained to be so.*

Virtue

Conformity of life and conduct with moral principles; voluntary adherence to laws or standards of right conduct; moral excellence, uprightness.

Virtues

Character traits or dispositions that we consistently exhibit.

Examples might be:

- Courage
- Justice
- Temperance
- Practical wisdom

Virtuous behaviour is admired. The virtues are admirable qualities.

Exercise

Scenario 1: Your institution has an error reporting system and a policy that says you must report errors. However, you've reported errors before and nothing has ever changed. Furthermore, there has never been any feedback. Do you continue to report errors?

Scenario 2: An error was made and a patient was underdosed by 2%. Do you tell the patient and/or their family?

Which of the four possible courses of action for each scenario represents a Virtue ethics (Aristotlian) approach?

Selected streams of ethical enquiry:

- Utilitarianism.
- Duty ethics..
- Virtue ethics
- Values-based ethics

Values-based Ethics

Values-based Ethics is the study of an individual's and society's values and the actions which follow.

Values

The principles or **moral** standards of a person or social group; the generally accepted or personally held judgement of what is valuable or important in life.

Values

Features of our existence which are important to us.

Examples might be:

- Financial security
- Freedom
- Family/friends

In the absence of constraints values govern our behaviours and actions?

Values-based Ethics: working definition

Values-based ethical behaviour is that which reflects the values of the community relevant to the situation.

The relevant community might be your professional group, your academic institution, society at large, etc.

Values based Ethics

Depending on the situation some values may take precedence over others.

Exercise

Scenario 1: Your institution has an error reporting system and a policy that says you must report errors. However, you've reported errors before and nothing has ever changed. Furthermore, there has never been any feedback. Do you continue to report errors?

Scenario 2: An error was made and a patient was underdosed by 2%. Do you tell the patient and/or their family?

Which of the four possible courses of action for each scenario represents a values based approach?

Outline

- **What is Ethics?**

To try to figure out what Ethics actually is.

- **Ethical Thought.**

To discuss selected streams of ethical thought.

- **History of Medical Ethics.**

To explore some of the key developments in medical ethics.

- **Practical Ethics**

To suggest a practical stepwise approach to situations with an ethical dimension.

The Nuremburg Code

1945 – International Military Tribunal

1946 – The Doctors Trial

1947 – The Nuremberg Code

Drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners.

The Nuremburg Code

The Nuremberg code became the prototype of many later codes intended to assure that research involving human subjects would be carried out in an ethical manner.

1. Established necessity of **informed consent**
2. Introduced concept of **beneficence**
3. Introduced the notion of **proportionality between risk and benefit**

Beneficence – the quality or state of being beneficent

Beneficent – doing or producing good; performing acts of kindness or charity

The Helsinki Agreement

Developed in 1964 by the World Medical Association, it serves as a revision of the Nuremberg code to reflect changes in medical research practices.

Widely adopted by Journals who required that research be conducted in accordance with the Declaration.

1. Allowed for **proxy consent.**
2. Introduced concept of oversight by an **independent review committee** (sounds a lot like Institutional Review Boards).
3. States more clearly that the **wellbeing of the patient takes precedence over societal benefit**.

ESTRO school

The Belmont Report

Background - The **Tuskegee syphilis experiment** was a clinical study conducted between 1932 and 1972 in Tuskegee, Alabama, by the U.S. Public Health Service.

Purpose - To learn whether syphilis had a different pathological course in black men than in white men.

Noble Beginnings - When the study began in **1932**, standard medical treatments for syphilis were toxic, dangerous, and of questionable effectiveness. Part of the study goal was to determine if patients were better off not being treated with such toxic remedies.

Study Design - Investigators recruited 623 impoverished African-American subjects with and without syphilis. They would be followed throughout their lives and autopsied at death to determine how the disease had progressed.

The Belmont Report

New Developments - Penicillin was validated as an effective cure for syphilis in the **1947**. Despite this, infected subjects were not treated.

Problem 1 - Researchers actively conspired with physicians in the area to prevent these subjects from obtaining treatment.

Problem 2 - Researchers actively lied to subjects about their condition to prevent them from seeking treatment elsewhere.

The End – Journalist reports abuses. Study closed in **1972**.

The Belmont Report

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Ethical Principles and Guidelines for Research Involving Human Subjects

A. Boundaries Between Practice and Research

B. Basic Ethical Principles

1. Respect for Persons
2. Beneficence
3. Justice

C. Applications

1. Informed Consent
2. Assessment of Risk and Benefits
3. Selection of Subjects

Beneficence – the quality or state of being beneficent

Beneficent – doing or producing good; performing acts of kindness or charity

Outline

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So practically, what ought I to do?

(What should my behaviour be in a specific situation?)

So practically, what ought I to do?

(What should my behaviour be in a specific situation?)

Step 1.

Identify and practice the virtues (moral excellences) associated with my role.

If I do this I will intuitively follow the right course of action.

(How should I live – Virtue Ethics)

So practically, what ought I to do?

(What should my behaviour be in a specific situation?)

Step 2.

Ensure my proposed course of action is not in conflict with any relevant professional Code of Ethics or Conduct.

This is particularly important in patient related situations.

So practically, what ought I to do?

(What should my behaviour be in a specific situation?)

Step 3.

Look for options that maximize the benefit to all involved parties.

So practically, what ought I to do?

(What should my behaviour be in a specific situation?)

Step 4.

Ensure as far as possible that my proposed actions reflect the values of my relevant community.

So practically, what ought I to do?

(What should my behaviour be in a specific situation?)

Step 1. Exercise the virtues and your intuition.

Step 2. Comply with applicable Codes of Ethics.

Step 3. Maximize the benefit to all involved.

Step 4. Act in conformity with the values of the community.

So practically, what ought I to do?

(What should my behaviour be in a specific situation?)

Practical Ethics

- Exercise the virtues and your intuition.
- Comply with applicable Codes of Ethics.
- Maximize the benefit to all involved.
- Act in conformity with the values of the community.

Streams of Ethical Enquiry

- Virtue Ethics and Intuitionism.
- Duty Ethics
- Utilitarianism.
- Values-based ethics

Summary

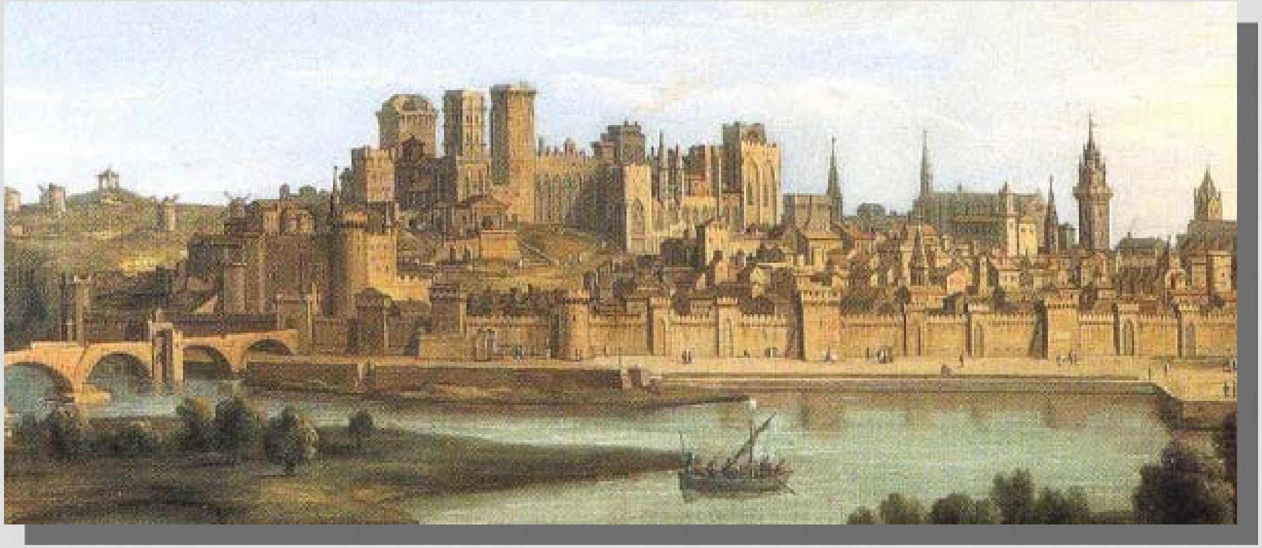
- We have tried to figure out what Ethics actually is.

- We have discussed selected streams of ethical thought.

- We have explored some of the key developments in medical ethics.

- We have suggested a practical stepwise approach to situations with an ethical dimension.

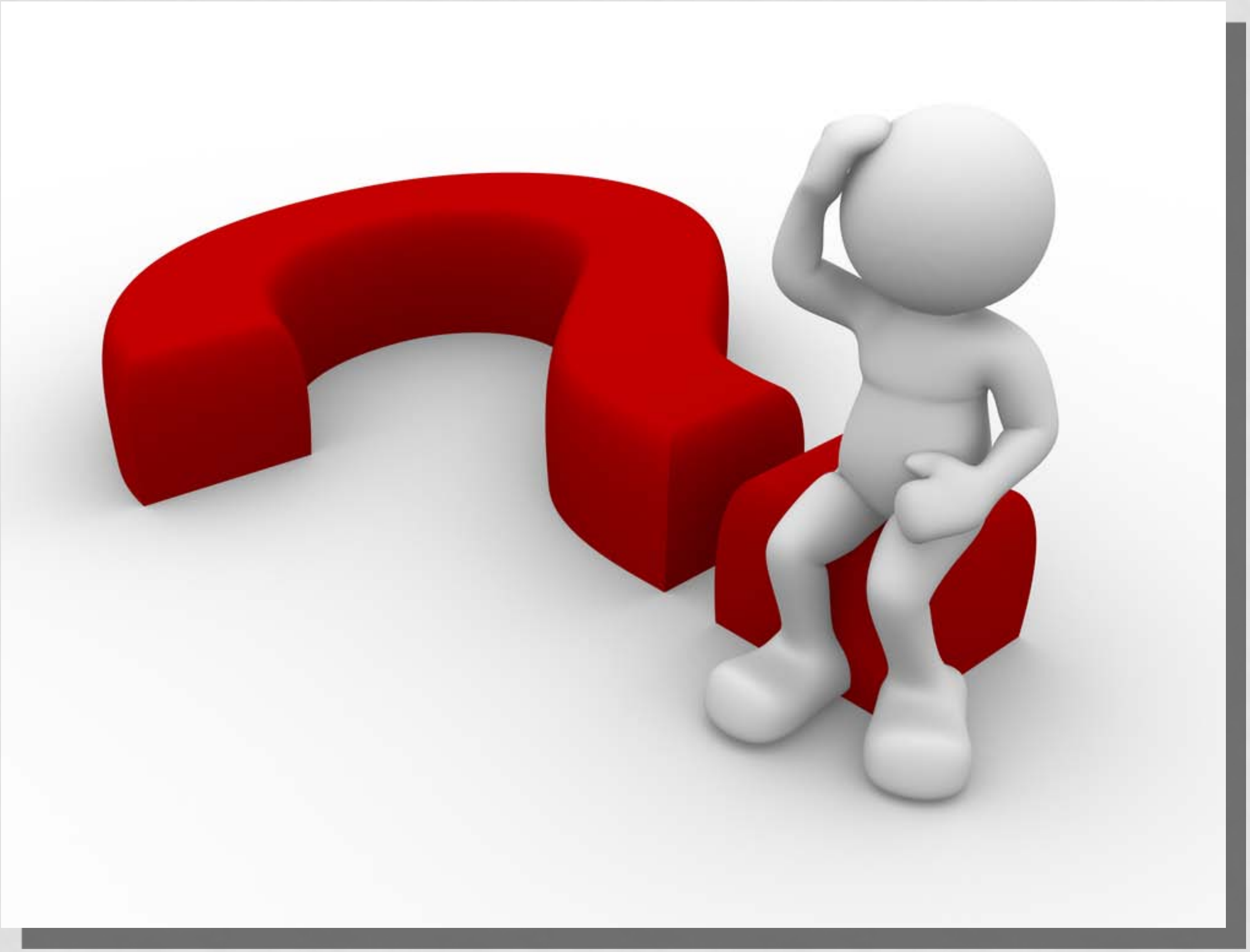
ESTRO school



A JUST CULTURE

ESTRO – Avignon Oct 1-4th, 2016

SO, WHAT ARE HUMAN FACTORS?



SO, WHAT ARE HUMAN FACTORS?

Anything that affects human performance

European Human Factors Advisory Group EASA (2008)

BLAME CULTURE

BLAME CULTURE

A culture in which, if something goes wrong, the primary response is to apportion blame to one or more individuals and apply sanction.

Usually

the operator

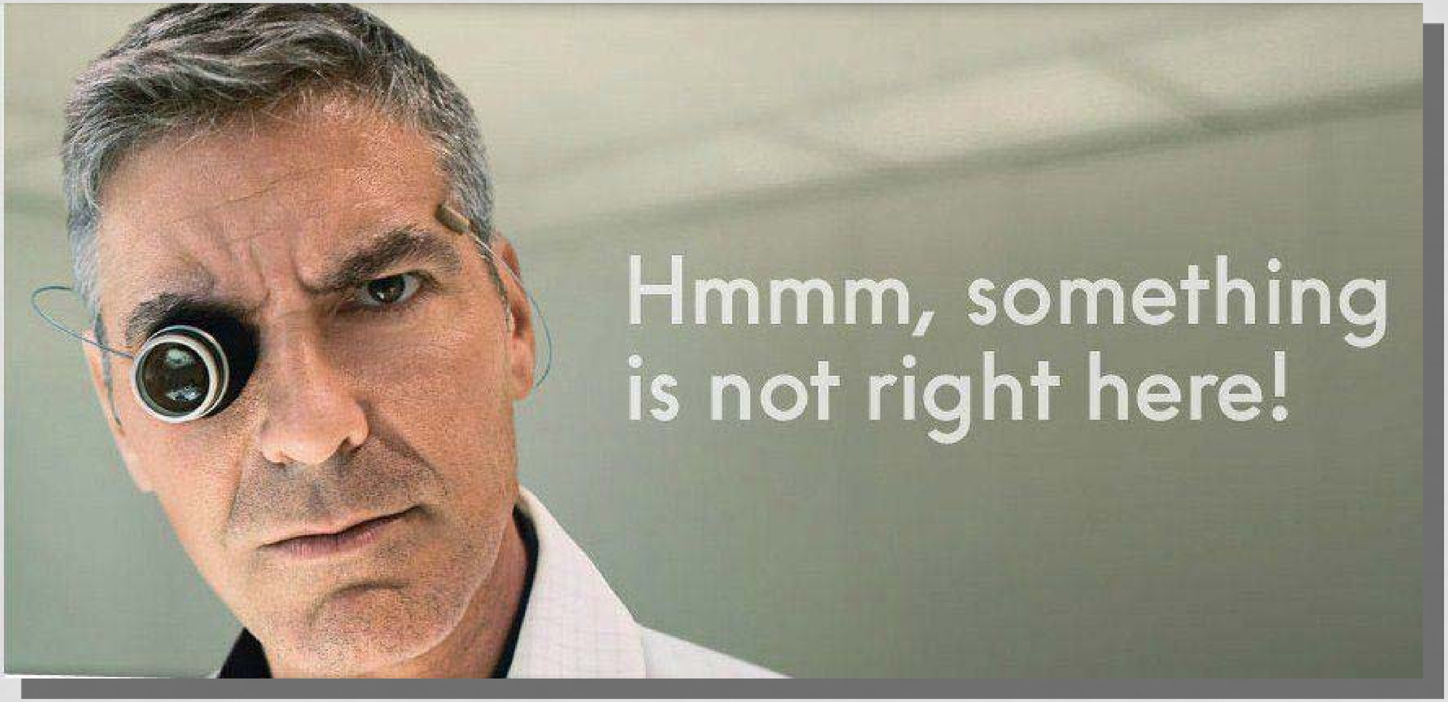
PROBLEMS WITH A BLAME CULTURE

- It is much easier to blame the last person who touched the patient than those responsible for their working conditions

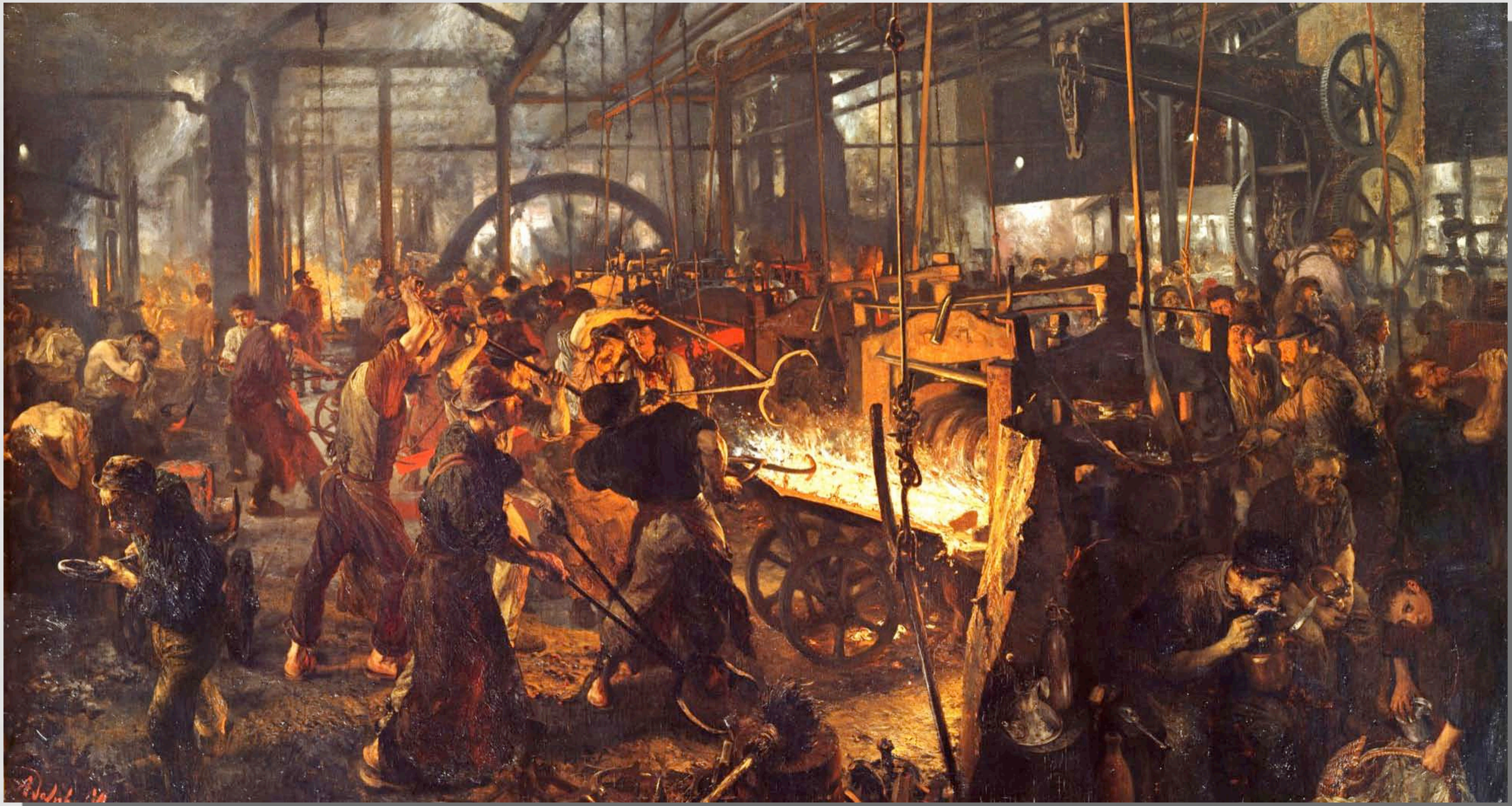
Directive 2003/42/EC (Occurrence Reporting)

PROBLEMS WITH A BLAME CULTURE

- In many cases the individual is not the problem.



PROBLEMS WITH A BLAME CULTURE

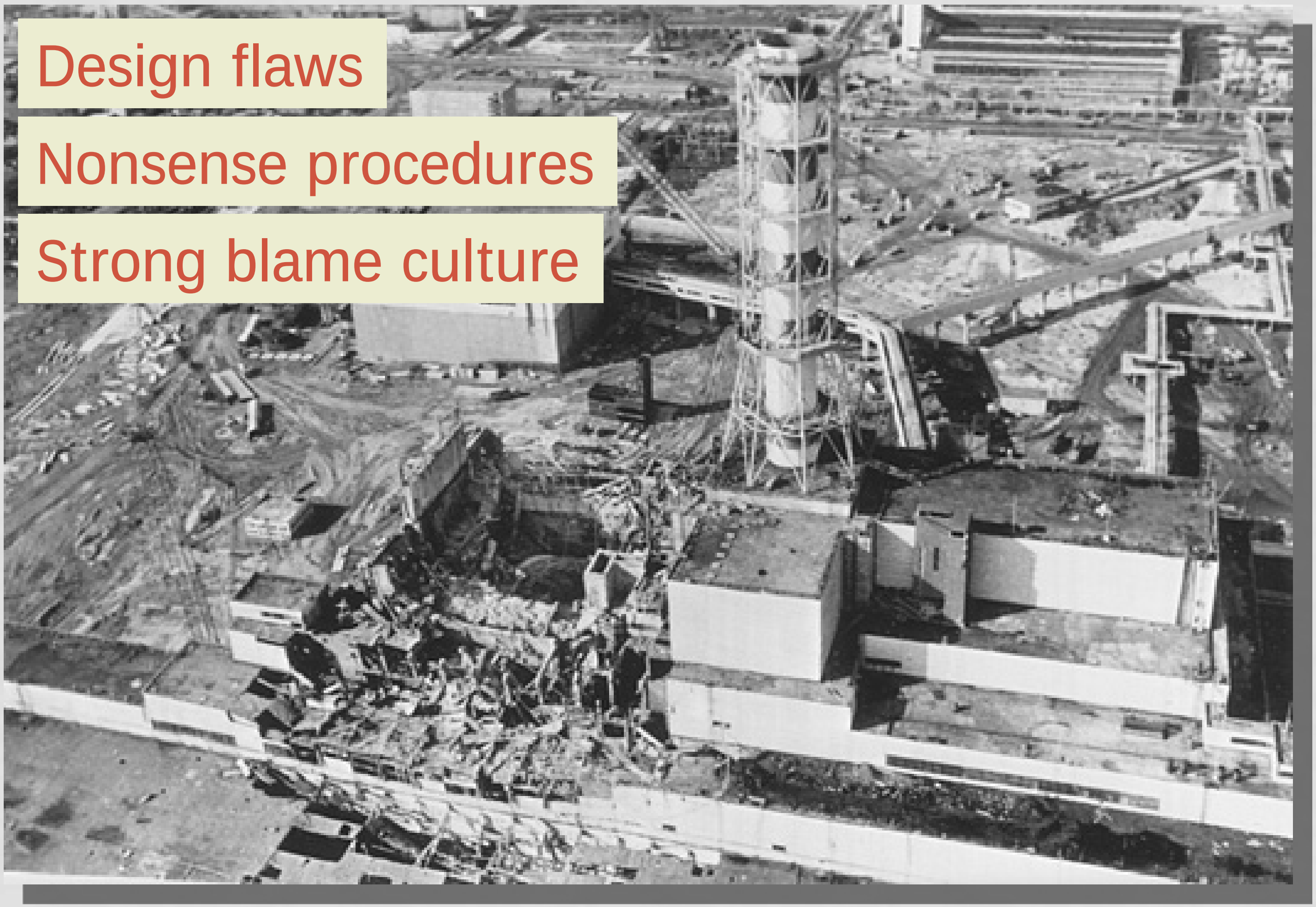


TCHERNOBYL

Design flaws

Nonsense procedures

Strong blame culture



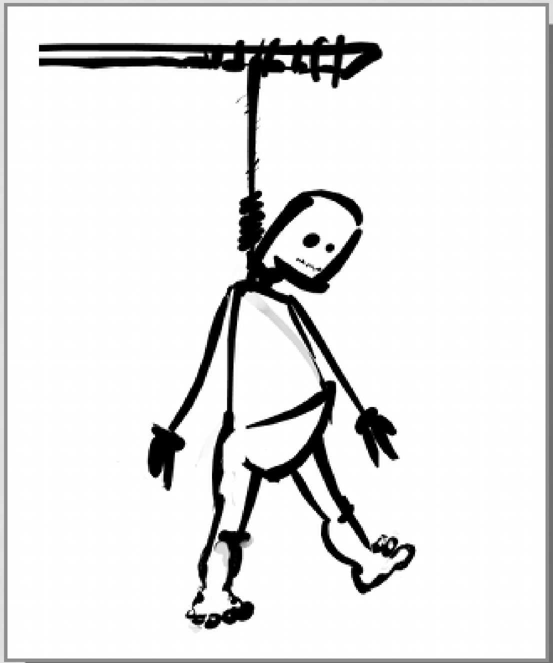
PROBLEMS WITH A BLAME CULTURE

Operators are victims of a poorly designed environment rather than responsible of errors.

PROBLEMS WITH A BLAME CULTURE

- There is not one culprit.
- Line management shares responsibility.
- Upper management too.

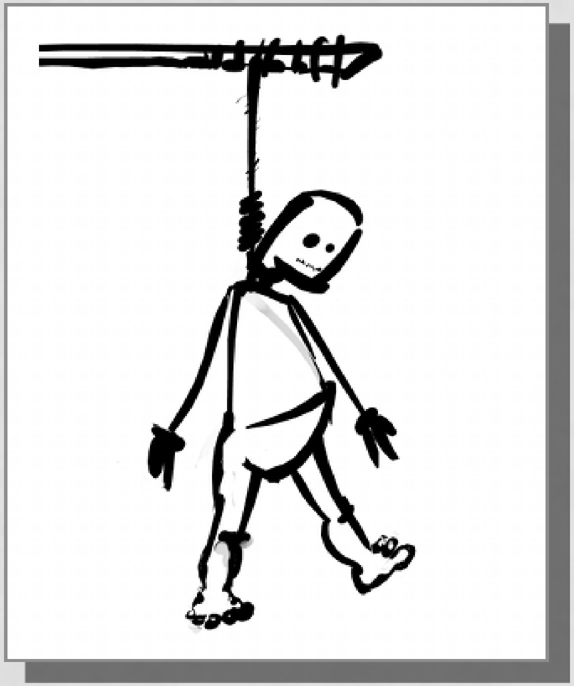
So, shooting at the pianist is unfair.



PROBLEMS WITH A BLAME CULTURE

In addition, blame culture discourages reporting of incidents and co-operation with investigations so:

- The problem can get worse.
- We do not have accurate data on incident levels.
- We do not gain rich information to understand incidents.
- We have a weak basis for prevention.

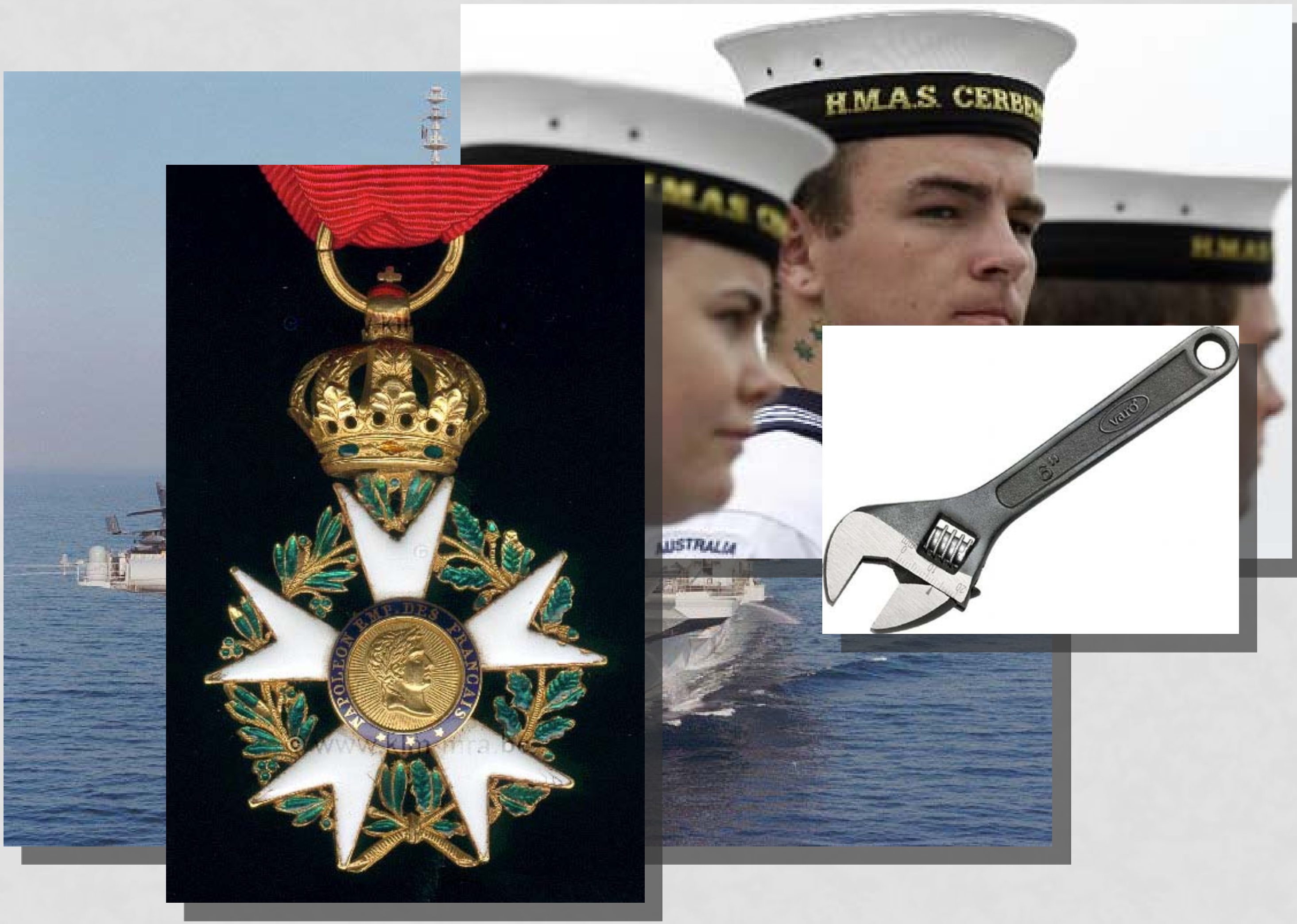


NO-BLAME CULTURE

A culture where individuals are exempted from disciplinary action if they report their errors and co-operate with investigations.

SAFETY RULES ON AN AIR CARRIER

SAFETY RULES ON AN AIR CARRIER



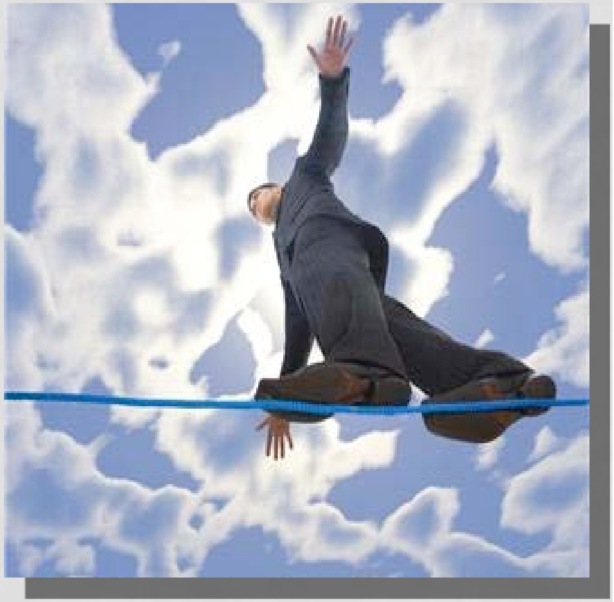
PROBLEMS WITH A NO-BLAME CULTURE

- Can give immunity to reckless or malicious individuals
- Can put an organisation out of step with society and its institutions – regulators, police, etc.
- Violation with the intent of self-reporting to escape sanction.
- Introduction of a no-blame policy is not enough to bring about a no-blame culture; the blame reflex is highly resilient.

A 'Just' Culture

"Is an atmosphere of trust in which people are encouraged, even rewarded, for providing essential safety-related information… but in which they are also clear about where the line must be drawn between acceptable and unacceptable behavior."

Prof. James Reason



JUST CULTURE

- Blame not automatic or even normal in response to human error
- Primary objective to understand, explain and prevent
- Clear policy defining when discipline is appropriate – e.g. negligence, recklessness

Why we do need a “Just” Culture?

“…one million people injured by errors in treatment at hospitals each year in the US, with 120,000 people dying from those injuries

Because of the punitive work environment, health care workers would report only what they could not conceal (hide)

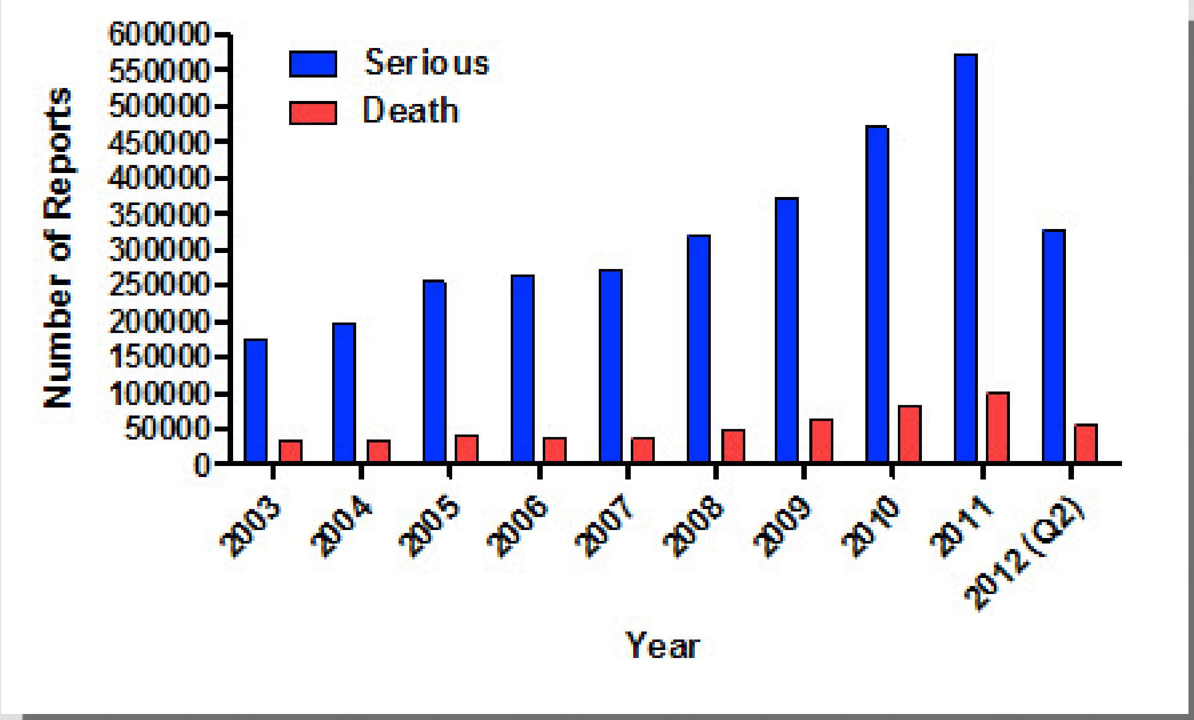
Dr. Lucian Leape professor at Harvard briefing a US Congressional subcommittee

Why we do need a “Just” Culture?

