

ICRP

Accident prevention in to-day clinical radiation therapy practice

ICRP Symposium on the International
System of Radiological Protection

ICRP
SYMPOSIUM
October 24-26
2011

October 24-26, 2011 – Bethesda, MD, USA

Mario R Baeza MD
ICRP Committee 3

Accident prevention in to-day clinical radiation therapy practice

- “radiotherapy is seen as a mysterious procedure by patients and the public alike....
-there is an air of mystery that adds to the perception of danger.”

MV Williams; BJR 80:297, 2007

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- “Although radiotherapy is perceived as risky and complex, the risk of mild to moderate injurious outcome to patients from radiotherapy errors was about 1,500 per million treatment courses that were much lower than hospital admission rates for a adverse drug reaction in Canada and US (about 65,000 per million admissions).”

Munro AJ et al BJR 80:955, 2007

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- A radiotherapy error has been defined as “a non-conformance where there is an unintended divergence between a radiotherapy treatment delivered or a radiotherapy process followed and that defined as correct by local protocol”

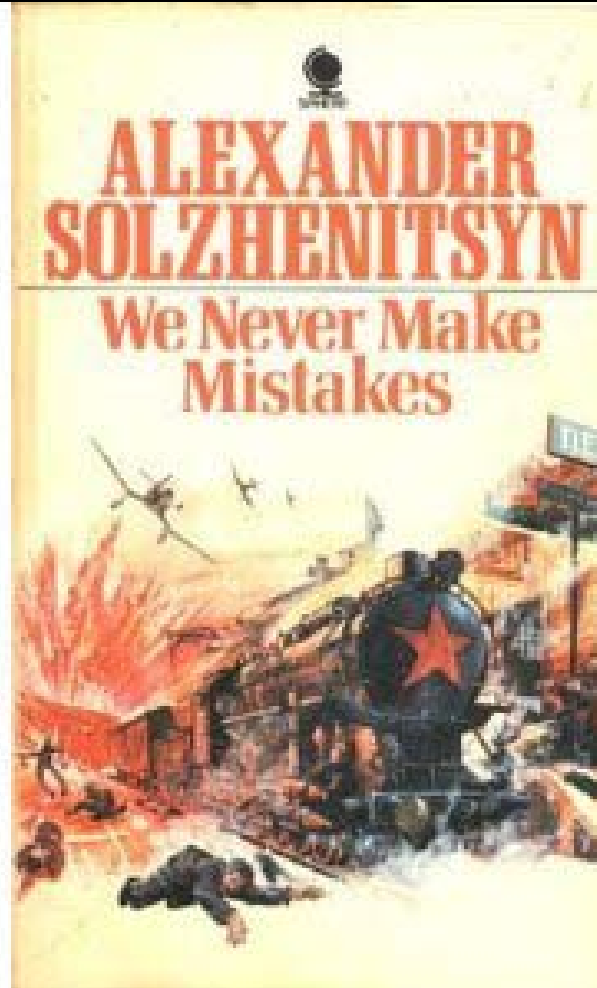
MV Williams, TL Frew, IJROBP 79:1601, 2011

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“safety generally relates to preventing errors (frankly right versus wrong decisions and actions) that can have major therapeutic implications (eg. Treatment of the wrong patient, treatment with the wrong plan, incorrect placement of a block or wedge, failure to correctly transfer electronic data between the various computer systems).”

BA Fraas et al, PRO 1:188, 2011

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Accident prevention in to-day clinical radiation therapy practice

- “A routine course of radiation therapy has some 270 separate nodes of potential error.”

Ford EC et al, IJROBP 74: 852, 2009

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- “nearly 50% of cancer patients undergo radiotherapy, with figures estimating that roughly one in 500 experiences an error, most of which are likely to be clinically insignificant....
- These error rates do not compare favorably to other ultrasafe industries such as commercial aviation or nuclear power generation....”

Health imaging.com, July 2011

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- “a major limitation in this comparison is the severity of the incidents. The airline accidents rate quoted here is for serious injury or death, whereas the overwhelming majority of radiation delivery errors often have much less severe consequences”

Ford EC, Terezakis S, IJROBP 78:321, 2010

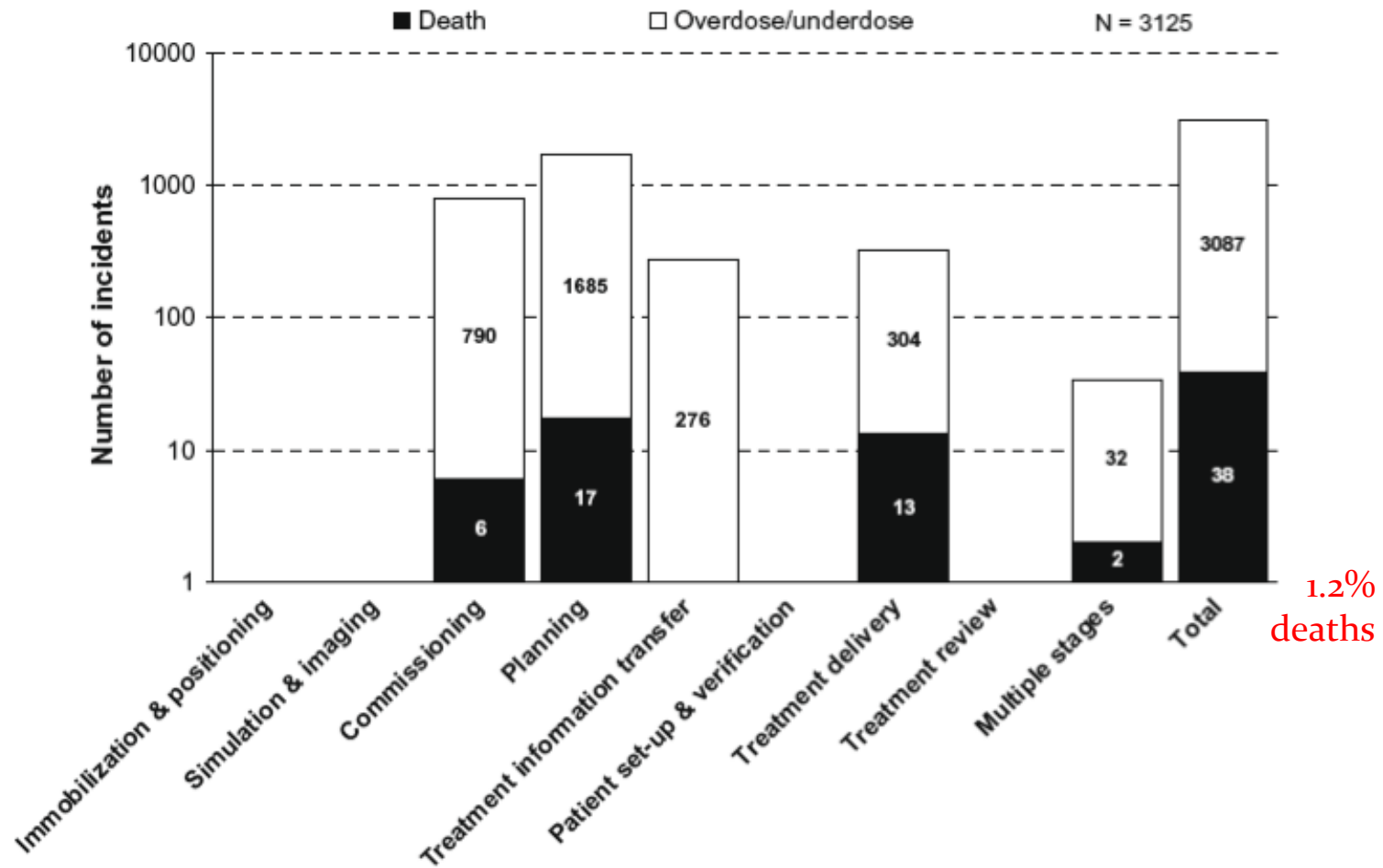


Fig. 2. Radiotherapy incidents with adverse patient outcomes (1976–2007) by stage of treatment.

J. Shafiq et al. / Radiotherapy and Oncology 92 (2009) 15–21

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- The risk of death arising directly from maladministration of radiotherapy was estimated at 2 per million courses in the UK (Munro AJ BJR 80:955, 2007)
- The risk of an airplane crash is about 4 per million departures
(Baker SP et al Aviation, Space and Environmental Medicine 80:381, 2009)

MV Williams, TL Frew, IJROBP 79:1601, 2011

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Radiotherapy and airplane safety:

- “A correction for the number of passengers would increase the risk to 40-400 crashes per million passenger flights.”

