WORKSHOP

Il rischio clinico in radioterapia oncologica

LA GESTIONE DELLE NUOVE TECNOLOGIE

Cinzia Iotti

Azienda Arcispedale S. Maria Nuova – IRCCS
Reggio Emilia

The New York Times
January 23, 2010

THE RADIATION BOOM

Radiation Offers New Cures, and Ways to Do Harm

Mr. Scott Jerome-Parks died 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

Radiotherapy is generally safe.

- about 2% of treatment courses have incidents discovered after treatment has begun

- 0.1% - 1% may have significant clinical consequences

- the risk of incidents leading to serious clinical consequences is less than this by factors of at least 10.

Munro (BRJ 2007)

The rates are significantly lower than those reported for other medical procedures.

Int. J. Radiation Oncology Biol. Phys., Vol. 81, No. 4, pp. e673–e679, 2011

TECHNOLOGICAL ADVANCEMENTS AND ERROR RATES IN RADIATION THERAPY DELIVERY

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Brigham & Women's Hospital/Dana Farber Cancer Institute. 2004-2009

Goals:

1. to determine the rate of reported errors in RT delivery since the introduction of **IMRT**
2. to characterize the types of errors associated with IMRT compared with 3D-conformal and conventional RT
3. to use the knowledge regarding error types to inform the QA processes

Category	Error description
Data errors	Errors in data input or data interpretation
Setup errors	Errors in patient setup or patient identification
Machine errors	Errors in field, gantry, or monitor unit parameters
Accessory errors	Errors involving the use of a block, bolus, wedge, immobilization, or positioning device

All human errors

Error type	3D/Conventional	IMRT	Total
Data	38 (28.8%)	6 (31.6%)	44 (29.1%)
Setup	39 (29.5%)	3 (15.8%)	42 (27.8%)
Machine	25 (18.9%)	9 (47.4%)	34 (22.5%)
Accessory	30 (22.7%)	1 (5.3%)	31 (20.5%)
Total	132	19	151*

Conclusion: The rate of errors in RT delivery is low. The types of errors differ significantly between IMRT and 3D/conventional RT, suggesting that QA processes must be uniquely adapted for each technique. There was a lower error rate with IMRT compared with 3D/conventional RT.

DN Margalit, Red J 2011

New technology has reduced the probability of many types of medical events, but new types of errors are now being seen and their effects can be more severe