… the single greatest impediment to error prevention is … that we punish people for making mistakes”

Dr. Lucian Leape professor at Harvard briefing a US Congressional subcommittee

A PROBLEM IN 1996



From FDA Adverse Event reporting System 2014
98.518 related death in 2011

A PLANE CRASH A DAY

PROBLEMS WITH A JUST CULTURE

- Introduction of a “just” disciplinary policy is not enough to bring about a just culture; the blame reflex is highly resilient
- More difficult to define and communicate than a blame or no-blame policy
- Difficult to clearly define the boundaries of acceptable behaviour
- Requires a more sophisticate understanding of human behaviour and human error than many are willing to take

JUST CULTURE CODE OF PRACTICE (1)

Free and full reporting is the primary aim

- Use the ‘substitution test’ – would another individual who was similarly trained and experienced have made **the same error?**

JUST CULTURE CODE OF PRACTICE (2)

Individuals should not attract punitive action unless:

- The act was intended to cause deliberate harm or damage.
- They not have a constructive attitude towards complying with safe operating procedures.
- They knowingly violated procedures that were readily available, workable, intelligible and correct.

Culpability decision tree for unsafe acts (Reason 1990)

Near Misses and Barriers to Error Propagation

Peter Dunscombe

UNIVERSITY OF CALGARY

Disclosures

- Occasional Consultant to Varian
- Occasional Consultant to the IAEA
- Director, TreatSafely, LLC
- Director, Center for the Assessment of the Radiological Sciences.

What is a Near Miss?

Near Miss is the most commonly used term to describe an error that is discovered and rectified before it impacts a patient.

Other descriptions include:

•Near hit

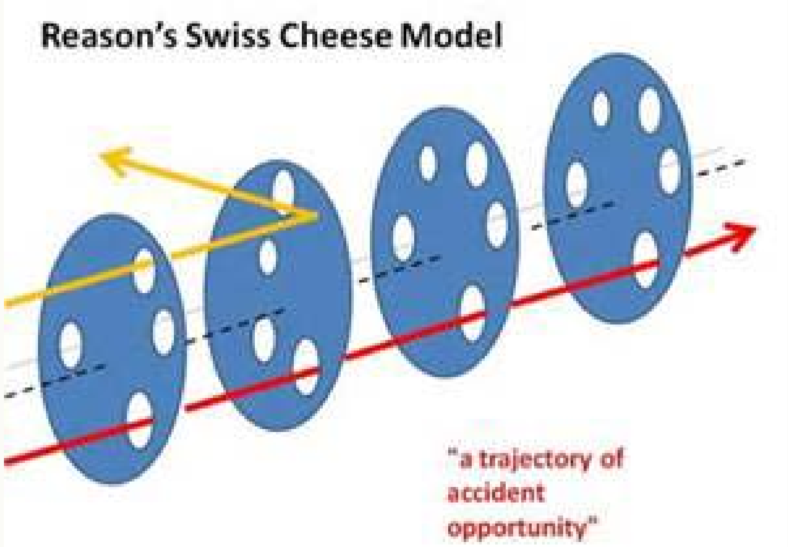
•Free lesson

•Potential incident

•Close call

What is a Safety Barrier?

A **Safety Barrier** is an obstacle to the propagation of errors.



Learning Objectives

- To review what we already know about near misses.
- To look at how current Incident Learning Systems handle near misses.
- To briefly discuss minimizing the chance of an error occurring in the first place.
- To consider suggestions for barriers to error propagation.

Exercises

- After each taxonomy we'll do a short Exercise
- You can work on your own or in a group
- There's no "wrong" answer!
- Later in the School we'll look at your anonymized and aggregated answers.

Outline

•Near Misses

To review what we already know about near misses.

•Incident Learning Systems

To look at how current Incident Learning Systems (ILS) handle near misses.

•Safe Infrastructure

To briefly discuss minimizing the chance of an error occurring in the first place.

•Safety Barriers

To consider suggestions for barriers to error propagation.

Near Misses and Barriers to Error Propagation

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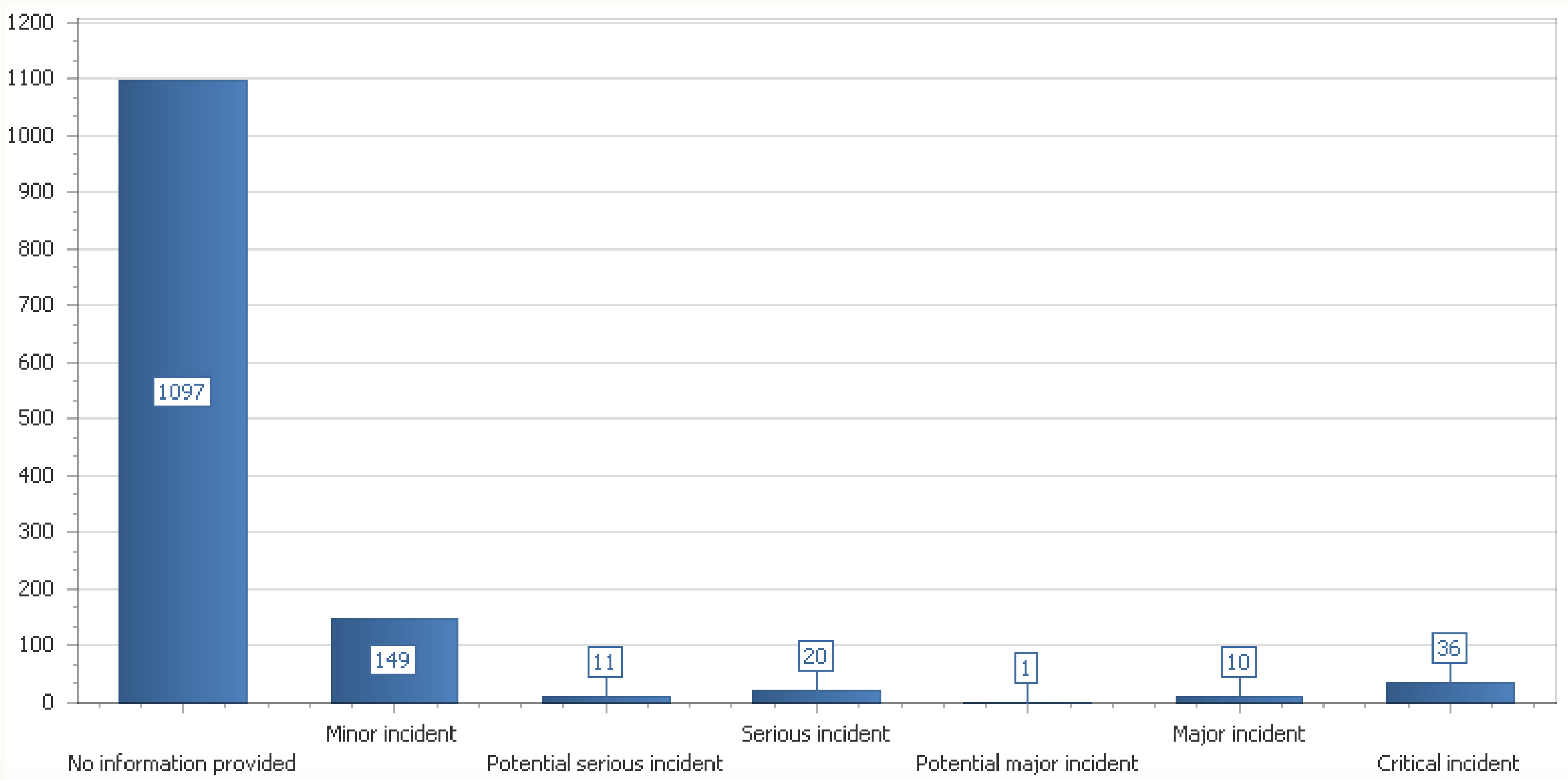
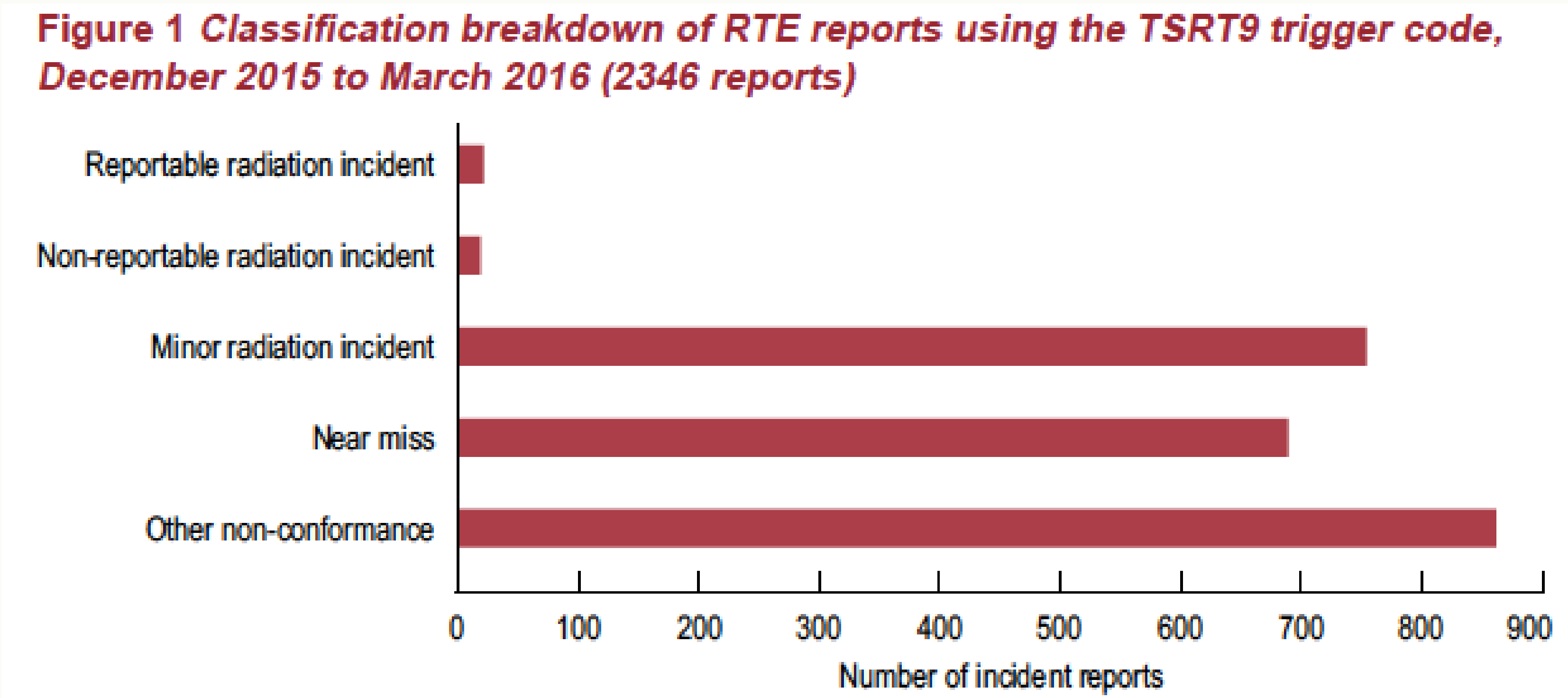
Near Misses and Barriers to Error Propagation

International experience (SAFRON)



Near Misses and Barriers to Error Propagation

National experience (UK)



http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1317141150324

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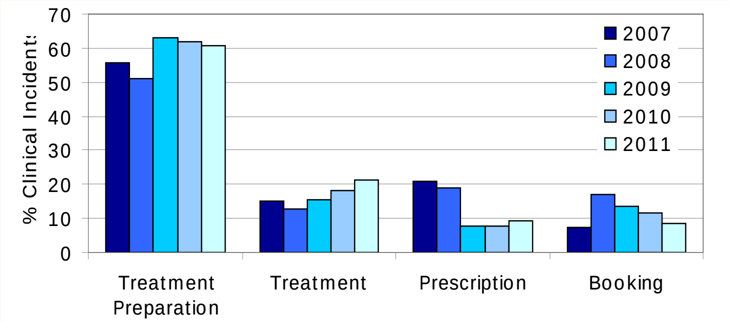
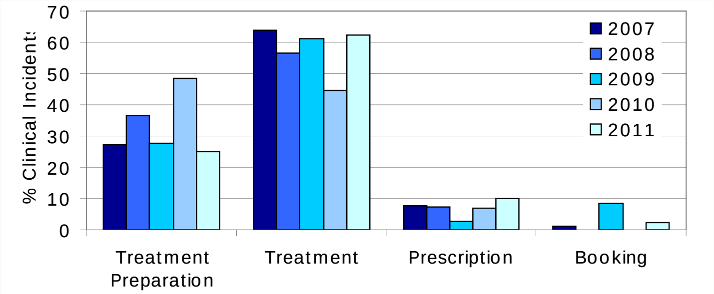
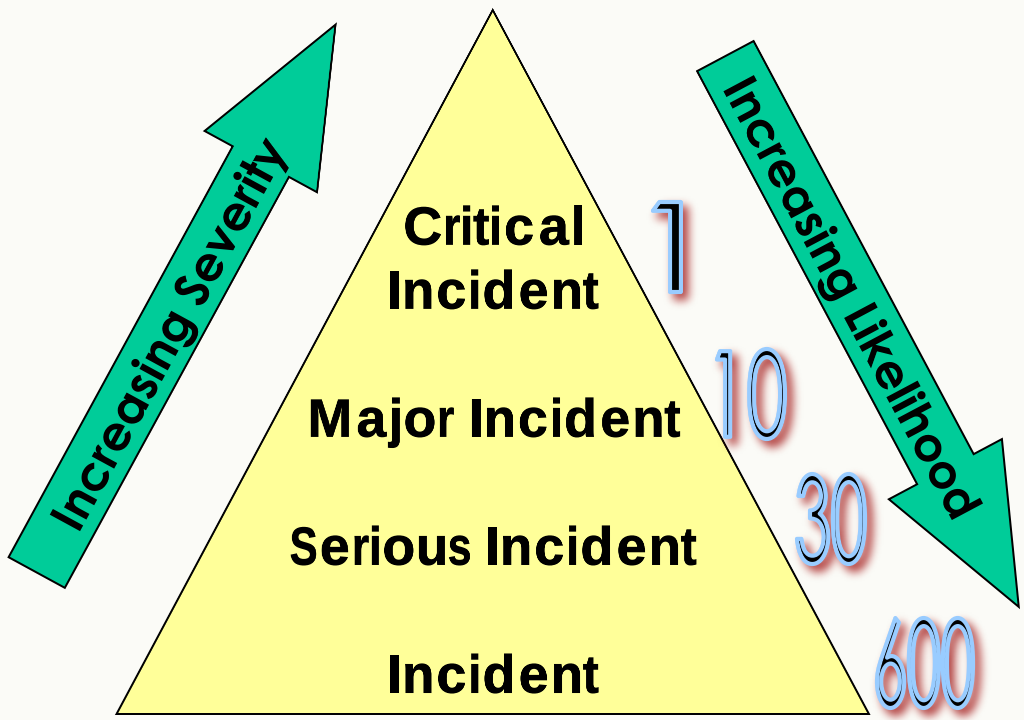
Local experience (Ottawa)

From 2007-11 the Ottawa Hospital Cancer Centre logged 2500 Incident reports with a ratio of Potential/Minor to Actual, non-minor of 51





Near Misses and Barriers to Error Propagation



Bird and Germain, 1986

What do we know about Near Misses?

- Full reporting will generate many more reports of potential incidents (near misses) than actual incidents.
- It is generally recognized that the more incidents reported the better.
- If the ratio of potential (near miss) to actual incidents is increasing and the overall severity is decreasing your safety program is effective.

Exercise 1: Reporting

It is generally recognized that the more incidents (both actual and near miss) reported the better.

Please rank the following as factors which would encourage **you** to report **near misses**:

- Just culture
- Department leadership
- Regular feedback to staff

Exercise 1: Reporting

It is generally recognized that the more incidents (both actual and near miss) reported the better.

Please rank the following as factors which would encourage **you** to report **near misses**:

Factor	Rank
Just Culture	1
Department leadership	2
Regular feedback to staff	3

Outline

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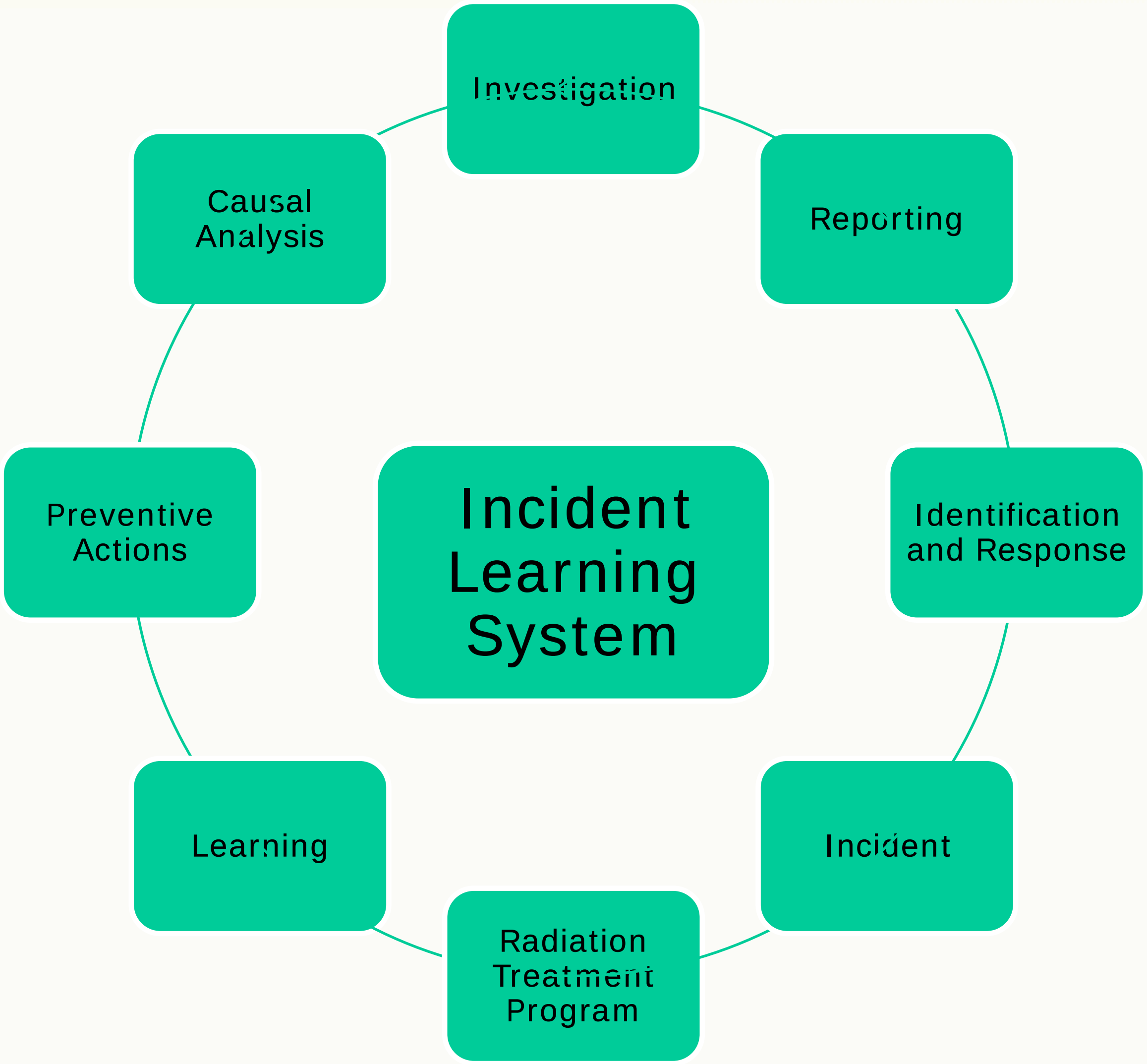
To consider suggestions for barriers to error propagation.

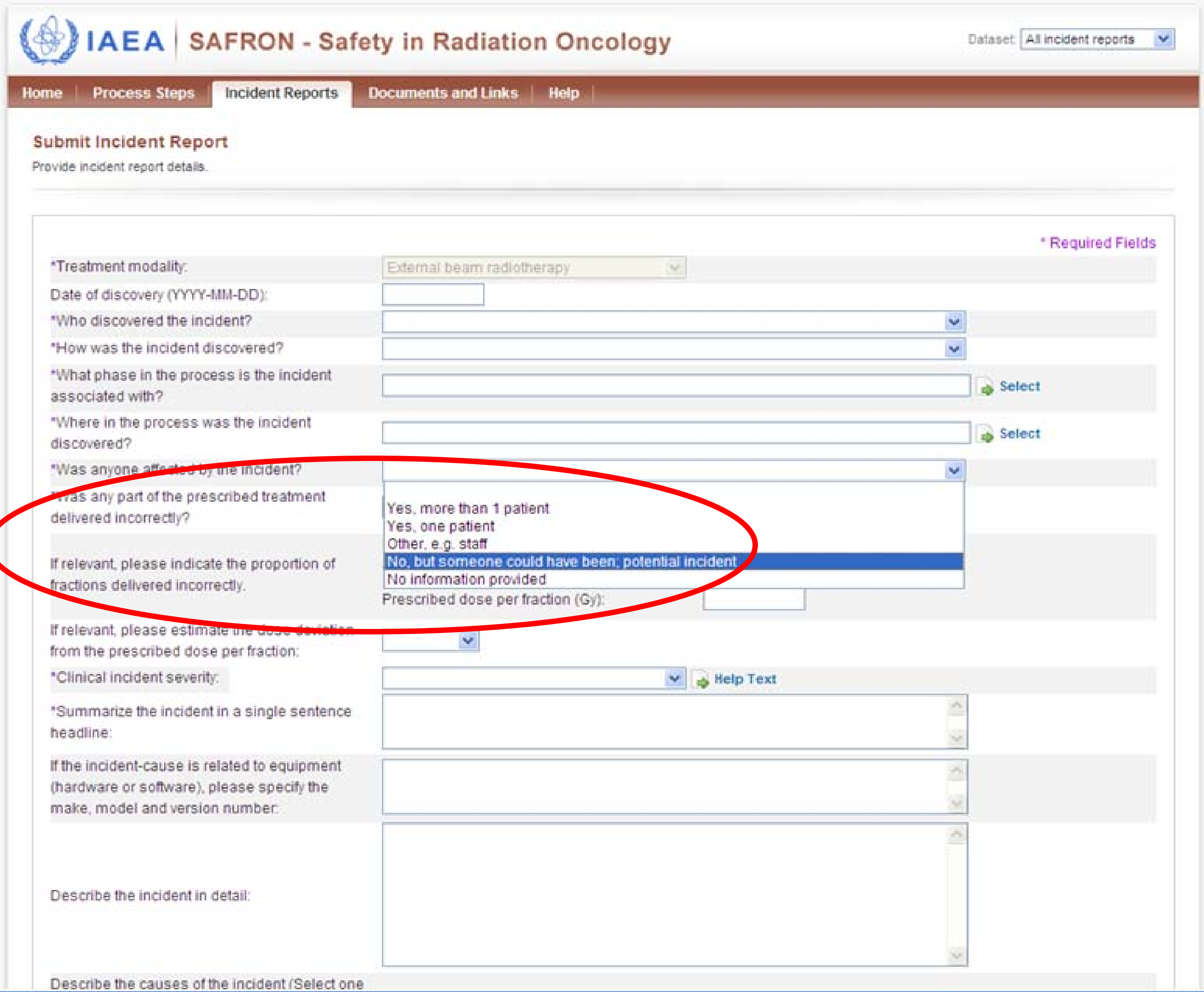
Near Misses and Barriers to Error Propagation



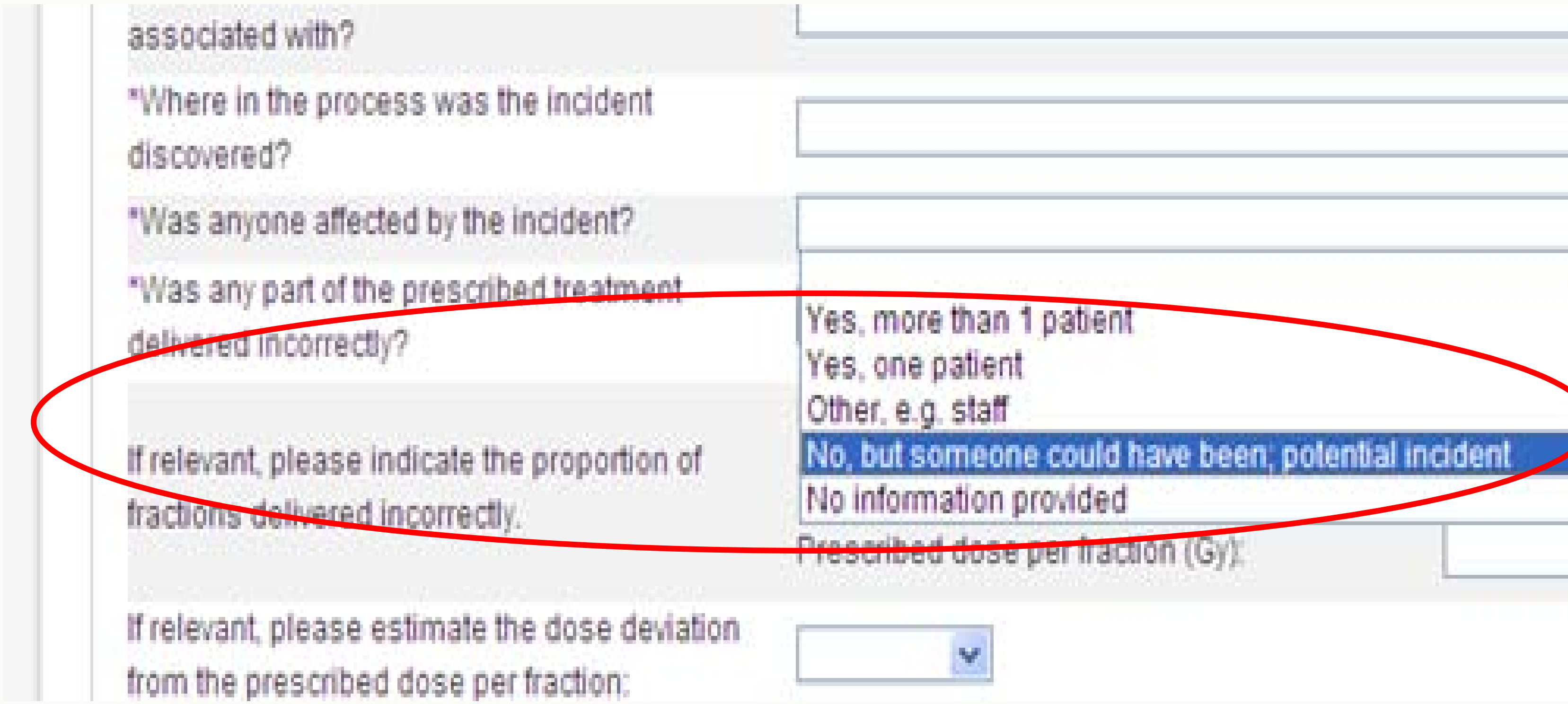
Near Misses and Barriers to Error Propagation

SAFRON

Near Misses and Barriers to Error Propagation



Near Misses and Barriers to Error Propagation



associated with?

*Where in the process was the incident discovered?

*Was anyone affected by the incident?

*Was any part of the prescribed treatment delivered incorrectly?

Yes, more than 1 patient
Yes, one patient
Other, e.g. staff
No, but someone could have been; potential incident
No information provided

If relevant, please indicate the proportion of fractions delivered incorrectly.

Prescribed dose per fraction (Gy):

If relevant, please estimate the dose deviation from the prescribed dose per fraction:

What do we know?

- We've moved beyond just reporting errors.

- Modern Incident Learning Systems are being set up to encourage near miss reporting.

Exercise 2: Incident Learning

Modern Incident Learning Systems are being set up to encourage near miss reporting.

Please rank the following factors in order of importance for an Incident Learning System:

- On-line access
- Anonymous reporting
- Confidential reporting
- Taxonomies such as drop downs, etc

Exercise 2: Incident Learning

Modern Incident Learning Systems are being set up to encourage near miss reporting.

Please rank the following factors in order of importance for an Incident Learning System:

Factor	Rank
On-line access	
Anonymous reporting	
Confidential reporting	
Taxonomies such as drop downs	

Near Misses and Barriers to Error Propagation

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Near Misses and Barriers to Error Propagation

Safe Infrastructure:
Stopping errors before they happen

- Systemic measures must be in place as a pre-requisite for safe operation.
- However, it is not possible to construct a perfectly safe system so barriers are introduced to catch those errors that inevitably arise.

Near Misses and Barriers to Error Propagation

frontiers in ONCOLOGY

REVIEW ARTICLE
published: 28 September 2012
doi: 10.3389/fonc.2012.00129

Recommendations for safer radiotherapy: what's the message?

*Peter Dunscombe**

Department of Oncology, University of Calgary, Calgary, AB, Canada

Training (7)	Staffing/skills mix(6)
Documentation/SOP (5)	Incident Learning System (5)
Communication/questioning (4)	Check lists (4)
QC and PM (4)	Dosimetric Audit (4)
Accreditation (4)	Minimizing interruptions (3)
Prospective risk assessment (3)	Safety Culture (3)

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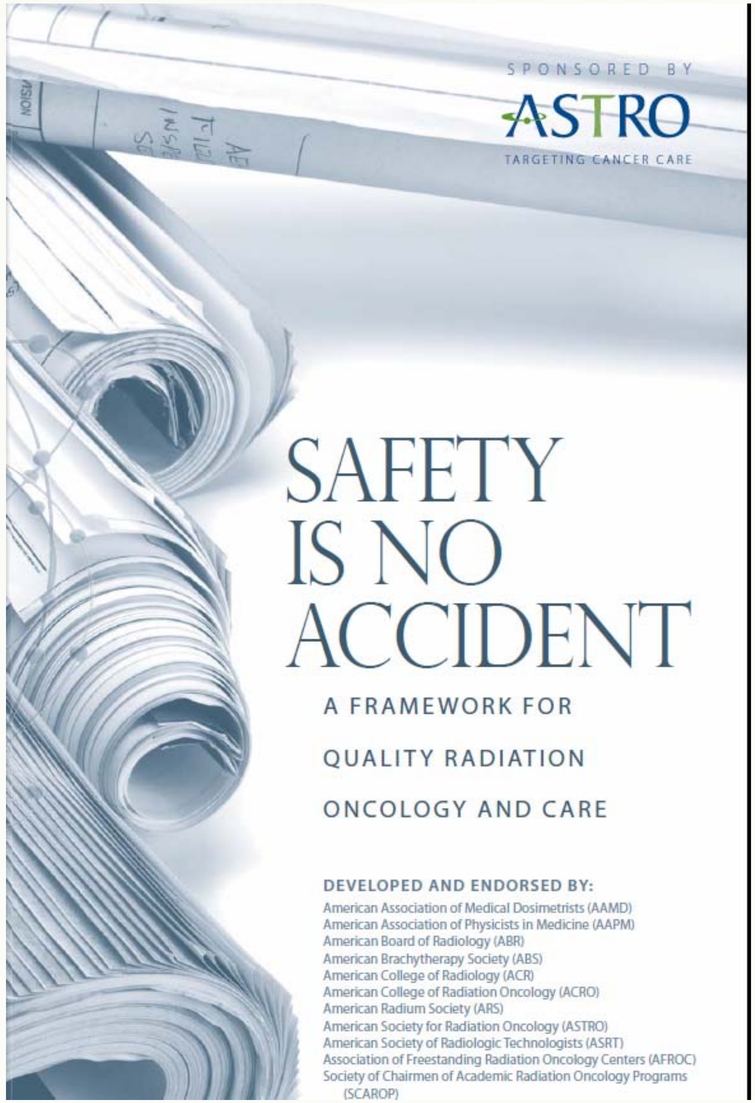
Near Misses and Barriers to Error Propagation



Near Misses and Barriers to Error Propagation

Staffing/Schedules

Communication/Facilities

Workflow/Efficiency

Standardization

Hierarchy of Effectiveness

Human Factors Engineering

Incorporating QA Tools/functionality into Software

Peer and Interdisciplinary Review

Daily Morning Meetings

Safety Rounds

Routine Public Announcements/Updates

Address Errors and Near-Misses

Quality Assurance Committee

Credentialing and Training

What do we know?

- Recent recommendations have largely addressed the safety infrastructure.
- But no system is 100% safe.
- That's why we need additional **Safety Barriers.**

Exercise 3: Safe Infrastructure

Recent recommendations have largely addressed the safety infrastructure.

Please rank the following in importance for a safe infrastructure:

- Standard operating procedures
- Periodic competency assessment
- Adequate staffing
- External accreditation

Exercise 3: Safe Infrastructure

Recent recommendations have largely addressed the safety infrastructure.

Please rank the following in importance for a safe infrastructure:

Factor	Rank
Comprehensive standard operating procedures	
Periodic competency assessment	
Adequate staffing	
External accreditation	

Near Misses and Barriers to Error Propagation

Outline

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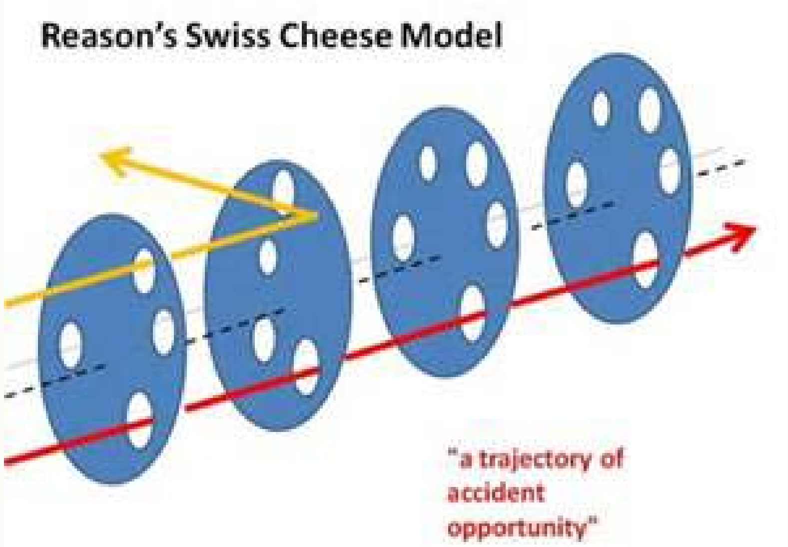
  To consider suggestions for barriers to error propagation.

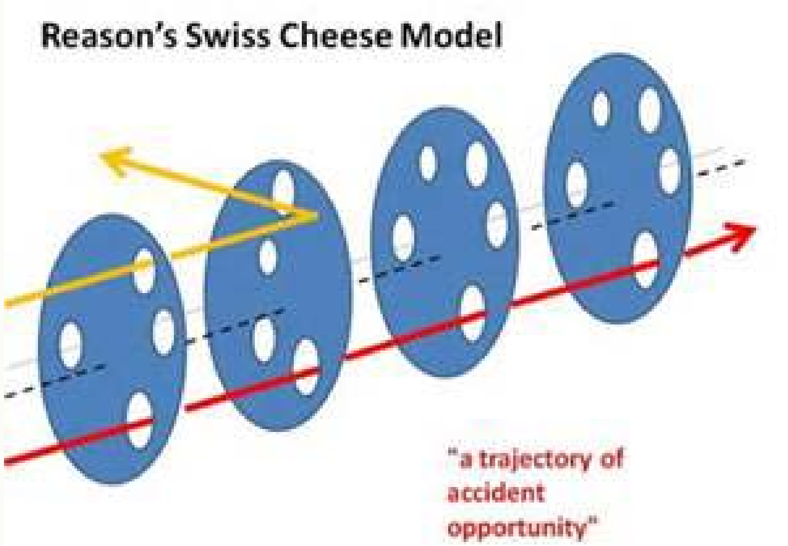
What is a Safety Barrier?