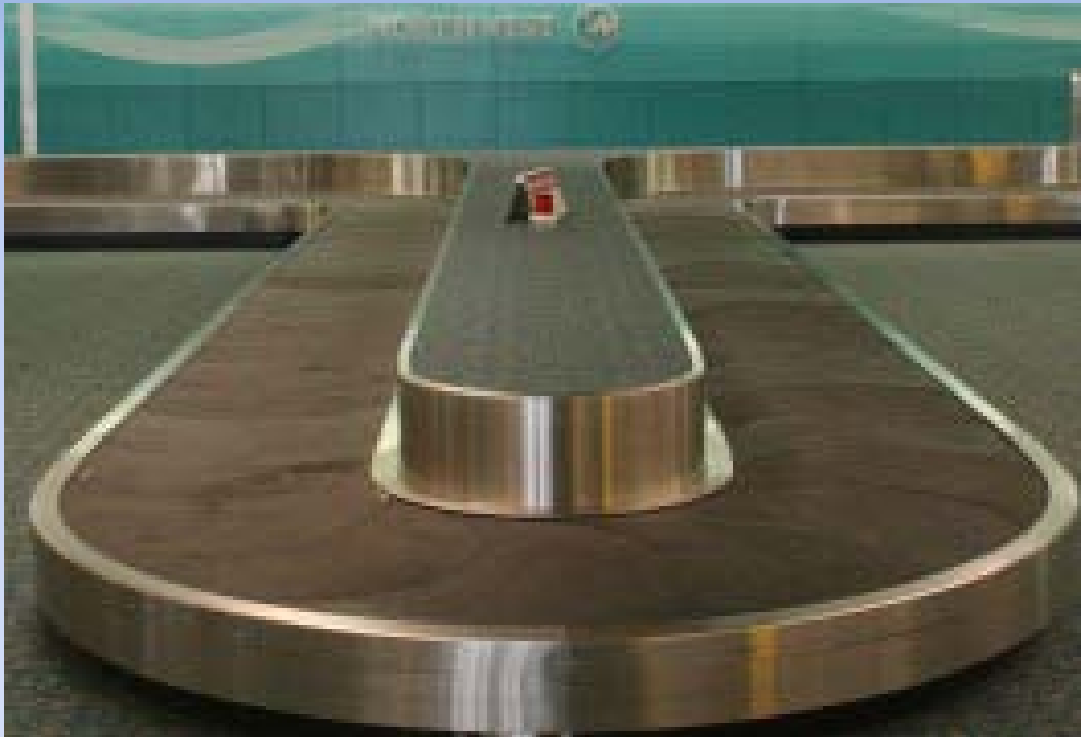
MV Williams, TL Frew, IJROBP 79:1601, 2011

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- “radiotherapy errors considered moderate or minor are common; however, so are problems with commercial flights, including poor catering, lost baggage, delayed departure, cancellation, delayed arrival, and landing at the wrong airport.”

MV Williams, TL Frew, IJROBP 79:1601, 2011

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Air travel safer than Radiotherapy???

CNNMoney
A Service of CNN, Fortune & Money

FORTUNE ▾

Money ▾

Home

Video

Business News

Markets

Term Sheet

Economy

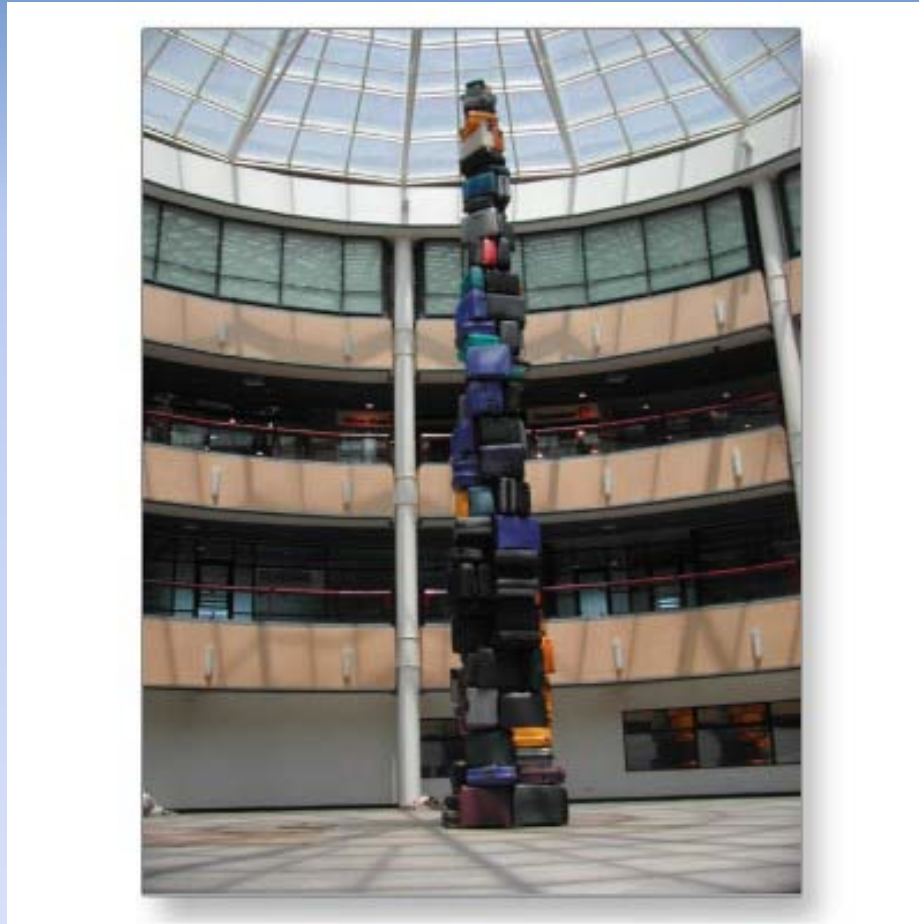
Tech

Personal Finance

Grumbling grows among airline passengers

Government report shows nearly 10,000 lost bags a day, increase in arrival delays.

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ART
at Santiago's
airport

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Radiotherapy and airplane safety:

- Airline safety has been compared with radiotherapy safety, but when a plane falls the pilot dies together with the passengers, when a patient is injured, the radiation oncologists is not.....

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- The radiation oncologist faces a different kind of risk....

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We have new definitions: Radiation Tolerance

- The maximum dose tolerated by the patient's lawyers?

N James, S A Hussain, Semin Radiat Oncol 15:19, 2005

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-so, the radiation oncologist faces a different kind of risk....
- and it is probably it is that risk that makes more difficult the reporting of accidents.....

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- Some history
- New developments
- Old problems
- Some solutions
- The actual problem
- A new culture

Accident prevention in to-day clinical radiation therapy practice

-60% of all cancer cases would require radiotherapy in some phase of their treatment.....
- If by 1980, 50% of all new cancer cases were diagnosed in developing countries, by 2000 this figure rose to 55% and it has been estimated that it will reach **70%** by 2020
- Around **85%** of the world's population lives in developing countries, but is served by only approximately **30%** of the world's radiotherapy facilities.

IAEA Human Health Reports No3, inequity in cancer care, 2011

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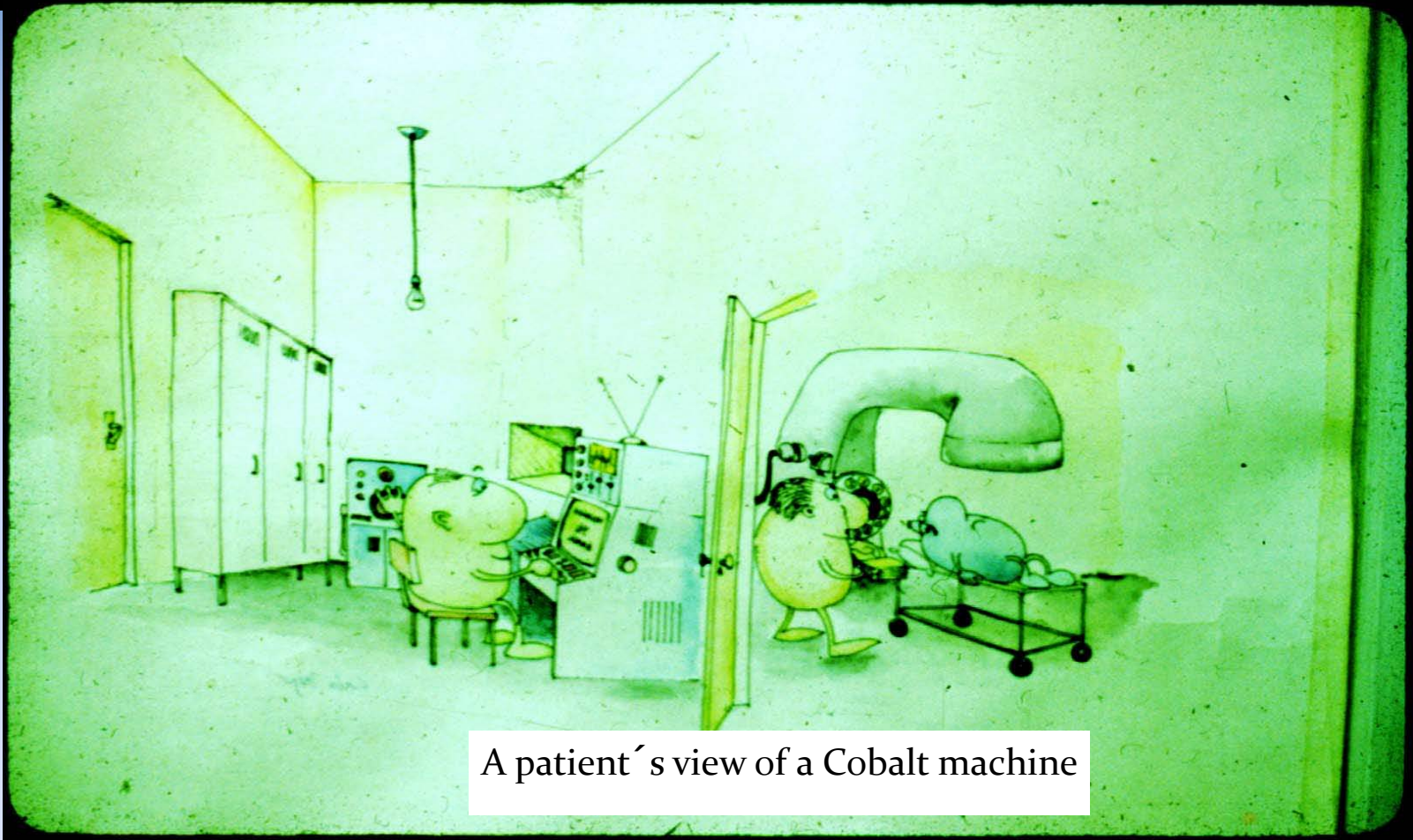
- The most serious problem in developing countries is the severe limitation of treatment capacity.
- In developing countries it is often difficult to maintain equipment and obtain spare parts

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- “The basic treatment machine for radiotherapy in developing countries should be the cobalt unit”
- (regarding accelerators) “Expert personnel must be available....more staff are needed than for a cobalt unit”