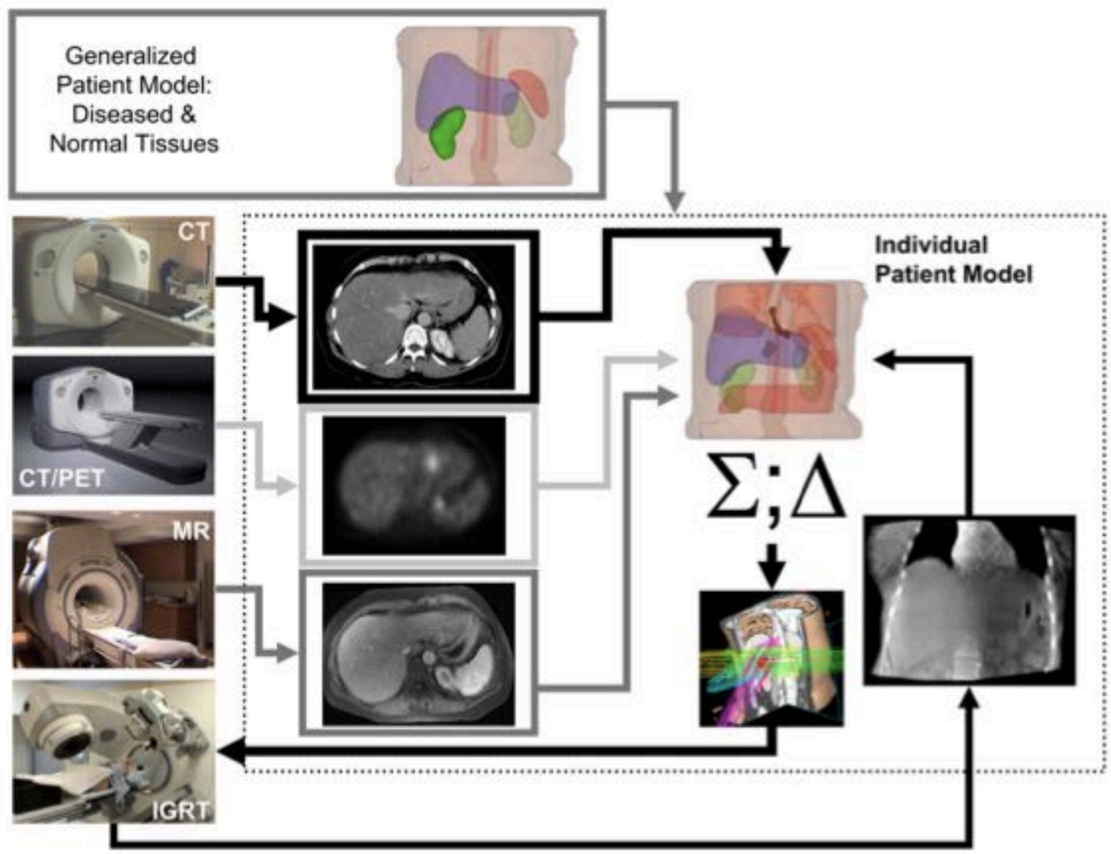
The modern radiotherapy technologies

Factors affecting the clinical risk

More than just IMRT

The simultaneous implementation of supplementary technology *

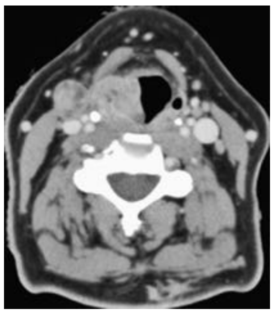
- *imaging modalities*
- *image guidance*
- *computer software*
- *IT systems*
- *radiobiology*
- *dose painting*
- *…….*



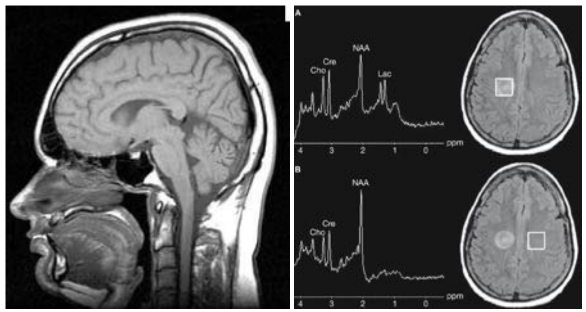
* *MEDICAL TECHNOLOGY: encompasses all drugs, devices, and medical and surgical procedures used in medical care as well as the organizational supportive systems within which such care is provided*

In the areas of diagnosis, treatment simulation, tumor and tissue contouring, and treatment planning we are witnessing an increasing reliance on **complex, software driven multi-modality imaging technology**