A **Safety Barrier** is an obstacle to the propagation of errors.



Near Misses and Barriers to Error Propagation

Where do you put safety barriers and what should they be?



Near Misses and Barriers to Error Propagation

Where do you put safety barriers and what should they be?

- For established processes you can conduct expert analysis of reported incidents.
- Or you can query a well constructed Incident Learning System.
- For a new process you can use Fault Tree Analysis.

Near Misses and Barriers to Error Propagation

Where do you put safety barriers and what should they be?

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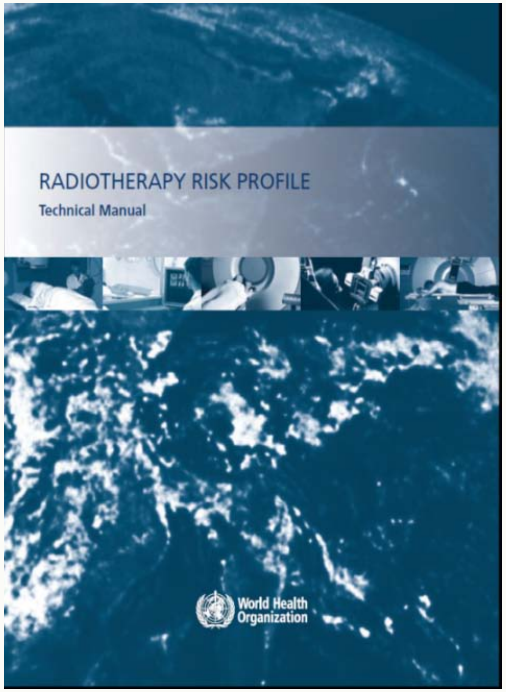
- Or you can query a well constructed Incident Learning System.
- For a new process you can use Fault Tree Analysis.

Near Misses and Barriers to Error Propagation

Risk Reduction Interventions

The top three interventions

- Planning protocol checklist (20 identified risks)
- Independent checking (12 identified risks)
- Competency certification (11 identified risks)



Near Misses and Barriers to Error Propagation

Consensus recommendations for incident learning database structures in radiation oncology

E.C. Ford[1], L. Fong de Los Santos[2], T. Pawlicki[3], S. Sutlief[4], and P. Dunscombe[5]

[1]Johns Hopkins University, [2] Mayo Clinic, [3] University of California San Diego, [4] Seattle Veterans Affairs Administration, [5] University of Calgary

AAPM Work Group on Prevention of Errors

Medical Physics. 39, 7272-7290. 2012

Near Misses and Barriers to Error Propagation

The AAPM's Safety Barriers

4. Pre-Treatment Review and Verification		
SB	4.1	Physics plan review
SB	4.2	Independent dose calculation
	4.3	Plan data transfer to treatment unit
SB	4.4	Verification of parameters at treatment unit
SB	4.5	Pretreatment patient specific plan measurement (e.g. IMRT QA)
SB	4.6	Physics verification/approval
SB	4.7	Physician plan peer review (e.g. chart rounds)
SB	4.8	Therapists chart check
	4.9	Other

Near Misses and Barriers to Error Propagation

Where do you put safety barriers and what should they be?

- For established processes you can conduct expert analysis of reported incidents.

- Or you can query a well constructed Incident Learning System.

- For a new process you can use Fault Tree Analysis.

Near Misses and Barriers to Error Propagation

SAFRON

What safety barrier	failed to identified the incident?	identified the incident?	might have identified it?
Verification of patient ID	☐	☐	☐
Verification that pretreatment condition have been taken into account	☐	☐	☐
Verification of imaging data for planning (CT scan, fusion, imaging modality, correct data set)	☐	☐	☐
Verification reference points	☐	☐	☐
Physician peer review	☐	☐	☐
Review of treatment plan	☐	☐	☐
Independent confirmation of dose	☐	☐	☐
Time out	☐	☐	☐
Use of record and verifying system	☐	☐	☐
Verification of treatment accessories	☐	☐	☐
Image based position verification	☐	☐	☐
In vivo dosimetry	☐	☐	☐
Intra-treatment monitoring	☐	☐	☐
Regular independent chart checks	☐	☐	☐
Regular clinic patient assessment	☐	☐	☐
Post treatment evaluations (evaluation of clinical and process)	☐	☐	☐
Independent review of commissioning	☐	☐	☐

Near Misses and Barriers to Error Propagation

SAFRON

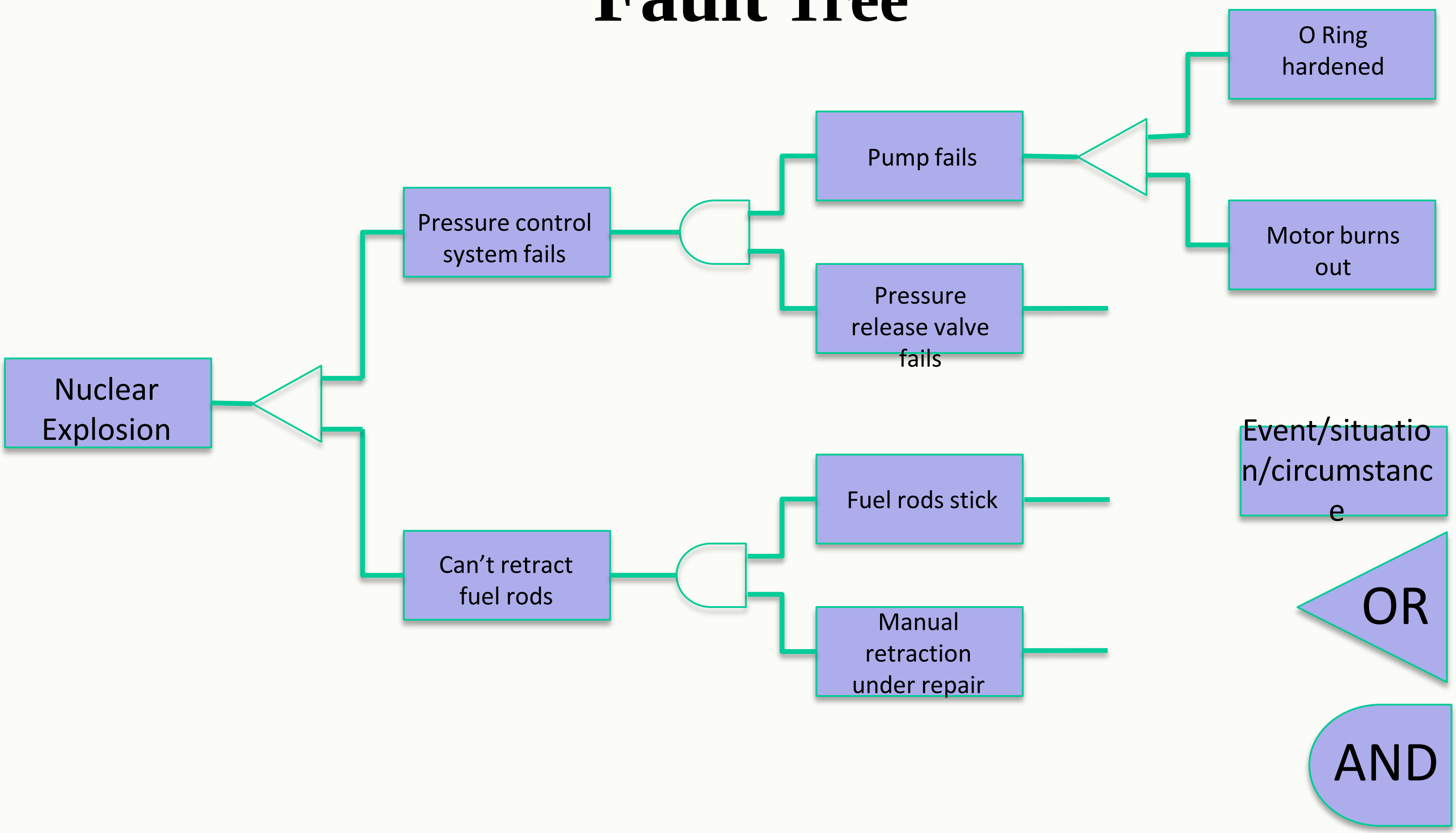
Safety barriers which failed.

Where do you put safety barriers and what should they be?

- For established processes you can conduct expert analysis of reported incidents.
- Or you can query a well constructed incident learning system.
- For a new process you can use Fault Tree Analysis.

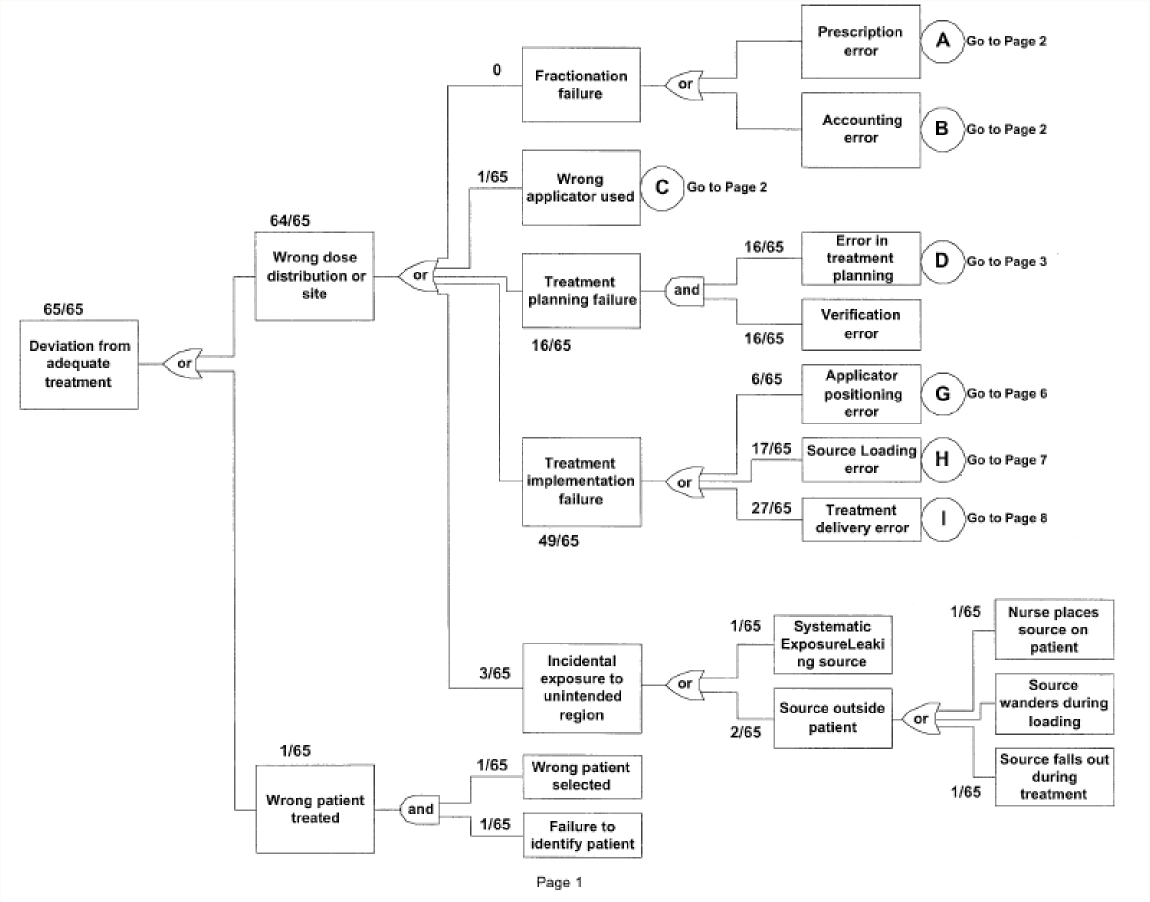
Near Misses and Barriers to Error Propagation

Fault Tree



Near Misses and Barriers to Error Propagation

Fault Tree

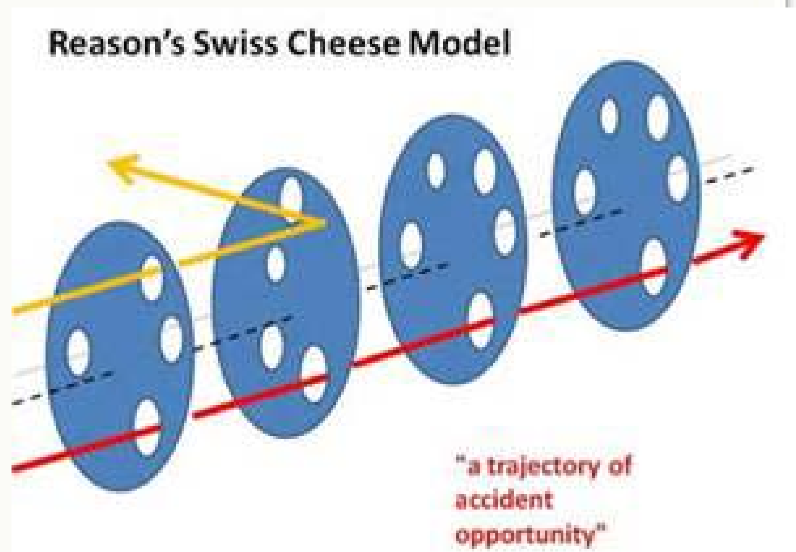


Int J Radiat Oncol Biol Phys 57 (2003) 149

Near Misses and Barriers to Error Propagation

What do we know?

- Our equipment might be safe and our procedures well documented but, as humans, we make mistakes.
- **Safety barriers** are an integral component of a safe system.
- However, we know little about which barriers are the most cost-effective.



Exercise 4: Safety Barriers

We know little about which barriers are the most cost-effective

Please rank the following in order of cost-effectiveness in your opinion:

- Radiation Therapist time-out
- Check lists
- Portal imaging
- Physics plan review

Exercise 4: Safety Barriers

We know little about which barriers are the most cost-effective

Please rank the following in order of cost-effectiveness in your opinion:

Factor	Rank
Radiation Therapist time-out	
Check lists	
Portal imaging	
Physics plan review	

Summary

- We have reviewed what we already know about near misses.
- We have looked at how current Incident Learning Systems handle near misses.
- We have briefly discussed minimizing the chance of an error occurring in the first place.
- We have considered suggestions for barriers to error propagation.

IAEA's e-learning program

E-learning - Safety and Quality in Radiotherapy

Welcome to "Safety and Quality in Radiotherapy"! This e-learning program is designed to provide continuing education for radiotherapy professionals regarding safety and quality in radiotherapy. Throughout this e-learning course, the participants are expected to:

1) Improve their understanding of safety in radiotherapy
2) Learn techniques to reduce and avoid radiotherapy incidents;
3) Understand the value and use of incident learning systems;
4) Learn about useful sources of information to enhance safety in radiotherapy;
5) Gain insight into improving safety culture in medical clinics/facilities.

The estimated time for the entire course is 3 hours. After the completion of the course, the participants can receive a certificate. This e-learning is provided in English.

What do I need to know before starting the course?

IAEA’s e-learning program

- MODULE 1: INTRODUCTION
- MODULE 2: MAJOR INCIDENTS IN RADIOTHERAPY
- MODULE 3: LEARNING FROM INCIDENTS
- MODULE 4: PROCESS MAPS, SEVERITY METRICS, BASIC CAUSES & SAFETY BARRIERS
- MODULE 5: REPORTING INCIDENTS USING SAFRON
- MODULE 6: ROOT CAUSE ANALYSIS 1. HUMAN FACTORS & BASIC CAUSES
- MODULE 7: ROOT CAUSE ANALYSIS 2. SAFETY BARRIERS & PREVENTIVE ACTIONS
- MODULE 8: FAILURE MODES AND EFFECTS ANALYSIS
- MODULE 9: FAULT TREE ANALYSIS
- MODULE 10: SAFETY CULTURE
- MODULE 11: USEFUL RESOURCES
- MODULE 12: AND NOW WHAT? ENHANCING QUALITY AND SAFETY IN YOUR CLINIC

SAFETY IN THE RT DEPARTMENT

AUDE VAANDERING (RTT/QM)

ESTRO – Avignon October 1st – 4th

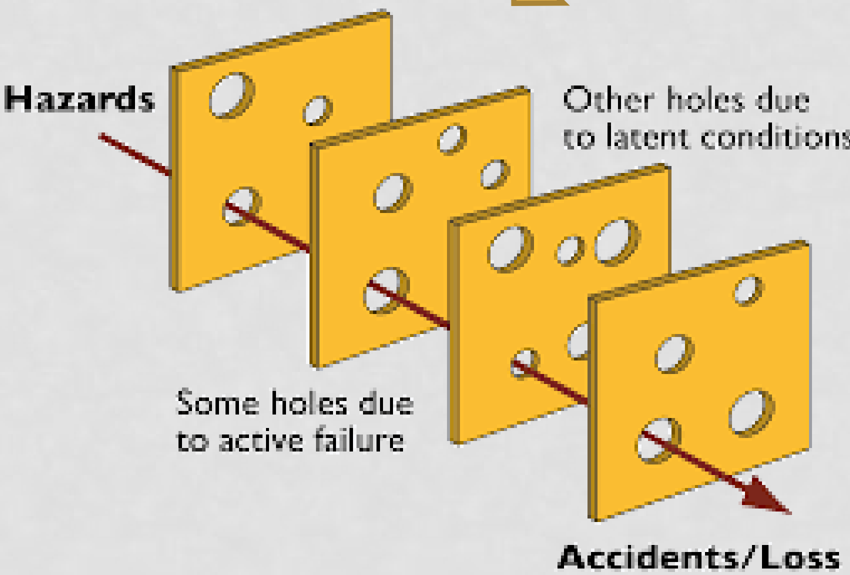
LEARNING OBJECTIVES

- To discuss the effectiveness of different approaches in preventing errors (automation, standardization…)

HUMAN COMPLEXITY

Technical failures

Human failures

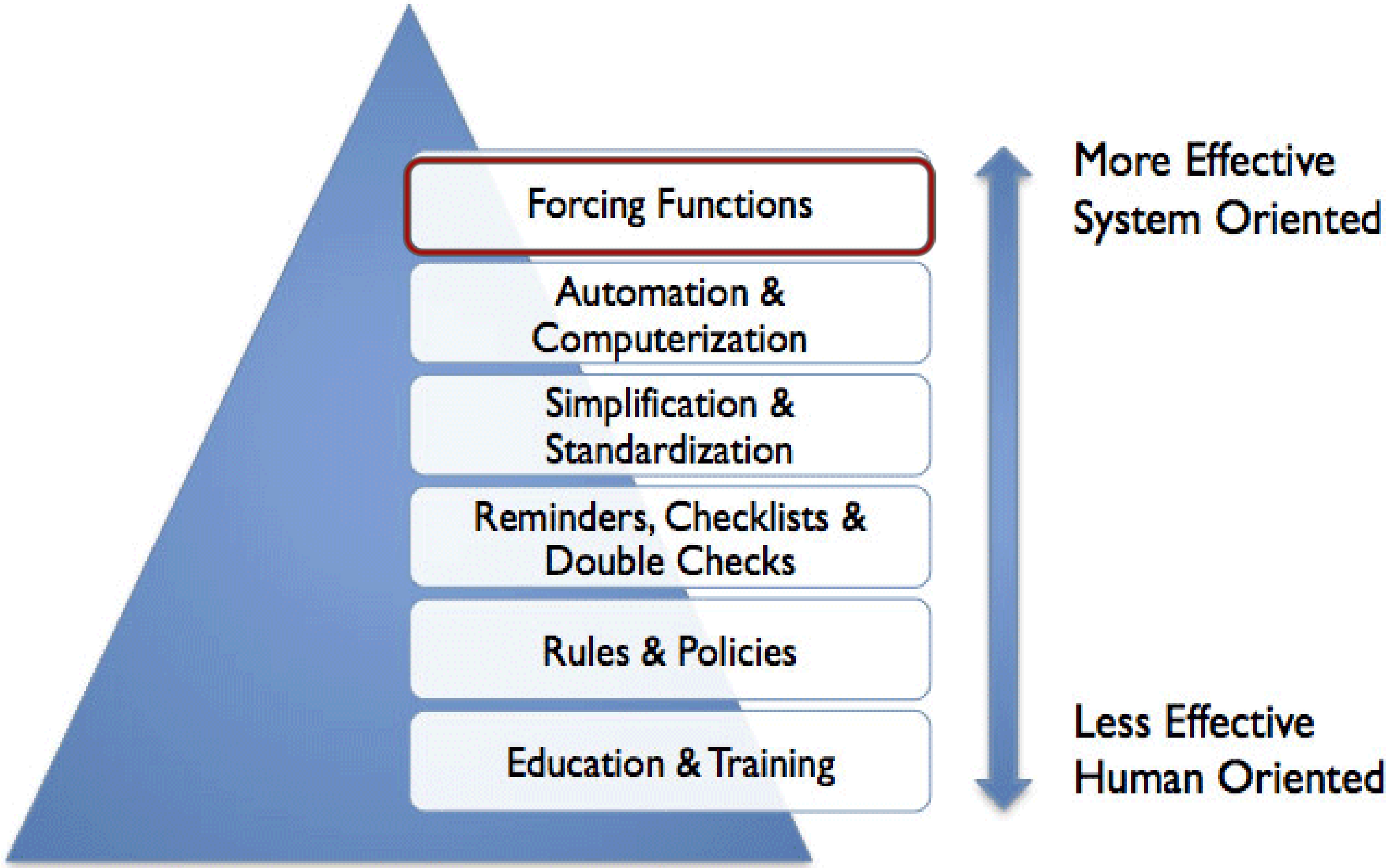


Organizational failures

<u>Reason's model</u>

- <u>Human errors</u>: active failure
- <u>Environment</u>: latent failures

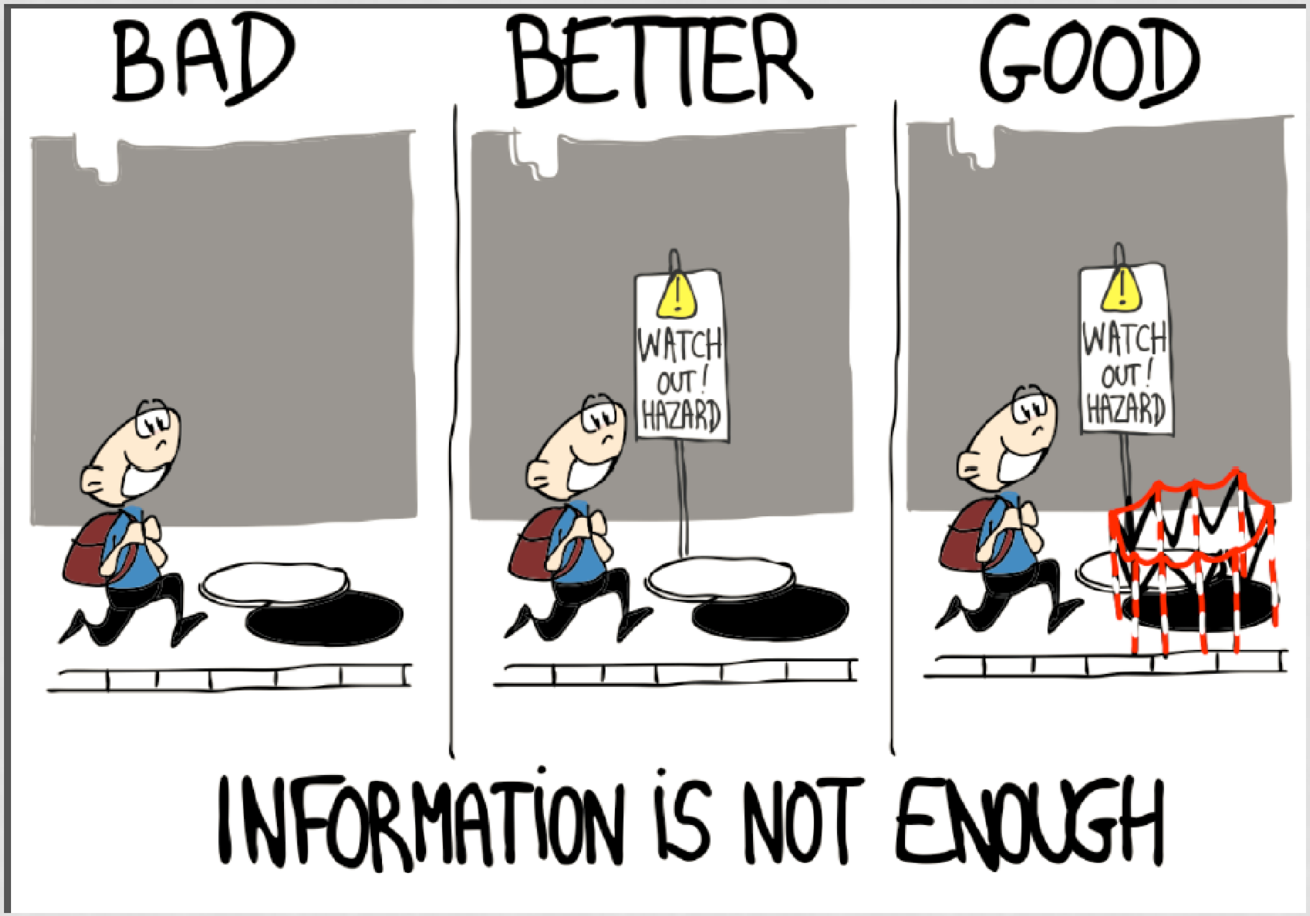
EFFECTIVENESS OF DIFFERENT APPROACHES IN PREVENTING ERRORS



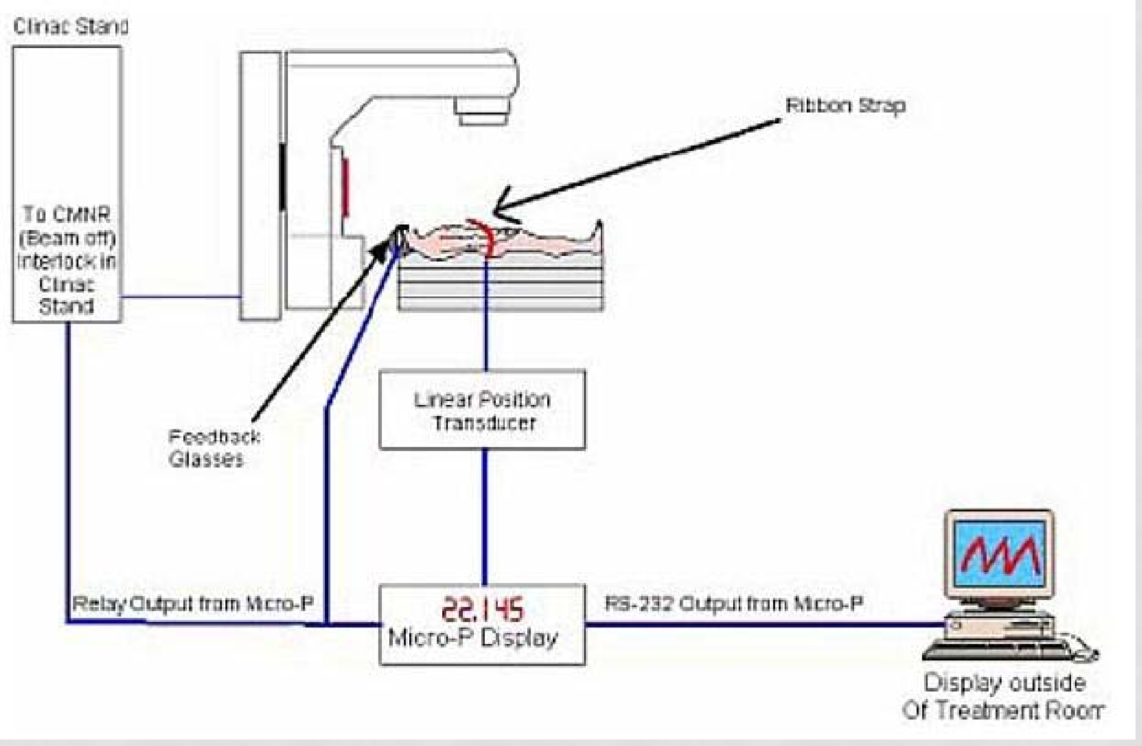
http://www.cassiemcdaniel.com/blog/hierarchy-of-effectiveness-process/

Institute for Safe Medical Medication practices. Medication error prevention "toolbox". Med Safe Alert 1999;4:1.

FORCING FUNCTIONS



FORCING FUNCTIONS



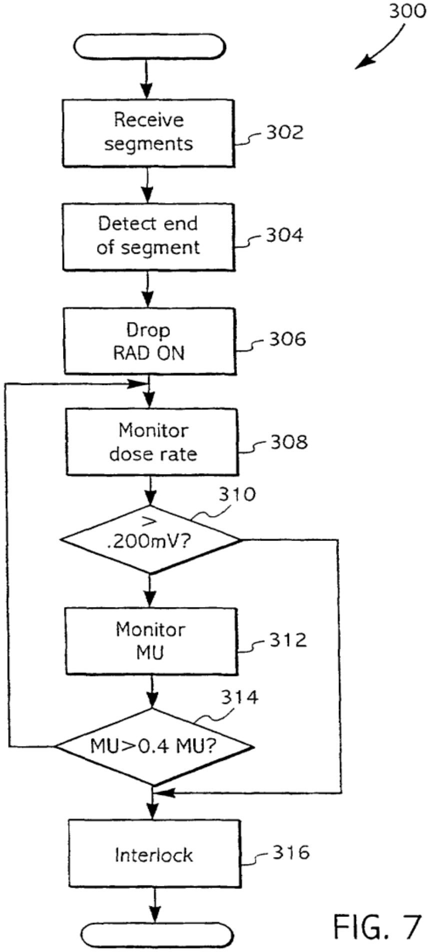
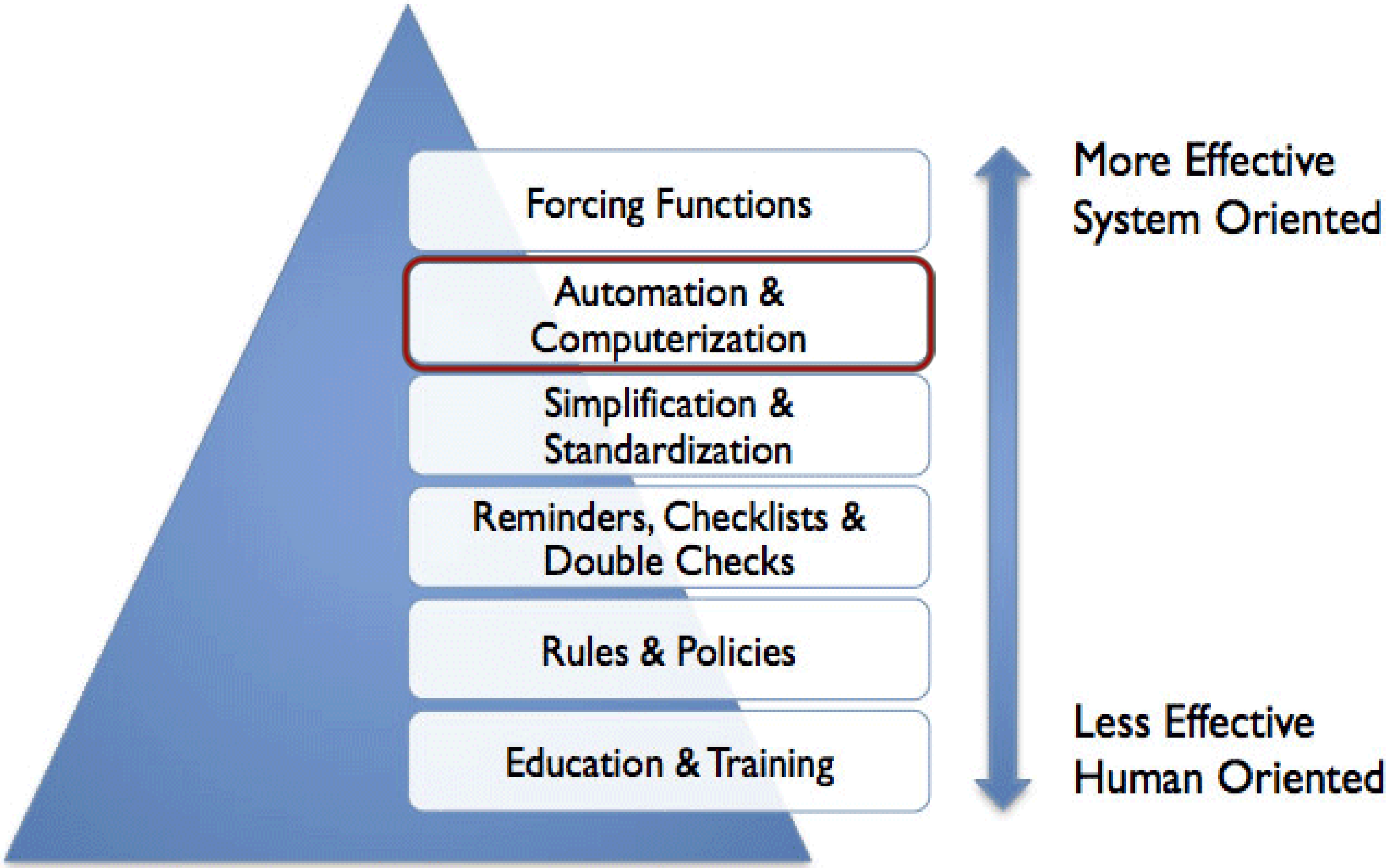


FIG. 7

Interlocks

EFFECTIVENESS OF DIFFERENT APPROACHES IN PREVENTING ERRORS

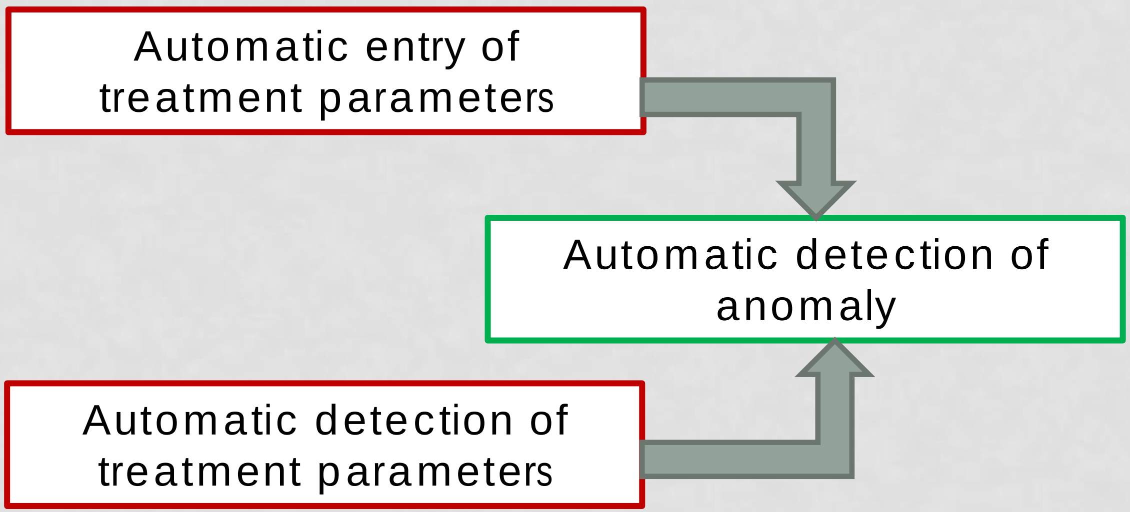


http://www.cassiemcdaniel.com/blog/hierarchy-of-effectiveness-process/

Institute for Safe Medical Medication practices. Medication error prevention "toolbox". Med Safe Alert 1999;4:1.