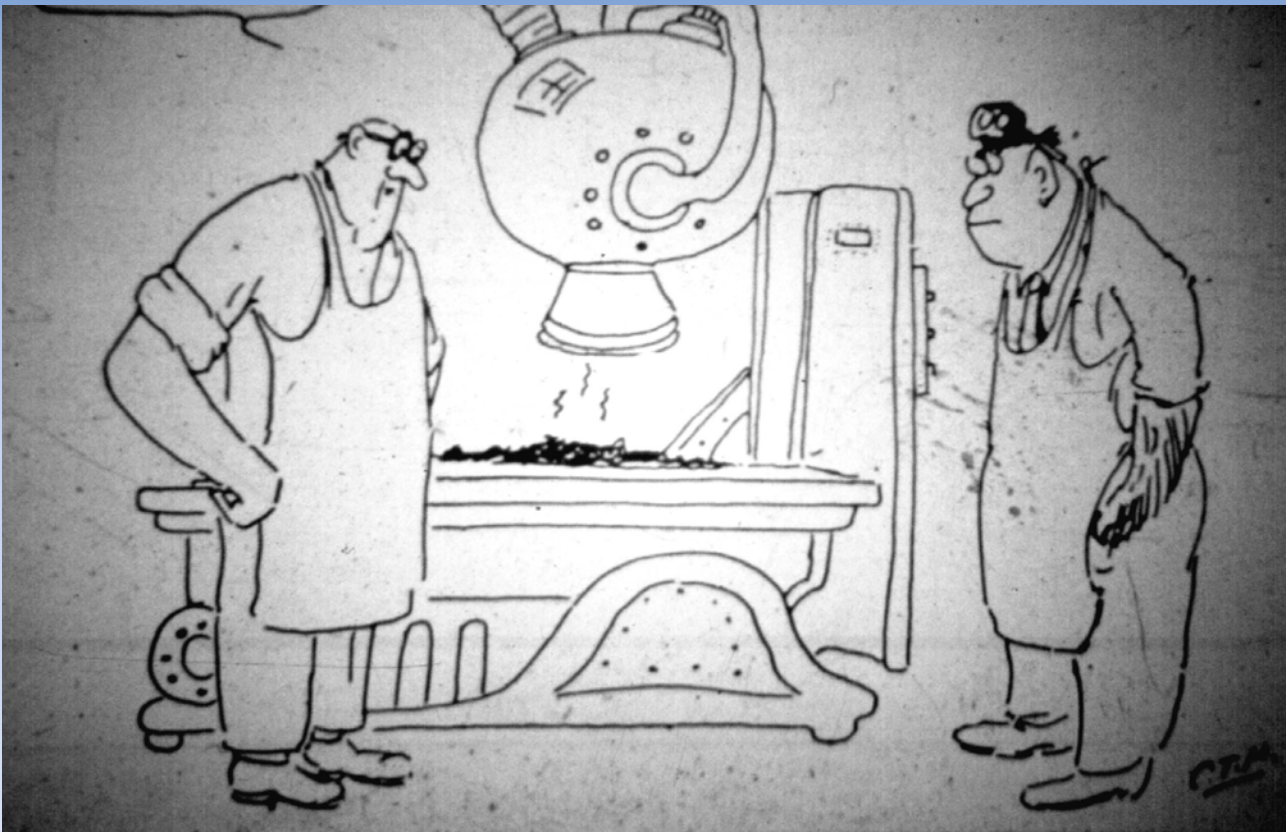
Optimization of radiotherapy, Technical report series 644, WHO. **1980**

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A patient's view of a Cobalt machine

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In the old
times
overdoses
were easy to
detect

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Largest errors are likely to occur in....

- “uncertainties in anatomical information, including the location, size, and shape of the tumor and the assessment of its response to treatment”
- Inaccuracies in target volume definition and correction and compensation procedures;
- Inaccuracies in positioning the patient and in delivering the radiation dose”

It seems that problems in 1980 are similar to those in 2011

Optimization of Radiotherapy, Technical report series 644, WHO.

1980

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- Some history
- New developments **IMAGES**
- Old problems
- Some solutions
- The actual problem
- A new culture

Mistakes/accidents in
treatment delivery

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s.elsevierhealth.com/pdfs/journals/0167-8140/PIIS0167814007005555.pdf

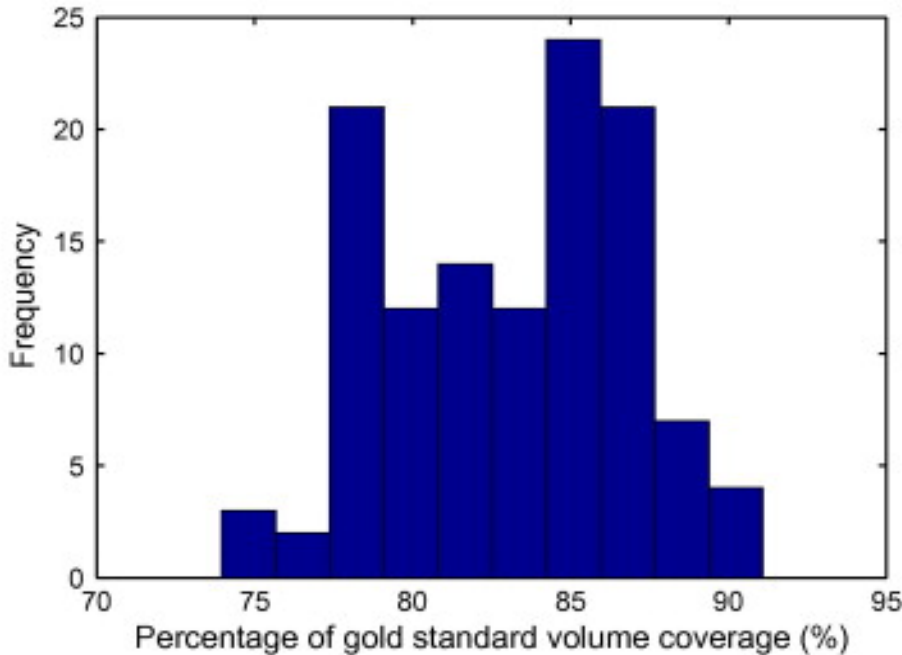
112% Find

Radiotherapy and Oncology 85 (2007) 173–175
www.thegreenjournal.com

Editorial

Now you see it. . . Imaging in radiotherapy treatment planning

virtual simulation, Prostate



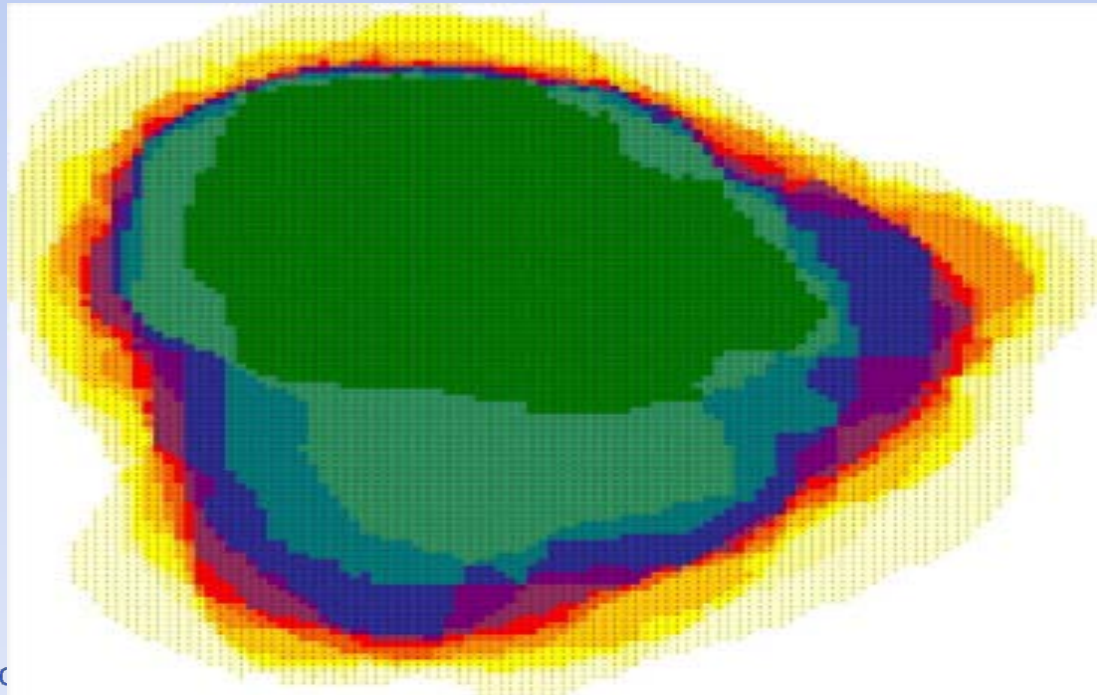
A group of 3 experts choose a Gold Standard volume
Six radiation-oncologists delineated the prostate 20 times three days apart on a CT image.
The volume delineated was larger than the GS
None of them included the whole prostate in a single session.
The delineation fluctuated between a minimum of 79% and a maximum of 91% of the prostate