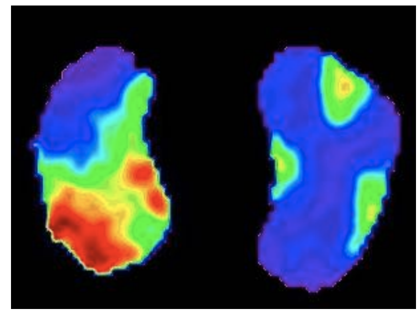
CT



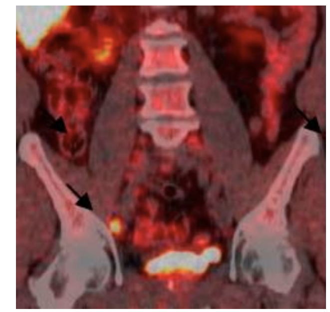
MRI



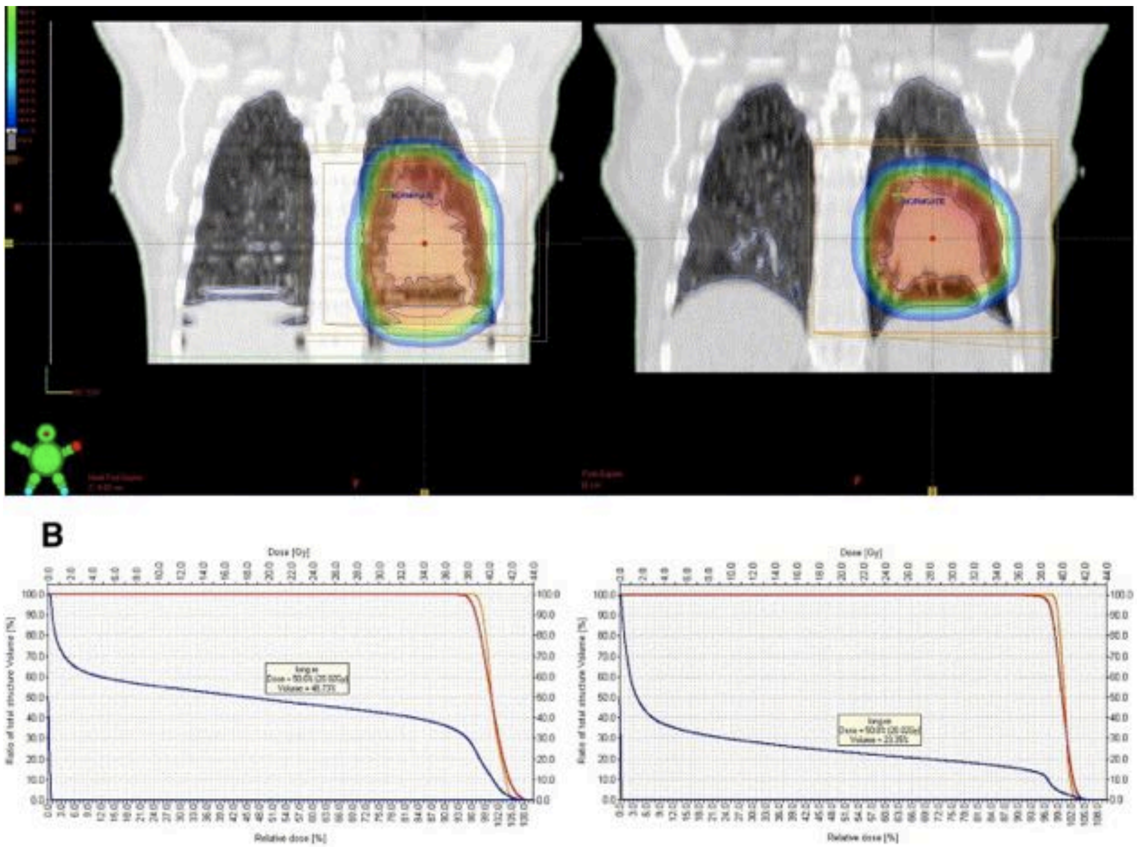
SPECT



PET-CT



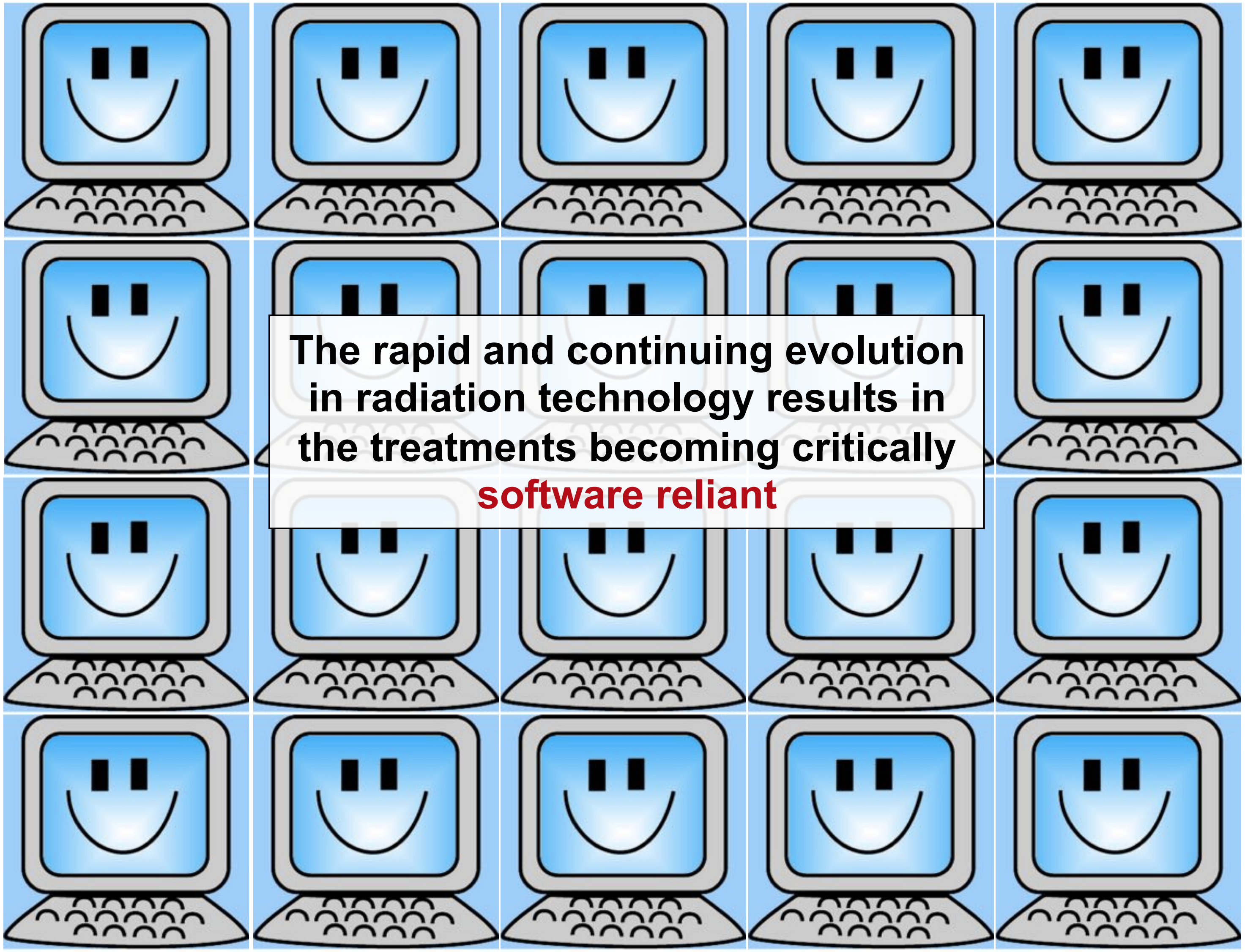
The IGRT has led to even more reliance on computer control of patient setup and even real time corrections for intrafractional target motion, so-called dynamic adaptive radiation therapy (DART)