AUTOMATION AND COMPUTERIZATION

“Advanced” treatment techniques



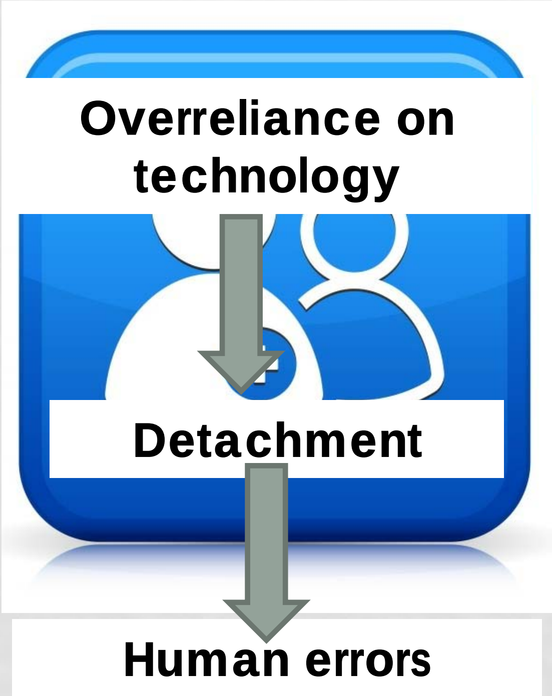
AUTOMATION AND COMPUTERIZATION

“Advanced” treatment techniques

Automatic entry of treatment parameters

Automatic detection of anomaly

Automatic detection of treatment parameters



AUTOMATION AND COMPUTERIZATION

"Advanced" treatment techniques

Automatic entry of treatment parameters

Automatic detection of anomaly

Automatic detection of treatment parameters

Human errors

Need for user friendly and user centered environments/software

AUTOMATION AND COMPUTERIZATION

Radiation safety

The use of human factors methods to identify and mitigate safety issues in radiation therapy

Alvita J. Chan[a,b,*], Mohammad K. Islam[b,c,d], Tara Rosewall[c,d], David A. Jaffray[b,c,d,e], Anthony C. Easty[a,b], Joseph A. Cafazzo[a,b,f]

[a] *Healthcare Human Factors, University Health Network, Ontario, Canada;* [b] *Institute of Biomaterials and Biomedical Engineering, University of Toronto, Ontario, Canada;* [c] *Radiation Medicine Program, Princess Margaret Hospital, University Health Network, Ontario, Canada;* [d] *Department of Radiation Oncology;* [e] *Department of Medical Biophysics; and* [f] *Health Policy, Management and Evaluation, University of Toronto, Canada*

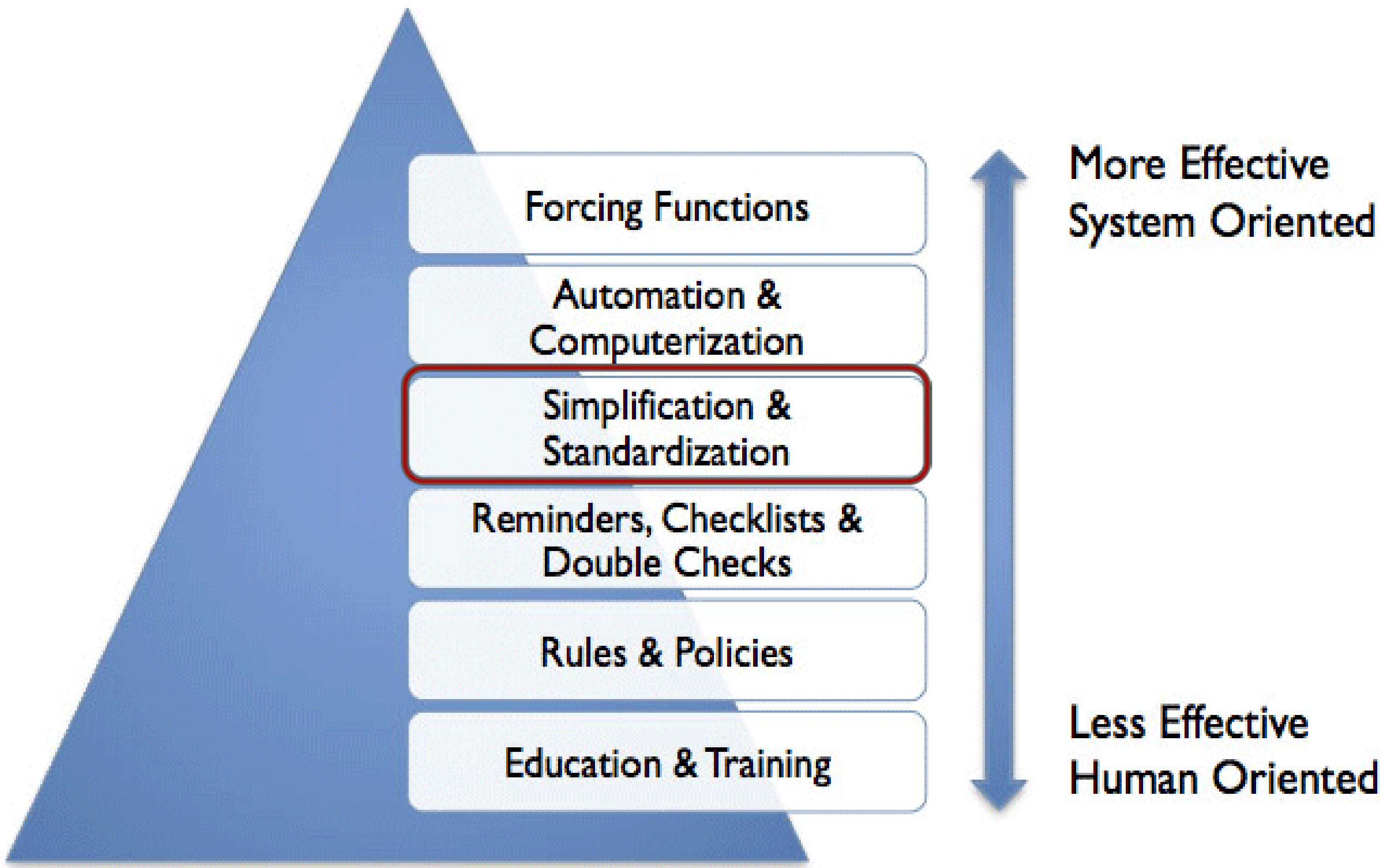
Redesign of their MOSAIQ® interface applying human factors methods which takes into account "*human behaviour, abilities and limitations to design systems for safe and effective human use*"

Results:

- diminished error rates
- improved mean task completion time
- Increased user satisfaction

Chan et al. The use of human factors methods to identify and mitigate safety issues in radiation therapy. Radiotherapy and Oncology 97 (2010) 596-600

EFFECTIVENESS OF DIFFERENT APPROACHES IN PREVENTING ERRORS



http://www.cassiemcdaniel.com/blog/hierarchy-of-effectiveness-process/

Institute for Safe Medical Medication practices. Medication error prevention "toolbox". Med Safe Alert 1999;4:1.

SIMPLIFICATION AND STANDARDISATION

Lean action such as standardization and SOP development results in*:

- Continuous improvement
- More process stability
- Increased efficiency
- Increased sense of responsibility

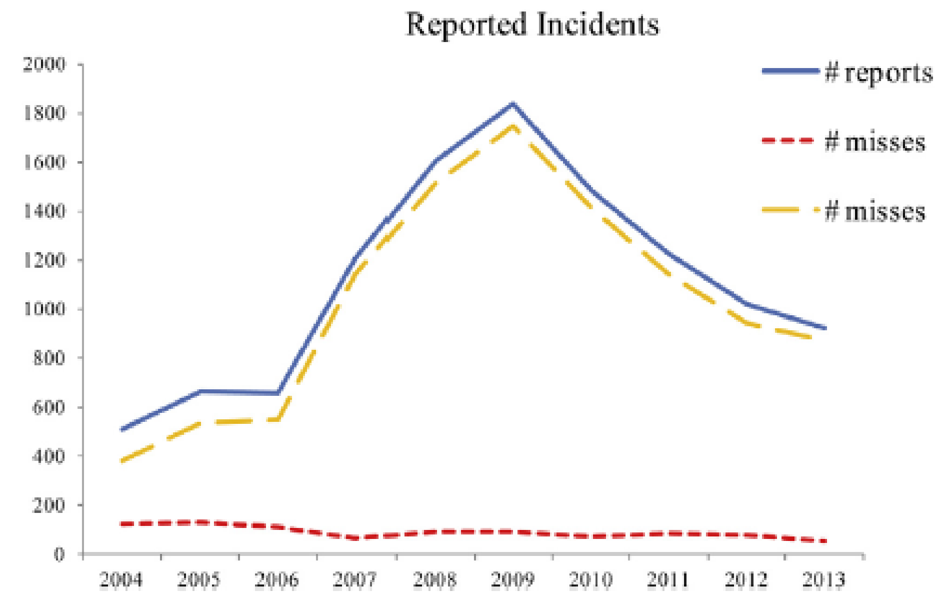
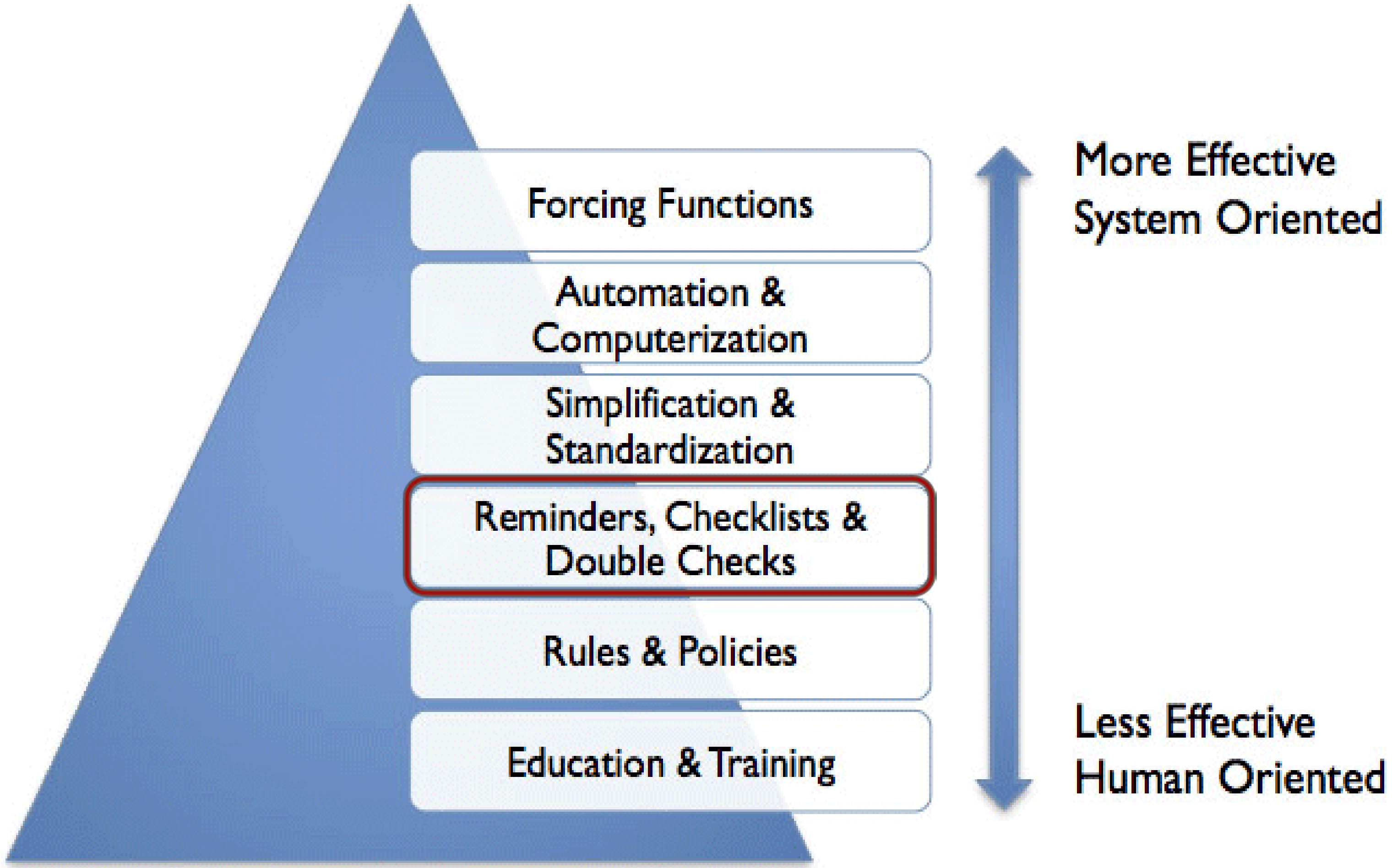


Fig. 4. Results from the Incident Reporting System for 2004 until 2013. The number of reported incidents reaching the patient-level (misses) decreased only slightly from 122 in 2004 to 48 in 2013. The number of reported incidents that did not reach the patient-level (near misses) increased from 2004 to 2009 followed by a decrease in reports.

**Does lean management improve patient safety culture? An extensive evaluation of safety culture in a radiotherapy institute. Simons PA, et al.. Eur J Oncol Nurs. 2015 Feb;19(1):29-37.*

EFFECTIVENESS OF DIFFERENT APPROACHES IN PREVENTING ERRORS



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CHECKLIST

<u>Checklist</u>:

list of items, tasks or behaviours arranged in a <u>consistent manner</u>, which allows the user to <u>record</u> the presence (or absence) of individual items
→ Item checked off as it is completed/verified/identified or answered

CHECKLIST

International Journal for Quality in Health Care 2008; Volume 20, Number 1: pp. 22–30 10.1093/intqhc/mzm062
Advance Access Publication: 11 December 2007

Development of medical checklists for improved quality of patient care

BRIGETTE HALES[1], MARIUS TERBLANCHE[2], ROBERT FOWLER[1] AND WILLIAM SIBBALD[1]

[1]Sunnybrook Health Sciences Centre, Toronto, Canada, and [2]Guy's & St Thomas' NHS Foundation Trust, London, United Kingdom

Surgical Safety Checklist — World Health Organization | Patient Safety

Before induction of anaesthesia → **Before skin incision** → **Before patient leaves operating room**

Before induction of anaesthesia (with at least nurse and anaesthetist)

- Has the patient confirmed his/her identity, site, procedure, and consent?
  - ☐ Yes
- Is the site marked?
  - ☐ Yes
  - ☐ Not applicable
- Is the anaesthesia machine and medication check complete?
  - ☐ Yes
- Is the pulse oximeter on the patient and functioning?
  - ☐ Yes
- Does the patient have a:
- Known allergy?
  - ☐ No
  - ☐ Yes
- Difficult airway or aspiration risk?
  - ☐ No
  - ☐ Yes, and equipment/assistance available
- Risk of >500ml blood loss (7ml/kg in children)?
  - ☐ No
  - ☐ Yes, and two IVs/central access and fluids planned

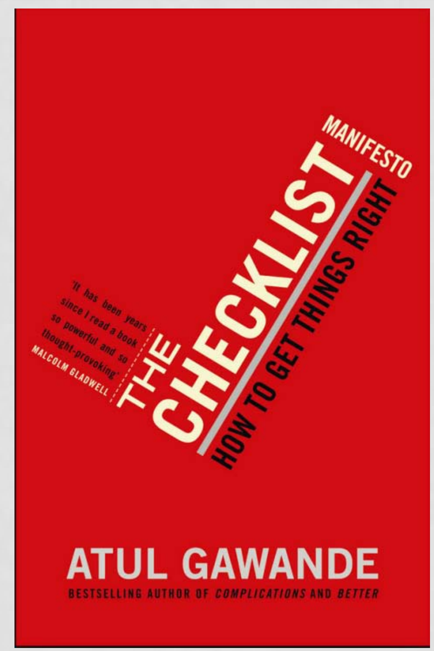
Before skin incision (with nurse, anaesthetist and surgeon)

- ☐ Confirm all team members have introduced themselves by name and role.
- ☐ Confirm the patient's name, procedure, and where the incision will be made.
- Has antibiotic prophylaxis been given within the last 60 minutes?
  - ☐ Yes
  - ☐ Not applicable
- Anticipated Critical Events
- To Surgeon:
  - ☐ What are the critical or non-routine steps?
  - ☐ How long will the case take?
  - ☐ What is the anticipated blood loss?
- To Anaesthetist:
  - ☐ Are there any patient-specific concerns?
- To Nursing Team:
  - ☐ Has sterility (including indicator results) been confirmed?
  - ☐ Are there equipment issues or any concerns?
- Is essential imaging displayed?
  - ☐ Yes
  - ☐ Not applicable

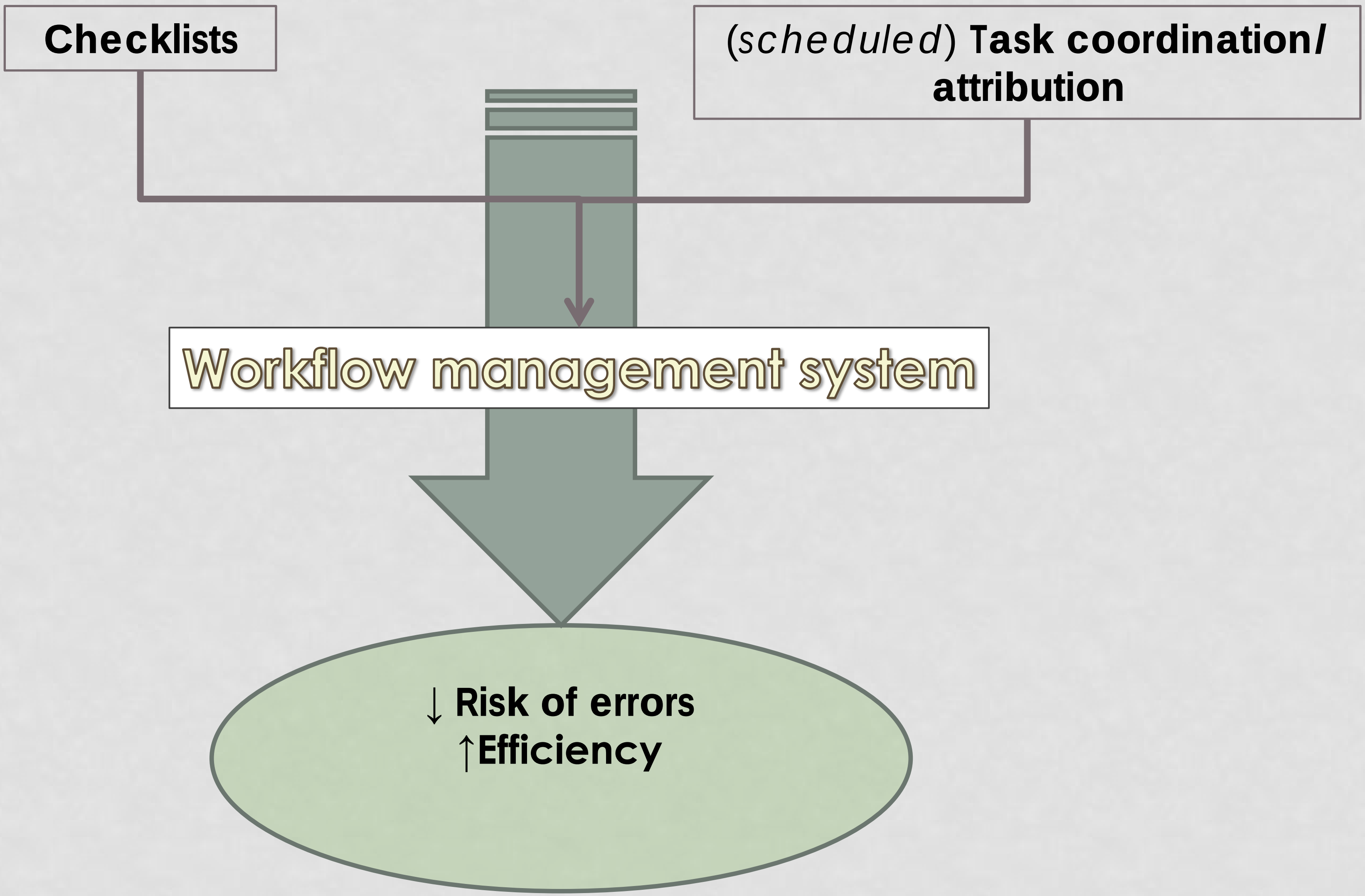
Before patient leaves operating room (with nurse, anaesthetist and surgeon)

- Nurse Verbally Confirms:
  - ☐ The name of the procedure
  - ☐ Completion of instrument, sponge and needle counts
  - ☐ Specimen labelling (read specimen labels aloud, including patient name)
  - ☐ Whether there are any equipment problems to be addressed
- To Surgeon, Anaesthetist and Nurse:
  - ☐ What are the key concerns for recovery and management of this patient?

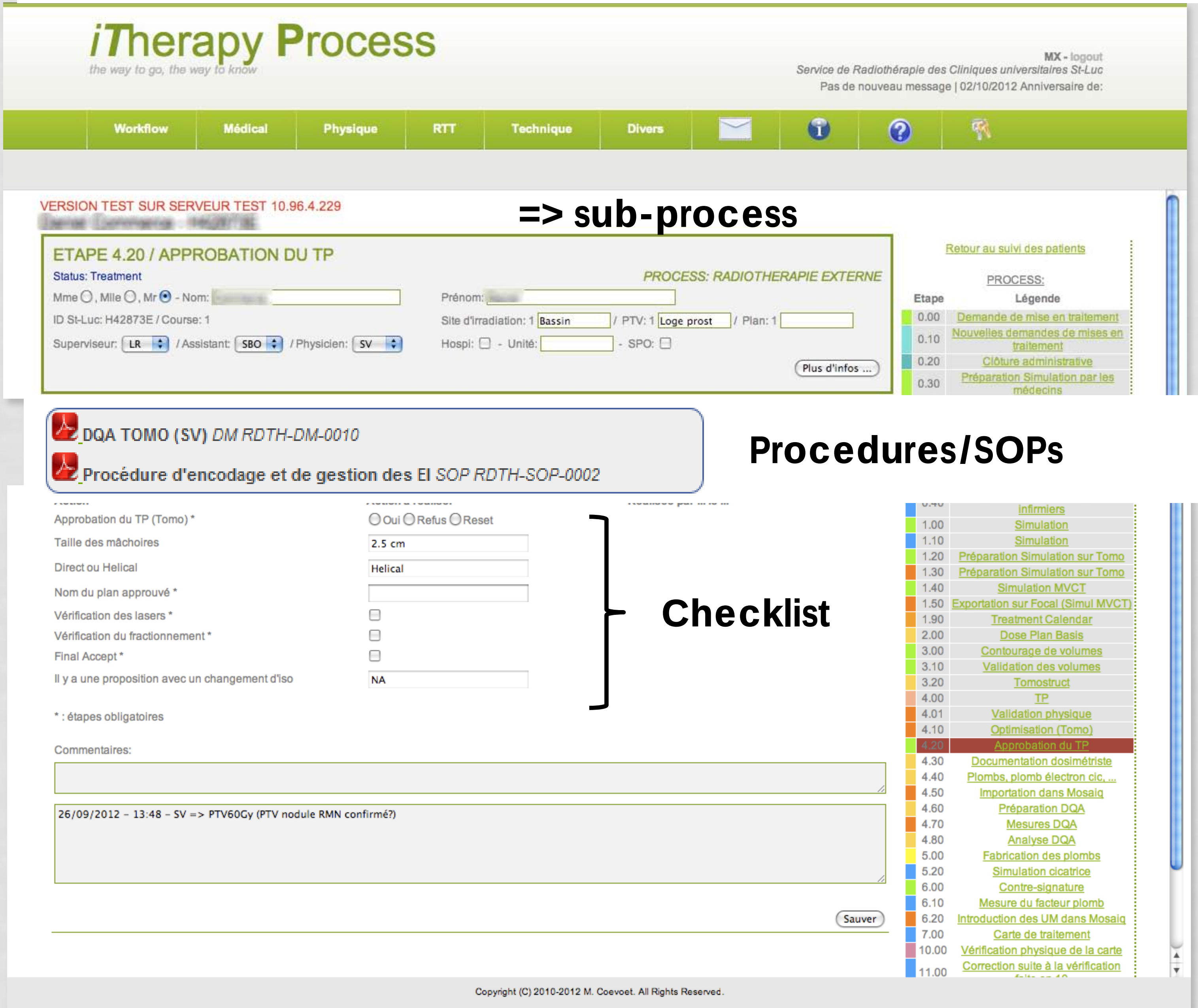
This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged. Revised 1 / 2009 © WHO, 2009



WORKFLOW MANAGEMENT SYSTEMS



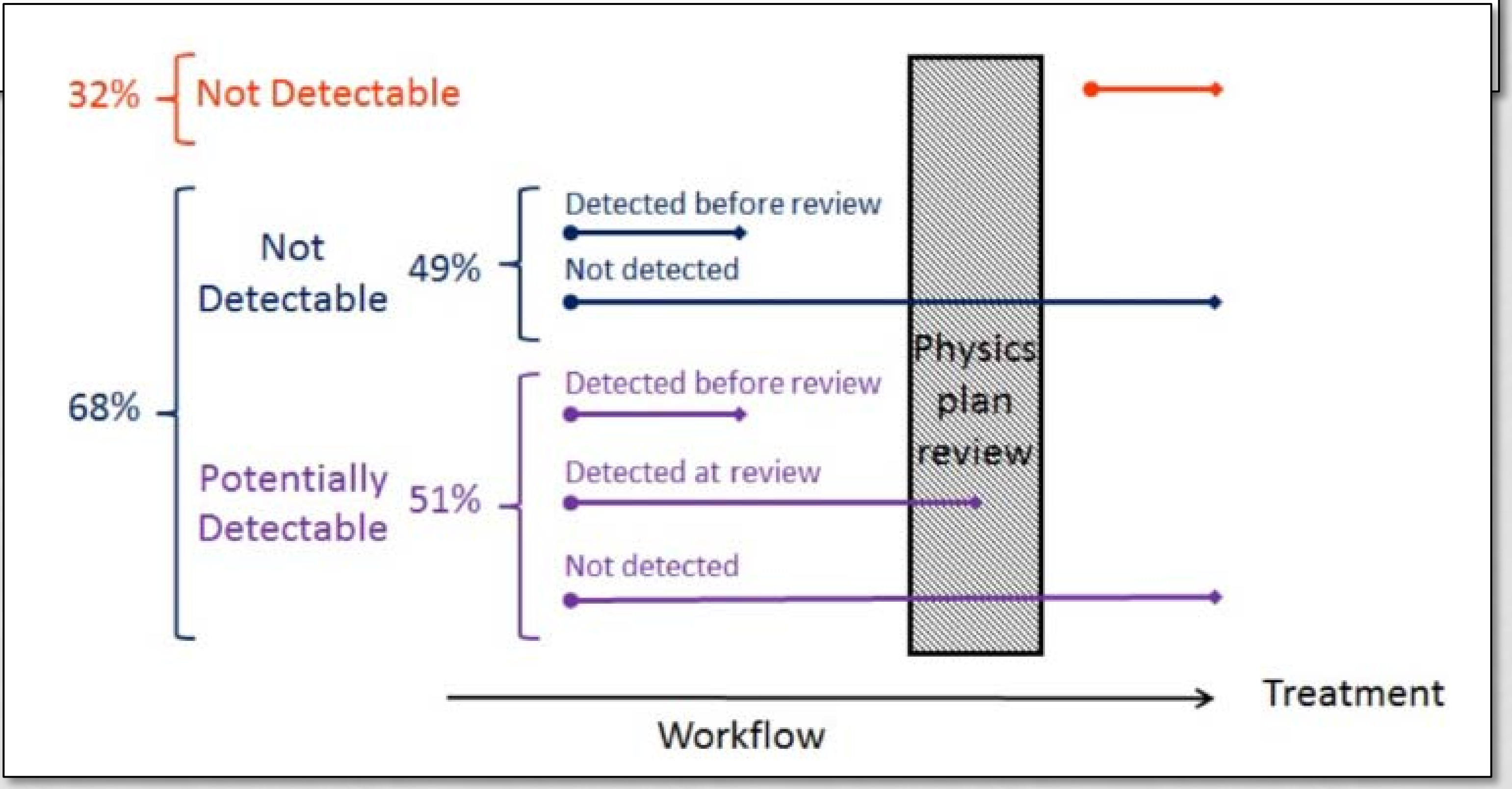
OPEN SOURCE SOLUTION – ITP



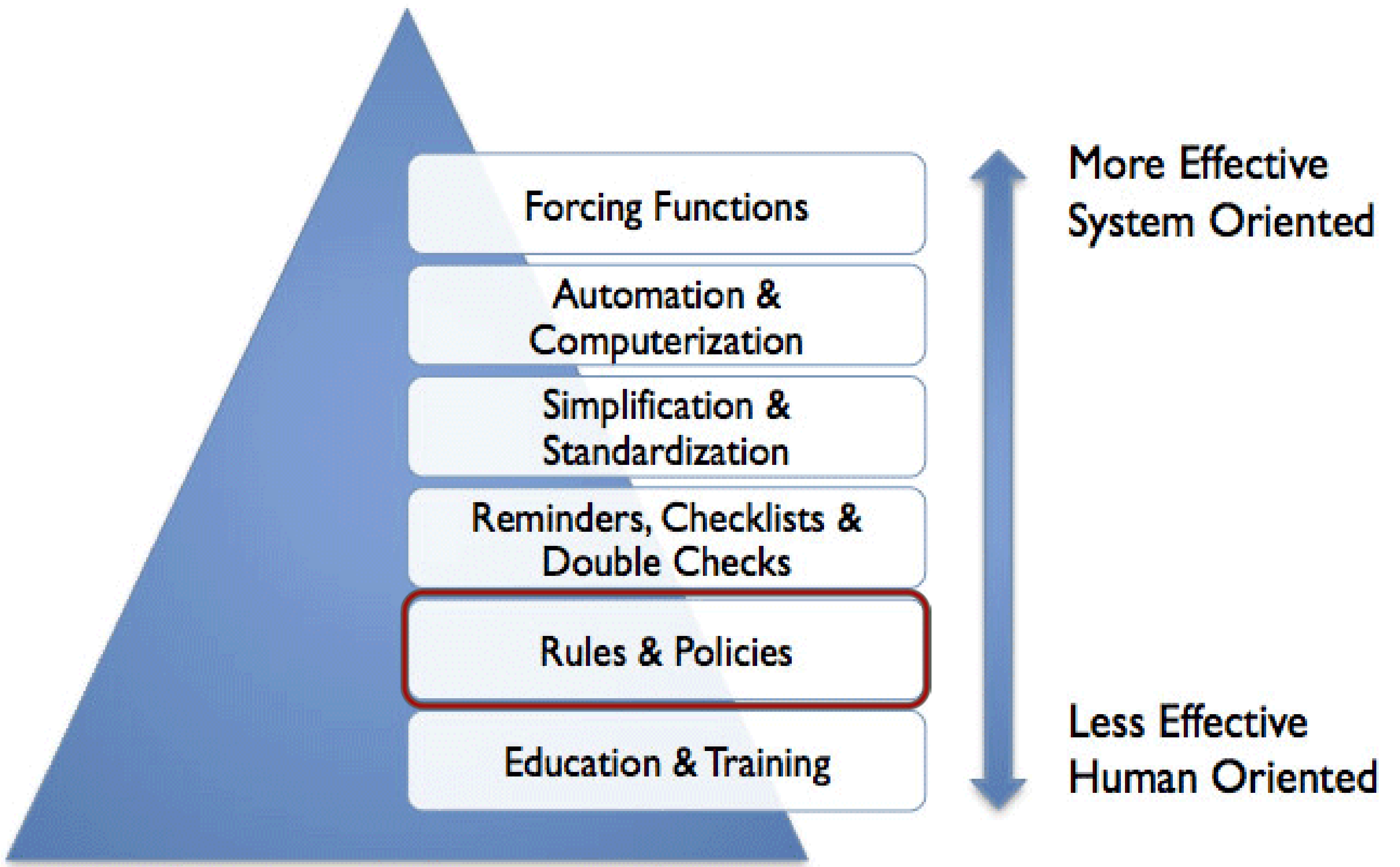
DOUBLE CHECKS

The effectiveness of pretreatment physics plan review for detecting errors in radiation therapy

Olga Gopan, Jing Zeng, Avrey Novak, Matthew Nyflot, and Eric Ford[a)]
Department of Radiation Oncology, University of Washington Medical Center, 1959 NE Pacific Street, Box 356043, Seattle, Washington 98195



EFFECTIVENESS OF DIFFERENT APPROACHES IN PREVENTING ERRORS



http://www.cassiemcdaniel.com/blog/hierarchy-of-effectiveness-process/

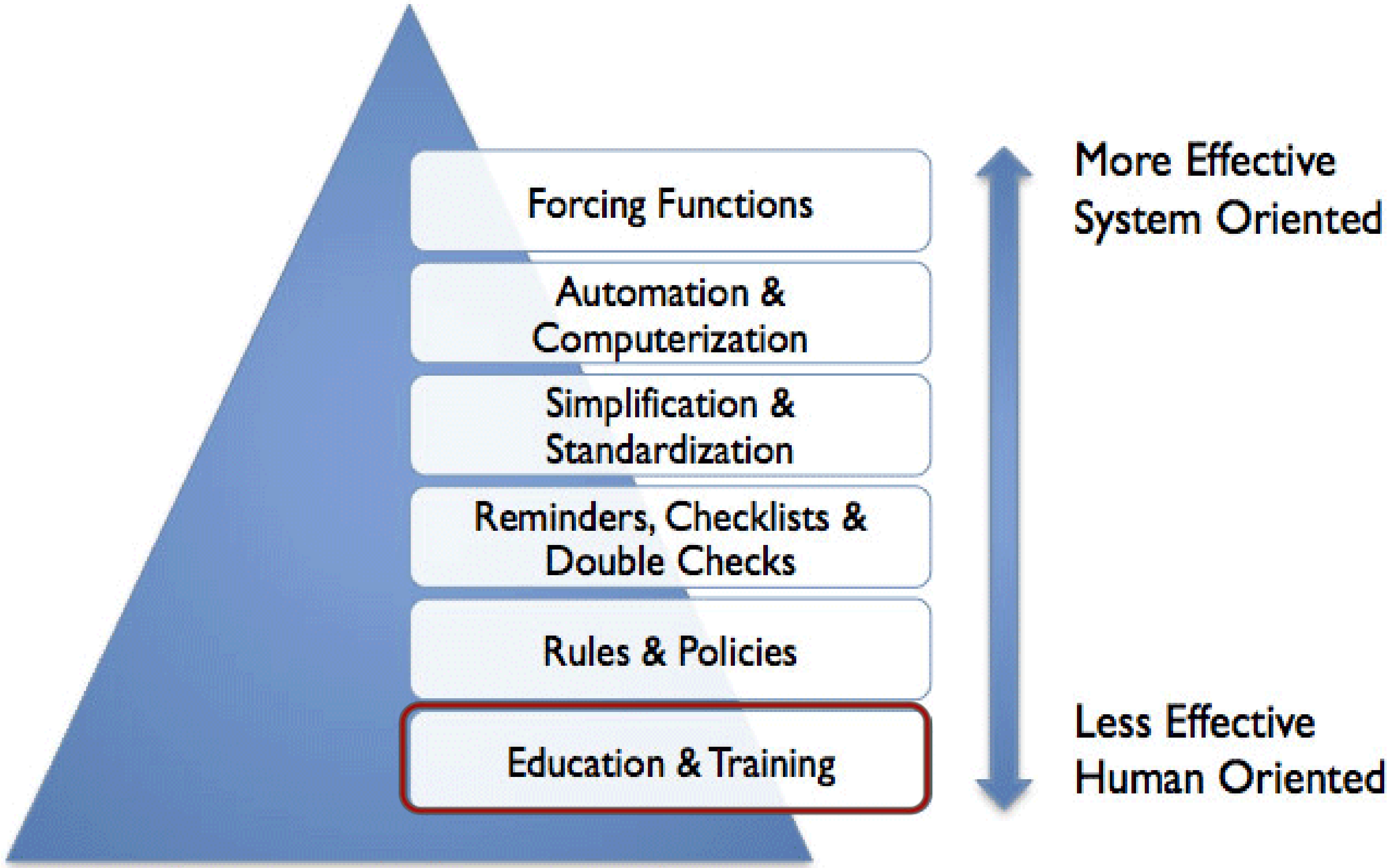
Institute for Safe Medical Medication practices. Medication error prevention "toolbox". Med Safe Alert 1999;4:1.

Plan Cancer
Kankerplan

PLAN CANCER 2014-2019

GUÉRIR ET PRÉVENIR LES CANCERS : DONNONS LES MÊMES CHANCES À TOUS, PARTOUT EN FRANCE

EFFECTIVENESS OF DIFFERENT APPROACHES IN PREVENTING ERRORS



http://www.cassiemcdaniel.com/blog/hierarchy-of-effectiveness-process/

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TRAINING

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]

POINTS TO REMEMBER

- Barriers can be put into place to prevent errors from reaching the patient

- Focus should be on system based barriers and this more specifically on a technical and organizational level

REFERENCES

Gopan, O., Zeng, J., Novak, A., Nyflot, M., & Ford, E. (2016). **The effectiveness of pretreatment physics plan review for detecting errors in radiation therapy**. *Medical Physics*, *43*(9), 5181–5187. http://doi.org/10.1118/1.4961010

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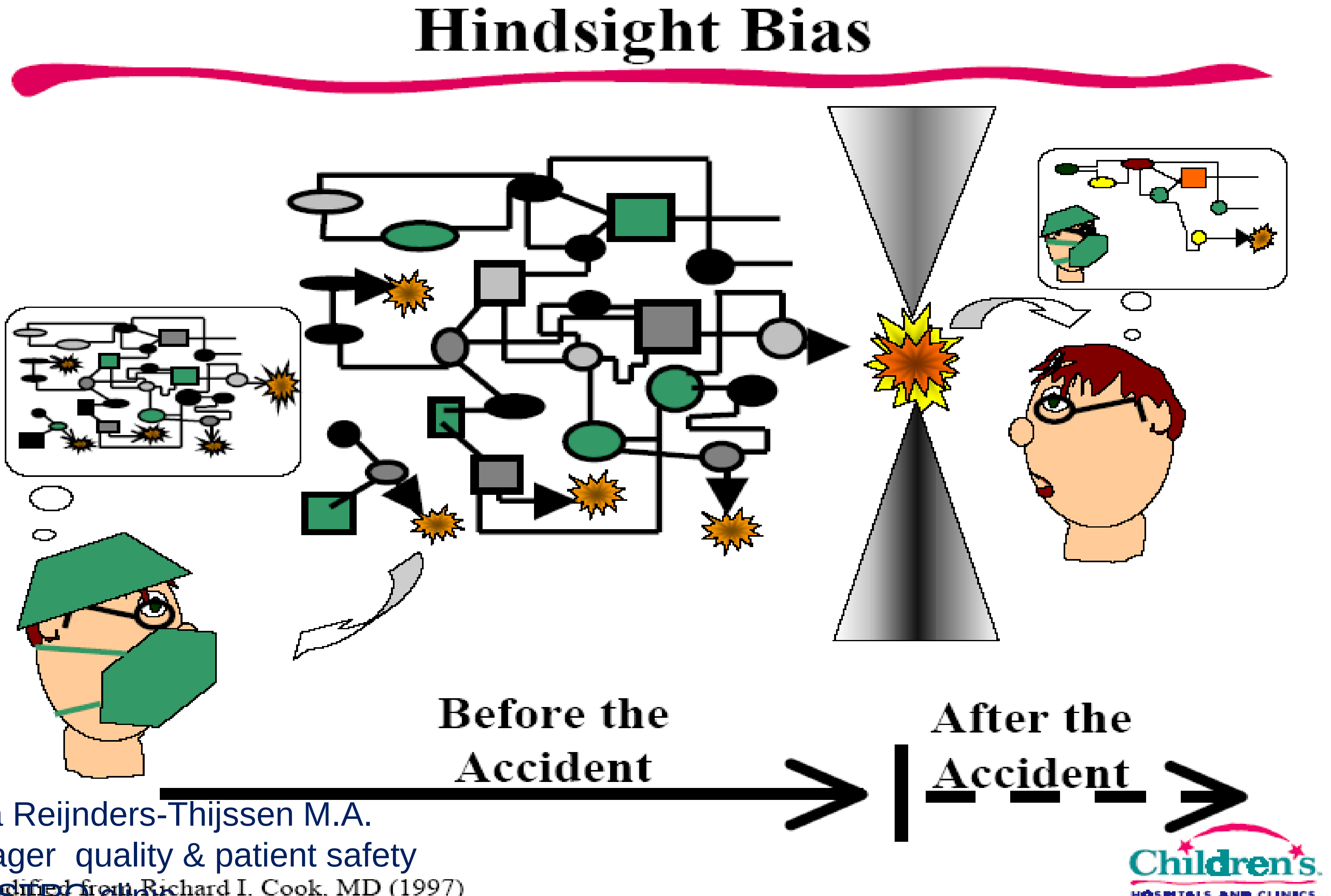
Simons, P. A. M., Houben, R., Benders, J., Pijls-Johannesma, M., Vandijck, D., Marneffe, W., … Groothuis, S. (2014). **Does compliance to patient safety tasks improve and sustain when radiotherapy treatment processes are standardized?** *European Journal of Oncology Nursing*, *18*(5), 459–465. http://doi.org/10.1016/j.ejon.2014.05.003

Huq, M. S., Fraass, B. A., Dunscombe, P. B., Gibbons, J. P., Ibbott, G. S., Mundt, A., … Yorke, E. D. (2015). **the Report of Task Group 100 of the Aapm : Application of Risk Analysis Methods To Radiation Therapy Quality**. Retrieved from https://www.aapm.org/pubs/reports/RPT_283.pdf

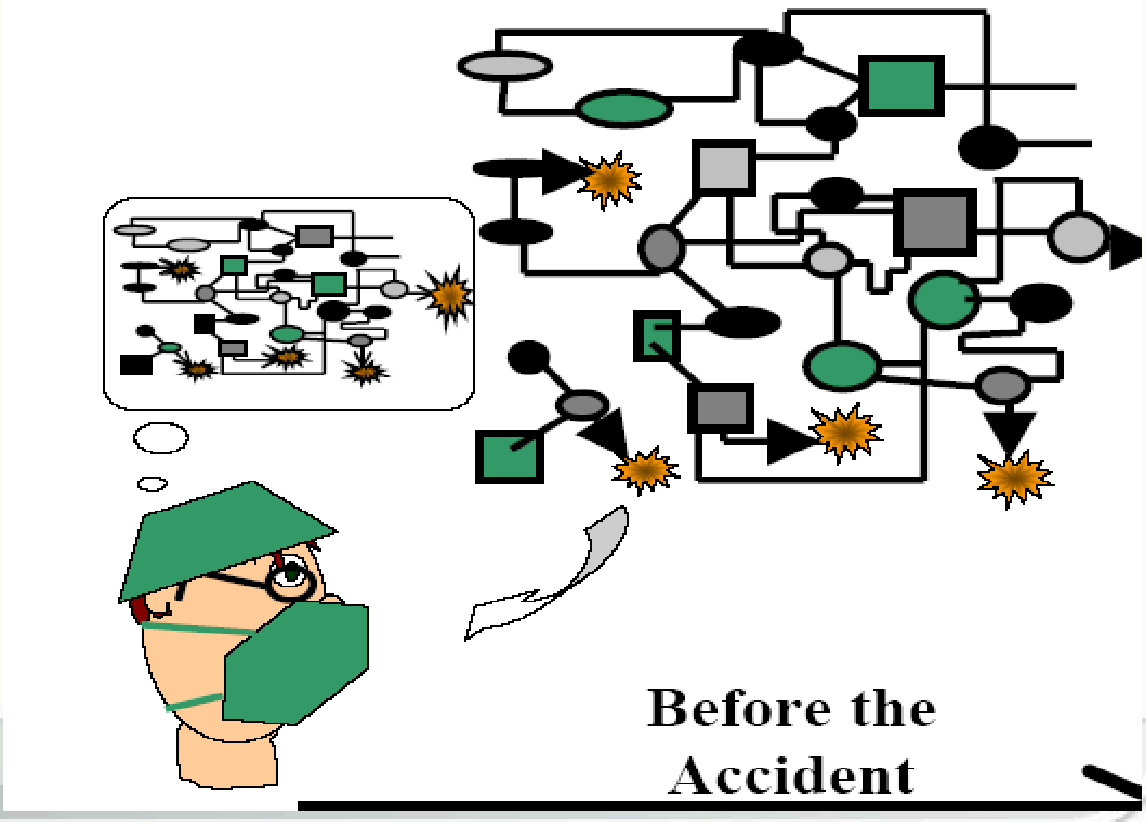
Health care Failure Mode and Effects Analysis (HFMEA), a prospective method



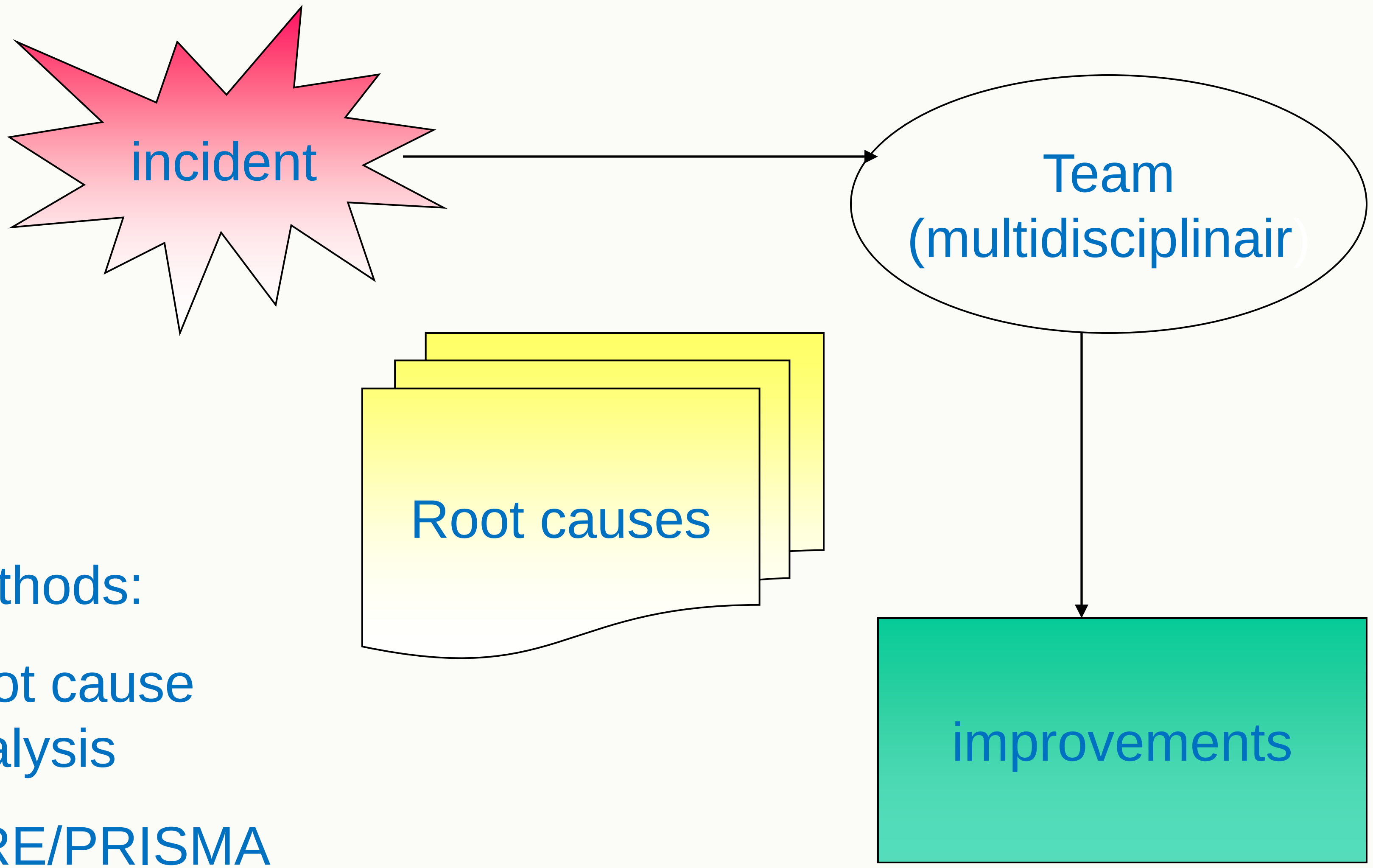
Petra Reijnders-Thijssen M.A.
Manager quality & patient safety
MAASTRO clinic
www.maastro.com

content of presentation

- prospective riskmodels
- the method HFMEA
- experience MAASTRO clinic



Retrospective

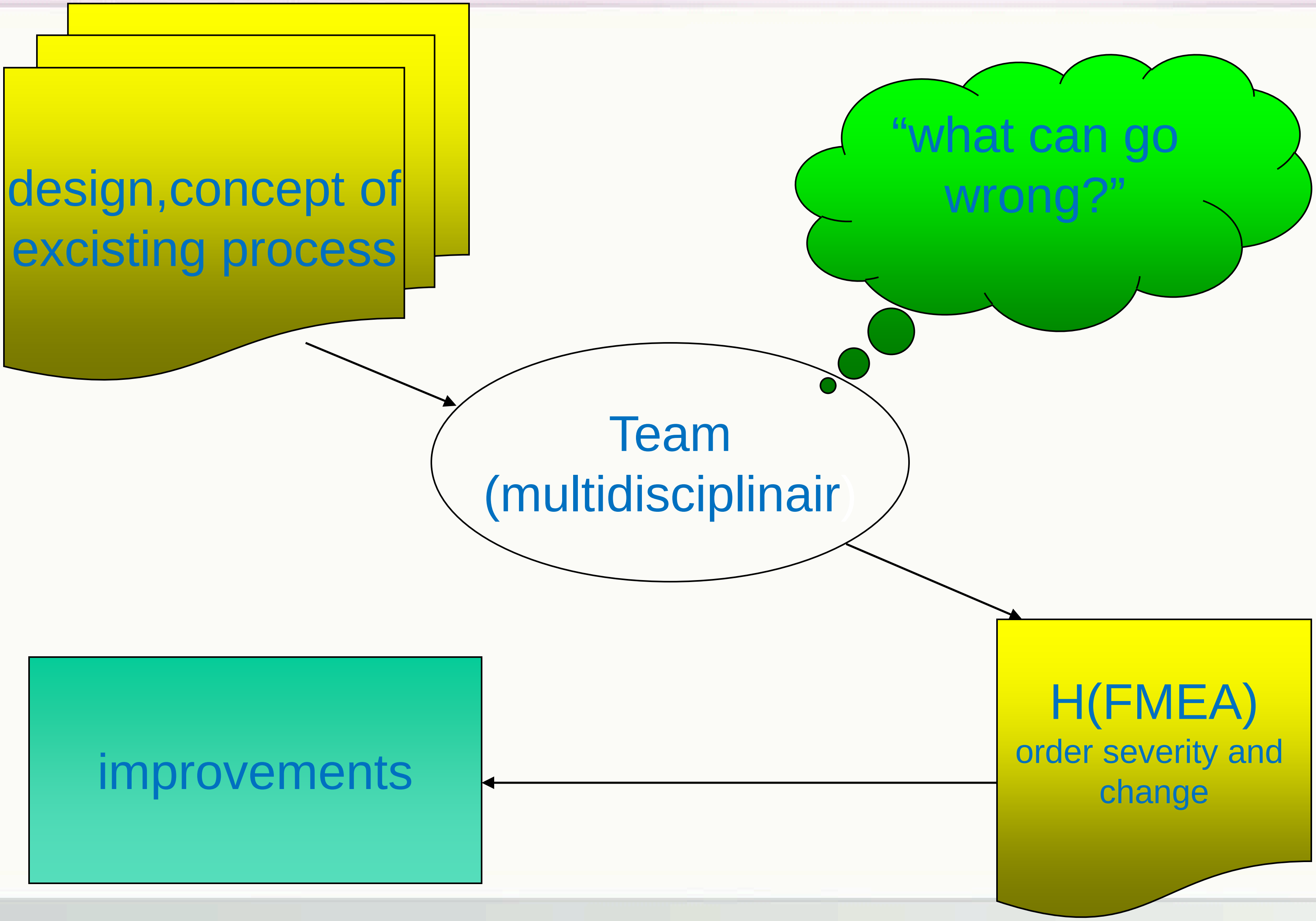


Methods:

Root cause analysis

SIRE/PRISMA

Proactive


design,concept of excisting process
"what can go wrong?"
Team (multidisciplinair)
H(FMEA)
order severity and change
improvements

proactive is also a predictive riskmodel

Learning Objectives

- To learn about the different proactive riskmodels
- To understand the use of Health care Failure Mode and Effects Analysis (HFMEA)
- To learn the steps to developing HFMEAs

prospective risk models

Why

- Methodology that facilitates process improvement
- Focuses on prevention
- Improves Safety

overview proactive risk models

Food and drink industry: HACCP

Commercial modellen : IFAC-FMAC

Multifactor model

Six sigma model (motorola)

HAZOP / HAZAN (chemical)

FMEA (NASA)

COSO (financial business), ERM

And others

Rough deviation of the models

Organisational models:

COSO/ERM

Six Sigma

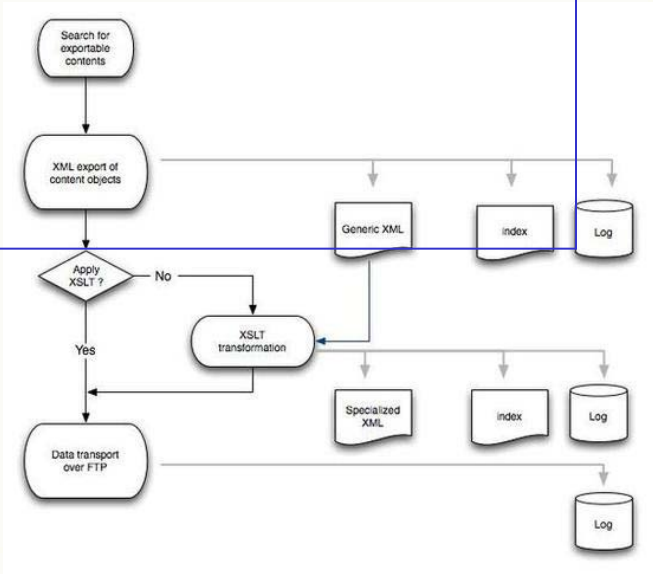
IFAC-FMAC

Process models:

HACCP

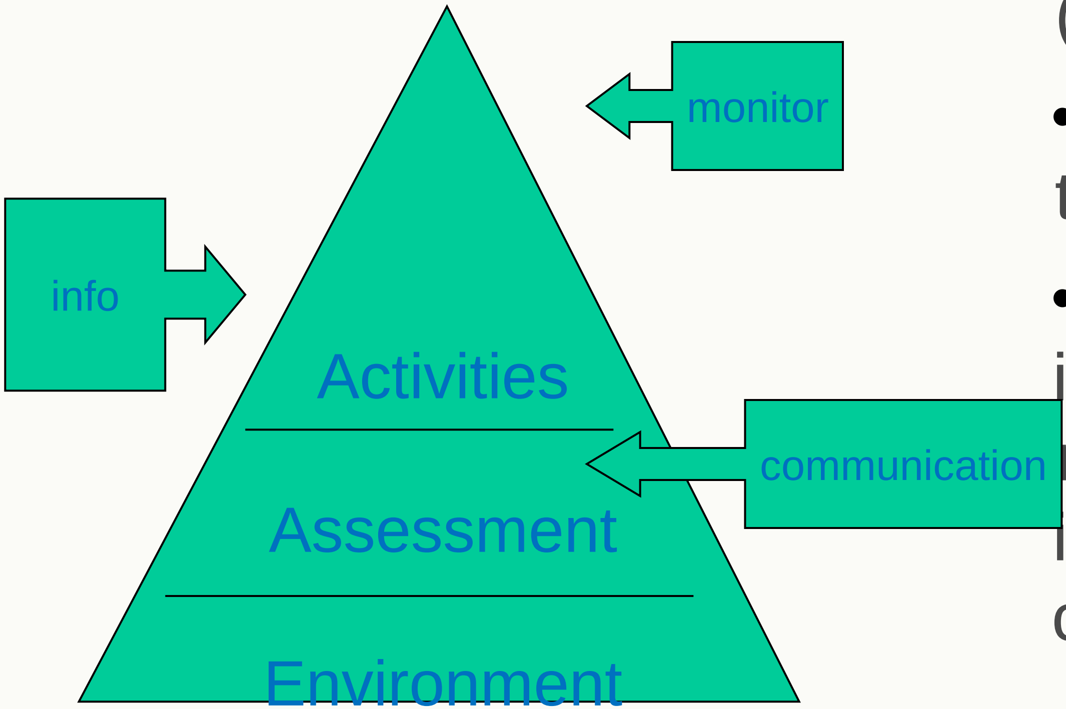
HAZOP / HAZAN

FMEA



COSO / ERM

PIRAMID COSO



- Trigger: Watergate (1992)
- Internal control by the piramid
- Optimal coverage of identified risks by monitoring, control, information and communication

Six Sigma / Lean

Key players

- Motorola
- Less defects of the production
- Hierarchy in organisation by the players in the six sigma game

lean sigma (variant)

Food and drink industry: HACCP

- Hazard Analyses of Critical Control Points
- Original developed 30 years
- 7 principles based on eliminating mistakes which induces diseases

Step	Potential Hazard	Justification	Hazard to be addressed in plan?	Control measure

HAZOP / HAZAN

- Hazards and operability studies/hazard analyses
- Year 70 – Chemical industry
- questions using guide words

Deviation	Cause	Consequence	Safeguards	Action

What is (H)FMEA?

A structured approach to:

- Identifying the ways in which a process can fail
- Estimating risk associated with specific causes
- Prioritizing the actions that should be taken to reduce risk

History of FMEA

- First used in the 1960's in the Aerospace industry during the Apollo missions
- In 1974, the Navy developed *MIL-STD-1629* regarding the use of FMEA
- In the late 1970's, the automotive industry was driven by liability costs to use FMEA
- Later, the automotive industry saw the advantages of using this tool to reduce risks related to poor quality
- Health care (HFMEA), developed by the "VA National Center for Patient Safety http://www.patientsafety.gov
- In the Netherlands, called SAFER, toolbox and video is developed in 2006 (collaboration MAASTRO clinic, UMCU, Tue University)

A systematic approach to identify and prevent problems within a process or product

(H)FMEA

(Healthcare) failure mode and effect analyses

organizational suspicion

HFMEA

When

New process being designed
New equipment developed or purchased
Process is redesigned
Process is analyses as being unsafe

HFMEA-organization

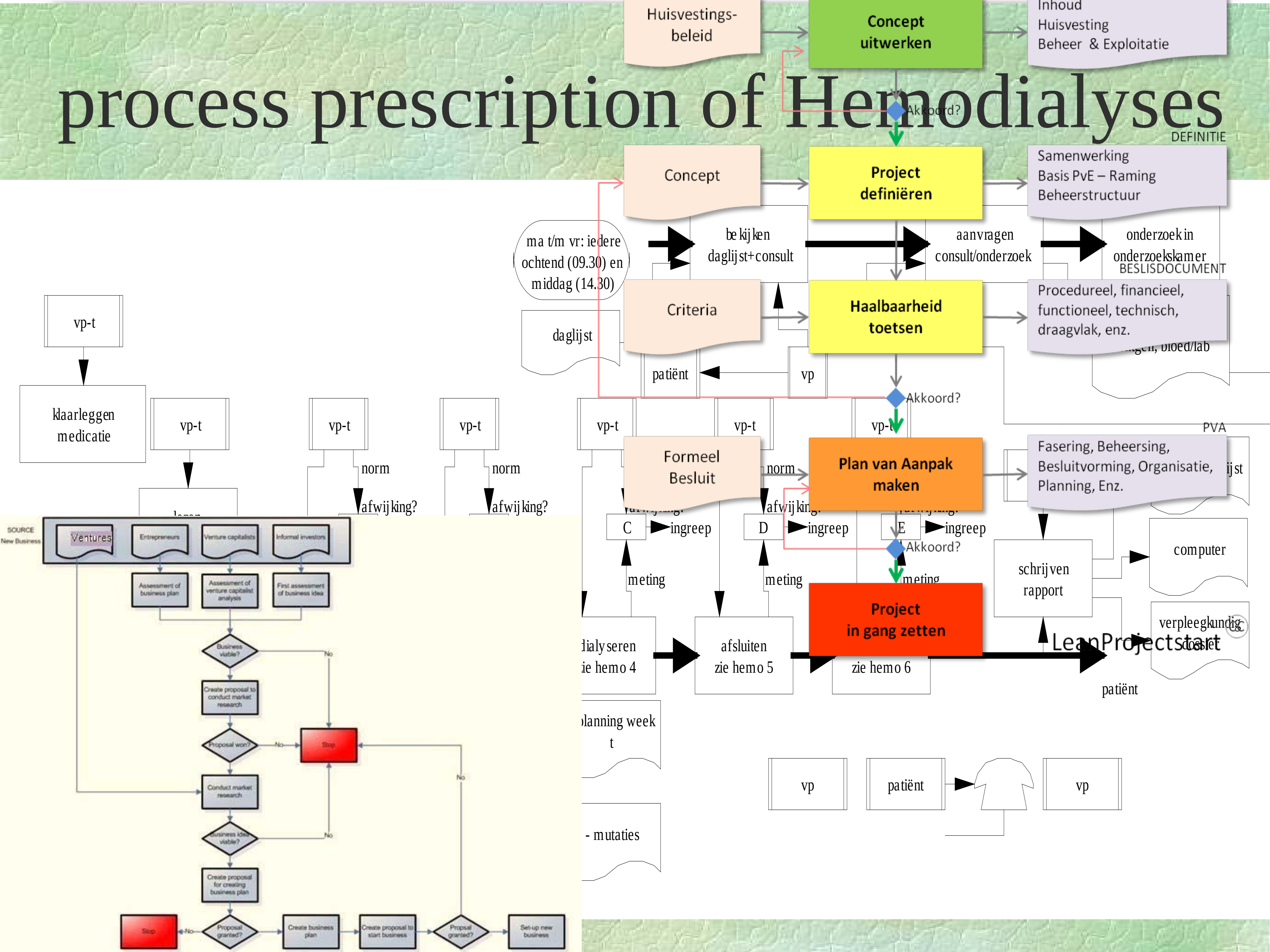
How

- Knowledgeable team is formed
- They outline the steps in a process
- They define any sub steps
- They identify potential failure modes an potential causes
    - They assign severity to the effect of this failure mode
    - They assign frequency of occurrence to the potential cause of failure and likelihood of detection
- Team calculates a Risk Priority Number by multiplying severity times frequency of occurrence (times likelihood of detection)
- Team uses ranking to focus process improvement efforts or response plans

Process prescription as fundament for HFMEA

- Process prescription structurizes the meetings to be systematic
- Process prescription ables the membres to revaluate the flow of the process
- Process prescription sets the mindset of the membres

process prescription of Hemodialyses



Process prescription f.e.

Process is “treatment on the linac”

Subprocesses are:

1. Patient arrives in organisation
2. Patient arrives in waiting room
3. RTT calls the patient in
4. RTT inserts the patient data etc…..

Processteps: 1.1……….

Next slide

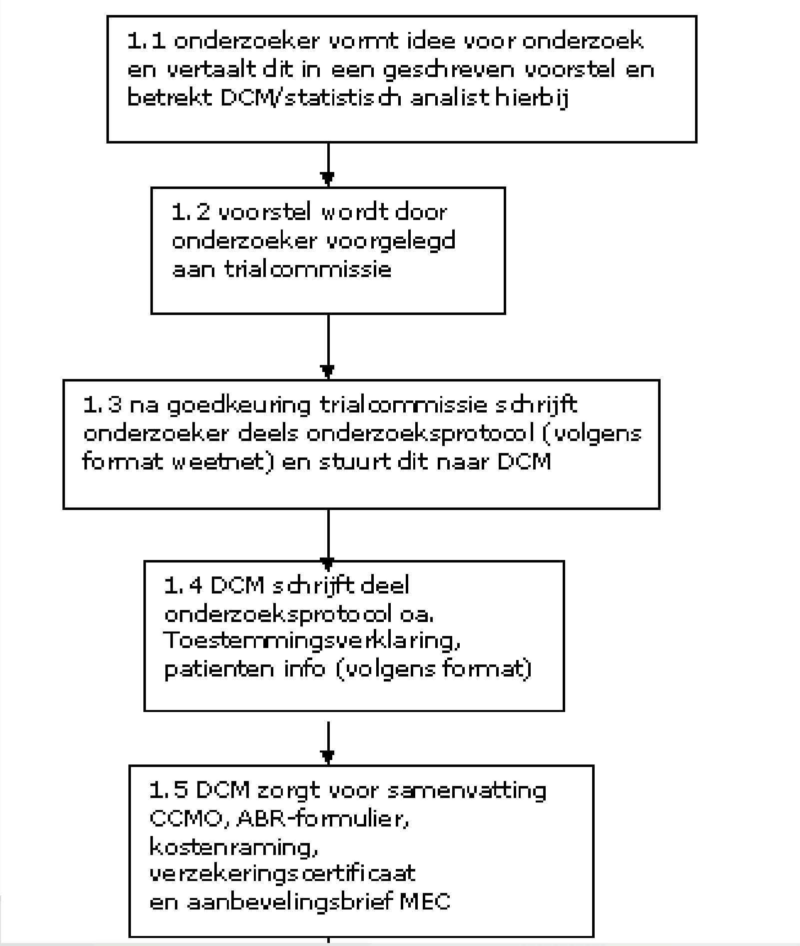
tips for process description

activity pro the person and location

coding the steps

f.e:

1.1 The RTT positions the patient on the linac table in the linacroom



What is a Failure Mode?

A **Failure Mode** is:

The way in which the component, product, or process could fail to perform its intended function

or

Things that could go wrong

6 M's to define the failure modes

Man

Machine

Method

Material

Measure

Milieu

HFMEA Procedure (1)

1. For each process step determine the ways in which the step can go wrong (failure mode)
2. For each failure mode, determine effects

   Select a severity level for each effect

3. Identify potential causes of each failure mode

   Select an occurrence level for each cause

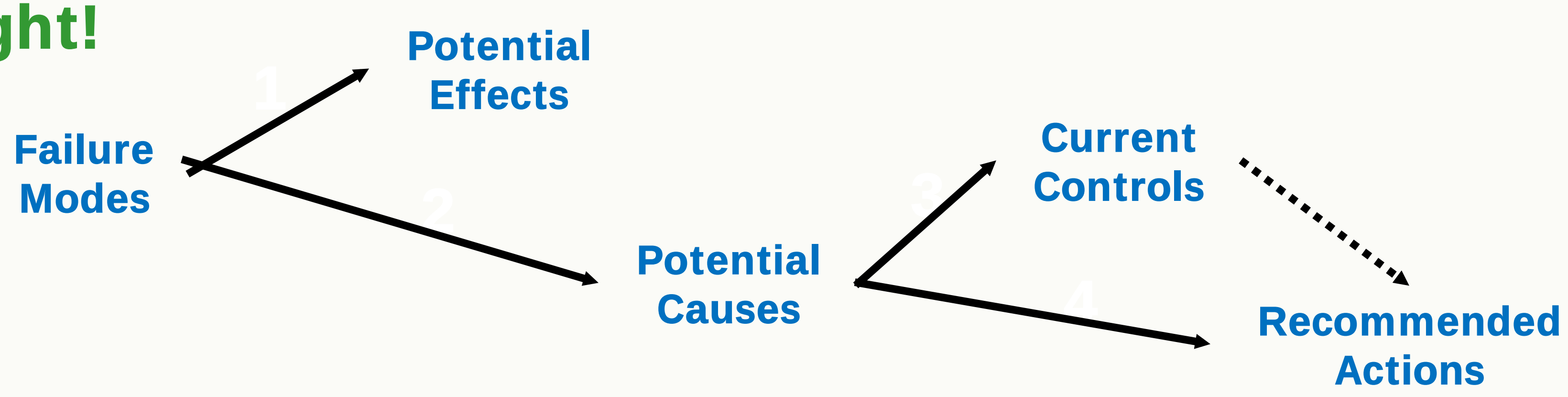
HFMEA Procedure (2)

4. Calculate the Risk Priority Number (RPN)
5. Develop recommended actions, assign responsible persons, and take actions
   - Give priority to high RPNs.
   - Some actions may need an improvement project to rectify.
   - To reduce severity, redesign the process; to reduce occurrence or detection, institute process controls.
6. Assign the predicted severity, occurrence, and detection levels and compare RPNs

Flow of the Analysis

Wrong…

Right!



Risk Priority Number (RPN)

RPN is the product of the severity and probability/occurrence scores

Severity x **Occurrence** = **RPN**

		severity			
		Catastrofical	large	medium	small
occurence	Often	16	12	8	4
	Regular	12	9	6	3
	Rare	8	6	4	2
	never	4	3	2	1

Rating Scales

- There are a wide variety of scoring “anchors” both quantitative or qualitative
- Two types of scales are 1 - 5 or 1 - 10
- The 1 - 5 scale makes it easier for the teams to decide on scores
- The 1 - 10 scale allows for better precision in estimates and a wide variation in scores (most common)
- For either scale it is important to use operational definitions for the scores to insure consistency

Scaling severity and probability (for example)

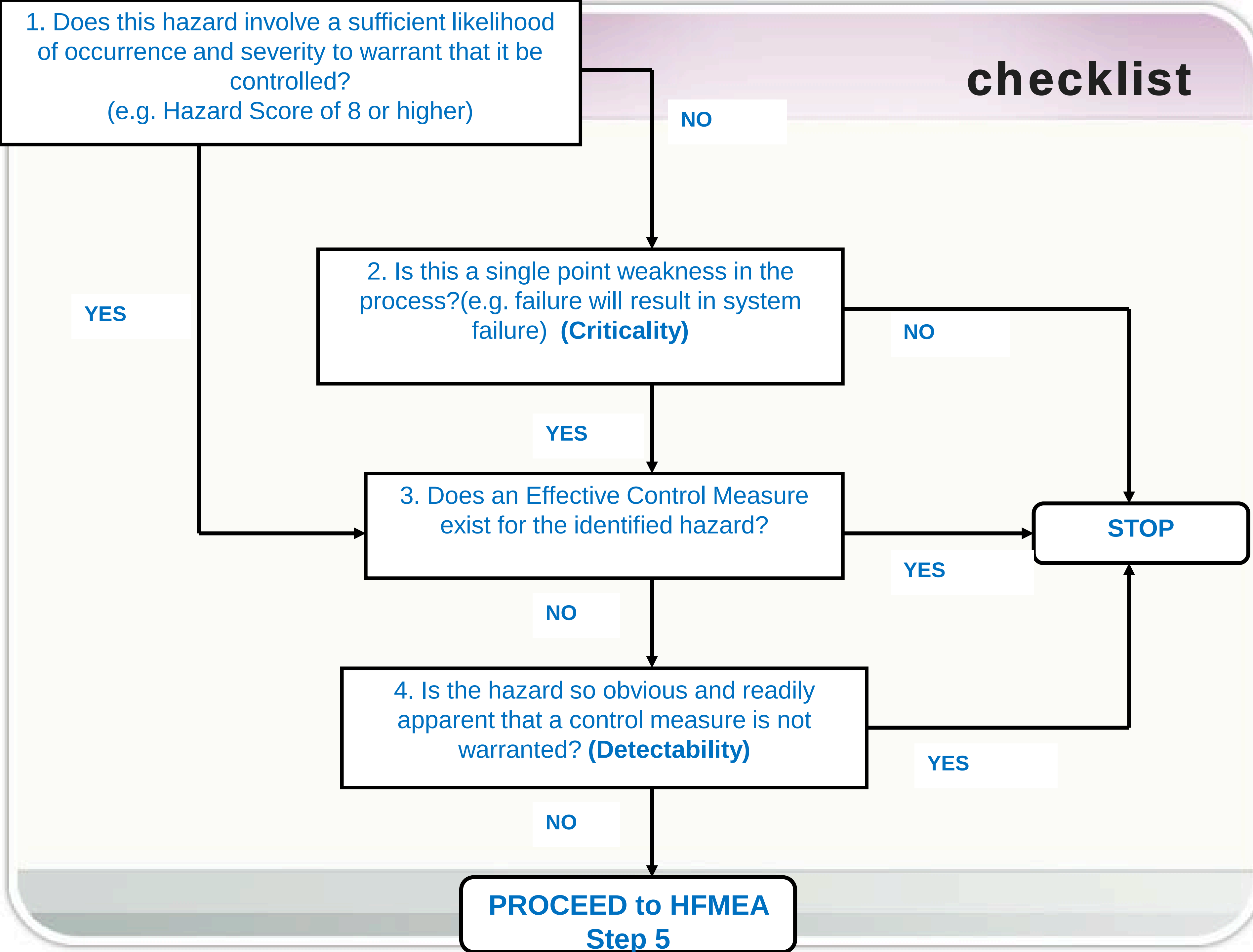
severity / specification

1	no effect on patient and following process steps
(2)3	no effect on patient. slightly discomfort in following process steps
(4)5(6)	effect on patient and/or following process steps
(7)8	temporary consequence for patient
9	lasting consequence for patient
10	fatal consequences

occurence / specification

1	never
2	in our organization never
(3)4	rare
(5)6(7)	regular
8	often
(9)10	(nearly)always

checklist


1. Does this hazard involve a sufficient likelihood of occurrence and severity to warrant that it be controlled?
(e.g. Hazard Score of 8 or higher)
NO
YES
2. Is this a single point weakness in the process?(e.g. failure will result in system failure) **(Criticality)**
NO
YES
3. Does an Effective Control Measure exist for the identified hazard?
YES
STOP
NO
4. Is the hazard so obvious and readily apparent that a control measure is not warranted? **(Detectability)**
YES
NO
PROCEED to HFMEA Step 5

HFMEA form

HFMEA Subprocess Step Title and Number												
HFMEA Step 4 - Hazard Analysis											HFMEA Step 5 - Ident	
Failure Mode: First Evaluate failure mode before determining potential causes		Potential Causes		Scoring			Decision Tree Analysis				Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping
				Severity	Probability	Haz Score	Single Point Weakness?	Existing Control Measure ?	Detectability	Proceed?		
1B	**verkeerde gegevens invoer WW en WL (is verschillend per aandoening)**	→										
		1B1	O: paraatheid van gegevens betreffende WW en WL	moderate	frequent	8	y	n	y (stap 4)	y	eliminate	refentielijst met variaties: taak : laborant EPID
		1B2	T: layout in te voeren items dwingt niet tot optimalisatie WW en WL	moderate	frequent	8	y	n	y(stap 4)	n	accept	tehnische customizing niet mogelijk, nadruk op procedure van uitvoering door handleiding en uitleg

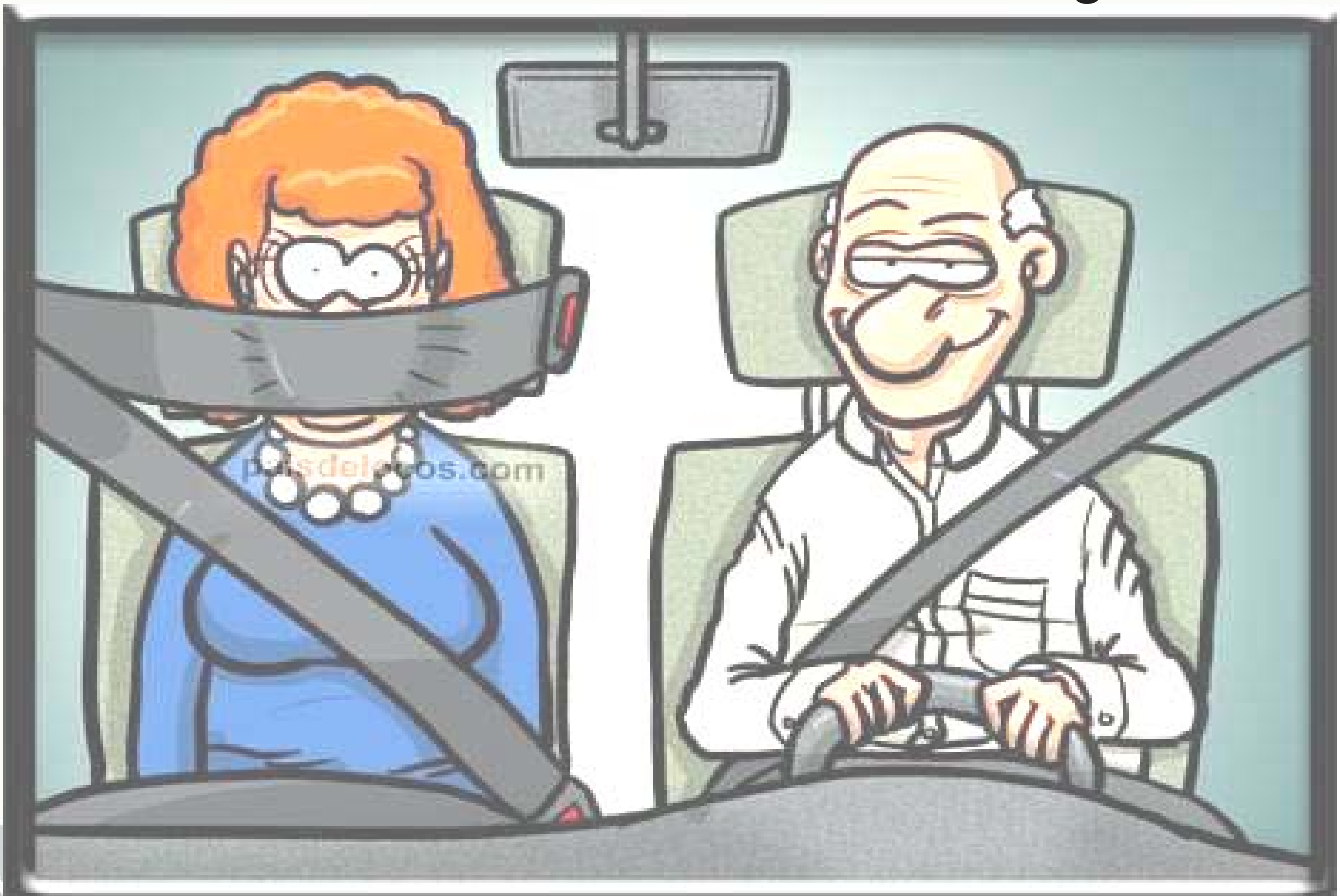
After Calculation RPN

- Decide where to focus effort
- Determine recommended actions for those steps with high RPN

conclusions

- Systematic process analyses: selects interventions
- Multi-disciplinary: broad focus of different professionals defines the objectivity of the analyses
- Uniformity of documentation stimulates comparing processes

Are there no incidents after doing a HFMEA?



MAASTRO's experience

- Starting FMEA in 2003 pilot brachytherapy, presentation management resulted in further implementation in 2004:

  4 big process analyses
- Criteria: new and en high risk processes which are selected by management
- phase of design, phase of implementation and phase of process redesign
- Now: every year on average 10 HFMEA's and several updates of older HFMEA's

research within MAASTRO

- translation to Dutch health environment of HFMEA (in the Netherlands called SAFER) incl. DVD and manual
- comparison of retrospective and prospective data
- deviations of HFMEA-method called SAFER light

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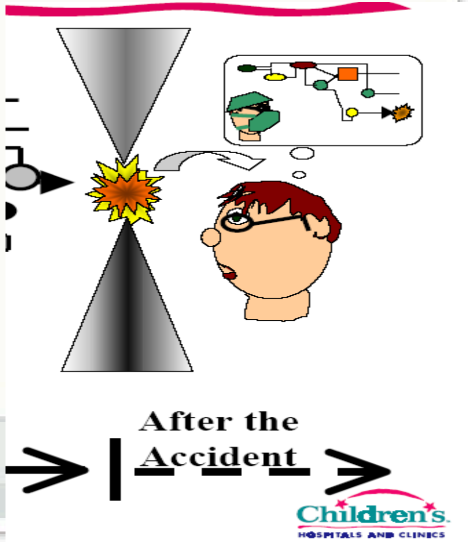
Tips and tricks

- Feedback to management
- Facilitate the actions/activities (time and people). To be organized by management!!!
- Monitor effects by using incident reporting, observations etc.



tip

(H)FMEA is flexible to use :
HFMEA/SAFER light version

Flexibility:

- amount and diversity of team membres,
- risk matrix (colour coding),
- process description

HFMEA and the RCA Process

Similarities

- Focus on systems issues
- Interdisciplinary Team
- Actions and outcome measures developed
- Scoring matrix (severity/probability)
- Use of triage/triggering questions, cause & effect diagram, brainstorming

Differences

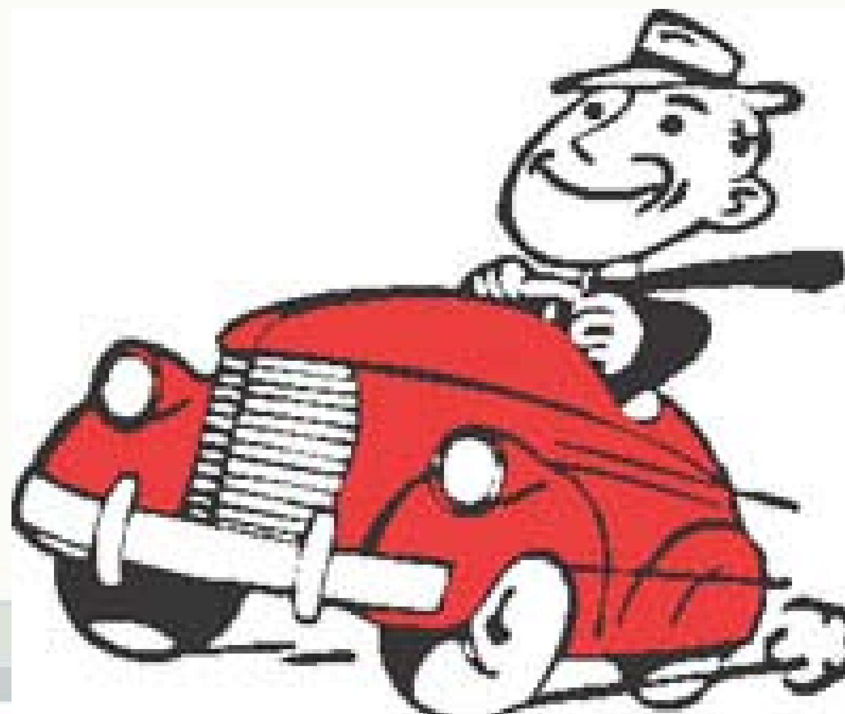
- Process vs. chronological flow diagram
- Prospective (what if) analysis
- Choose topic for evaluation
- Emphasis on testing intervention
- Develop flow diagram

questions!!!!

simple exercise

process:

weaking up until arriving at work



sub processes

1. waking up and getting dressed
2. taking breakfast
3. starting car
4. driving car to work
5. parking car

2. taking breakfast

2.1 butter up the pan

2.2 heat up the pan

2.3 break an egg

2.4 make an omelet

2.5 put omelet on a plate

2.3 break an egg

failures

no egg available

egg doesnot break

rotten egg

HFMEA worksheet

Failure Mode: First Evaluate failure mode before determining potential causes	Potential Causes		Scoring			Decision Tree Analysis				Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible
			Severity	Probability	Haz Score	Single Point Weakness?	Existing Control Measure ?	Detectability	Proceed?				
2.3 break an egg 2.3.1 no egg available 2.3.2 egg doesnot break 2.3.3 rotten egg													
	2.3.1 A	did do any shopping	2	4	8	no	no	no	yes	eliminate	shopping list with the item: eggs	amount of eggs	mom
		eggs were broken											

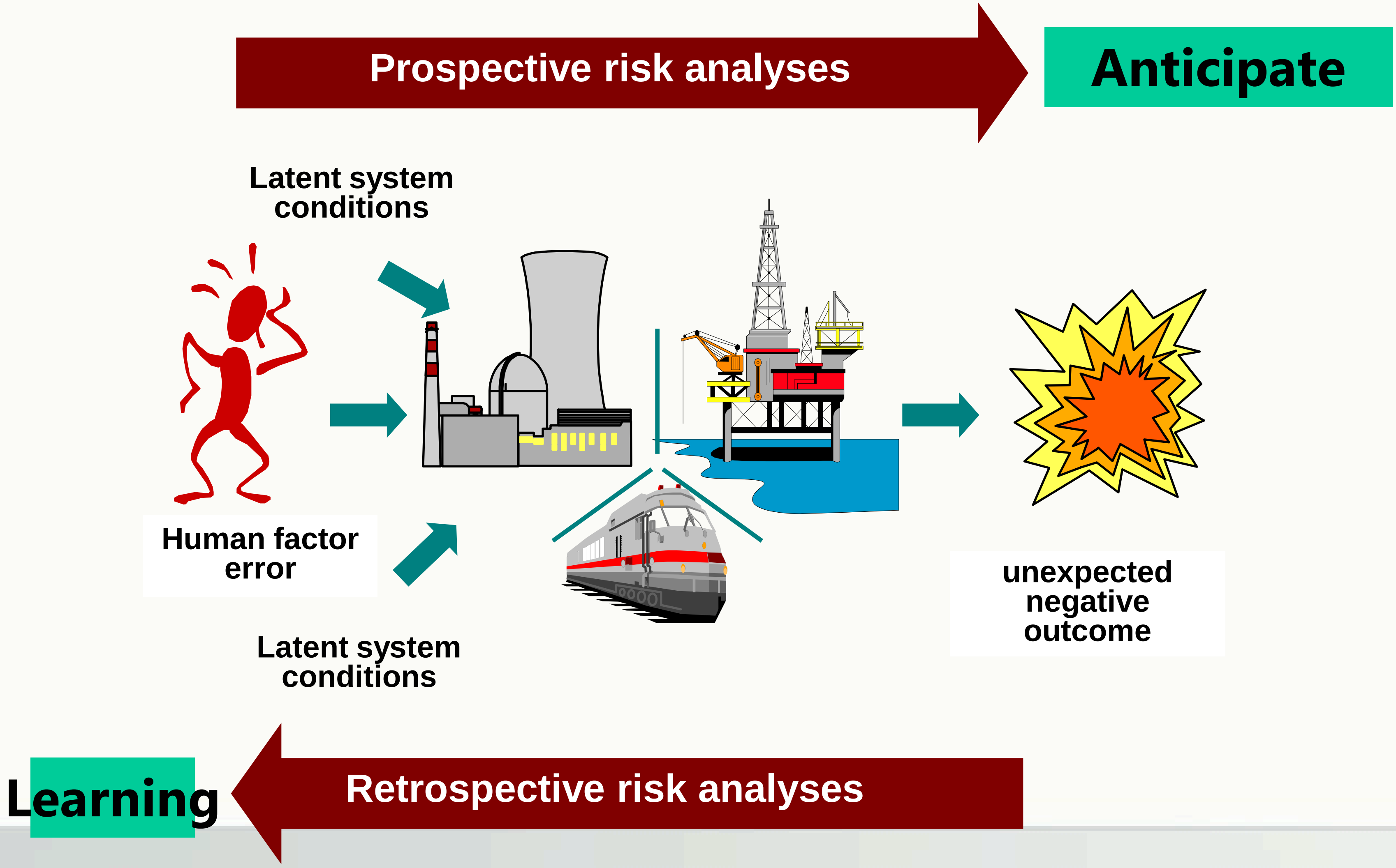
HFMEA analyses MAASTRO

Examples of recent HFMEA's :

- Process of working on bi location
- PET-CT process as shared resource
- Eclips –planningsprocess
- Aria 11
- Blood sampling

Voor 2005
Brachy
Digitale koppelingen
Stereotactie
Siemens versneller (SAFER light)
2006
Epi-poces
Linac
Administratieve verwerking pat. gegevens
Biobank
Virtueel simuleren
Vrijgave versneller na storing
XIO
EMD globale RI dbc facturering
DCM
2007
TBI
Digitaal aftekenen plannen
CT-PET
CT(PET) kwaliteitscontrole
Brachy
2008
IMRT prostaat
Stereotactie bij longen
Craniospinale as
Rectum ballon
Cone beam CT
2009
IMRT long
EMD intake module long
Soarian
Linac-pool
Ultra sound
Artiste
2010
Craniele stereotactie
Afspraken bureau (SAFER light)
TLI
Spiro lever
Salaris tot stand koming
IMRT HH
PET boost studie
2011
SPACEOR (SAFER light)
Long nieuw beleid
Aria
Eclips
True beam
2012
SAFER PET-CT Venlo / MAASTRO adm.
SAFER PET-CT Venlo / MAASTRO inhoudelijk
SAFER light HH true beam
FMEA product digitrans via Sioux
SAFER SBRT lever incl spirometer

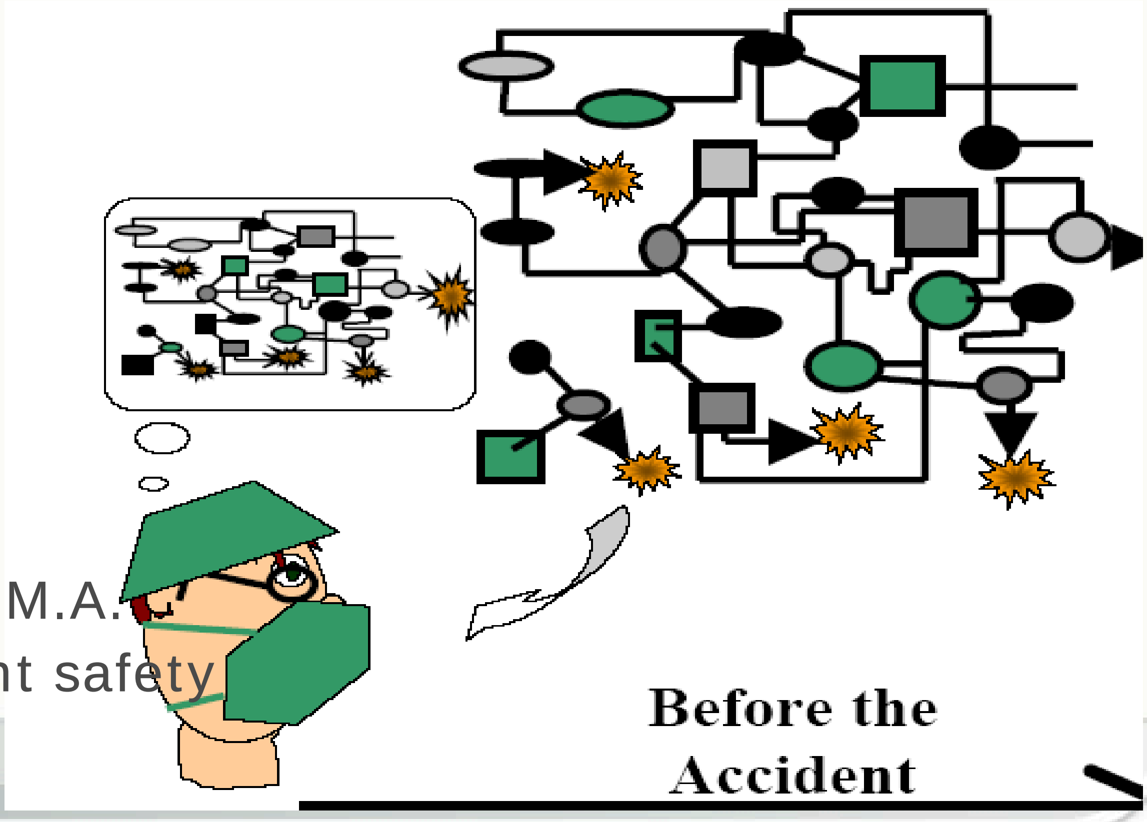
Relationship between prospective and retrospective risk analyses



questions!!!!

workshop HFMEA

identifying management actions to reduce the risks



Petra Reijnders-Thijssen M.A.
Manager Quality & patient safety
MAASTRO clinic

Learning Objectives

1. To learn the steps to developing HFMEAs
2. To perform an exercise to actually perform an HFMEA

(H)FMEA

(Healthcare) failure mode and effect analyses

organized mistrust

method

- multi-disciplinary meetings
- based on experience (professionals)
- process prescription – flowcharts- lists-coding
- each process step : failures ,causes
- hazard score: severity * occurence
- documentation

HFMEA Organisation (1)

1. Selection of a process by management;
2. Selection of the teammembers and facilitating the meetings by management;
3. Visualize process and identify sub processes by the chairman and 1 process expert;
4. Visit work place and check these processes and subprocesses with the teammembers;

(2)

5. Define failures and causes with the HFMEA team;
6. Define severity and occurence: (first move by the chairman and a process expert);
7. HFMEA team discusses the filling out, makes corrections and points out the responsible people;
8. Completion of the HFMEA worksheet by the chairman and a process expert .

Division of roles between membres and Time involved

Tasks of the membres :

- Chairman: responsible for documentation, reporting and planning.
- Chairman organizes process prescriptions
- Team (HFMEA) members give feedback within their own groups of profession

Time involved:

- Preparation : process prescription (1 hour)
- Meetings: minimum of 4 meetings each 1,5 hour
- Feedback in organization (1 hour)

Exercise

- Think of a high risk process or an event that has occurred at your organization
- Make a process prescription
- Create an HFMEA for this process

examples of process

- patient identification on a lineair accelerator
- brachy therapy process or other RT process
- using cone beam on a lineair accelerator
- Quality assurence
- New RT device

(Or for the desperate ones “cooking potatoes”)

define process / subprocesses and select a piece of a subprocess

0. process selection (2 min)
1. define several subprocess and process steps (10-15 min)
2. first define failures and causes for all these steps (15 min)
3. define risk score and decision tree (10 min)
4. define actions and fill in the HFMEA form (20 min)
5. Feedback from the groups (10 min)

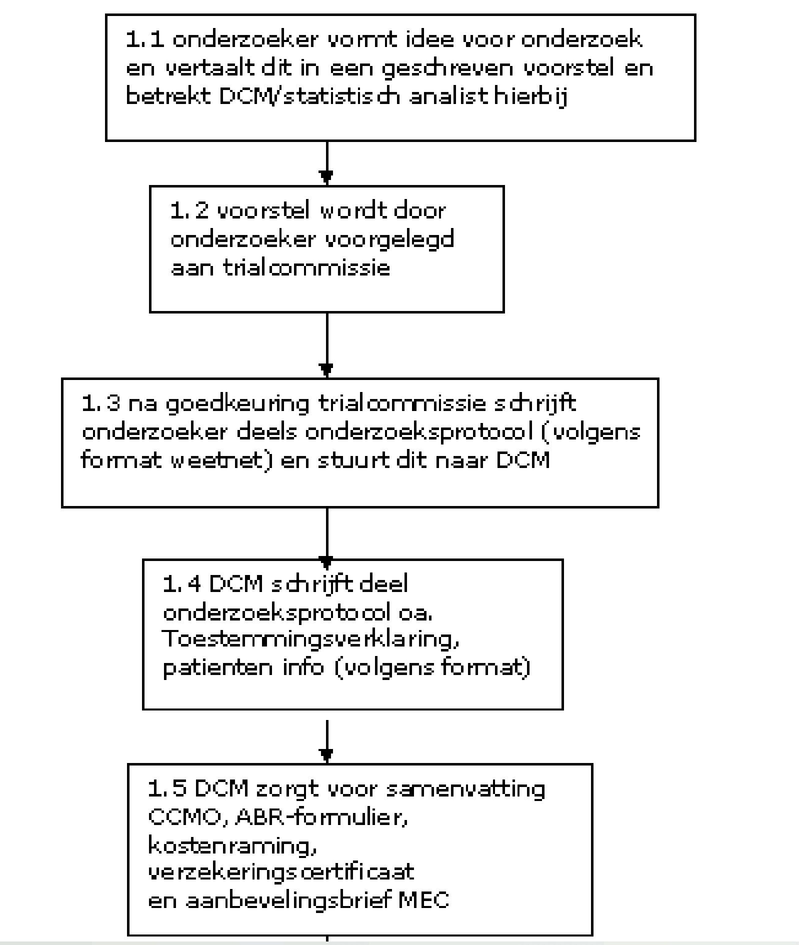
tips for process description

activity pro the person and location

coding the steps

f.e:

1.1 The RTT positions the patient on the linac table in the linacroom



Questions for the feedback of the groups

1. What was the topic and subprocesses?
2. Problems in defining the process?

2. What did you find practical?
3. What were issues?
4. General experience

questions!!!!


Pracitical example how to use
Patient Safety
tools during transition
combining prospective and
retrospective risk management

MAASTRO

MAASTRO = MAASTricht Radiation Oncology

Independent Radiotherapy Centre

Scientific research collaboration with:

- Academic Hospital Maastricht
- Maastricht University
- Eindhoven University of Technology
- Hospitals and Cancer Centres Worldwide

Facts - Staff

3 main groups:

- MAASTRO research
- Patient care
- Support staff

Basic numbers:

- 250 employees (+/- 220 fte)
- ± 32% male, 68% female
- ± 70% Bachelor- or University degree
- 17 Radiation Oncologists
- 7 Medical Physicists

MAASTRO CLINIC

Facts- Treatments

Number of patients per year:

–Teletherapy ± 3500

–Brachytherapy ± 400

Per day:

–Total number of radiation treatments ± 210

–Radiation performed on 6 TrueBeams (incl. Venlo)

–Operating Time, 2 shifts:

- 08.00 - 16.30
- 16.30 - 21.30

MAASTRO CLINIC

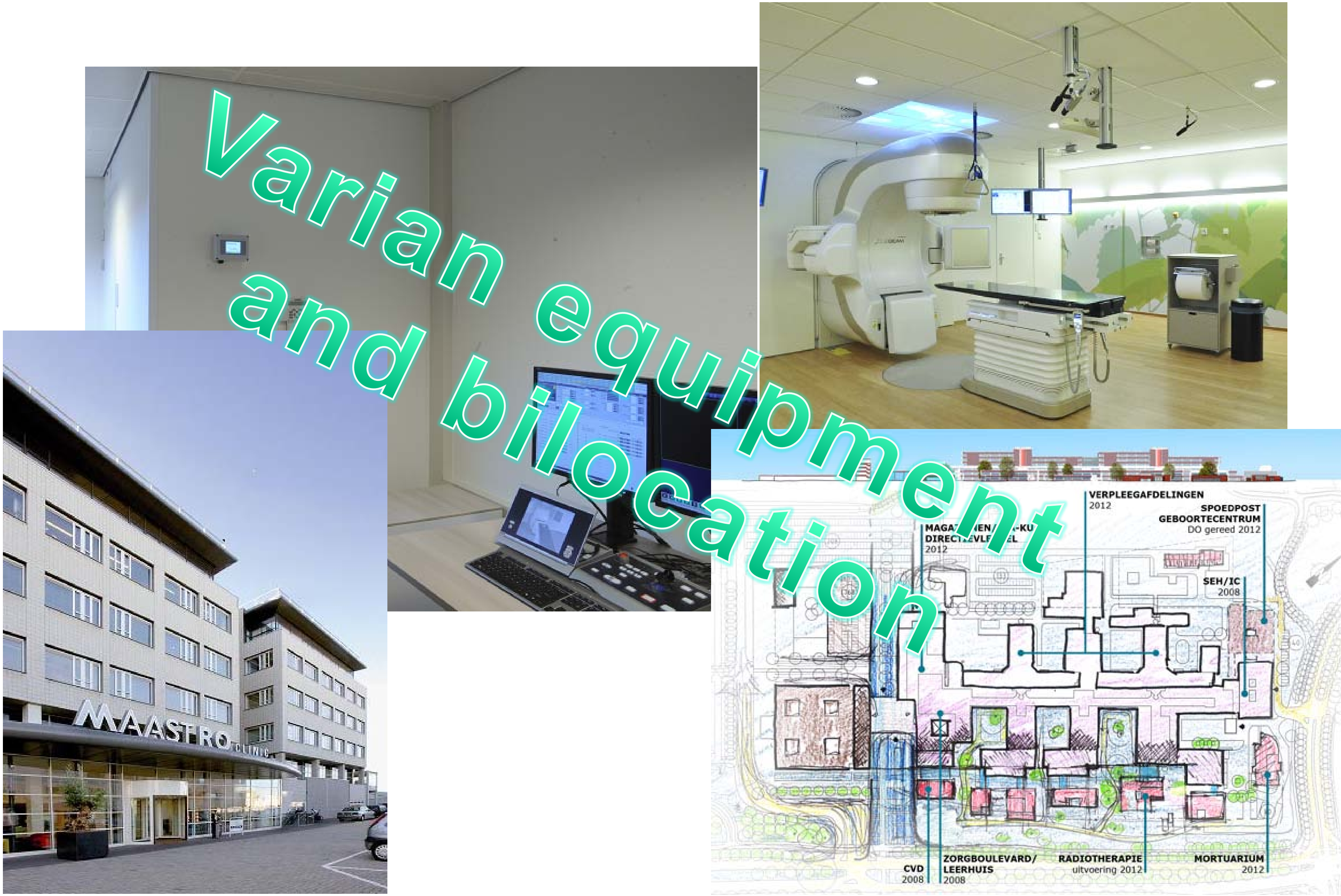
content of the presentation

- Transtions in MAASTRO 2011-2012
- Safety tools used
- Dutch publication
- ERM/enterprise risk management

Transitions are definitive dangerous because of lack of knowledge, rules and skills

MAASTRO CLINIC

Risk Rt and transitions



Varian equipment and bilocation

Impact transitions

Varian equipment

- Different layout
- Different process flow
- Different verification
- Different planning system

- New knowledge
- No experience
- Short transfertime (one year)
- All round ship RTT

Bilocation Venlo

- Distance 75 km
- Preparation of xRT in Venlo
- Shared resources
- 2 organizations working together
- Different patient identification

tools used

Andrea F.

1. PRISMA
2. HFMEA/SAFER
3. Selective treatment check
4. Visitation
5. Safety Awareness Training / Human factor
6. RCA
7. Reliability research
8. Organization of safety

1: PRISMA - model

Prevention and **R**ecovery
System **I**nformation
for **M**onitoring and
Analysis

developed by
prof. T.W.v.d Schaaf

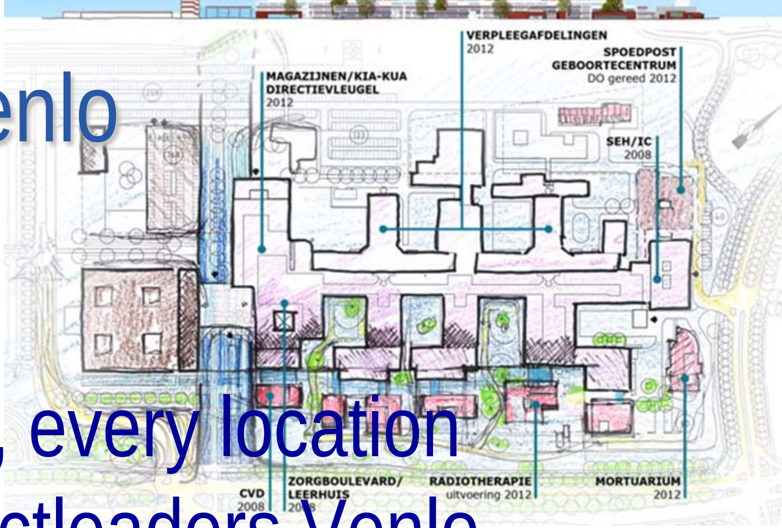
CLINIC

Varian equipment

- In report selection of Vendor
- During implementation phase, every Varian report was visual for the projectleaders Varian
- Analyses done on the Varian equipment

- Goal is effective short term action based on incident reporting
- Action examples: procedures, knowlegde & education, treattime inplanning

Bilocation Venlo

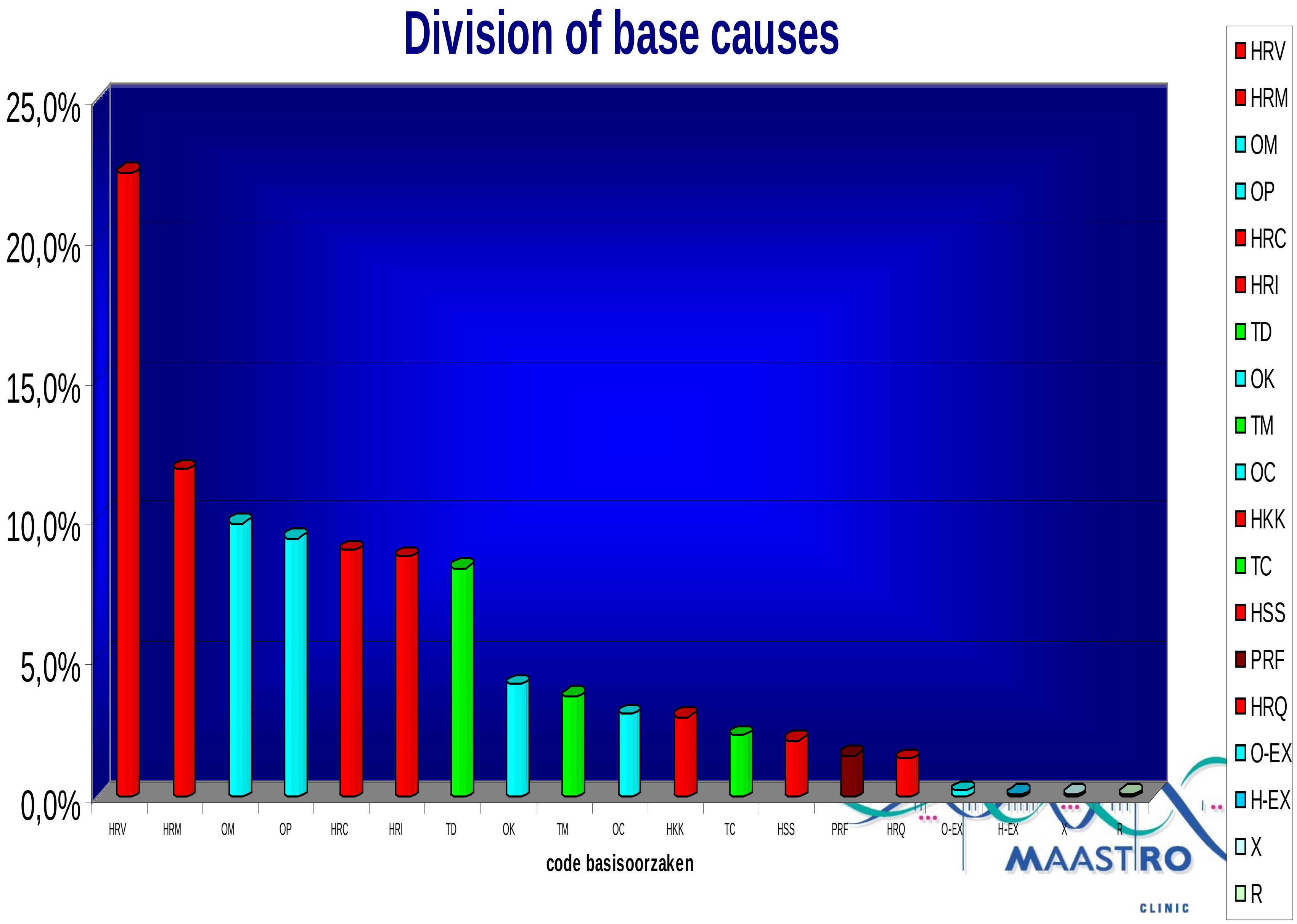


- In report selection of location
- During implementation phase, every location report was visual for the projectleaders Venlo
- Analyses done on the bilocation

- Goal is effective short term action based on incident reporting
- Action examples: change names of linacs, knowledge & education, id.differences and procedures

MAASTRO
CLINIC

Histogram of the classification code



MAASTRO CLINIC

tools used

Andrea F.

1. PRISMA
2. HFMEA/SAFER √
3. Selective treatment check
4. Visitation
5. Safety Awareness Training / Human factor
6. RCA
7. Reliability research
8. Organization of safety

Varian equipment

- 3 SAFER analyses performed:

SAFER planningsproces

SAFER datatransfer

SAFER light treatment proces

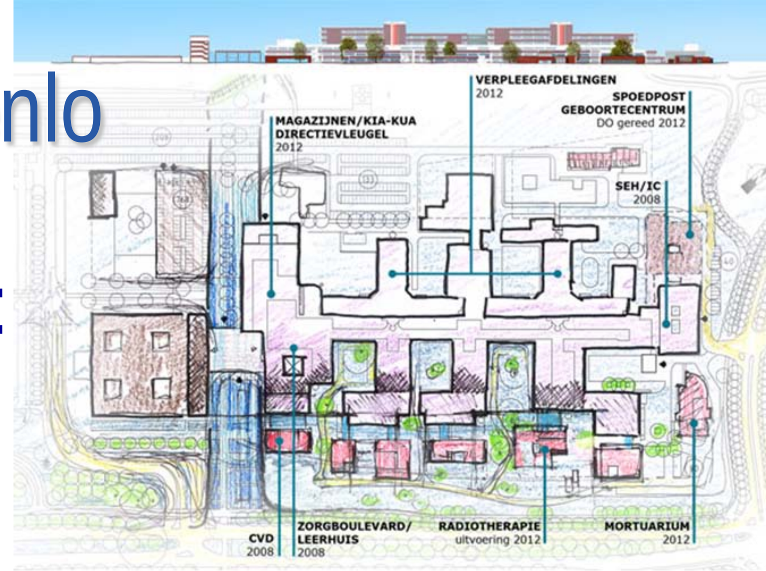
<u>Results</u>

Planningsproces: 27 actions defined

Datatransfer: 23 actions defined

Treatment: 20 actions defined

Bilocation Venlo



- 2 SAFER analyses performed:

SAFER CT administration and

SAFER CT-PET practice

SAFER's were performed by personal from Venlo and MAASTRO

<u>Results</u>

Administration: 62 actions

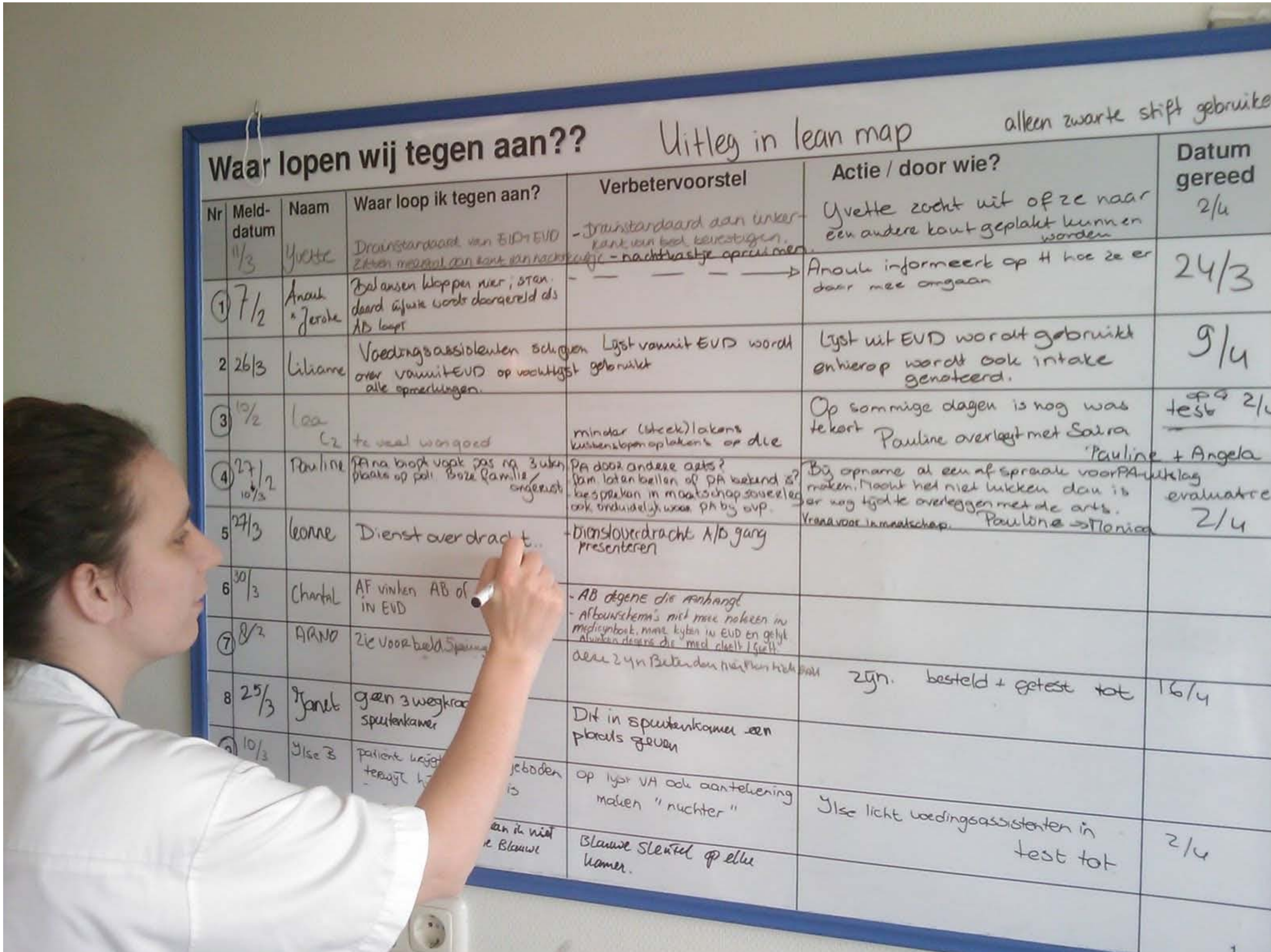
Practice: 52 actions

MAASTRO CLINIC

Subproces 1. _aanvraag en intake proces__RTO in Viecuri___

Faalwijzen	*code*	*Oorzaken*	*Ernst*	*Freq*	*Score*	*Besta ande proce*	*control eerbaa rheid*	*Doorgaan/actie*	*Verantwo ordelijke*	*Termijn*	*Afgerond*
0.1 patient past niet door deur onderzoekkamer	0.1.1	bedden kunnen niet door deuren	1	3	3	n	n	als voorwaarde voor ruimte keuze gesteld / Actie: doorgegeven aan verantwoordelijke (Jean Luyen)door Rene (29/3)/ Er is met Rinus afgesproken dat nieuwe patienten die met bed naar beneden moeten komen door de RTO op de afdeling gezien gaan worden. (Hierdoor is het evt. probleem van te smalle deuren op MDOP opgelost).	Rene	voor start VC	
								controle via id. VC incl pasfoto op pas en BSN. Actie 30/3 pasfoto staat standaard op pas.	Ton	19-apr	
								instructie MDOP VC controle id VC pas	Rene/Jean	voor start VC	
								instructie DA en RTO Maastro via VC controle id VC pas	Jean	voor start VC	
0.2 verkeerde patient binnen	0.2.1	identificatieverschil Viecuri en MAASTRO	4	2	8	n	n	communicatie aan pat. via brief en instructie PPL MAASTRO over id verschil in VC tov MAASTRO	Claudia	voor start VC	
								proces DA wordt voor RTO geplaatst/ dd: 19/4 In Venlo is Intake DA altijd vóór intake RTO	Jean	voor start VC	
	0.2.2	geen controlemogelijkheid van pasfoto in dossier bij intake RTO	4	2	8	n	n	koppeling VC pasfoto aan EMD MAASTRO (navraag bij Fred Korver)	Petra	voor start VC	
	1.1.1	patient weet niet waar hij/zij zich moet afmelden	2	3	6	n	j	afspraakbureau nr MAASTRO is toegevoegd aan brief pat. + telef. instructie door PPL	Claudia	voor start VC	
	1.1.2	patient op verkeerde lokatie	2	3	6	n	j	lokatie VC in brief en telefonische instructie door PPL	Claudia	voor start VC	
	1.1.3	patient heeft geen bericht ontvangen van afspraak en lokatie	2	3	6	n	j	acceptatie			
	1.1.4	brief te laat	2	3	6	n	j	acceptatie			
	1.1.5	adresgegevens onjuist	2	3	6	n	j	acceptatie			
	1.1.6	routing in Viecuri onbekend/onduidelijk voor patient	2	4	8	n	j	routing VC MAASTRO toevoegen aan folder en nr. lokatie toevoegen aan pat. brief (Ton nr. aanleveren en Claudia verwerking) Reactie: 29/3 Routenummer Maastro in Venlo zal 85 worden (dit blijft zo) Routenummer Onco poli is nog niet bekend, hangt af van de locatie. Men verwacht nummer 82 maar dit is nog zeker niet 100% zeker. Zodra een en ander bekend is zal ik dat met je delen	Ton/ Claudia	eind maart	
	1.1.7	patient heeft elders afspraken en deze zijn niet bekend bij MAASTRO	2	2	4	n	j	acceptatie			
	1..1.8	mobiliteit van patient en/of begeleiding	2	2	4	n	j	politaxi is operatoneel in VC	Ton	begin maart	
1.1 patient niet of te laat aanwezig								info over politaxi in VC bekend maken bij PPL Maastro	Claudia	voor start VC	
	1.2.1	Viecuri heeft poli lokatie nog niet geregeld voor start	2	3	6	n	n	acceptatie			
1.2 poli nog niet beschikbaar	1.2.2	alternatief/tussenoplossing poli niet geregeld	2	3	6	n	n	nummer lokatie alternatief idem als vaste lokatie behouden zodat communicatie idem is.	Ton	z.s.m.	
	1.3.1	ziekte/ geen vervanging	2	2	4	j	j	acceptatie			
	1.3.2	aanwezigheid RTO niet geregeld via MAASTRO	2	2	4	j	j	acceptatie			
1.3 RTO niet aanwezig	1.3.3	iedere 5 e woensdag /maand geen RTO aanwezig in Viecuri	2	3	6	j	n	telefonische bereikbaarheid RTO in MAASTRO voor VC regelen	claudia/ Roos	voor start VC	
	1.4.1	onvoldoende kennis van systemen in Viecuri	2	4	8	n	n	implementatiefase aandacht scholing systemen Viecuri aan medewerkers	Rinus/ Claudia	voor start VC	
1.4 kan systemen niet gebruiken	1.4.2	techniek falen	2	3	6	n	n	acceptatie			
	2.1.1	techniek falen	2	3	6	n	n	acceptatie			
2.1 aanvraag niet geschreven	2.1.2	verkeerde handeling van RTO door verschil in werkwijze ivm MAASTRO	2	4	8	n	j	instructie RTO mbt verzendfunctie	Rinus	voor start VC	
4.1 verkeerde vink gezet in relatie	4.1.1	menselijke handelen/vergissing	2	4	8	n	j	acceptatie			
tot nieuw EMD	4.1.2	instellingen staan default ingesteld	2	4	8	n	j	acceptatie			
4.2 verkeerde protocol	4.2.1	idem MAASTRO situatie	2	4	8	n		acceptatie			
4.3 verkeerde	4.3.1	nieuwe systemen/EMD nog niet beschikbaar	2	4	8	n	n	NB: afh van layout wijziging in nieuw EMD meenemen in SAFER uitvoering nieuw EMD/ Actie: PVT lid is lid van csie EMD	Petra/PVT		
protocolwijzigingen	4.3.2	onvoldoende kennis van systemen	2	4	8	n	n	instructie EMD	Rinus		
								overleg met Rinus mbt risico's en uitdiepen proces. Reactie"3/4/2012: De spraakverwarring rond Mould-Masker-Bolus lijkt niet te bestaan. Bolus en Mould zijn twee aparte EMD items. Bij Mould staat een apart "aanvinkitem"; "masker", alleen indien dit aangevinkt is kan het masker in venlo gemaakt worden, alle overige krijgen Mouldroomafspraak en CT in Maastricht Alle aan te vinken bolusitems zijn in Venlo te maken en komen automatisch op het Ct aanvraagformulier te staan./dd 19/4 Aanvragen			

Improve bord



tools used

Andrea F.

1. PRISMA
2. HFMEA/SAFER
3. **Selective treatment check** √
4. Visitation
5. Safety Awareness Training / Human factor
6. RCA
7. Reliability research
8. Organization of safety

New items for selective treatment check

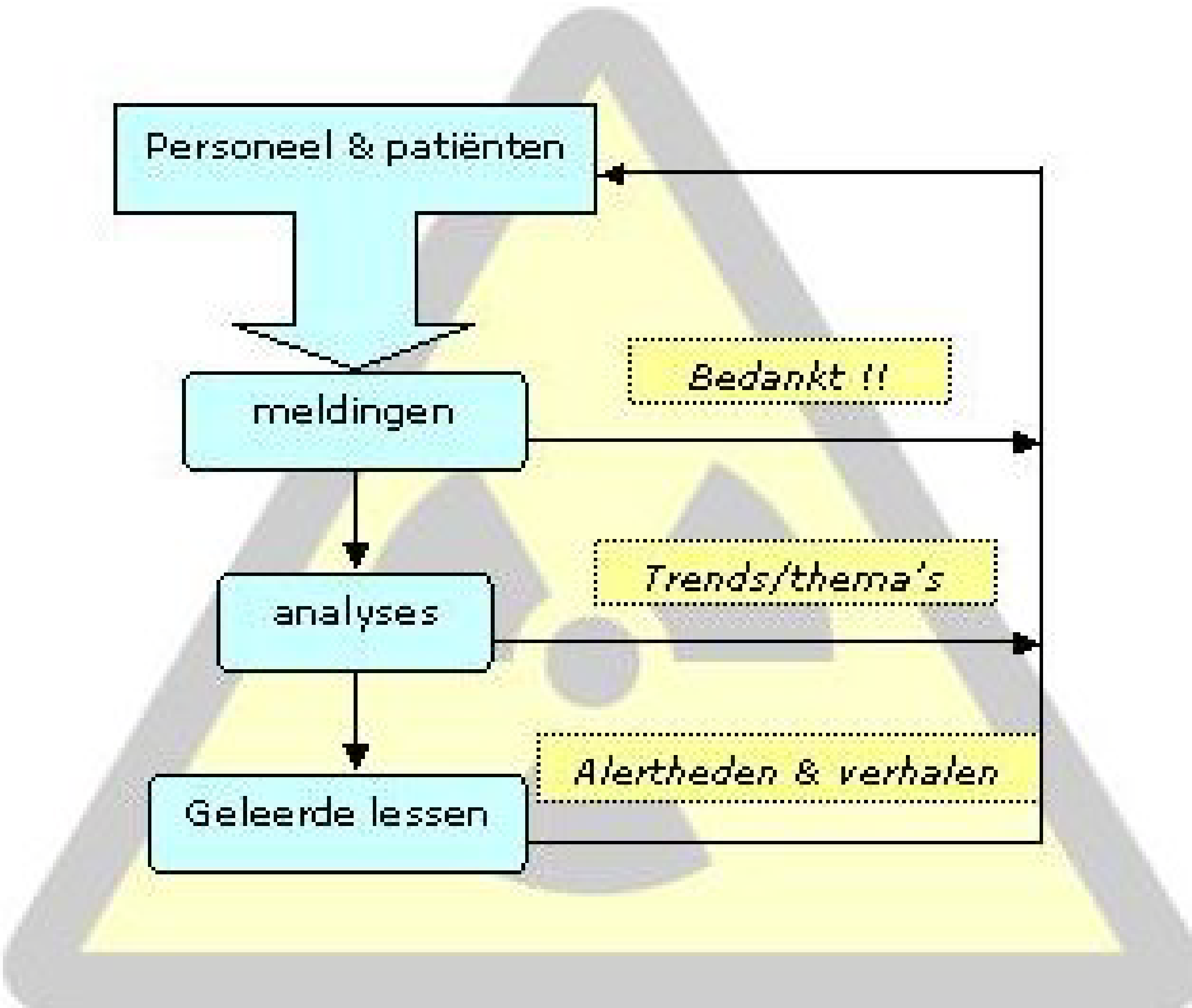
One RTT checks every month the following items:

- Overrides
- Performance of the weekly check of treatment data
- Pretreatment performance
- Check of the physicist during the EPID/MVI proces

Monthly reports

MAASTRO
CLINIC

Culture & communication



tools used

1. PRISMA
2. HFMEA/SAFER
3. Selective treatment check
4. **Visitation** √
5. Safety Awareness Training / Human factor
6. RCA
7. **Reliability research** √
8. Organization of safety

2013 visitation of our member of the board

- Process bilocation going to be visited

MAASTRO CLINIC

tools used

Andrea F.

1. PRISMA
2. HFMEA/SAFER
3. Selective treatment check
4. Visitation
5. Safety Awareness Training / Human factor √
6. RCA √
7. Reliability research
8. Organization of safety √

RTT with area of interest Patient safety

- Special RTT's with patient safety as an area of interest are assigned to the equipment transition and to the bilocation transition.

MAASTRO CLINIC

Publication national RTT journal

Gamma *Professional*

Casus uit MAASTRO clinic

Hoe verricht je een risico inventarisatie bij
introductie nieuwe workflow voorbereiding- en behandelingstraject

Veilig starten met een nieuwe workflow!

P. Reijnders-Thijssen M.A., manager Patiëntveiligheid,
R. Mannens, projectleider klinische workflow en training Varian apparatuur
MAASTRO clinic, Maastricht

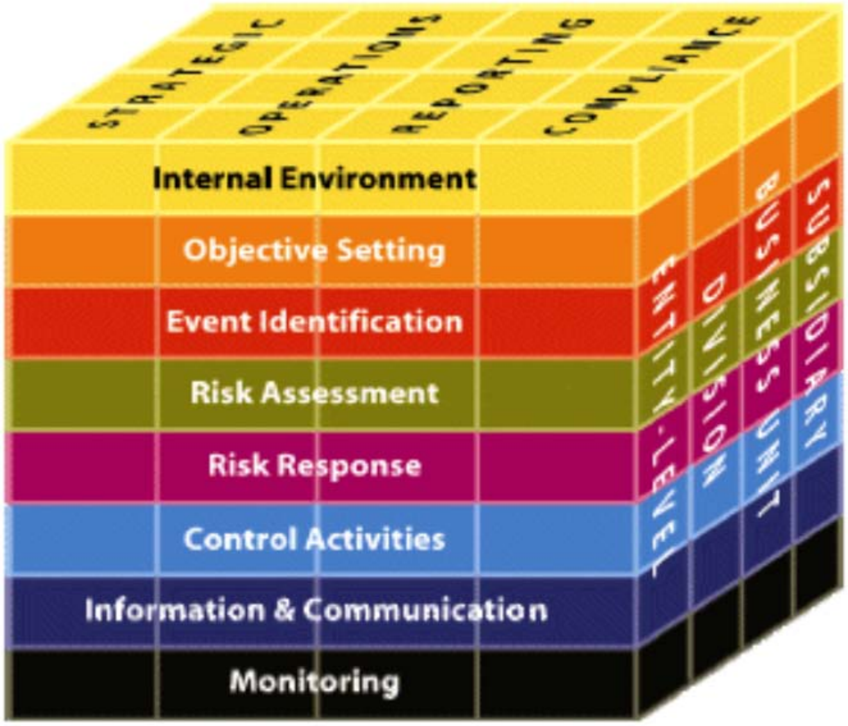
Starten met nieuwe apparatuur betekent risico's in de patiëntenzorg. Kennis, kunde en vaardigheden zijn nog niet routinematig aanwezig. Dit probleem is aanleiding voor MAASTRO clinic het invoeringstraject van deze nieuwe apparatuur systematisch te begeleiden door het inzetten van veiligheidsinstrumenten. Er is gebruik gemaakt van voorspellende (pro-actieve)risico-inventarisaties en van retrospectieve methodes onder andere meldingsanalyses. De casus van MAASTRO clinic kan als voorbeeld dienen voor andere instellingen. De conclusie is dat de pro-actieve en retrospectieve methodes elkaar versterken en daardoor de veiligheid voor de patiënt op een effectieve wijze verbeteren.

Inleiding

Op 7 november 2011 is in MAASTRO clinic de eerste True Beam versneller klinisch in gebruik genomen. Voorafgaande aan deze datum zijn er anders per fabrikant. Dat betekent dat de medewerkers van meerdere apparaten kennis moeten opdoen. Introductie van nieuwe apparatuur betekent hogere risico's op fouten

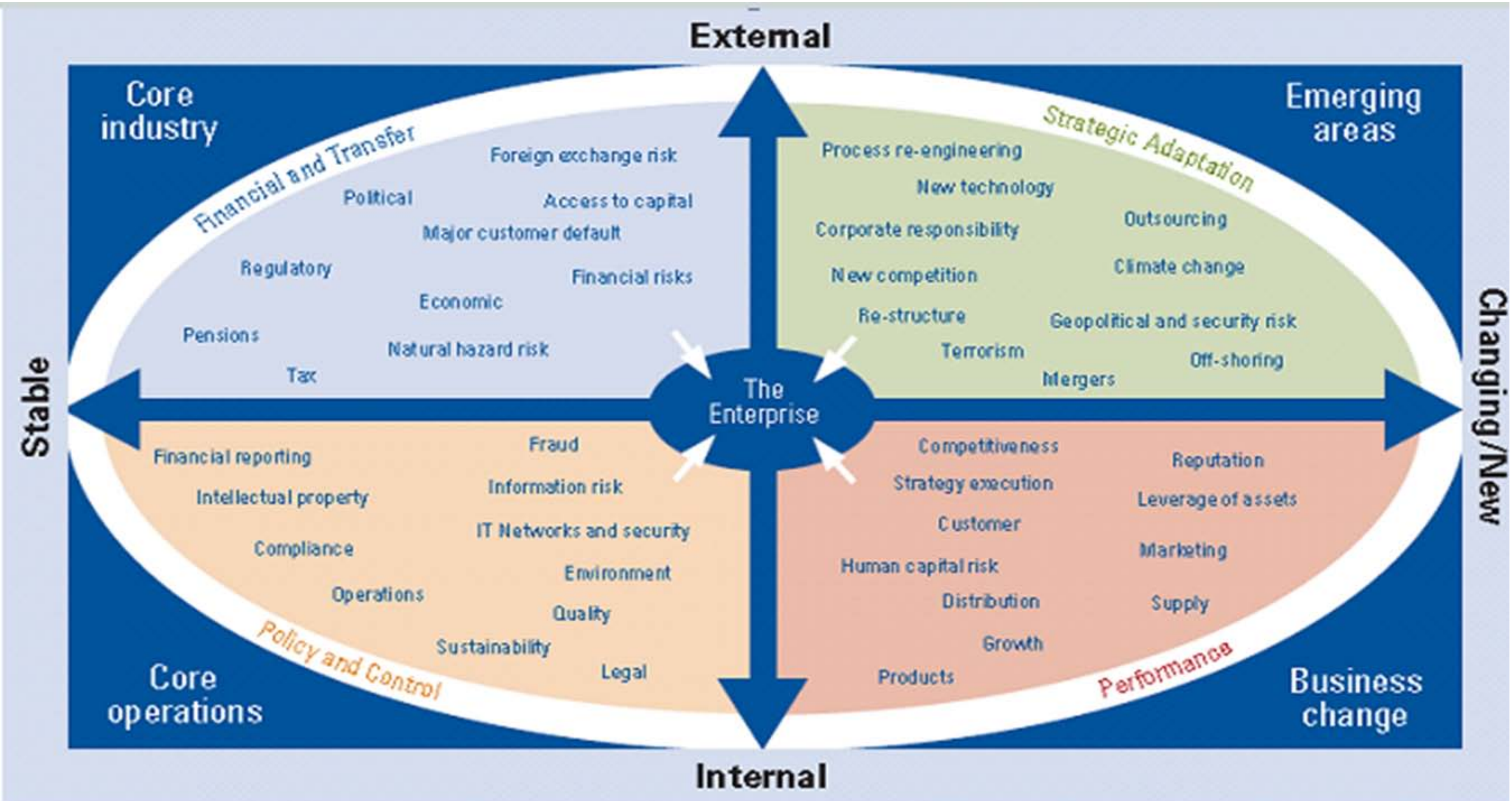
ERM/enterprise risk management

ERM is a process, effected by an entity's board of directors, management and other personnel, applied in strategy setting and across the enterprise, designed to identify potential events that may affect the entity, and manage risk to be within its risk appetite, to provide reasonable assurance regarding the achievement of entity objectives (COSO,2004)



MAASTRO CLINIC

Risk area's



(figuur afkomstig uit dok: The evolving Role of the head of risk, 2009 KPMG)

Bovenstaande portfolio is voor MAASTRO aangevuld door:
- researchontwikkeling en gelden
- ziektekostenverzekeraars

VRAGEN

Bussiness in CONTROL!

petra.reijnders@maastro.nl

COMMUNICATION IN SAFETY

ESTRO – AVIGNON OCT 1-4TH, 2016

AUDE VAANDERING

LEARNING OBJECTIVES

- Communication in the framework of a safety culture.
- Communication to and with the victims of incidents.

COMMUNICATION IN SAFETY

Includes:

- Communication in an optimal manner
- with the patient
- within a department
- within an organization
- Outside the organisation
- Post incident management

COMMUNICATION TO PREVENT ERRORS

- Miscommunication often involved in adverse error event

Contributory factors are:

- poor **communication** and **teamwork.**
- Poor design and documentation of procedures.
- Hierarchal departmental structure.
- Working environment.
- Changes in process.
- Fatigue and stress.

First thing : say hello, tell who you are, SGGT.
« I'm Jack Gray and I've been flying with this company for 5 years… ».
In case of crisis in flight : « Jack, flaps to zero… ».


US AIRWAYS

CHECKLIST IN SURGERY?

Surgical Safety Checklist

World Health Organization | Patient Safety
A World Alliance for Safer Health Care

Before induction of anaesthesia

(with at least nurse and anaesthetist)

Has the patient confirmed his/her identity, site, procedure, and consent?
- ☐ Yes

Is the site marked?
- ☐ Yes
- ☐ Not applicable

Is the anaesthesia machine and medication check complete?
- ☐ Yes

Is the pulse oximeter on the patient and functioning?
- ☐ Yes

Does the patient have a:

Known allergy?
- ☐ No
- ☐ Yes

Difficult airway or aspiration risk?
- ☐ No
- ☐ Yes, and equipment/assistance available

Risk of >500ml blood loss (7ml/kg in children)?
- ☐ No
- ☐ Yes, and two IVs/central access and fluids planned

Before skin incision

(with nurse, anaesthetist and surgeon)

- ☐ **Confirm all team members have introduced themselves by name and role.**
- ☐ **Confirm the patient's name, procedure, and where the incision will be made.**

Has antibiotic prophylaxis been given within the last 60 minutes?
- ☐ Yes
- ☐ Not applicable

Anticipated Critical Events

To Surgeon:
- ☐ What are the critical or non-routine steps?
- ☐ How long will the case take?
- ☐ What is the anticipated blood loss?

To Anaesthetist:
- ☐ Are there any patient-specific concerns?

To Nursing Team:
- ☐ Has sterility (including indicator results) been confirmed?
- ☐ Are there equipment issues or any concerns?

Is essential imaging displayed?
- ☐ Yes
- ☐ Not applicable

Before patient leaves operating room

(with nurse, anaesthetist and surgeon)

Nurse Verbally Confirms:
- ☐ The name of the procedure
- ☐ Completion of instrument, sponge and needle counts
- ☐ Specimen labelling (read specimen labels aloud, including patient name)
- ☐ Whether there are any equipment problems to be addressed

To Surgeon, Anaesthetist and Nurse:
- ☐ What are the key concerns for recovery and management of this patient?

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.

Revised 1 / 2009

COMMUNICATION TO PREVENT ERRORS

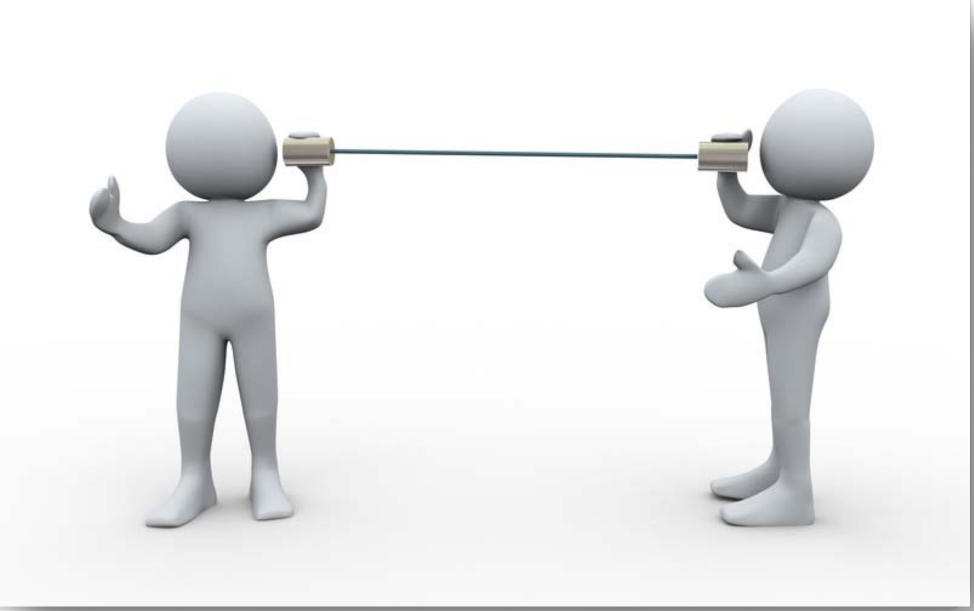
- Miscommunication often involved in adverse error event

Contributory factors are:

- poor **communication** and **teamwork.**
- Poor design and documentation of procedures.
- Hierarchal departmental structure.
- Working environment.
- Changes in process.
- Fatigue and stress.

COMMUNICATION WITHIN THE ORGANIZATION/WITH THE PATIENTS

- Clear lines of communication between staff
- Optimized communication with patients (empowerment)
- Need for tools:
  - Workflow management systems
  - Procedures
  - Checklists
  - Training



POST INCIDENT MANAGEMENT

Transparency, Compassion, and Truth
in Medical Errors » - Leilani Schweitzer

WHO ARE THE VICTIMS OF AN ERROR?

1st victims

Patient + family/friends

2nd victims

Healthcare professionals

3rd victims

Healthcare organization/other patients

WHAT THE PATIENT/FAMILY WANTS…

- « Honest and transparent communication ».
- « Full apology ».
- « Knowledge of the changes that have been made ».

WHAT THE PATIENT/FAMILY WANTS…

Why do people sue doctors? *The Lancet* 343: 1609, 1994

« The decision to take legal action was determined not only by the original injury, but also by insensitive handling and poor communication after the original incident…

Where explanations were given, less than 15% were considered satisfactory… »

COMMUNICATION WITH VICTIMS – **WHO**, WHEN AND WHAT

- Someone who is
  - Known to the patient
  - Familiar with the facts of the incident and the patients care
  - Senior
  - Good at interpersonal skills / communicating bad news
  - Able to offer reassurance and feedback
  - Willing to maintain a relationship with the patient
  - Trained in open disclosure

COMMUNICATION WITH VICTIMS – WHO, **WHEN** AND WHAT

- As soon as possible after the event
- Patient
  - Clinical condition
  - Emotional and psychological state
  - Availability of support person
  - Preference
  - Privacy and comfort
- Staff
  - Availability of key staff
  - Availability of support staff

COMMUNICATION WITH VICTIMS – WHO, WHEN AND **WHAT**

- Content of Disclosure Meeting:
  - Advise patient of identity and role of all staff at meeting
  - Express sympathy and regret for what has happened
  - Disclose the known and agreed facts
  - Be aware of their understanding, answer questions
  - Listen and respond to concerns of the patient

COMMUNICATION WITH VICTIMS – WHO, WHEN AND **WHAT**

- Content of Disclosure Meeting:
  - Discuss the next steps in treatment
  - Inform the patient about short- and long term effects
  - Reassure the patient that the incident will be thoroughly investigated, that they will be informed of results, and that changes will be made to prevent further recurrence
  - Offer support
  - Information on how to proceed further, e.g. complaints process

COMMUNICATING WITH THE SECOND VICTIMS

"Technological wonders, the apparent precision of laboratory tests, and innovations that present tangible images of illness have in fact created an expectation of perfection"

- TRUST
  - Treatment that is just
  - Respect
  - Understanding and compassion
  - Supportive care
  - Transparency and opportunity to contribute

THIRD VICTIM…


Radiation errors at St. Cloud cancer center under investigation

Concerns raised about radiation dosage, targeting.

By David Chanen and Jeremy Olson Star Tribune | JULY 4, 2015 — 7:34AM

GLEN STUBBE, STAR TRIBUNE

Betty Zollner was partly paralyzed when radiation treatments for a tumor damaged the nearby healthy tissue in her spine.

IMPORTANT POINTS TO REMEMBER

- Proper communication = safety barrier
- Communication for post-incident management

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Human Factors

Peter Dunscombe

UNIVERSITY OF CALGARY

ESTRO school

Human Factors

Session Objectives

- To review Rasmussen's categories of human performance.
- To look at how performance might be compromised, with clinical examples.
- To map error types on to human performance categories.
- To discuss Preventive Measures.

ESTRO school

Human Factors

Outline

1. Human performance
2. Compromising human performance
3. Error types
4. Preventive Measures

Human Factors

Outline

1. Human performance*
2. Compromising human performance
3. Error types
4. Preventive Measures

***Managing Maintenance Error: A Practical Guide.**

James Reason and Alan Hobbs, 2003

Human Factors

Jens Rasmussen defined three categories of human performance:

- Skill-based
- Rule-based
- Knowledge-based

Note: most activities encompass the three levels of performance

Human Factors

Skill-based performance

Applies to straightforward routine tasks which have been performed for some time. May or may not include checks along the way.

- Documentation rarely needs to be referred to.
- Skill can be increased through repetition.

Examples of predominantly skill based activities for the experienced practitioner:

1. Morning warm up on a machine.
2. Physics assistant monthly linac QC.
3. Taking a general medical history.

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Human Factors

Rule-based performance

Applies to more complex or critical tasks which may be only occasionally performed.

- Documentation (procedures, instruction manuals, protocols) need to be readily accessible.
- Regulated practices require rules.

Examples of predominantly rule based activities:

1. Adjusting lasers.
2. Working up a patient for a clinical trial.
3. Radiation Safety.

Human Factors

Knowledge-based performance

Applies to dealing with unfamiliar and/or unprepared-for tasks. The "rules" have to be made up and the "skills" developed during performance of the task.

- Prior specific documentation is not available.
- Uses more education than training.

Examples of predominantly knowledge based activities:

1. Deciding what to do if the marks don't fit.
2. Commissioning a new treatment technique for TBI.
3. Contouring on 4D-CT.

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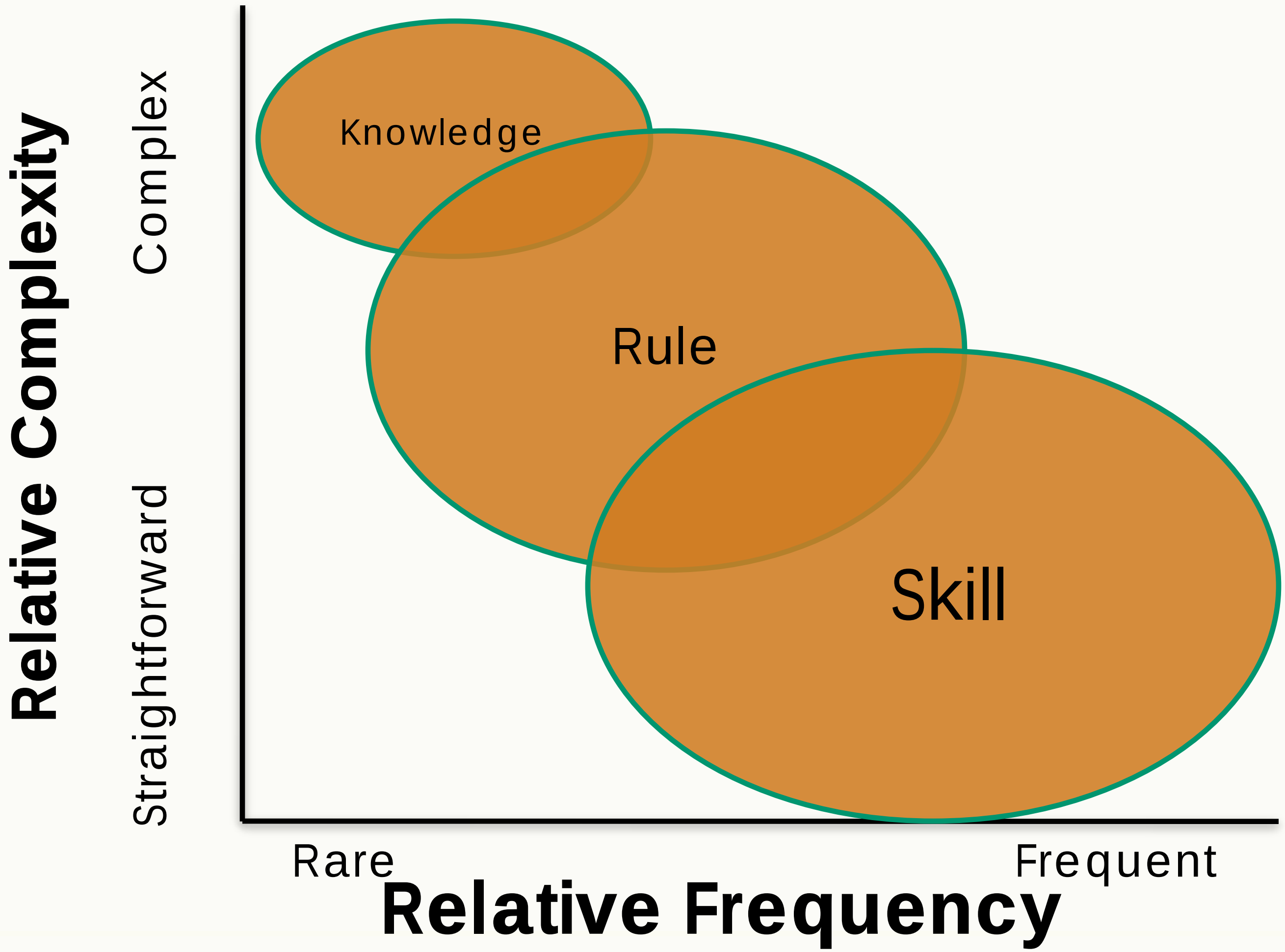
Human Factors

Performance categories



Human Factors

Where does **competency** fit in?

ESTRO defines **competency** to mean "to be able to adequately perform a professional act in a specific environment by integrating knowledge, skills and attitude"

If "attitude" encompasses following the rules then **competency** means to be able to function effectively in all three of Rasmussen's performance categories.

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Human Factors

Outline

1. Human performance
2. Compromising human performance
3. Error types
4. Preventive Measures

Human Factors

How might our performance be sub-optimal?

Definitions and distinctions:

Error: Actions do not go as planned

Mistake: Actions go as planned but plan is flawed

Violations: Intentional deviation from approved path

Note: We will use the generic term "error" to cover these three categories for most of the rest of this presentation.

ESTRO school

Error – Expanded definition

An error is the failure of planned actions to achieve their desired goal, where this occurs without some unforeseeable or chance intervention.

Human Factors

Skill – Based Errors

Recognition failures (1):

- *Misidentification*

Some examples are:

- Laterality errors in patient treatment
- Mistaking a mole for a tattoo
- Setting the wrong scale on an electrometer

Human Factors

Skill – Based Errors

Recognition failures (2):

- *Non-detection*

Some examples are:

- Focusing on complex calculations and missing simple errors
- Entering the time instead of the pressure into the output program
- Failure to observe metastasis on a CT.

Human Factors

Skill – Based Errors

Slips:

- *A step is missed in a frequently performed routine activity.*

Some examples are:

- Not pressing the Last Person Out button
- Omitting to set the electrometer zero between readings
- Letting the patient leave the consult before signing the approval sheet.

Skill – Based Errors

(Memory) lapses:

- *Forgetfulness*

Some examples are:

- Forgetting your password.
- Leaving the chart in the treatment room.
- Not setting the follow-up appointment.

Human Factors

Rule – Based Issues

Misapplying a good rule:

- *Using an inappropriate method or data*

Some examples are:

- Doing an SSD calculation for an SAD patient.
- Using a hard wedge factor for a dynamic wedge.

Human Factors

Rule – Based Issues

Applying a bad rule:

- *Maybe following a tradition (an unwritten rule).*

Some examples are:

- Completing the prescription sheet after the Oncologist has signed it.
- Clearing computer warnings automatically.
- Ignoring Mrs Smith's medical complaints because she is always complaining.

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Human Factors

Knowledge – Based Mistakes

Tackling unfamiliar problems:

Some examples are:

- Treating the first IGRT patient
- Commissioning a new TBI technique
- Prescribing to a new (for you) tumor site.

Knowledge – Based Mistakes

Reason and Hobbs asked aircraft maintenance personnel the following question: At work in the last year or so, how often have you done an unfamiliar job, despite being uncertain whether you were doing it correctly?

The answer was about 20% of the time!!

Would our experience be any different?

Human Factors

Violations

Routine violations:

- *Showing off, taking short cuts that are not in the written procedure, persistent carelessness.*

Some examples are:

- When setting up a phantom not checking both the ODI and the lasers
- Not checking the patient's ID properly before taking them in the room.
- Not informing the unit of a cancelled fraction

Human Factors

Violations

Thrill seeking violations:

- *Taking a risk for the sake of it*

Some examples are:

- Exceeding the speed limit without good reason.
- Skiing out of bounds.

Violations

Situational violations:

- *A pragmatic approach to getting the job done.*

Some examples are:

- Signing purchase orders without reading them.
- Not doing the full morning check so as not to delay patient treatments
- Double booking patients on a machine

Comparison of Error Types

Comparison of error types resulting in quality incidents and worker safety incidents

Adapted from Hobbs and Reason, Figure 4.4

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Human Factors

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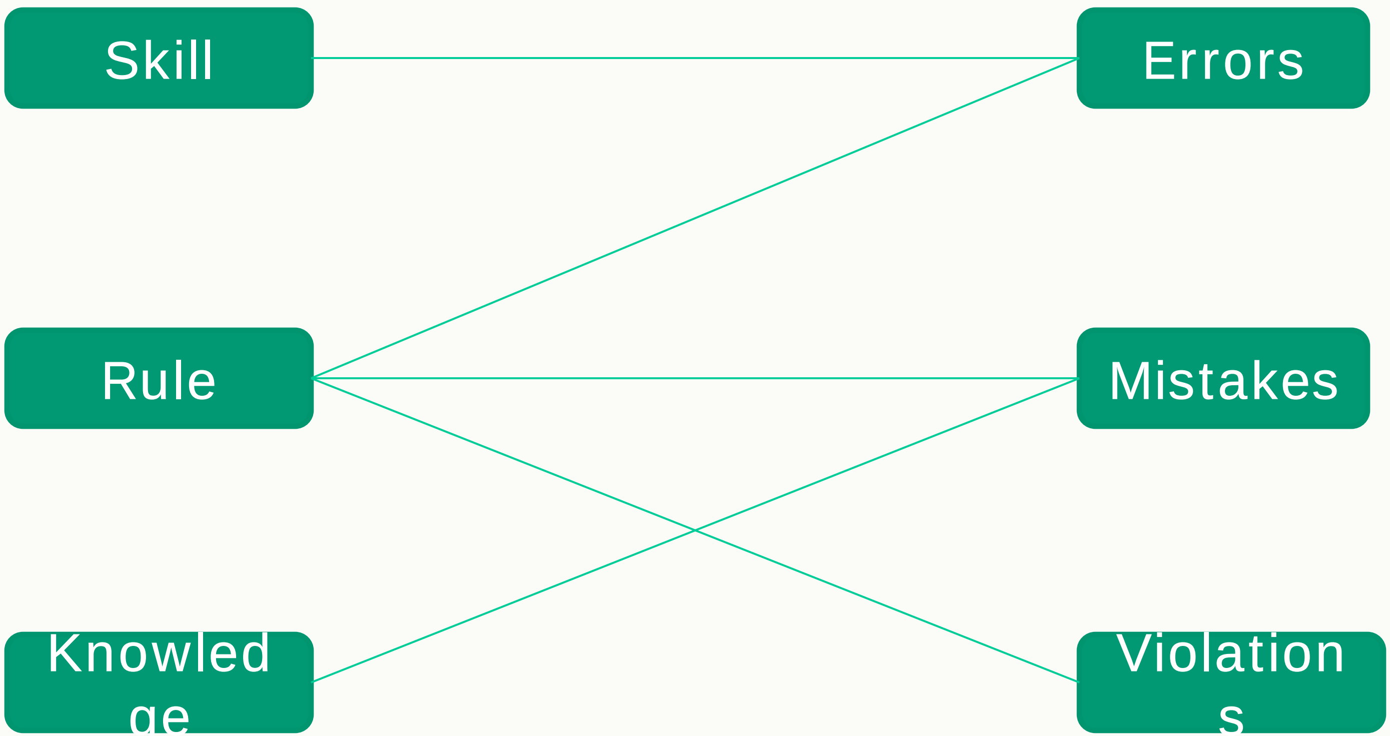
ESTRO school

Human Factors

Mapping Performance Levels to Error Types



Human Factors

Is There Another Way of Classifying Errors?

Sporadic:

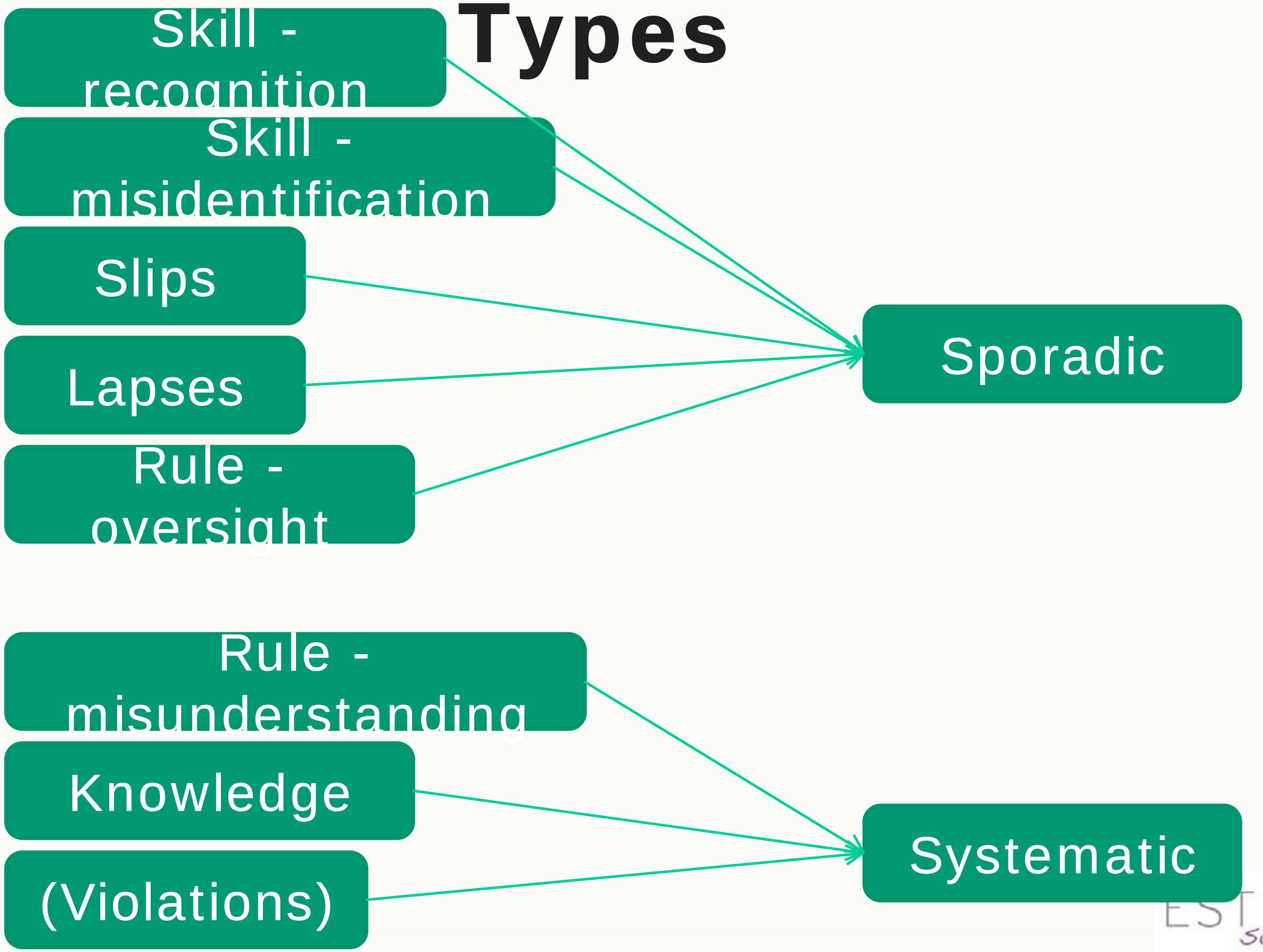
An error that happens once is not likely to occur at the same place in the process again.

Systematic:

The same error will occur under the same set of circumstances

Human Factors

Mapping Error Categories to Error Types



Human Factors

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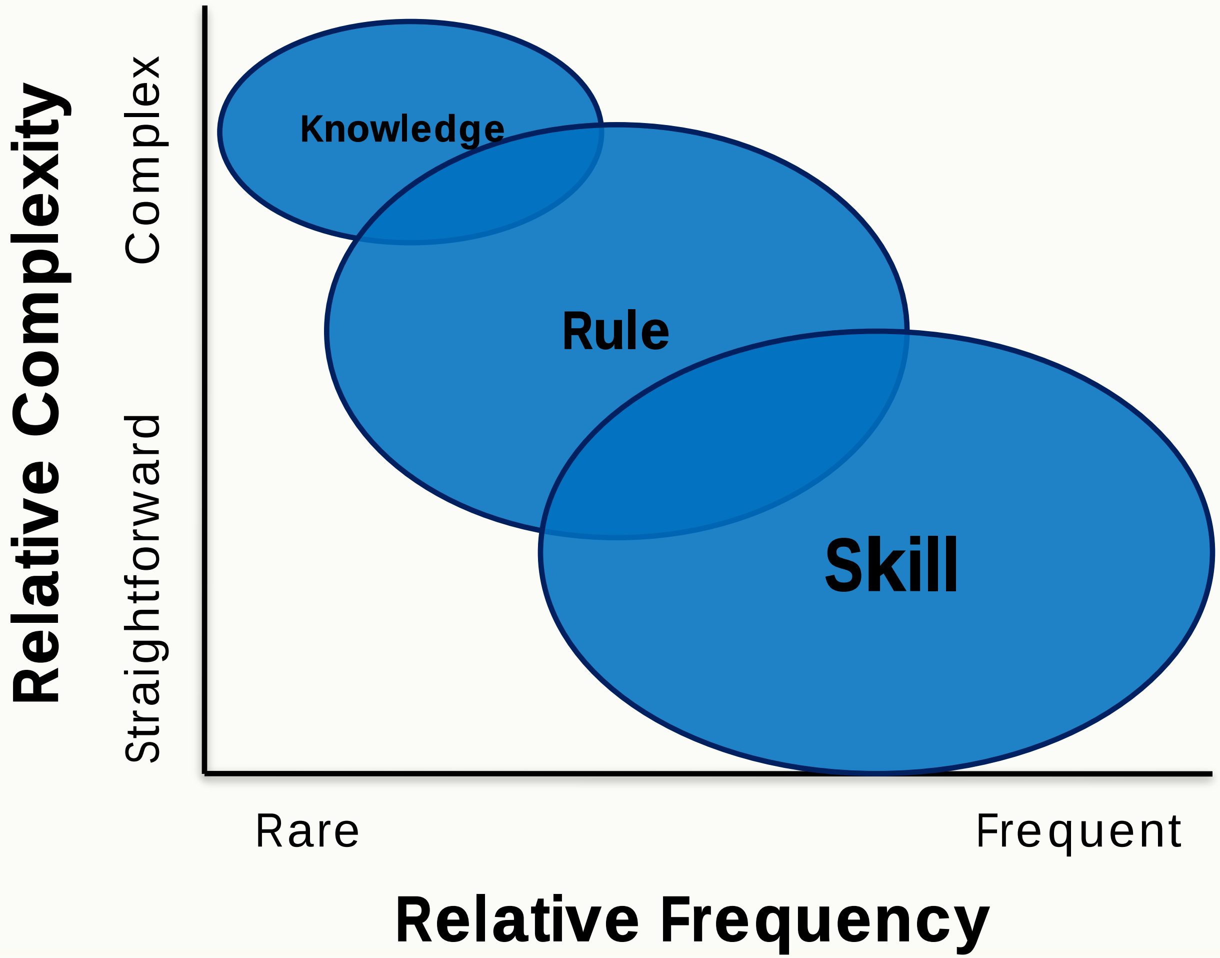
Human Factors

Performance categories



Violations – Preventive Measures

Violations can be routine, thrill seeking or situational.

- Is the rule being violated is really necessary and clearly written?

  If not fix it. If so, reinforce it with the staff.

- Is the violator careless, malicious, irresponsible?

  Invoke a Just Culture

Knowledge–Preventive Measures

Tackling unfamiliar problems:

- Ensure the individual performing the task has the appropriate educational background
- Allow adequate time for literature review and consultation with experts
- Do a Failure Modes and Effects Analysis
- Use independent dosimetry services as appropriate
- Compare results with other facilities

Rules – Preventive Measures

Applying a bad rule or misapplying a good one:

- Review Standard Operating Procedures regularly and in the light of experience.
- Have your program reviewed externally.

Skills – Preventive Measures

Skills are employed in straightforward routine tasks which have been performed for some time. May or may not include checks along the way.

We'll look at three measures:

- Time outs
- No interruption zones
- First date rule
- Checklists

Time-outs

- A Time-out in the context of radiation therapy is a pause immediately prior to the initiation of patient treatment, and at any time that a question or potential discrepancy is noted.
- A Time-out generally consists of
  - Patient identification by two means
  - Identification of the correct treatment site
  - Verification of the treatment parameters (energy, etc)
  - Patient positioning
  - Monitor units

Time-outs

- A Time-out in the context of a linear accelerator calibration might be a pause immediately prior to beam on in order to carefully check all aspects of the set-up.
- A Time-out in this context might consist of a careful check of
  - Geometry
  - Field size
  - Energy
  - MU
- Having the check performed by a second physicist would provide another layer of safety.

No Interruption Zone (NIZ)

- A NIZ could be in space or time
- It allows concentration on the task at hand without distractions
- Hence a NIZ minimizes the probability of slips

Human Factors

No Interruption Zone

- In 1981 the Federal Aviation Authority adopted a policy that prohibits non-essential tasks and communication in the cock pit during flight operations below 10,000 ft (sterile cockpit rule).
- Studies have shown that a NIZ can reduce the probability of medication errors occurring during dispensing pharmaceuticals in an Intensive Care Unit*

*Critical Care Nurse 30 (2010) 21-29

Human Factors

No Interruption Zone

- How many times have you interrupted
  - a therapist about to beam on?
  - a physicist checking a plan?
  - an oncologist contouring a CTV?

No Interruption Zone

- How many times have you interrupted yourself?
- Multitasking might make you look clever but it has the potential to compromise safety.

First Date Rule

Remember what your mother/father told you when you went on your first date?

First Date Rule

Remember what your mother/father told you when you went on your first date?

"If it doesn't feel right don't do it."

Mom (circa 1960)

Human Factors

Intuition

A powerful safety measure

Power Distance Index

The extent to which the less powerful members of groups expect and accept that power is unequally distributed

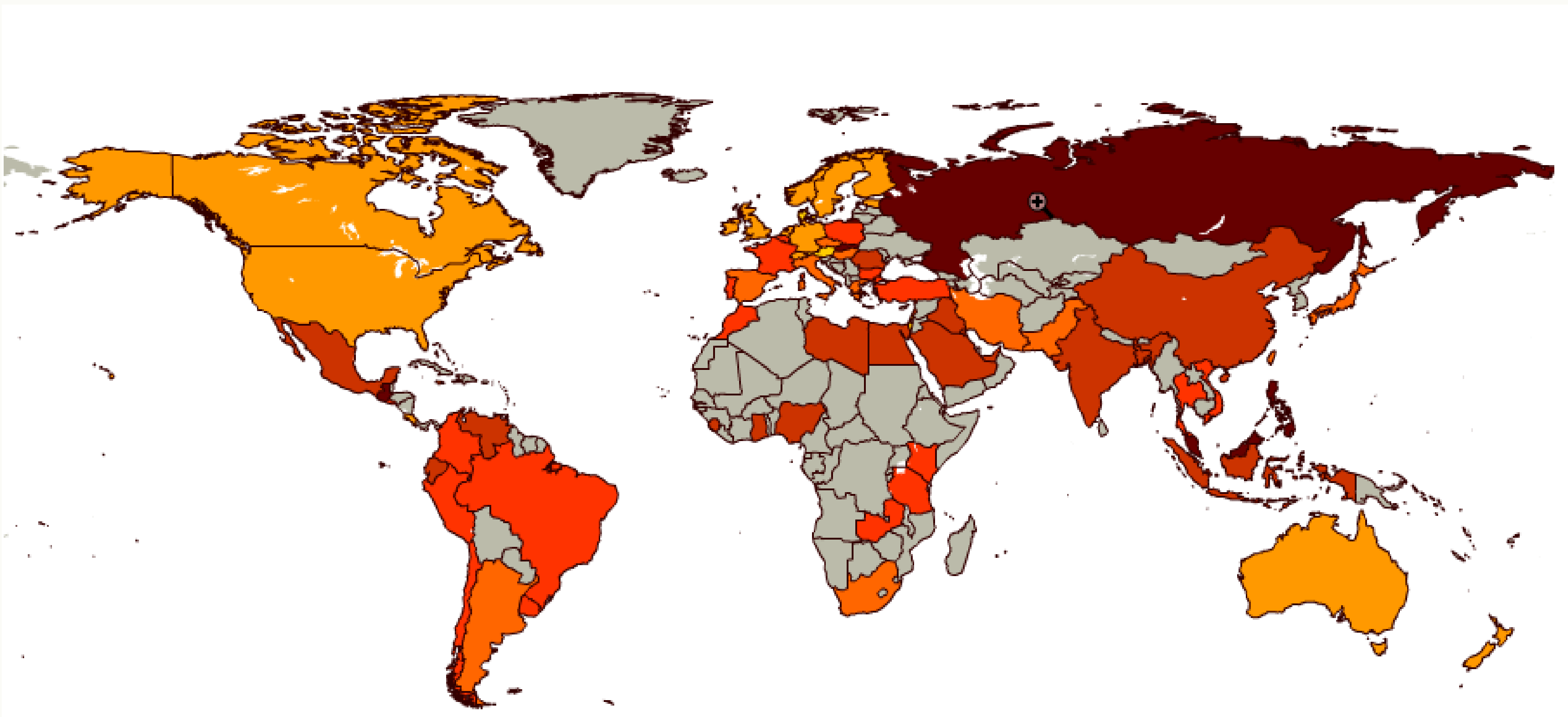
Power Distance Index

A few results:

Country	PDI
Malaysia	104
Salvador	66
Italy	20
Israel	13

Human Factors

Power Distance Index



Human Factors

Power Distance Index

Why is it relevant to safety?

If the environment is such that we are afraid to question our colleagues then errors are more likely to slip through with potentially serious consequences.

ESTRO school

Power Distance Index

- Why is it relevant to safety?
- If the environment is such that we are afraid to question our colleagues then errors are more likely to slip through.
- However, questioning should be:
  - limited to our sphere of knowledge/experience
  - respectful of others

Human Factors

Summary

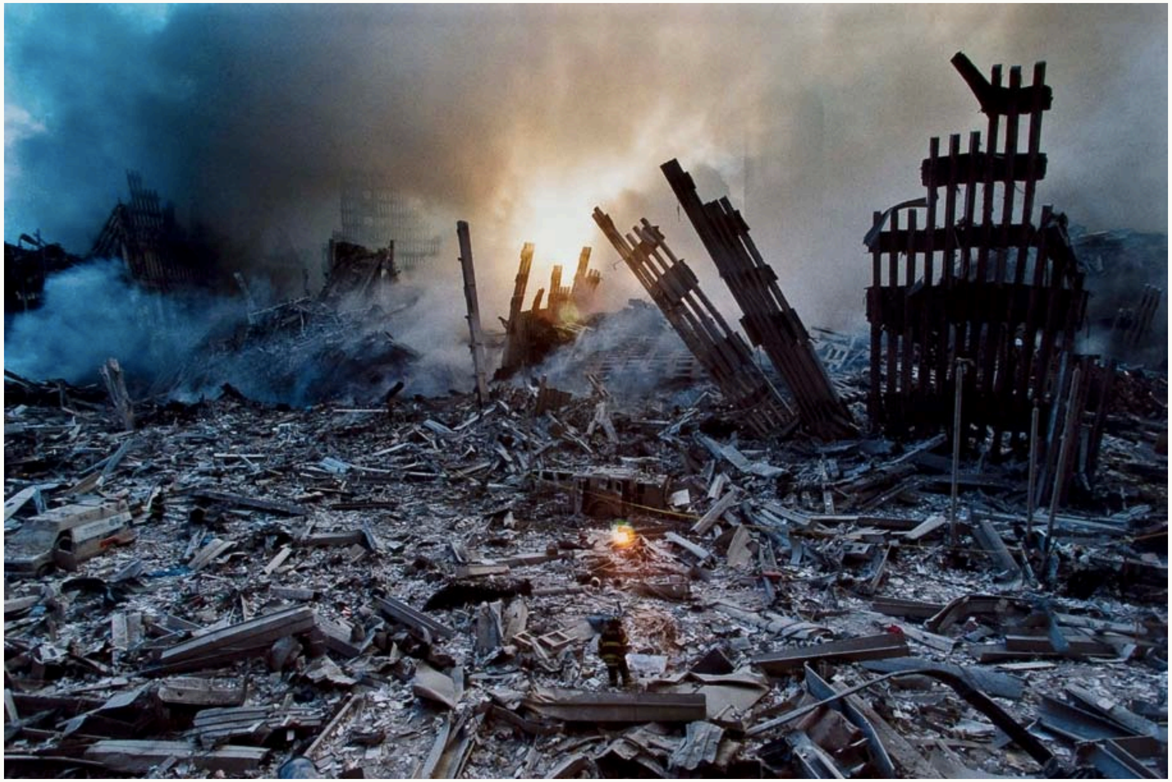
- We have reviewed Rasmussen's categories of human performance.
- We have looked at how performance might be compromised, with clinical examples.
- We have mapped error types on to human performance categories. We have looked at preventive measures for each category
- We have digressed into the Power Distance Index – a Safety Culture issue

A Caution

A Caution

A Caution

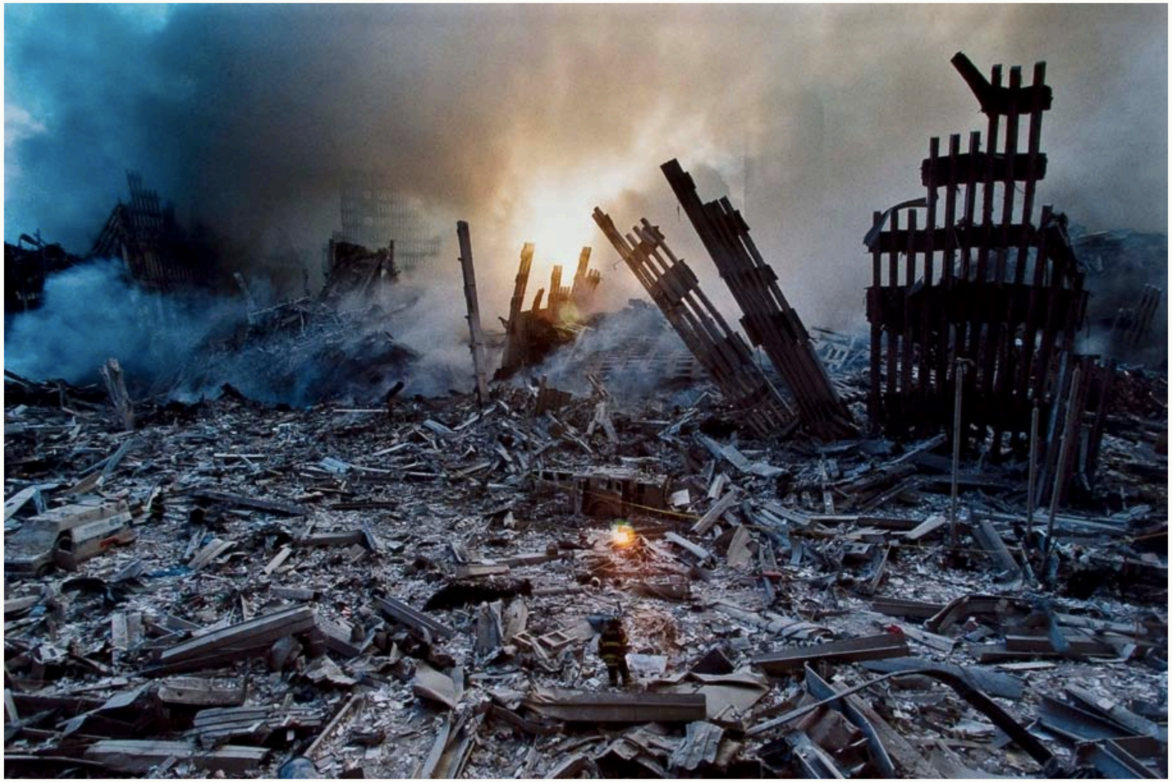
Nobody has forgotten this



11th September 2001

A Caution

One of the Preventive Actions taken



A Caution

was to lock the cockpit door from the inside

ESTRO school

A Caution

Seemed like a good idea. Keep the bad guys out

A Caution

But what if the bad guy is already in the cockpit

Germanwings suicide crash
24th March 2015

ESTRO school

A Caution

There is always a chance your Preventive Actions will make things worse

A Caution

A Caution

Whenever we change a system we should re-examine it for possible Failure Modes that we have inadvertently introduced.

ROLE PLAY

ESTRO – AVIGNON OCT 1-4TH, 2016

A VOLUNTARY

- The minister of Health
- The journalist
- The director of the inst
- The physician in charg
- The physicist responsib
- The Rtt's of the treatm
- A patient
- The patient's husband

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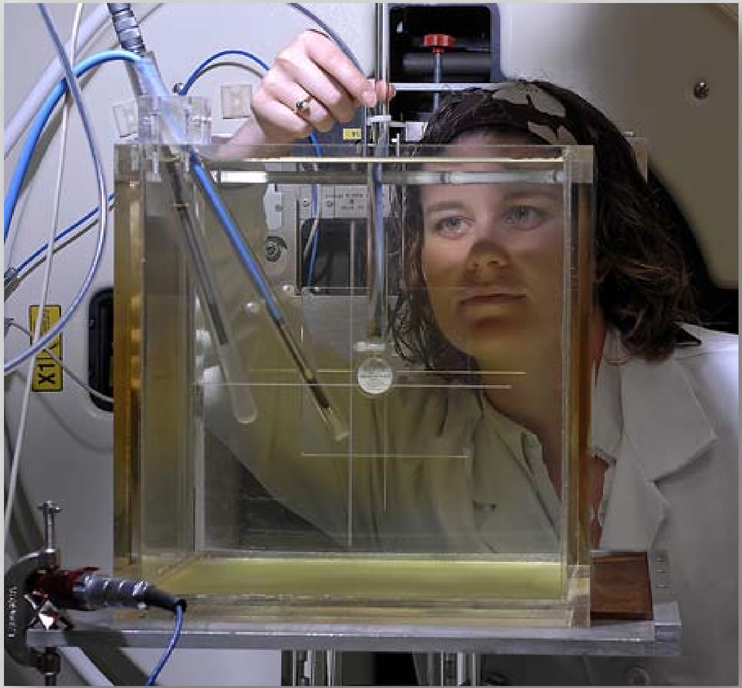

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THE SCENARIO

- An underdosing of 4.5 % has been found at the last maintenance of a linear accelerator. For 4 weeks, the linac has been miscalibrated, and underdosage affects a large number of patients.
- Although the reporting threshold is 5 %, the information leaks and all the stakeholders try to react in a professional way.
- But a journalist is there…
- Everybody is allowed to speak to everybody, this is a TV show with direct broadcast.