Z Gao et al, R&O 85:239, 2007⁷

Radiotherapy in lung cancer: advances

Baumann M et al R&O 91:279, 2009

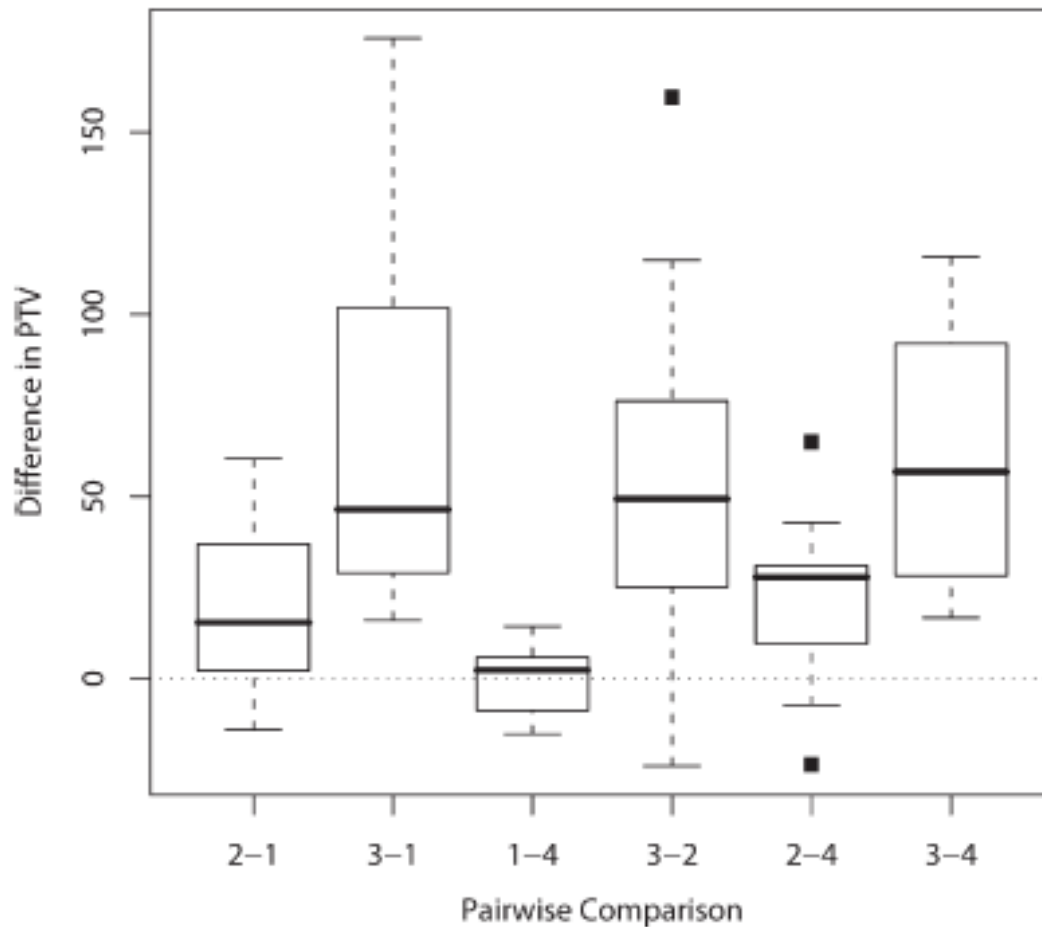
- **The delineation of the treatment volume is highly variable from observer to observer** (Vorwerk H et al, R&O 91:455, 2009)



Where is the tumor?

CLINIC

*Jo
Bosi



Breast

Ph.D. in
Radiation
Physics

D.,[§]
M.D.,[§]
S., M.D.[§]

Women's Hospital,
Gynecology and [§]Radiation
Oncology

- **So...With new technologies
we have new problems.....**

Now you see it...

- **“Target volume delineation is recognized to be one of the most significant geometric uncertainties in the radiotherapy process”**

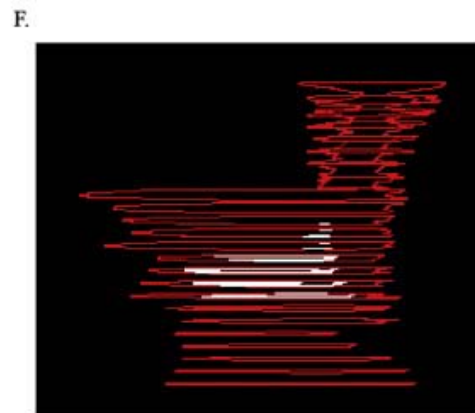
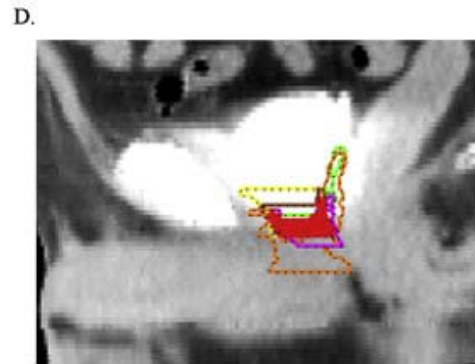
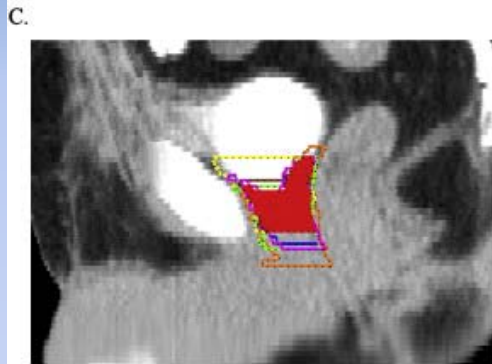
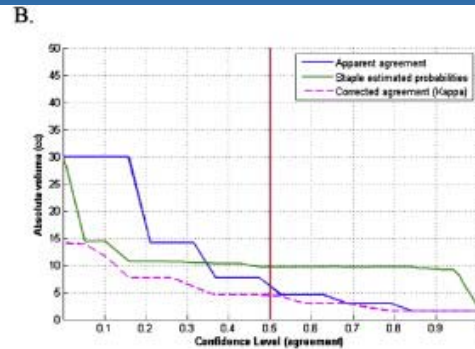
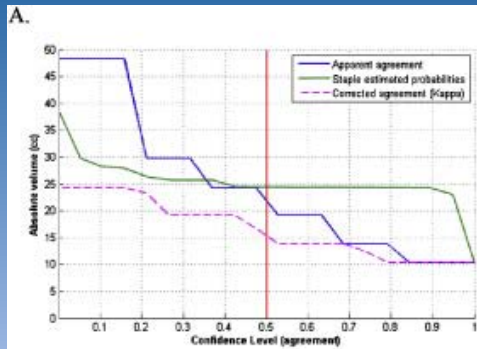
DR Olsen, DI Thwaites R&O 85:173, 2007

New technologies

- “ The imaging revolution in radiotherapy has many potential consequences for enhancing training and the need for

We need to learn how to recognize structures, i.e.: to know what we are seeing

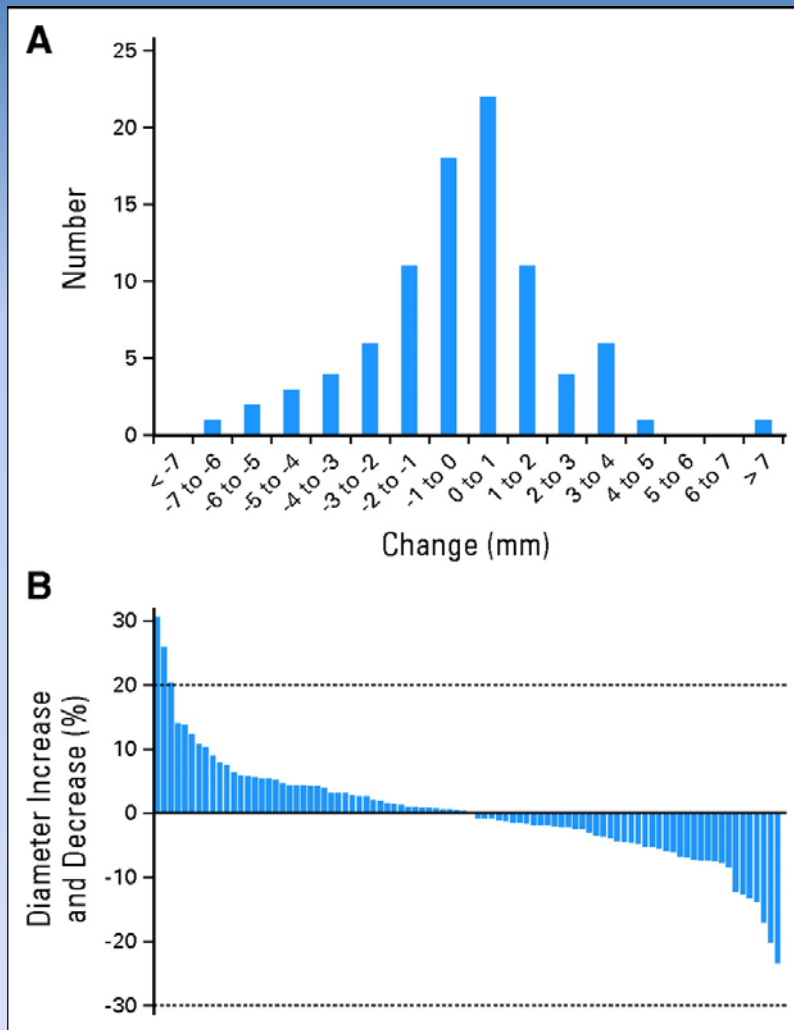
DR Olsen, DI Thwaites R&O 85:173, 2007



Ost et al, IJROBP
 81:e143, Nov 1, 2011
 Delineation of post prostatectomy
 bed following EORTC guidelines

Agreement: “moderate”
 (kappa value 50%)

(A) Distribution of measurement changes found on repeat computed tomography scans performed within 15 minutes of each other, in millimeters; there was a greater than 1-mm magnitude of change in the majority of lesions (57%).