Each of these advances introduces its own potential for problems and requires knowledge, expertise, validation and QA

QA for these modalities is beyond the expertise of most radiation therapy physicists resulting in reliance on manufacturer supplied image transfer, fusion and PACS, often with little understanding of how they work or even how to perform acceptance and commissioning tests for them.

THE OMNIPRESENCE OF COMPUTERS



The rapid and continuing evolution in radiation technology results in the treatments becoming critically software reliant

Systems have become less intuitive, less transparent.

Systems have **more defenses against failures**. But it is quite ironical that most accidents occur as a result of malfunctions in the ASDs (automatic safety devices) themselves.

Scalliet 2006

The new (dangerous) paradigm

Humans check computers

While computers are good at checking humans, the converse is not true

Computers are nearly always correct, therefore the tendency to become lax in the QA process is natural (**false sense of security**)

Many of the errors with new technologies are the result of software errors and corrupted data files, coupled with improper staff training in the use of new technologies

The inverted training and responsibility pyramid

IGRT: responsibility for treatment verification and image registration of radiation therapists rather than radiation oncologists.

R&V systems: responsibility for accuracy of treatment delivery of physicists performing system QA rather than radiation therapists delivering the treatments.

Responsibility for contouring of treatment planners rather than radiation oncologists.

HJ Amols Health Physics 2008

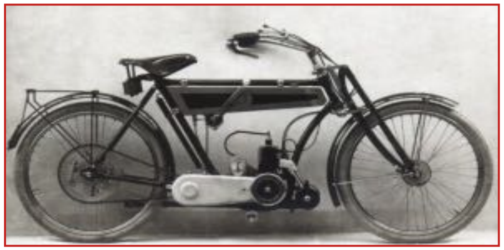
Staff training

Evolving and complex technologies require the acquisition of new skills by the entire team but these skills **are not easily acquired through didactic training.**

Bak K, BMC Health Services Research 2011

There is a continuous evolution of what is considered a "standard" technology for radiotherapy, towards more sophisticated equipment which, in turn, requires more automation to remain efficient, specific training and QA processes.

20s

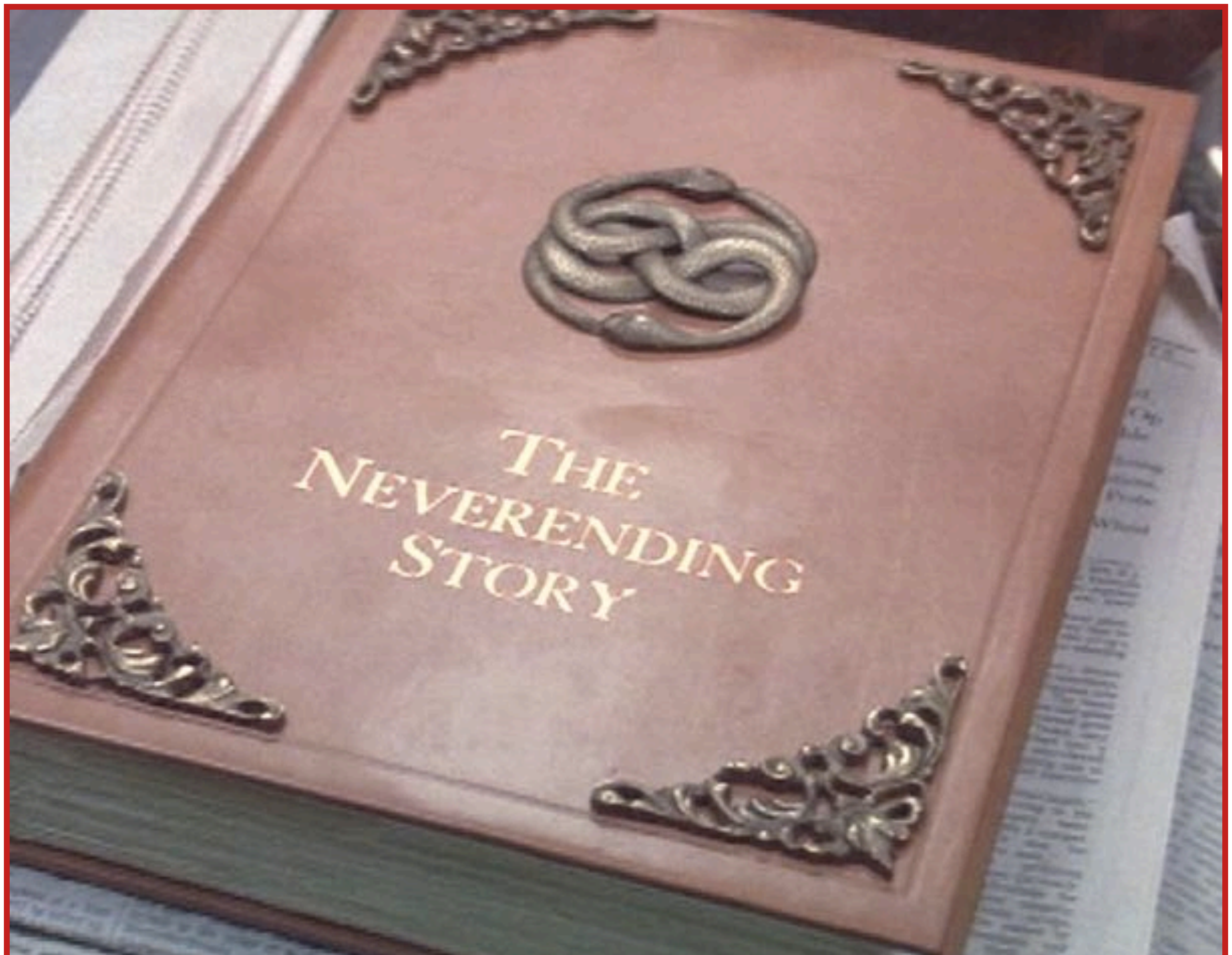


70s

2012

Tomorrow

Since the modern radiation department is constantly reinventing and evolving treatment approaches, these departments are in an ongoing state of technology implementation



Resources are becoming scarce

The following issues deserve separate discussion

- **The anatomy contouring**

  Please don’t forget OARs! Don’t restrict your focus only to the target volume

- **The planning and prescription variability**

  Same intended prescription different results!