Oxnard G R et al. JCO 2011;29:3114-3119

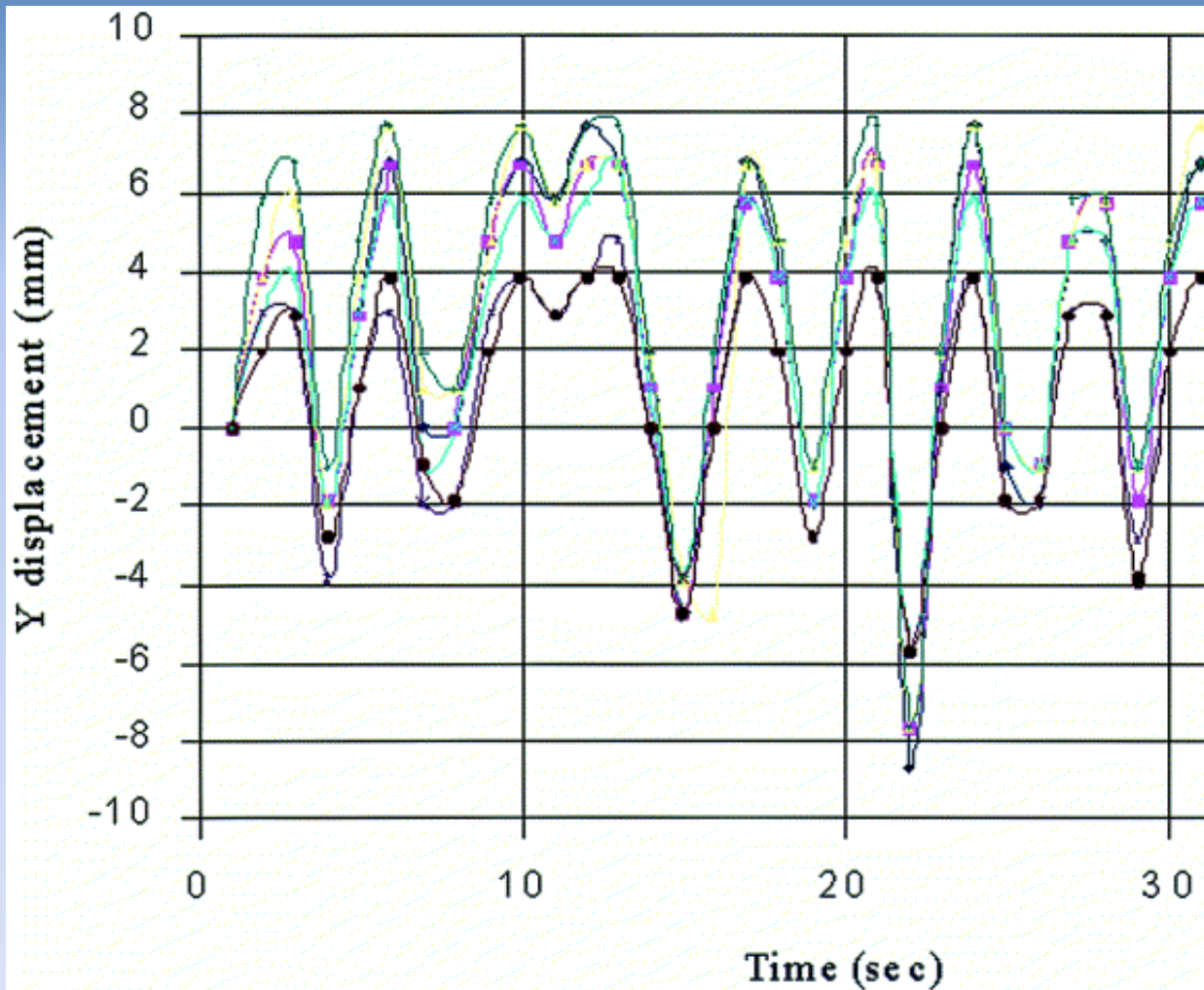
New technologies

we also have the problem of “the moving targets”

(the patients besides breathing, swallow, their heart beats etc , in summary they are alive)

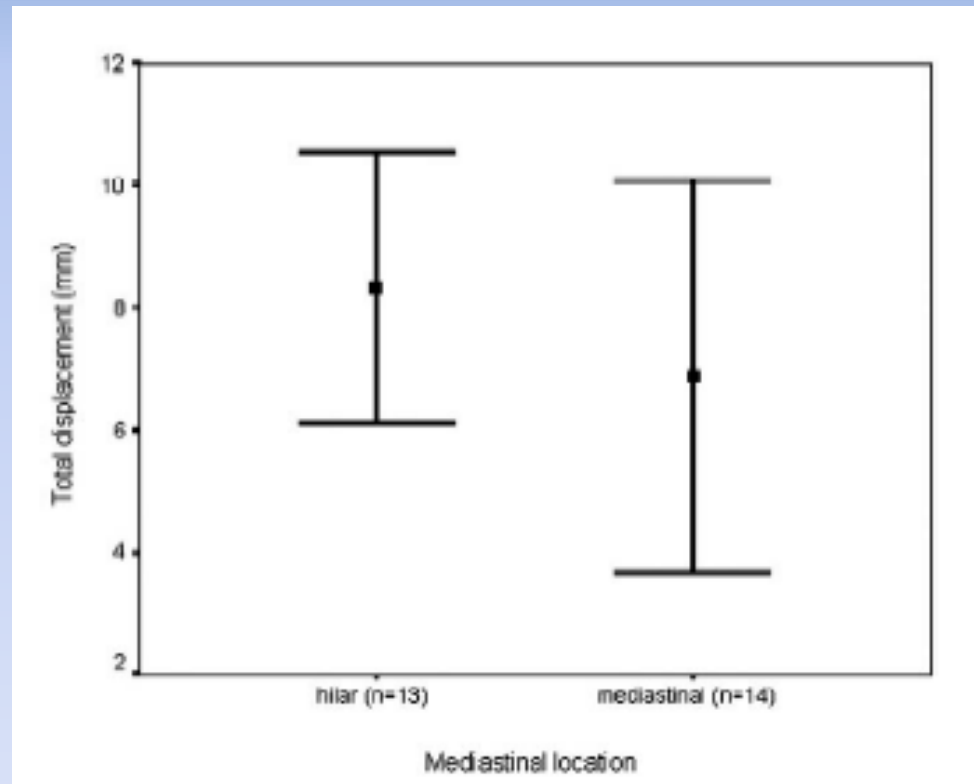
Movement of the pancreas while breathing.

H Suit, IJROBP 53:798, 2002.



Lymph node movement while breathing.

P Jenkins et al, IJROBP 61:329, 2005



New technologies

Then...

- **IMRT without IGRT means that IGWT**

(Intensity **M**odulated **R**adio **T**herapy without Image **G**uided **R**adio**T**herapy means that In **G**od **W**e **T**rust)

* RJ Schulz, AR Kagan. Med Phys 30:276, 2003

Accident prevention in to-day clinical radiation therapy practice

- Some history
- New developments
- Old problems?
- Some solutions
- The actual problem
- A new culture

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...if you can't see it...you can't hit it...

...if you can't hit it...you can't cure it...

William E Powers, MD

Accident prevention in to-day clinical radiation therapy practice

The more
radioresistent tumor
is the one which is not
irradiated

New technologies

- “The image has many potential for enhancing ed for

We need to learn how to recognize structures, i.e.: to know what we are seeing

So...we need more
EDUCATION AND TRAINING

DR Olsen, DI Thwaites R&O 85:173, 2007

Accident prevention in to-day clinical radiation therapy practice

- The new technologies of high dose rate brachytherapy, “gamma knife” therapy units, multi-leaf collimators, and intensity modulated radiotherapy (IMRT) may produce new types of accidental exposure”

J-M Cosset, ICRP 112

Accident prevention in to-day clinical radiation therapy practice

- “...new types of accidents have been encountered due to: the complexity of the present treatment preparations; the increased sophistication of the whole treatment process (with an increasing number of steps and more people involved); the omnipresence of computers with frequent and regular upgrading of more and more complicated software; and the difficulty of regularly and correctly training all the physicians, physicists, dosimetrists, engineers etc. Involved in a busy radiotherapy unit”

J-M Cosset, ICRP 112

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- “To err is human, to really foul things up you need a computer”

Accident prevention in to-day clinical radiation therapy practice

- Some history
- New developments
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- **Some solutions**
- The actual problem
- A new culture

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- “the advances come at high a cost, and this is by no means limited to the initial investment of buying the latest tool. The cost also includes the education; the knowledge transfer and the time needed to train practitioners in the use of the new technology....”

EDUCATION

A Beziak, JCO 29:2295, 2011

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- “The decision to implement a new technology for radiation therapy should be based on a thorough evaluation of the expected benefits, rather than being driven by the technology itself”

ICRP 112

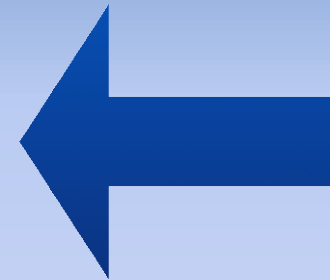
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And thus the whirligig of time brings in his revenges
William Shakespeare

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(that is a whirligig)

We've Got a Treatment, but What's the Disease?

or

A Brief History of Hypofractionation and its Relationship to Stereotactic Radiosurgery

DAVID I. ROSENTHAL, ELI GLATSTEIN

Department of Radiation Oncology, Harold C. Simmons Comprehensive Cancer Center, University of Texas,
Southwestern Medical Center at Dallas, Dallas, Texas, USA

Key Words. *Stereotactic radiosurgery · Fractionation · Brain tumors · Malignancy · Gamma knife · Linear accelerator*

The Impact of new technologies in Radiotherapy

- **“...no evidence of superiority has yet been shown for the advanced technologies in prospective randomized trials”**

New technologies

- **“Even the vendors need to recognize that the only thing that has improved survival in prospective, randomized clinical trials over the past 3 decades is combined modality treatment”**