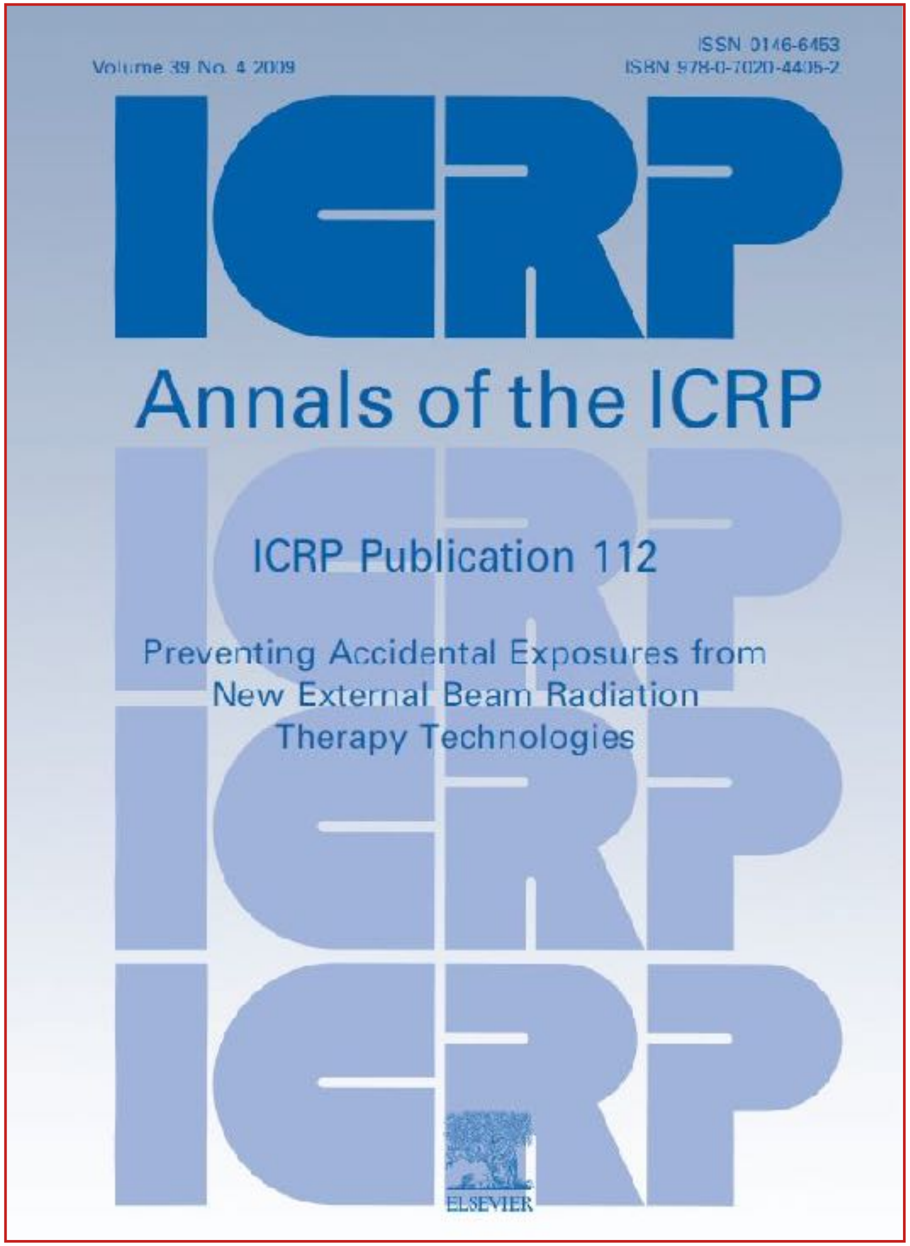
- **The tendency to use altered (hypo) fractionation**

- **The exposure outside the target and the risk of second cancer**

  IMRT and other advanced dynamic techniques,

  and IGRT

Help and recommendation



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ICRP

Annals of the ICRP

ICRP Publication 112

Preventing Accidental Exposures from New External Beam Radiation Therapy Technologies

ELSEVIER

Pubblicazione 112 dell'ICRP

Pubblicazione ICRP 112

PREVENZIONE DELLE ESPOSIZIONI ACCIDENTALI NELL'USO DI NUOVE TECNOLOGIE PER LA RADIOTERAPIA CON FASCIO ESTERNO

Traduzione della *ICRP Publication 112*
'Preventing Accidental Exposures from New External Beam Radiation Therapy Technologies'
Annals of the ICRP Volume 39 Issue 4, 2009

2009 (Resolution 2)

ACR–ASTRO PRACTICE GUIDELINE FOR IMAGE-GUIDED RADIATION THERAPY (IGRT)

1. *Qualifications and responsibilities of personnel*
2. *IGRT implementation*
3. *Documentation*
4. *Quality control and improvement, safety, and patient education*

Revised 2011 (CSC/BOC)*

ACR –ASTRO PRACTICE GUIDELINE FOR INTENSITY MODULATED RADIATION THERAPY (IMRT)

1. *Qualifications and responsibilities of personnel*
2. *QA for the imrt treatment planning system*
3. *IMRT treatment plan implementation*
4. *IMRT delivery system quality assurance*
5. *Patient-specific quality assurance*
6. *Documentation*
7. *Quality control and improvement, safety, and patient education*

ESTRO BOOKLET NO. 9:
GUIDELINES FOR THE VERIFICATION OF IMRT

CONTENTS:

ESTRO BOOKLET NO. 9:
GUIDELINES FOR THE VERIFICATION OF IMRT

ESTRO

Practical Radiation Oncology (2011) 1, 190–195

practical radiation oncology
pro
www.practicalradonc.org

QA white paper

Special Article

Safety considerations for IMRT: Executive summary

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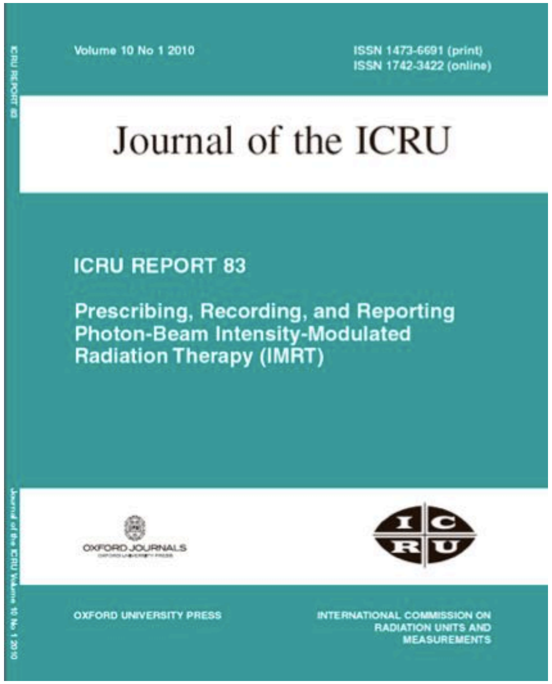
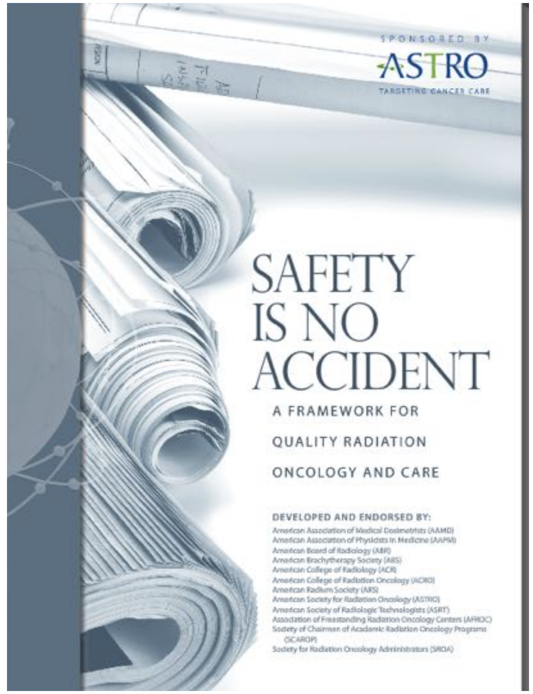
Received 19 April 2011; accepted 27 April 2011

Outline of the full report (available online only at www.practicalradonc.org).






ISTITUTO SUPERIORE DI SANITÀ

Indicazioni per l'assicurazione di qualità nella radioterapia ad intensità modulata

A cura di
Fabrizio Banci Buonamici (a), Cinzia De Angelis (b), Cinzia Iotti (c), Marta Paiusco (d), Patrizia Olmi (e), Antonella Rosi (b) e Maria Antonella Tabocchini (b)

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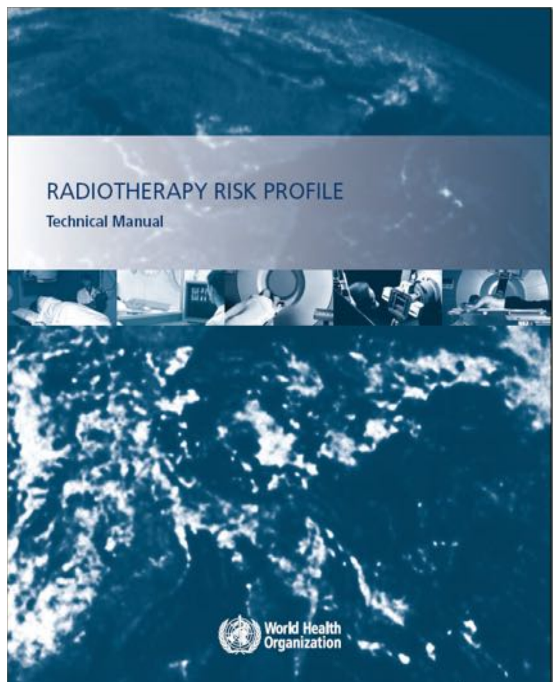
Rapporti ISTISAN
08/12



2011	15	Working Group on Recommendations for Radiotherapy External Beam Quality Assurance Task Group #154
2010	37	Working Group on Recommendations for Radiotherapy External Beam Quality Assurance Task Group #148
2012	20	Working Group on Recommendations for Radiotherapy External Beam Quality Assurance Task Group #147
2009	15	Work Group on IMRT Task Group #119
2009	72	Task Group 104 of the Therapy Imaging Committee

The American Association of Physicists in Medicine

New QA processes

Transition from exclusive performance-based QA to **process-based and risk-based QA** is necessary.

A good QA program must be **continually adapted** to new technologies and treatment techniques.

This may require the design of new tests, or the modification and validation of existing test

Prioritization is obviously necessary

HJ Amols Health Physics 2008
Saw CB, BIIJ 2009

Factors enabling a correct and safe implementation and use of a new technology

- **Standardization**
- **Collaboration**
- **Training Training Training Training Training Training**
  - The mastery of a complex technology requires a solid understanding of the science that underlies the technology
  - **The last line of defense in any QA system is a well trained and *attentive* professional staff.**

- **Participation in clinical trials**
  - Promotes uniformity in the use of new technology
  - Helps to validate the new technology itself
- **Compliance with evidence and appropriateness**

Assessment of the role of image guided hypofractionated IMRT in the treatment of prostate, lung, oropharyngeal cancers, and GBM


Regione Emilia-Romagna

Osservatorio Regionale per l'Innovazione

Innovative Radiation Treatment in Cancer

IGRT/IMRT
(Image Guided Radiation Therapy-
Intensity Modulated Radiation Therapy)

HEALTH TECHNOLOGY ASSESSMENT

ORIentamenti

1. *A randomized phase III study of hypofractionated image guided radiation therapy (IGRT) vs conventional fractionation in low and intermediate risk prostate cancer*
2. *A randomized phase III study of chemo-radiation for stage III-IVA oropharynx cancer: IG-IMRT with dose/fraction escalation vs IMRT with conventional fractionation*
3. *Impact on overall survival and disease free survival of image guided radio-chemotherapy and hypofractionation in stage IIIA-IIIB non small cell lung cancer: a randomized phase III study*
4. *A randomized phase II study: hypofractionated radiotherapy delivered every other day vs daily hypofractionated. IG-IMRT in patients with poor prognosis glioblastoma (V and VI RPA*

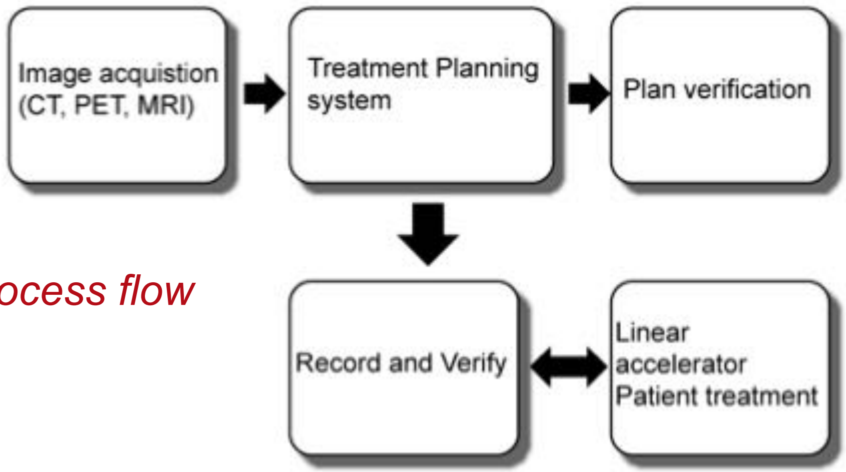
JOURNAL OF APPLIED CLINICAL MEDICAL PHYSICS, VOLUME 10, NUMBER 4, FALL 2009

Information technology resource management in radiation oncology*

R. Alfredo Siochi,[1,a] Peter Balter,[2] Charles D. Bloch,[3] Harry S. Bushe,[4] Charles S. Mayo,[4] Bruce H. Curran,[5] Wenzheng Feng,[6] George C. Kagadis,[7] Thomas H. Kirby,[8] Robin L. Stern[9]

Patient-related data are generated when patients are imaged, planned, localized, and treated. Data integrity from one step to the next must be preserved.

A typical RT process flow



These new demands require new models of RO IT resource management. Reliance on the clinic's IT staff alone will not suffice, not only because manpower is limited, but also because a majority of IT personnel do not fully understand the critical needs of the RO IT environment

CONCLUSIONS

View of Delft – J. Vermeer

A View of Delft after the Explosion of 1654 – E. van Der Poel

A risk replaced another risk.

from Scalliet 2006

Sharing danger is the hallmark of modernity

Radiotherapy is the most cost-effective cancer treatment, of course in optimal synergy with other cancer treatment modalities, and also that it is one of the safest medical specialities.

New technology can introduce new hazards but if it is optimally implemented, appropriately applied and robustly assured will continue to support both these messages

Invest in safety

Change is in the air in radiation oncology

It's not the strongest of the species that survives, or the most intelligent, but the one most responsive to change.

C. Darwin

You don't have to (change)—survival is not compulsory.

W. Edwards

Thanks