E Glatstein, IJROBP 76:1283, 2010

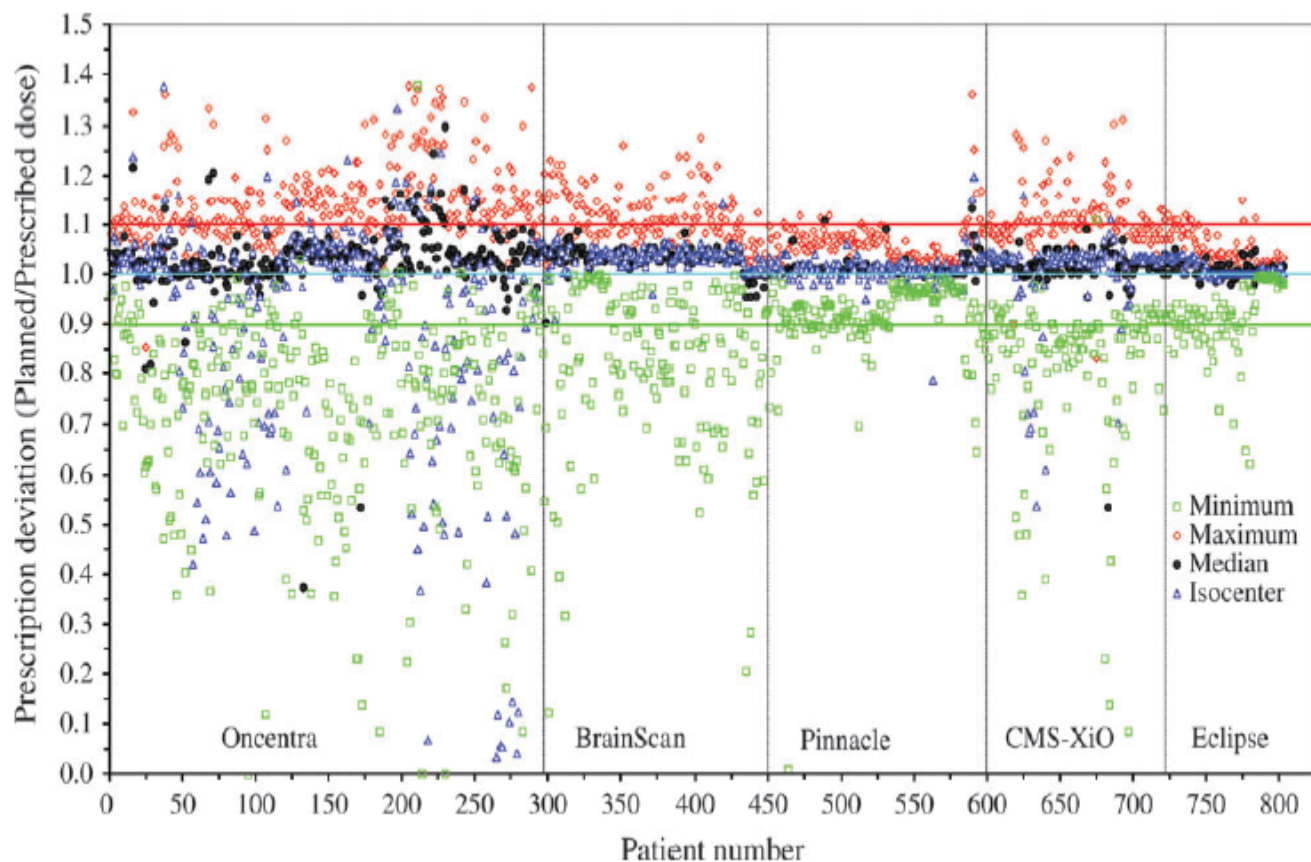
ARTICLE

J Natl Cancer Inst 2008;100: 300 – 307

Intensity-Modulated Radiation Therapy Dose Prescription, Recording, and Delivery: Patterns of Variability Among Institutions and Treatment Planning Systems

Indra J. Das, Chee-Wai Cheng, Kashmiri L. Chopra, Raj K. Mitra, Shiv P. Srivastava, Eli Glatstein

Figure 1. Dosimetric variations between the prescribed and planned doses among 803 patients from five medical institutions with different treatment planning systems. **Vertical lines** separate the data according to treatment planning system (from left to right: Oncentra, BrainScan, Pinnacle, CMS-XiO, Eclipse). The **horizontal line** at 1.0 represents no dose deviation; the **horizontal lines** at 1.1 and 0.9 represent dose deviations of +10% and -10%, respectively, between the planned dose and the prescribed dose.



J Natl Cancer Inst 2008;100: 300 – 307

Contribution

In IMRT, the prescribed dose rarely corresponded to the planned, or delivered, dose. At all five institutions, dosimetric variation was smallest for the prostate cancer cases and largest for the head and neck cancer cases. The recorded delivered dose varied from the prescribed dose for all disease sites and treatment planning systems.

J Natl Cancer Inst 2008;100: 300 – 307

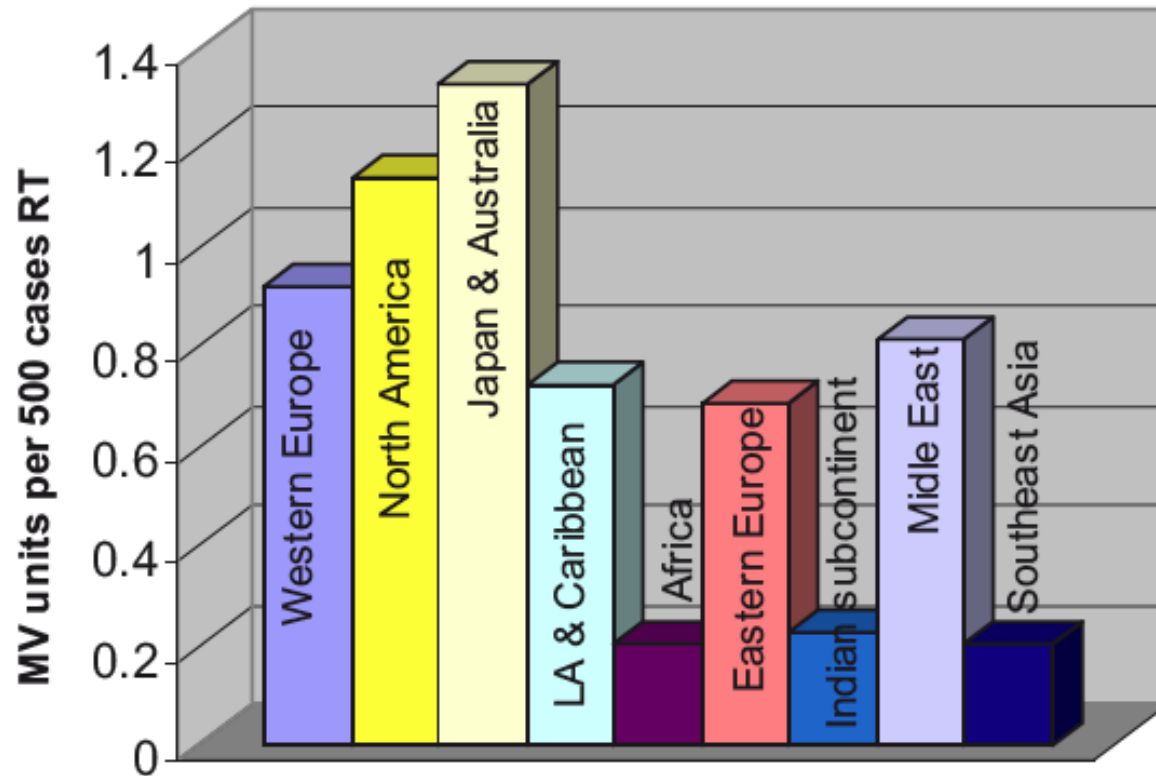
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JNCI 10 May 2011

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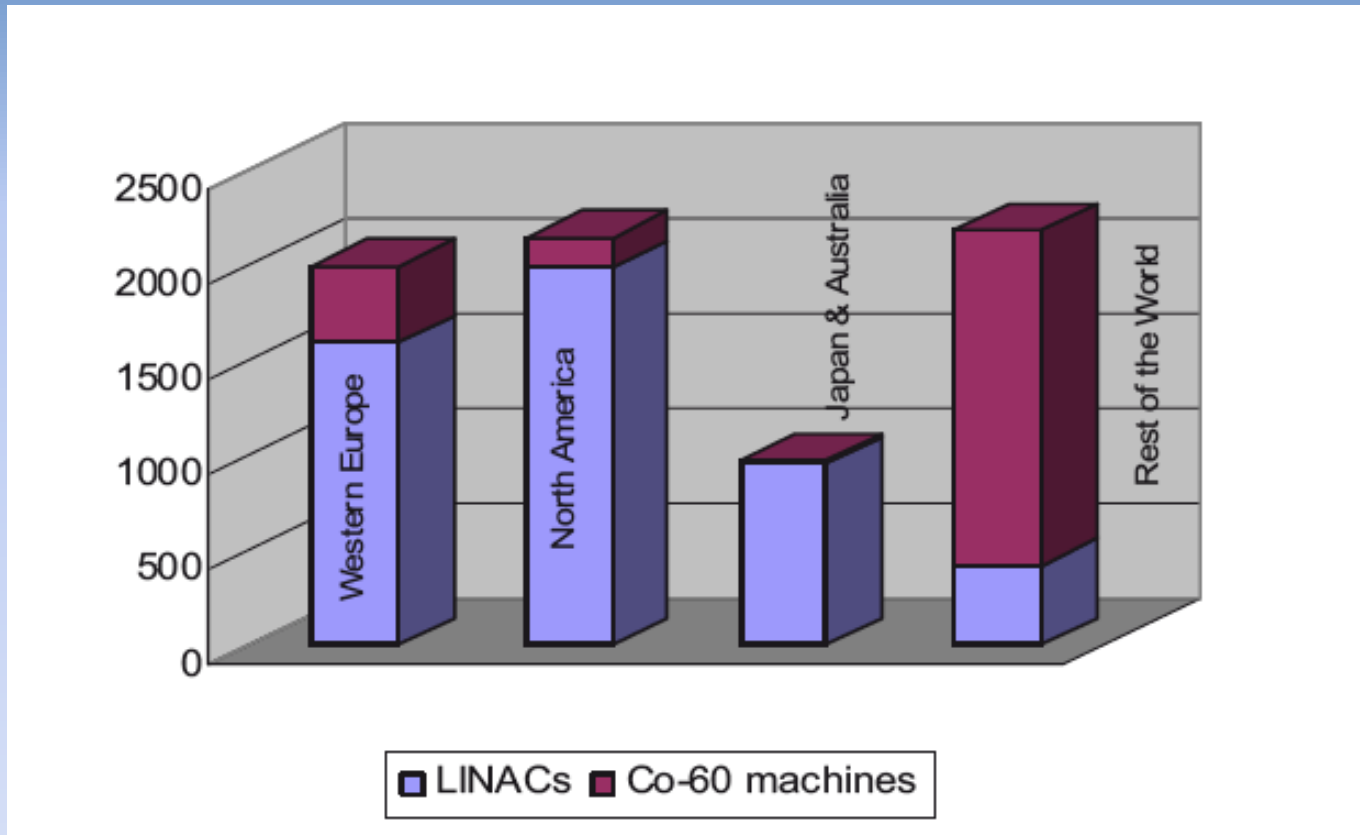
- Some numbers

MV units and cases



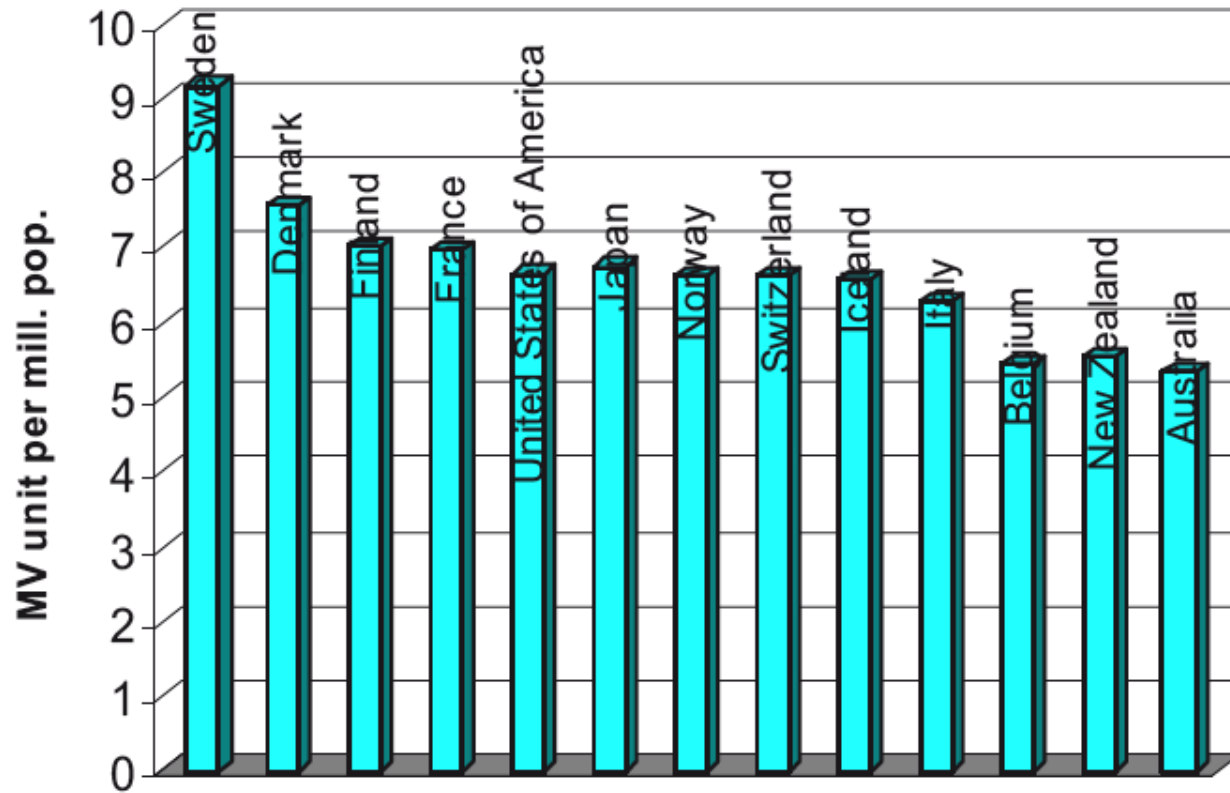
IAEA Human Health Reports No3, inequity in cancer care, 2011

equipment distribution



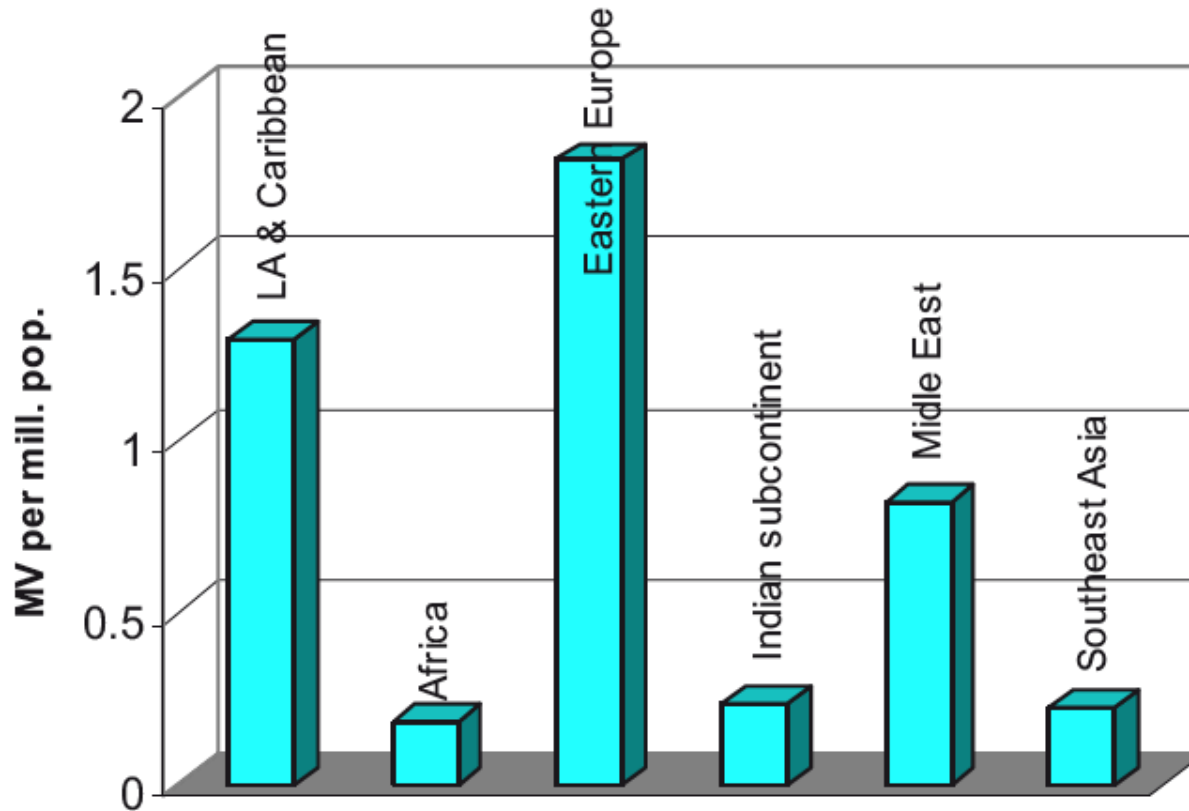
IAEA Human Health Reports No3, inequity in cancer care, 2011

MV units in wealthy countries



IAEA Human Health Reports No3, inequity in cancer care, 2011

MV units, rest of the world



IAEA Human Health Reports No3, inequity in cancer care, 2011

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Recommendations regarding the number of patients treated per machine per year:

- 365-507 (Optimization of Radiotherapy, Technical report series 644, WHO. 1980)
- 300 (NCI/NIH, Blue Book, 1981)
- 400-450 (increasing complexity, IAEA, Human Health Report 14, 2010)

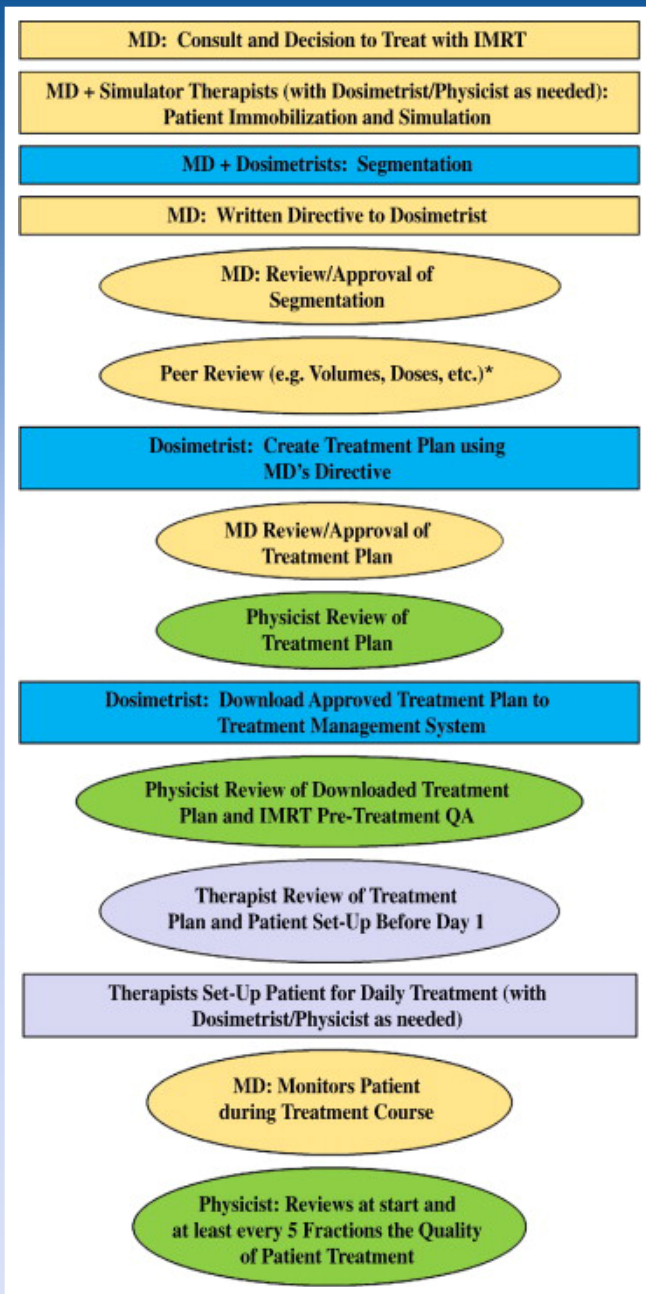
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Accident prevention in to-day clinical radiation therapy practice

- “.....reliance on common sense is no longer feasible in IMRT”

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ASTRO white paper on IMRT,
 JM Moran et al
 Practical Radiation Oncology
 (2011) 1, 190–195

Accident prevention in to-day clinical radiation therapy practice

- “IMRT is time and resource intensive..... Timely treatment is important, but undue pressure and real-time changes to the treatment plan can lead to errors”

PRO 1: 190, 2011

Accident prevention in to-day clinical radiation therapy practice

- “new technologies are meant to bring substantial improvement to radiation therapy. However, this is often achieved with a considerable increase in complexity, which in turn brings opportunities for new types of human error and problems with equipment. **Dissemination of information on these errors or mistakes as soon as it becomes available is crucial in radiation therapy with new technologies”**

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AMERICAN SOCIETY FOR RADIATION ONCOLOGY
2010 YEAR IN REVIEW

TARGET SAFELY

ASTRO

TARGETING CANCER CARE



INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

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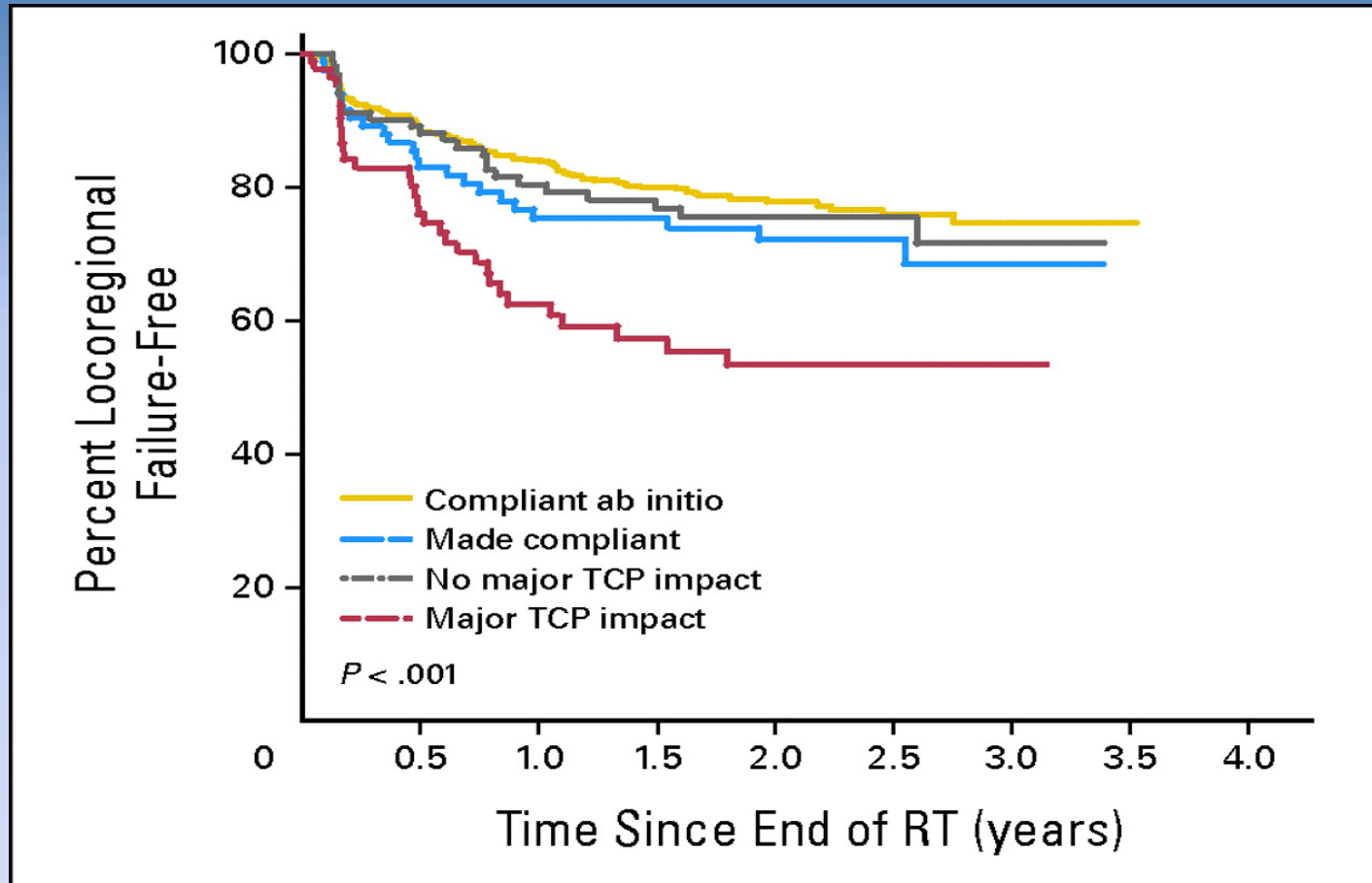
(but ... there is a remarkable absence of reports from developing countries)

Accident prevention in to-day clinical radiation therapy practice



**New Technologies
are wonderful,
but... what about
quality control?**

Time to locoregional failure by deviation status.



Peters L J et al. JCO 2010;28:2996-3001

JOURNAL OF CLINICAL ONCOLOGY

Accident prevention in to-day clinical radiation therapy practice



If you don't know what it does don't fool with it!

Accident prevention in to-day clinical radiation therapy practice

- “If a decision is taken to use the new technologies, time dedication, training, and competence of staff need to be re-assessed. Once these issues have been addressed properly, a smooth, step-by-step, and safe transition over several years is necessary to maintain safety. Failure to do so may not only a waste of resources but may also increase the likelihood of accidental exposures of patients”

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New technologies

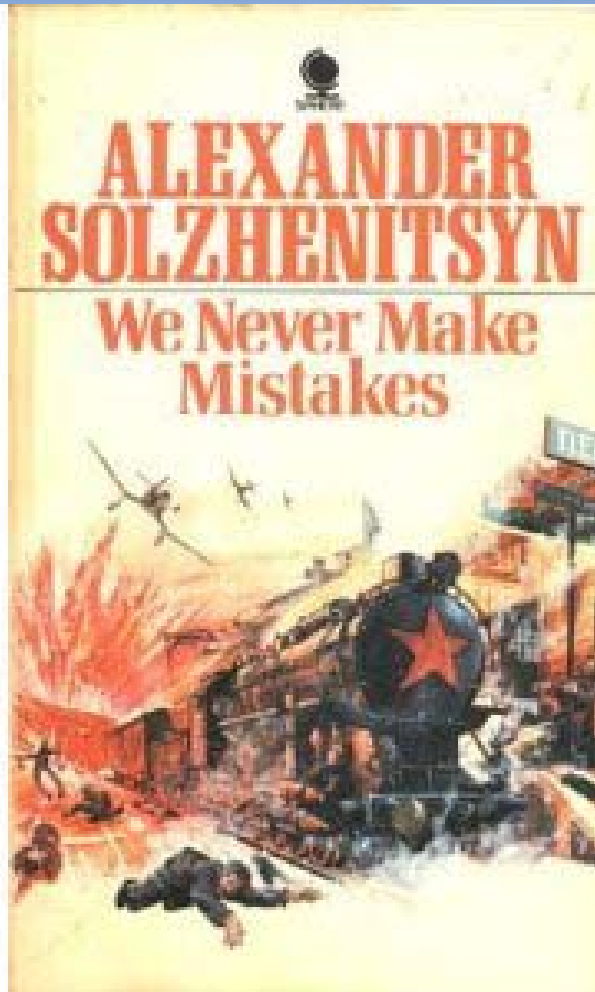
- A fool with a tool is still a fool

Accident prevention in to-day clinical radiation therapy practice

- “the increased complexity of planning and treatment and rapid adoption of new technologies in the setting of increased patient volume may thus create an environment with more potential for treatment mishaps to occur.”

Shafiq J et al, R&O 92:15, 2009

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Is that so???

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- “Each radiotherapy service should individually and repeatedly examine its risk profile and incidents as well as near missed should be prospectively collected, measured and categorized”

Shafiq J et al, R&O 92:15, 2009

Accident prevention in to-day clinical radiation therapy practice

- “A no-blame culture should exist in each department so that any “errors” are reported immediately and mechanisms are in place to examine the reason or reasons for the error, to ensure the likelihood of it occurring again is minimized”

G Morgan;IJROBP 79:1602, 2011

Accident prevention in to-day clinical radiation therapy practice

Recommendations:

- “First, learning from the past should be consolidated by setting up a publicly available website to hold copies of the reports of previous radiotherapy incident enquiries.
- Second, dissemination of learning from near misses and non reportable incidents should be improved
- Third, the development of a more open culture for reports...”

MV Williams, BJR 80:297, 2007

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Danish Act on Patient Safety

- It obliges frontline personnel to report adverse events to a national system. The purpose is to learn, not punish, and the act contains a paragraph protecting staff from sanctions: an individual who reports an adverse event cannot as a result of that report be subject to investigation or disciplinary action by the employer, the Board of Health, or the Court of Justice.

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- “minimizing the risk of accidental exposures of radiation therapy patients has been based largely on compliance with regulatory requirements, codes of practice, and international standards”

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- In other words:
QUALITY CONTROL & EDUCATION

Accident prevention in to-day clinical radiation therapy practice

We have plenty of rules and recommendations....do we need more ?

Perhaps what it is needed is to enforce what we have, with an emphasis in training and education towards developing a real **CULTURE** of safety, reporting errors and mistakes but focusing in solving the problem rather than signaling the blame.

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INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION