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Patient Safety in Radiation Oncology

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SAMSUNG MEDICAL CENTER SAMSUNG

Justification and Optimization in ICRP

- Justification
  - more good than harm
- Optimization
  - level of protection should be the best including economic and societal factors

Justification in ICRP 105

- Principle: More good than harm
- Harm
  - Detriment from radiation
  - Economic and societal cost
- Made on the basis of
  - Experience
  - Professional judgment
  - Common sense
  - Quantitative decision-aiding techniques should be considered

Justification in in ICRP 105

Level I: General Level

More good that harm to society Is now taken for granted

Level II: Defined Radiological Procedures

Benefit to health, family and to society

Justification is depend on the national conditions

Consider the exposure to staff and public and accidental or unintended exposures

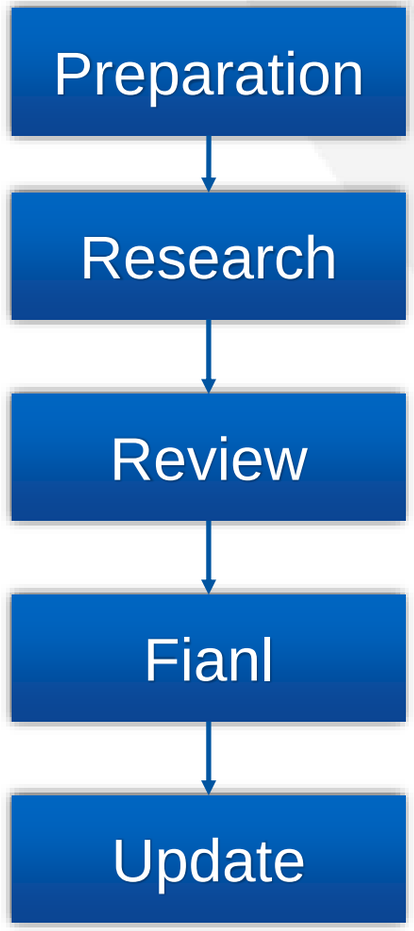
The decisions should be reviewed.

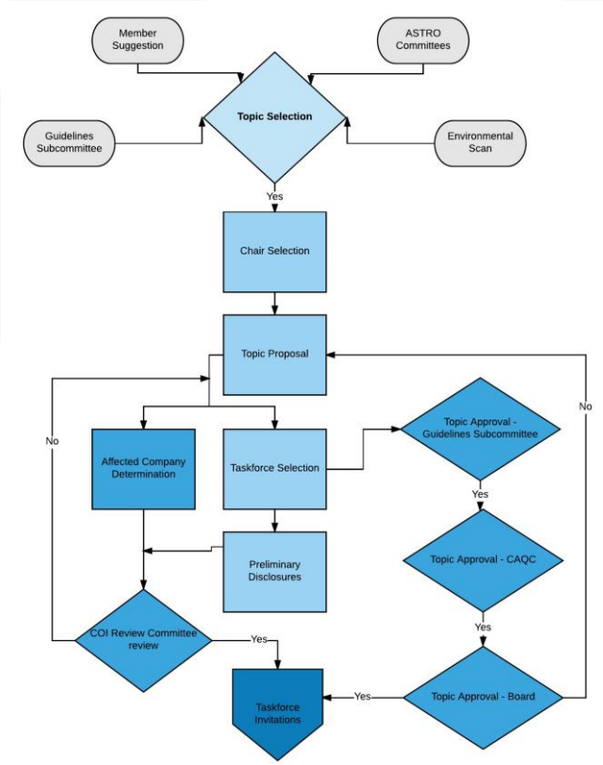
Level III: A Procedure for an Individual Patient

Alternative procedures, characteristics of the individual patient, expected dose, previous or expected examinations or treatment

Justification in Radiotherapy

- Approaches of ASTRO: Evidence-based Guidelines
- Reviews of Phase III Multi-Institutional Prospective Studies
- In ASTRO web site, guideline development process have been guided





Justification in Radiotherapy

- Approaches of ASTRO: Evidence-based Guidelines
- Reviews of Phase III Multi-Institutional Prospective Studies
- In ASTRO web site, guideline development process have been guided.

Practical Radiation Oncology (2017) 7, 295-301

www.practicalradonc.org

Special Article

Stereotactic body radiation therapy for early-stage non-small cell lung cancer: Executive Summary of a ASTRO Evidence-Based Guideline

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Supplementary material for this article (http://dx.doi.org/10.1016/j.prro.2017.04.014) can be found at www.practicalradonc.org.

Conflicts of interest. Before initiating work on this guideline, all task force members completed disclosure statements and pertinent disclosures are published within this report. Where potential conflicts are detected, remedial measures to address them are taken and noted here.

MG: honoraria and travel expenses from Elekta; CK: previous research funding from Varian; KL: stock in Pfizer and Synta Pharmaceuticals; SL: previous research funding from Elekta and previous travel expenses and honoraria from Accuray; DM: previous travel expenses from Varian, previous honoraria for Augmenix; BM: research funding and travel expenses from Varian and Philips, patents with Henry Ford Health System (no royalties received), and National Cancer Institute small business grant with Humanetics; AR: research funding from Varian, Boehringer Ingelheim, and Pfizer, previous advisory board for AstraZeneca; MR: previous travel expenses from BTG, Varian, and Elekta; RT: research funding from Varian, Accuray, and Elekta.

These disclosures were reviewed by the Guidelines Subcommittee chairs (for task force chairs), the task force chairs (for task force members), and the Conflict of Interest Review Committee. They were determined to be sufficiently managed by disclosure to the task force and in this publication.

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VOLUME 33 · NUMBER 26 · SEPTEMBER 10 2015

JOURNAL OF CLINICAL ONCOLOGY | ASCO SPECIAL ARTICLE

Postoperative Radiation Therapy for Endometrial Cancer: American Society of Clinical Oncology Clinical Practice Guideline Endorsement of the American Society for Radiation Oncology Evidence-Based Guideline

Larissa A. Meyer, Kari Bohlke, Matthew A. Powell, Amanda N. Fader, Gregg E. Franklin, Larissa J. Lee, Daniela Matei, Lourie Coallier, and Alexi A. Wright

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Published online ahead of print at www.jco.org on July 6, 2015.

Clinical Practice Guideline Committee approval: January 30, 2015.

Editor's note: This American Society of Clinical Oncology (ASCO) clinical practice guideline endorsement provides recommendations based on the review and analyses of the relevant literature in "The Role of Postoperative Radiation Therapy for Endometrial Cancer: An ASTRO Evidence-Based Guideline" by Klopp et al, published in 2014 in *Practical Radiation Oncology*. Additional information, which may include a Methodology Supplement, Data Supplements, slide sets, patient versions, frequently asked questions, and other clinical tools and resources, is available at www.asco.org/endorsements/endometrial.

Authors' disclosures of potential conflicts of interest are found in the article online at www.jco.org. Author contributions are found at the end of this article.

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0732-183X/15/3326w-2908w/$20.00

DOI: 10.1200/JCO.2015.62.5459

A B S T R A C T

Purpose
To provide guidance on the role of adjuvant radiation therapy in the treatment of endometrial cancer.

Methods
"The Role of Postoperative Radiation Therapy for Endometrial Cancer: An ASTRO Evidence-Based Guideline" by Klopp et al, published in 2014 in *Practical Radiation Oncology*, was reviewed for developmental rigor by methodologists. The American Society for Radiation Oncology (ASTRO) guideline content and recommendations were further reviewed by the American Society of Clinical Oncology (ASCO) Endorsement Panel.

Results
The ASCO Endorsement Panel determined that the recommendations from the ASTRO guideline are clear, thorough, and based on the most relevant scientific evidence. ASCO endorsed the ASTRO guideline with several qualifying statements.

Recommendations
Surveillance without adjuvant radiation therapy is a reasonable option for women without residual disease in the hysterectomy specimen and for women with grade 1 or 2 cancer and < 50% myometrial invasion, especially when no other high-risk features are present. For women with grade 1 or 2 cancer and ≥ 50% myometrial invasion or grade 3 cancer and < 50% myometrial invasion, vaginal brachytherapy is as effective as pelvic radiation therapy at preventing vaginal recurrence and is preferred. Patients with grade 3 cancer and ≥ 50% myometrial invasion or cervical stroma invasion may benefit from pelvic radiation to prevent pelvic recurrence. For women with high-risk early-stage disease and advanced disease, the ASCO Endorsement Panel added qualifying statements to the ASTRO recommendations to provide stronger statements in favor of chemotherapy (with or without radiation therapy).

J Clin Oncol 33:2908-2913. © 2015 by American Society of Clinical Oncology

INTRODUCTION

Endometrial cancer is the most common gynecologic cancer among women in the United States, with roughly 54,000 new cases expected in 2015.[1] Worldwide, endometrial cancer is the second most common gynecologic cancer (after cervical cancer) and the sixth most common cancer overall among women.[2]

Surgery is the primary treatment for endometrial cancer, and many women with early-stage endometrial cancer and a low risk of cancer recurrence require no additional treatment.[3,4] Adjuvant treatment for women with an intermediate or high risk of recurrence continues to evolve, and options include radiation therapy, chemotherapy, or a combination of these modalities. To provide guidance on the use of postoperative radiation therapy for endometrial cancer, the American Society for Radiation Oncology (ASTRO) published evidence-based recommendations in *Practical Radiation Oncology* in 2014.[5]

The purpose of this American Society of Clinical Oncology (ASCO) guideline is to critically appraise and endorse the ASTRO guideline on postoperative radiation therapy for endometrial cancer. This endorsement reinforces the recommendations provided in the ASTRO guideline and

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JOURNAL OF CLINICAL ONCOLOGY | ASCO SPECIAL ARTICLE

Radiation Therapy for Glioblastoma: American Society of Clinical Oncology Clinical Practice Guideline Endorsement of the American Society for Radiation Oncology Guideline

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Author affiliations appear at the end of this article.

Published at ascopubs.org/journal/jco on November 28, 2016.

E.P.S and S.M.C. are co-chairs.

Clinical Practice Guideline Committee Approved: September 22, 2016.

Editor's note: This ASCO Clinical Practice Guideline provides recommendations, with comprehensive review and analyses of the relevant literature for each recommendation. Additional information, including a Data Supplement with additional evidence tables, a Methodology Supplement, slide sets, clinical tools and resources, and links to patient information at www.cancer.net, is available at www.asco.org/glioblastoma-radiotherapy-endorsement and www.asco.org/guidelineswiki.

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0732-183X/17/3503w-361w/$20.00

A B S T R A C T

Purpose
The American Society for Radiation Oncology (ASTRO) produced an evidence-based guideline on radiation therapy for glioblastoma. Because of its relevance to the ASCO membership, ASCO reviewed the guideline and applied a set of procedures and policies used to critically examine guidelines developed by other organizations.

Methods
The ASTRO guideline on radiation therapy for glioblastoma was reviewed for developmental rigor by methodologists. An ASCO endorsement panel updated the literature search and reviewed the content and recommendations.

Results
The ASCO endorsement panel determined that the recommendations from the ASTRO guideline, published in 2016, are clear, thorough, and based on current scientific evidence. ASCO endorsed the ASTRO guideline on radiation therapy for glioblastoma and added qualifying statements.

Recommendations
Partial-brain fractionated radiotherapy with concurrent and adjuvant temozolomide is the standard of care after biopsy or resection of newly diagnosed glioblastoma in patients up to 70 years of age. Hypofractionated radiotherapy for elderly patients with fair to good performance status is appropriate. The addition of concurrent and adjuvant temozolomide to hypofractionated radiotherapy seems to be safe and efficacious without impairing quality of life for elderly patients with good performance status. Reasonable options for patients with poor performance status include hypofractionated radiotherapy alone, temozolomide alone, or best supportive care. Focal reirradiation represents an option for select patients with recurrent glioblastoma, although this is not supported by prospective randomized evidence. Additional information is available at www.asco.org/glioblastoma-radiotherapy-endorsement and www.asco.org/guidelineswiki.

J Clin Oncol 35:361-369. © 2016 by American Society of Clinical Oncology

INTRODUCTION

In all of oncology, the treatment of patients with glioblastoma continues to be one of the greatest challenges. Although a rare tumor with an average annual incidence in the United States of approximately 11,000, glioblastoma is the most common primary brain malignancy in adults and one of the most lethal.[1] Because of its infiltrative nature, surgical resection alone leads to median survivals of only 3 to 6 months.[2-4] Since the 1960s, this duration of survival improved significantly with the addition of adjuvant radiation, which has been extensively reported in trials from the Brain Tumor Study Group (later called the Brain Tumor Cooperative Group).[5-7] In the modern era, radiation alone leads to median survivals of approximately 1 year, and the addition of the oral alkylating agent temozolomide to radiation extends survival to 14 to 16 months.[8-10]

Approaches to radiation therapy have evolved substantially over the decades since its early use for treatment of glioblastoma. Initially used to treat the whole brain,[11,12] radiation volumes have decreased, and inverse planning and dose modulation with intensity-modulated radiation therapy have allowed for more-precise targeting and

ASSOCIATED CONTENT

Appendix
DOI: 10.1200/JCO.2016.70.7562
Data Supplement
DOI: 10.1200/JCO.2016.70.7562

DOI: 10.1200/JCO.2016.70.7562

Practical Radiation Oncology (2017) 7, 4-12

www.practicalradonc.org

Special Article

Palliative radiation therapy for bone metastases: Update of an ASTRO Evidence-Based Guideline

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Received 4 May 2016; revised 15 July 2016; accepted 3 August 2016

Abstract

Purpose: The purpose is to provide an update the Bone Metastases Guideline published in 2011 based on evidence complemented by expert opinion. The update will discuss new high-quality literature for the 8 key questions from the original guideline and implications for practice.

Methods and materials: A systematic PubMed search from the last date included in the original Guideline yielded 414 relevant articles. Ultimately, 20 randomized controlled trials, 32 prospective nonrandomized studies, and 4 meta-analyses/pooled analyses were selected and abstracted into evidence tables. The authors synthesized the evidence and reached consensus on the included recommendations.

Results: Available literature continues to support pain relief equivalency between single and multiple fraction regimens for bone metastases. High-quality data confirm single fraction radiation therapy may be delivered to spine lesions with acceptable late toxicity. One prospective, randomized trial confirms both peripheral and spine-based painful metastases can be successfully and safely palliated with retreatment for recurrence pain with adherence to published dosing constraints. Advanced radiation therapy techniques such as stereotactic body radiation therapy lack high-quality data, leading the panel to favor its use on a clinical trial or when results will be collected in a registry. The panel's conclusion remains that surgery, radionuclides, bisphosphonates, and kyphoplasty/vertebroplasty do not obviate the need for

Supplementary material for this article (http://dx.doi.org/10.1016/j.prro.2016.08.001) can be found at www.practicalradonc.org.

Conflicts of interest. Before initiating work on this guideline, all panelists completed disclosure statements and pertinent disclosures are published within this report. Where potential conflicts are detected, remedial measures to address them are taken and noted here. TB received research funding from Templeton Foundation and leads ongoing bone metastases study. S.Lo. participated in international oligometastases consortium partially funded by Elekta and received honoraria and travel expenses from Accuray and Varian. These disclosures were shared with the panel. The panel and guideline subcommittee chair reviewed these relationships and determined that the disclosure here is sufficient to manage potential conflicts.

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http://dx.doi.org/10.1016/j.prro.2016.08.001

Justification in Radiotherapy

- Approaches of ASTRO: Evidence-based Guidelines
- R
- In
  gu

Recommendation strength: Conditional
Quality of evidence: Moderate
Consensus: 94%

KQ 2: When is SBRT appropriate for medically inoperable patients with T1-2, N0 NSCLC:

- With centrally located tumors
- With tumors >5 cm in diameter
- Lacking tissue confirmation
- With synchronous primary or multifocal tumors
- Who underwent pneumonectomy and now have a new primary tumor in their remaining lung?

For patients with centrally located tumors?

Statement KQ 2A: SBRT directed toward centrally located lung tumors carries unique and significant risks when compared to treatment directed at peripherally located tumors. The use of 3-fraction regimens should be avoided in this setting.

Recommendation strength: Strong
Quality of evidence: High
Consensus: 94%

Statement KQ 2E: SBRT can be delivered in patients who refuse a biopsy, have undergone nondiagnostic biopsy, or who are thought to be at prohibitive risk of biopsy. Prior to SBRT in patients lacking tissue confirmation of malignancy, patients are recommended to be discussed in a multidisciplinary manner with a consensus that the lesion is radiographically and clinically consistent with a malignant lung lesion based on tumor, patient, and environmental factors.

Recommendation strength: Strong
Quality of evidence: Moderate
Consensus: 100%

For patients with synchronous primary or multifocal tumors?

Statement KQ 2F: Multiple primary lung cancers (MPLCs) can be difficult to differentiate from intrathoracic metastatic lung cancer and pose unique issues for parenchymal preservation; therefore, it is recommended that they are evaluated by a multidisciplinary team.

Recommendation strength: Strong
Quality of evidence: Moderate
Consensus: 100%

Optimization in ICRP 105

Level I: Design and Construction of Equipment and Installation

Level II: Defined Radiological Procedures

Net benefit is maximized

From simple common sense to complex quantitative processes (financial costs, societal costs)

Do not mean the reduction of dosed to patients

Optimization in Radiotherapy

- AAPM has recommended QA techniques for each type of machine and RT techniques.

Improvement of RT Tech.

Timeline 1 | Early landmark discoveries in radiotherapy

- Discovery era
- Kilovoltage era
- Megavoltage era

1895 — Wilhelm Conrad Röntgen credited with discovering X-rays, and coining the term

1901 — Wilhelm Conrad Röntgen awarded Nobel Prize in Physics for the discovery of X-rays

1903 — Nobel Prize in Physics awarded to Henri Becquerel, Pierre Curie and Marie Curie (for their discovery of spontaneous radioactivity)

1911 — Marie Curie awarded Nobel Prize in Chemistry for the discovery of radium and polonium

1913 — William Coolidge invents the heated cathode X-ray tube, which enables external beam radiotherapy

1920s — Brachytherapy widely used to treat accessible tumours with radium needles (skin, oral cavity and anus) or tubes (uterus)

1925 — Philips introduces 50 kV equipment to treat superficial tumours

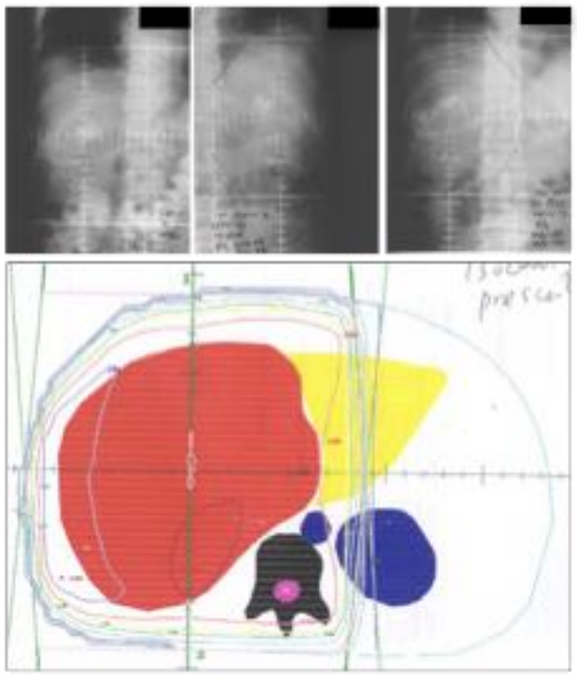
1928 — The International Commission on Radiological Protection (ICRP) is founded

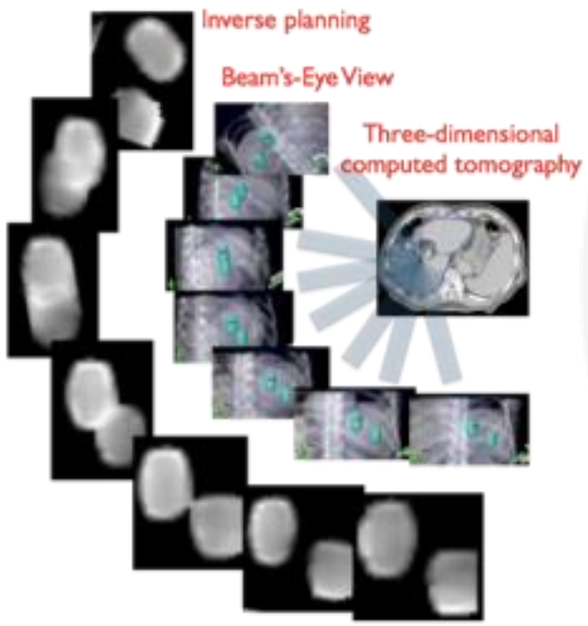
1948 — Radiotherapy with synthetic radioactive cobalt (telecobalt therapy) eliminated the skin barrier tolerance

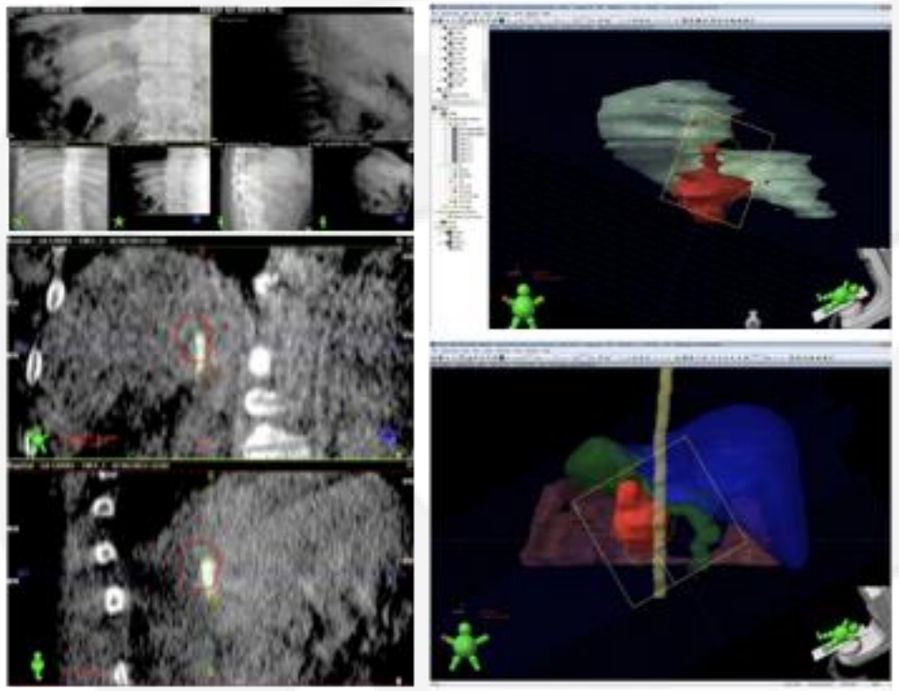
1953 — Linear accelerators deliver high-energy photons (6–20 MV) for deep-seated tumours and electrons for superficial lesions

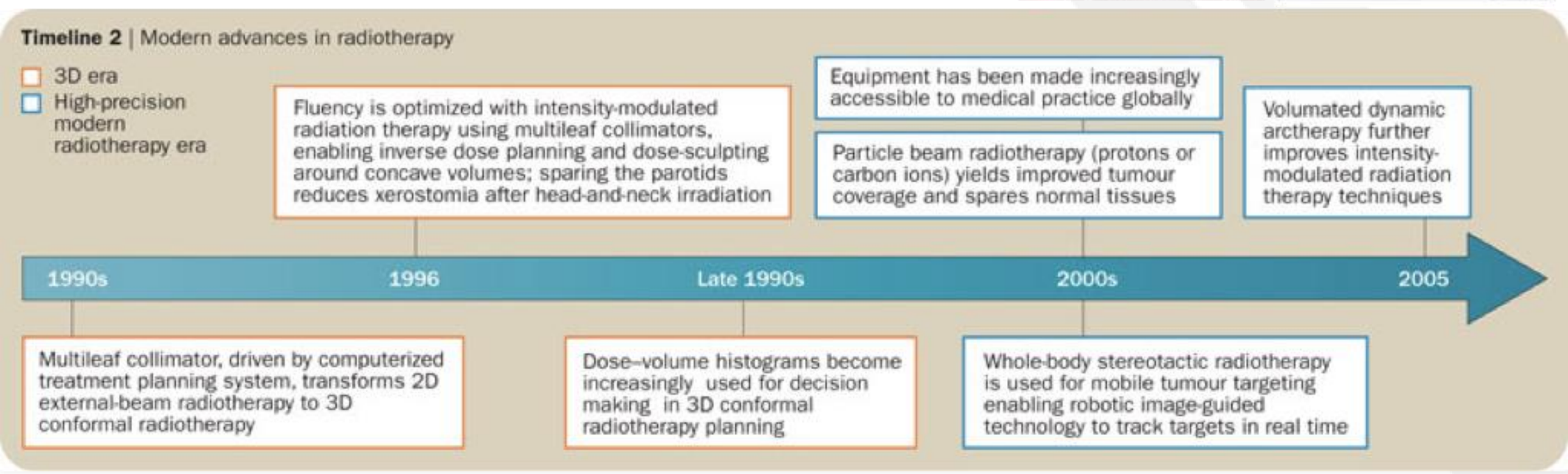
1970s — 2D simulators improve radiotherapy delivery using 2D projections

Improvement of RT Tech.



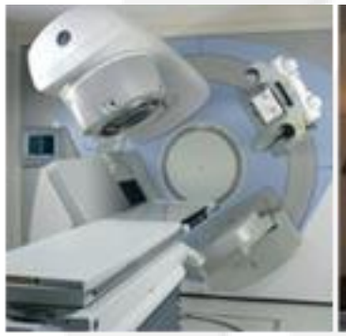






Improvement of Linac



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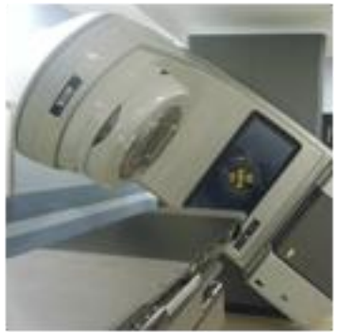
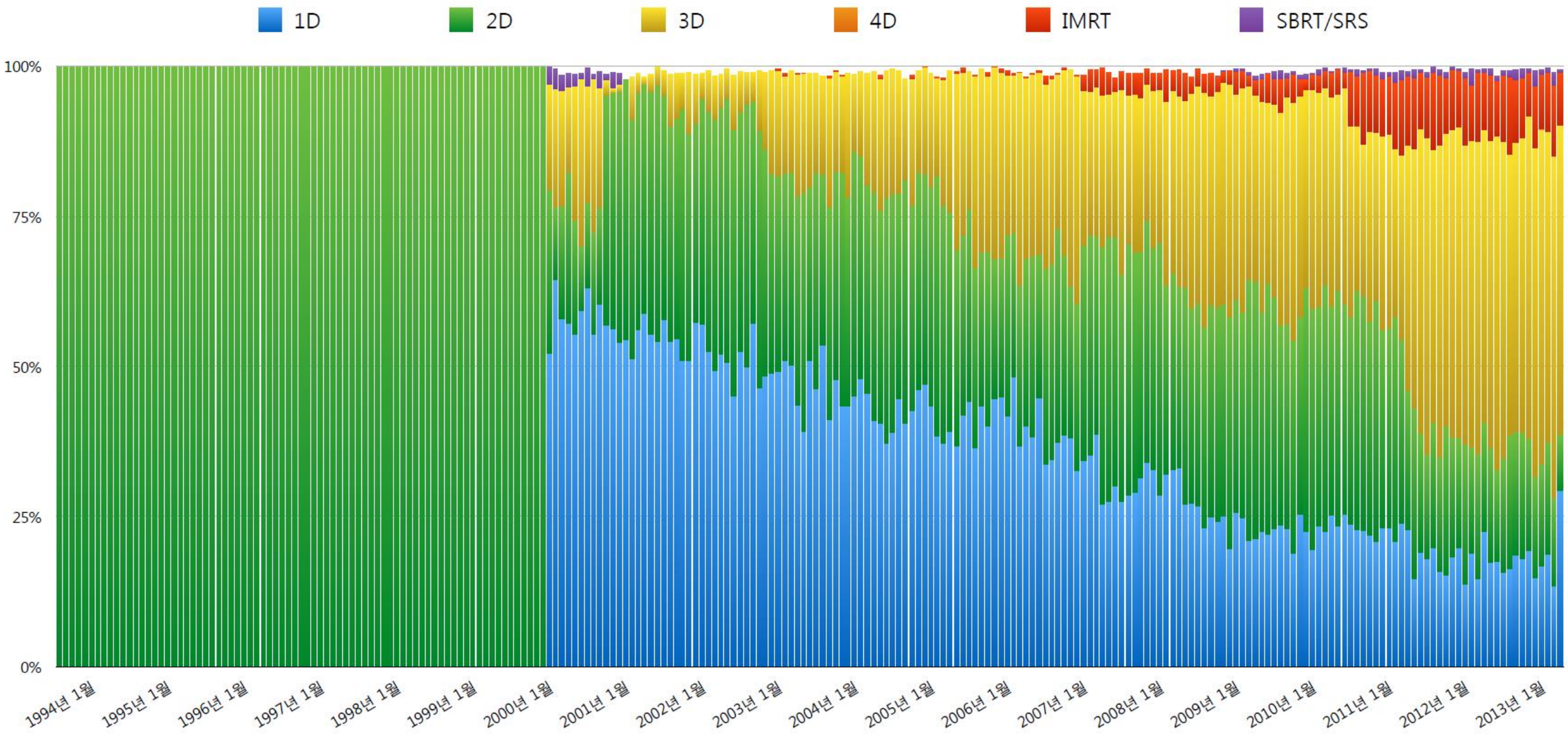




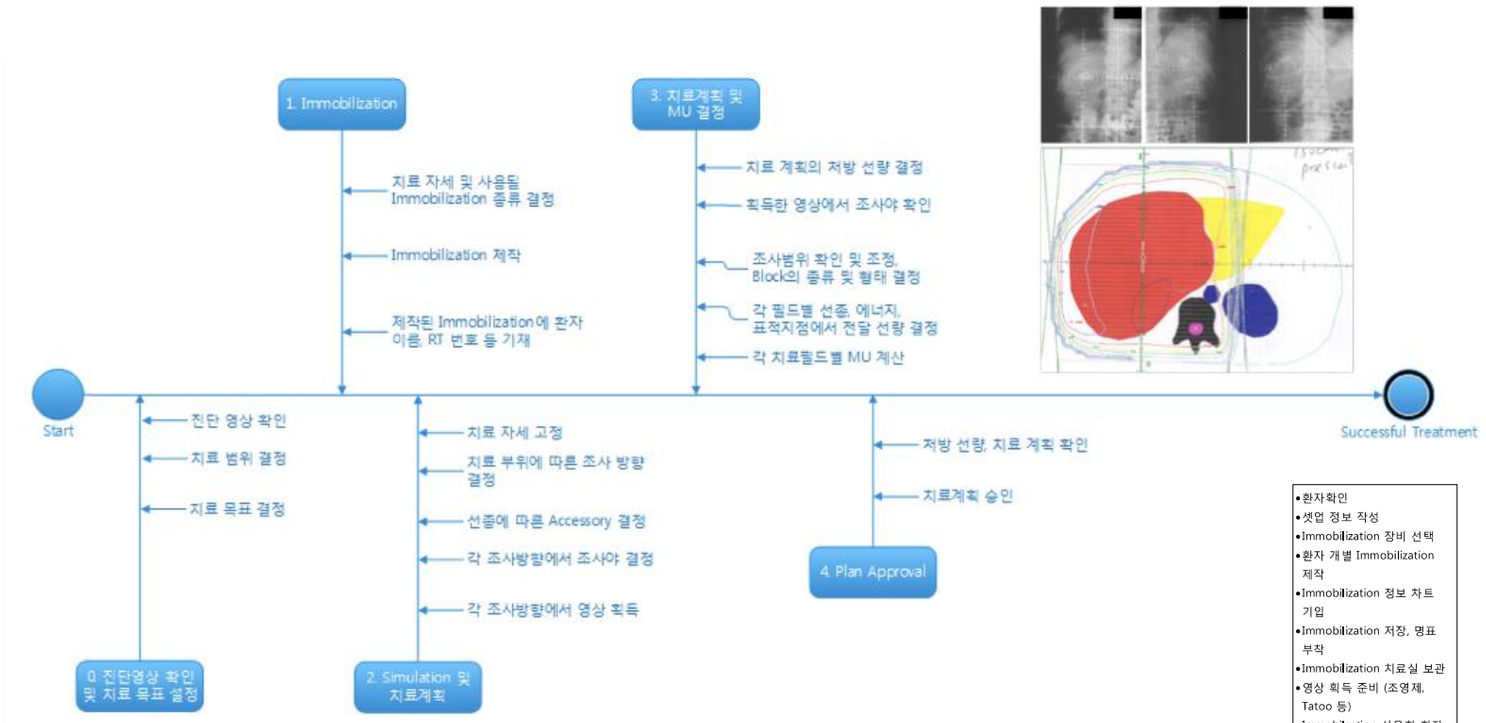



Radiation Therapy: More Complicated TX

Jan. 2013



Change of Process Map



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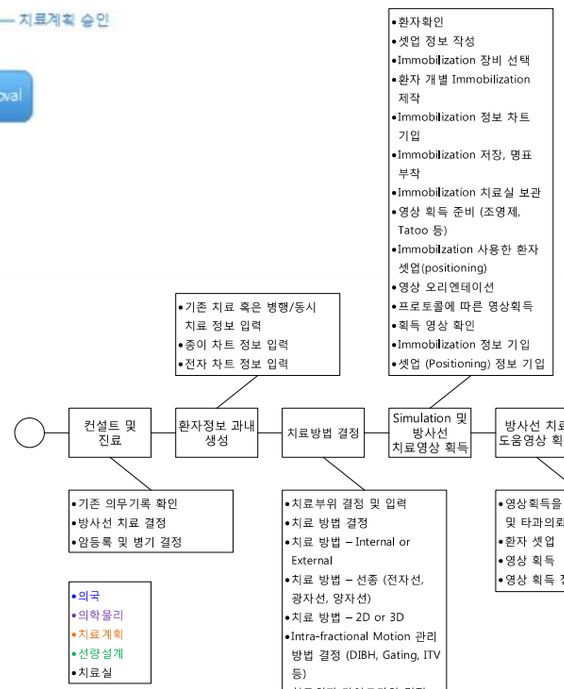
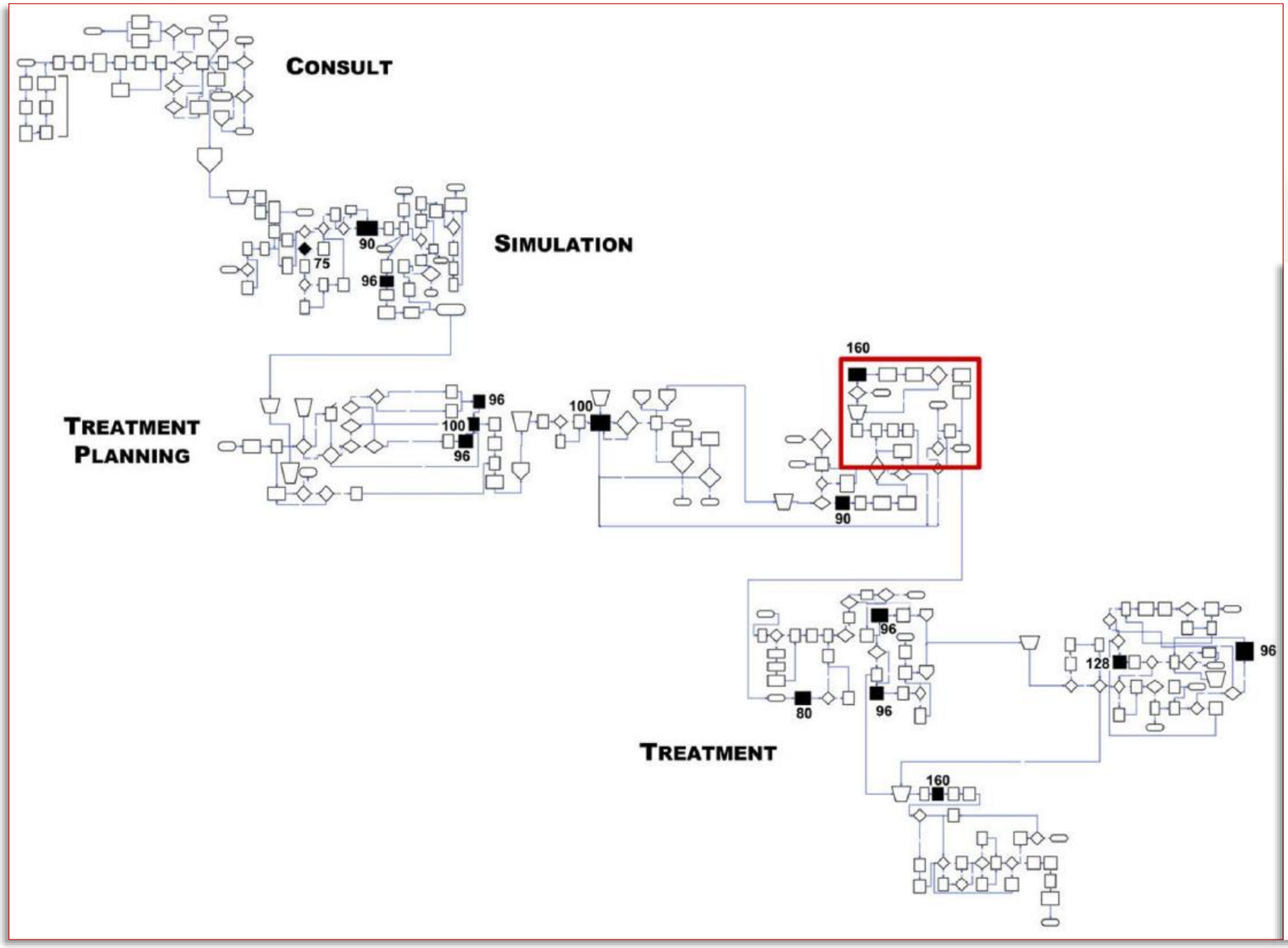
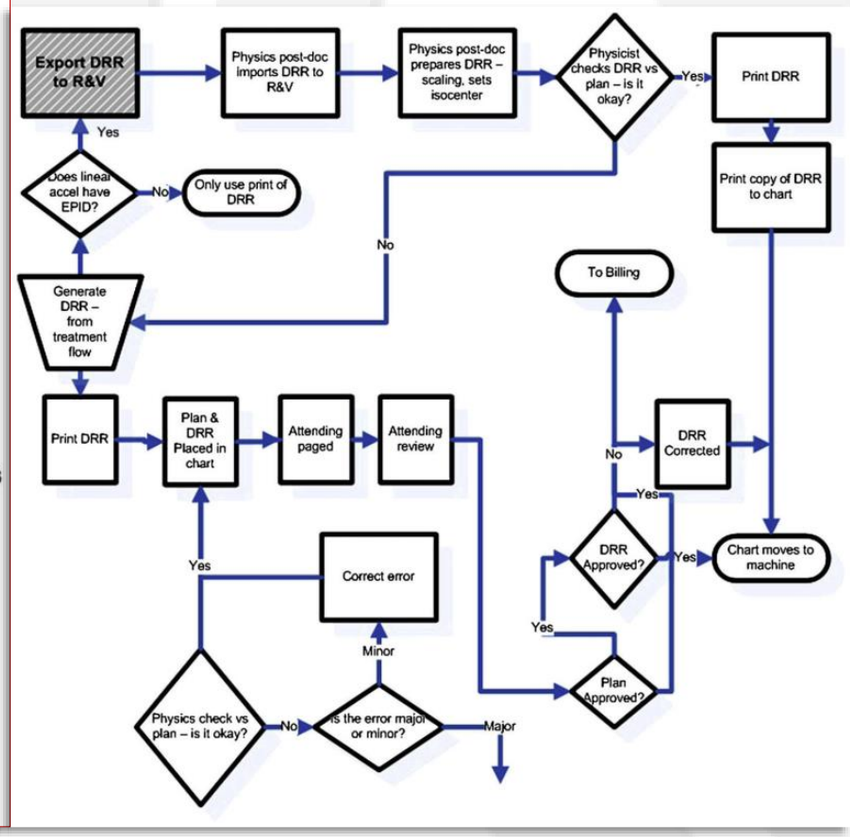
- 각도별 120개의 MLC 위치 및 MU



Process Map of Radiotherapy



External beam process map exhibiting 269 process nodes. Nodes highlighted in **black indicate the top 15 potential failure points** as ranked by the risk probability number (RPN).



Example of a process map highlighting the production and handling of digitally reconstructed radiographs (DRR) in the radiation treatment planning process

Optimization in Radiotherapy

- AAPM has recommended QA techniques for each type of machine and RT techniques.
- Role of quality assurance has been expanded to process-based quality management.
- AAPM recommended TG-100, how to manage quality using failure mode effects analysis (FMEA).

The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management

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Permissions

Career Services

Report 167 TG167

Guidelines by the AAPM and GEC-ESTRO on the use of innovative brachytherapy devices and applications: Report of Task Group 167

Optimization ir

- AAPM has recommended QA techniques for each type of machine and RT techniques.
- Role of quality assurance has been expanded to process-based quality management.
- AAPM recommended TG-100, how to manage quality using failure mode error analysis (FMEA).
- And collaborate with ASTRO and ACR to recommend how to manage quality and safety for each RT technique.

SUPPLEMENTAL MATERIAL

Practical Radiation Oncology (2011)

practical radiation oncology
pro

Quality and Safety Considerations in Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy

Timothy D. Solberg, Ph.D.[1], James M. Balter, Ph.D.[2], Stanley H. Benedict, Ph.D.[3], Benedick A. Fraass, Ph.D.2, Brian Kavanagh, M.D.[4], Curtis Miyamoto, M.D.[5], Todd Pawlicki, Ph.D.[6], Louis Potters, M.D.[7], Yoshiya Yamada, M.D.[8]

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This document was prepared by the SBRT experts invited by the Multidisciplinary Quality Assurance Subcommittee of the Clinical Affairs and Quality Committee of the American Society for Radiation Oncology (ASTRO) as a part of ASTRO's Target Safely Campaign.

The SBRT white paper was reviewed by 8 experts from the field of SBRT. All the comments were reviewed and discussed by the entire task group and appropriate revisions were incorporated in the paper with task group consensus.

We received approximately 22 comments from physicians, physicists, therapists, and representatives from radiation therapy manufacturers. Additionally, we received general and specific comments from the Association of Physicists in Medicine (AAPM), the American Association of Neurological Surgeons (AANS), and the Medical Imaging and Technology Alliance (MITA).

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Adherence to this white paper will not ensure successful treatment in every situation. Furthermore, this white paper should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding the propriety of any specific therapy must be made by the physician and the patient in light of all circumstances presented by the individual patient. ASTRO assumes no liability for the information, conclusions, and findings contained in its white papers. In addition, this white paper cannot be assumed to apply to the use of these interventions performed in the context of clinical trials, given that clinical studies are designed to evaluate or validate innovative approaches in a disease for which improved staging and treatment are needed or are being explored.

Optimization ir

Table 1. Essential planning aspects for developing a new SBRT program and/or considering new disease sites.

Recommendation	Duration or Frequency	Reference
Establish clinical program goals, specify disease sites, identify program specialists, develop guidelines for treatment, follow-up and assessment.	Initially	33-34, 36
Identify required resources: expertise, personnel, technology, time.	Initially, and for each new technology and/or disease site	32-33
Perform technology assessment commensurate with clinical goals, identify equipment and processes for simulation, immobilization, image guidance, management of organ motion, treatment delivery.	Initially, and for each new technology and/or disease site	32-33
Perform assessment of staffing levels, develop processes for initial and ongoing training of all program staff.	Initially, and for each new technology and/or disease site	32-35
Develop and use checklists for all aspects of SRS/SBRT processes.	Initially, and for each new technology and/or disease site	34-36
Provide documentation for a culture and environment fostering clear and open communication.	Ongoing	32
Develop quality assurance processes that encompass all clinical and technical SBRT program aspects, clearly following available guidance, with regard to procedures and tolerances.	Initially, and for each new technology and/or disease site	32-36, 43
Conduct clinical SBRT patient conferences for pre-treatment planning and post-treatment review.	Ongoing	
Develop processes for documentation and reporting, peer review, regular review of processes and procedures, updating clinical guidelines and recommendations, ongoing needs assessment, and continuous quality improvement.	Ongoing	32-35

quality management.

Table 2. Personnel qualifications of a stereotactic program

Recommendation	Duration or Frequency	Reference
All personnel must demonstrate initial attainment of knowledge and competence in their respective discipline through graduation from an approved educational program, board certification and licensure as appropriate.	Initially	32-33
All personnel must receive vendor provided equipment -specific training prior to involvement in an SBRT program.	16 hours per staff member	32, 34
All personnel must receive disease-site-specific training prior to involvement in a stereotactic program.	16 hours per staff member	32, 34
All personnel must maintain their skills by lifelong learning through continuing professional development. For physicians and physicists this is the ABR Maintenance of Certification process.	Ongoing	32, 34-35
There must be adequate resources in place to meet the demands of the stereotactic program with sufficient staff. Staff must have sufficient time to carry out the necessary tasks without undue pressure.	Ongoing	32-33, 37, 39
Job description and list of responsibilities should be clearly delineated in writing for all stereotactic program individuals.	Initially	32-33
Non-radiation oncology specialists can sometimes lend expertise in the area of target delineation for SBRT, given a deep fund of knowledge in the anatomy of various body sites. Examples of such specialists include neurosurgeons, pulmonologists, hepatologists, and oncologic surgeons.		

ACR to recommend how to manage quality and safety for each RT technique.

SUPPLEMENTAL MATERIAL

Practical Radiation Oncology (2011)

Medical Physicist

1. The medical physicist participating in an SRS or SBRT program must be certified in Therapeutic Radiological Physics or Radiological Physics by the American Board of Radiology (ABR), the American Board of Medical Physics (ABMP), or an equivalent international organization. The medical physicist must meet the American College of Radiology (ACR) Practice Guideline for Continuing Medical Education (CME). If the medical physicist's formal training did not include SRS / SBRT, then specific training in SRS / SBRT, including at least 5 CME credits and direct observation of at least 3 patient treatments, should be obtained prior to performing any SRS or SBRT procedures.
2. The medical physicist is responsible for the technical aspects of an SBRT program, which includes simulation, planning and treatment, and verification of output calibration.
3. The medical physicist is responsible for initial commissioning and acceptance testing of all planning, imaging, localization and immobilization, and delivery equipment, as well as periodic QA assessment to ensure proper performance of the treatment system(s) used.
4. On the day(s) of patient treatment, the medical physicist verifies the integrity of the patient setup at the treatment machine, verifies patient repositioning using image guidance, and is responsible for performing and/or supervising that the treatment plan meets or exceeds the radiation oncologist's prescription and is able to be delivered with a minimal chance for errors and with the highest quality. The medical physicist must be present for the entirety of each treatment.

Medical Dosimetrist:

1. Works with radiation oncologist and physicist in devising a treatment plan per the physician-defined clinical goals. This may include assistance with positioning and immobilization, segmentation, beam placement, and margin recommendation, and plan review to assure that the goals of the treatment directive are met.
2. Enters the approved plan information into the patient's chart and/or treatment management system.
3. Assists therapists with understanding the IMRT plan, and with treatment delivery as needed.

Neurosurgeon

1. The neurosurgeon participating in an SRS program must have completed an Accreditation Council for Graduate Medical Education (ACGME) approved residency program in neurosurgery, and must have obtained certification or be board-eligible in Neurosurgery by the American Board of Neurological Surgery (ABNS) or an equivalent national or international board. If the neurosurgeon's formal training did not include SRS, then specific training in SRS should be obtained prior to performing any SRS procedures.
2. The neurosurgeon generally participates in SRS cases of the brain or spine and works with the radiation oncologist in target definition and in assessing normal tissue structures and vital neurologic pathways close to the planned target.
3. The Neurosurgeon will review target and normal tissue contours and assess, with the radiation oncologist, the dose distribution.
4. In cases where head frames are required, the neurosurgeon will manage the care of placing and removing the head frame.

Radiation Therapist

1. A radiation therapist must fulfill any applicable state licensing or registration requirements and must have American Registry of Radiologic Technologists (ARRT) certification in radiation therapy. If the radiation therapist's formal training did not include SRS/SBRT, then specific initial and periodic training in SRS/SBRT should be obtained prior to performing any SRS or SBRT procedures.
2. The responsibilities of the radiation therapist include preparing the treatment room for the SRS or SBRT procedure, performing patient positioning/immobilization and assisting the treatment team answering any questions about the patient's setup, and operating the treatment unit after the radiation oncologist and medical physicist have approved the clinical and technical aspects for beam delivery.

Other Specialists

1. Other physicians may participate in the care of the patient undergoing SRS or SBRT by offering assistance derived from their own subspecialty training and expertise in the evaluation and treatment of the type of patient receiving SRS or SBRT.

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AGR to recommend how to manage quality and safety for each RT technique.

Table 1. Essential planning aspects for developing a new SBRT program and/or considering new disease sites.

Recommendation	Duration or Frequency	Reference
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Identify required resources: expertise, personnel, technology, time.	Initially, and for each new technology and/or disease site	32-33
Perform technology assessment commensurate with clinical goals, identify equipment and processes for simulation, immobilization, image guidance, management of organ motion, treatment delivery.	Initially, and for each new technology and/or disease site	32-3
Perform assessment of staffing levels, develop processes for initial and ongoing tr		
Develop ar		
Provide do and open c		
Develop qu technical S with regard		
Conduct cl and post-tr		
Develop pr regular rev guidelines continuous		

Table 3. Essential commissioning elements of a stereotactic program.

Recommendation	Dura
Appropriate resources, specialized equipment, personnel, time, must be evaluated and available prior to initiation of acceptance and commissioning processes and procedures.	8-16 w
Independent assessment of measured beam data should be performed prior to initiating a clinical SBRT program.	1 week
Independent verification of absolute calibration should be performed prior to initiating a clinical stereotactic program.	<1 wee
Comprehensive treatment planning system commissioning incorporating a full range of stereotactic delivery parameters and techniques, and specifically addressing use of inhomogeneity corrections with specific dose algorithm(s), must be performed prior to initiating a clinical stereotactic program.	4-8 we
Independent verification of system commissioning, utilizing appropriate specialized phantoms such as those from the Radiological Physics Center, should be performed prior to initiating a clinical stereotactic program and prior to initiating new clinical sites and/or treatment techniques.	2-4 we
Thorough commissioning of simulation devices and processes, including 4D CT if used, must be performed prior to initiating a clinical stereotactic program.	2-4 we
Management of respiratory motion is an essential element of SBRT simulation, planning and delivery. Measures must be developed to ensure effective and safe operation of these technologies.	2-4 we
Evaluation of individual and end-to-end localization capabilities of the image guidance system must be performed prior to initiating a clinical stereotactic program and prior to initiating new clinical sites and/or treatment techniques.	2 week
End-to-end commissioning procedures, incorporating simulation, treatment planning and dosimetry, image guidance, management of motion, and treatment management systems, must be performed prior to initiating a clinical stereotactic program and prior to initiating new clinical sites and/or treatment techniques. In addition, users may find it useful to deliberately introduce known errors, and evaluate the capabilities of the system and processes in detecting such errors.	2 week

Tabl

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All pers progra	
All personnel must maintain their skills by lifelong learning through continuing professional development. For physicians and physicists this is the ABR Maintenance of Certification process.	Ongoing
There must be adequate resources in place to meet the demands of the stereotactic program with sufficient staff. Staff must have sufficient time to carry out the necessary tasks without undue pressure.	Ongoing
Job description and list of responsibilities should be clearly delineated in writing for all stereotactic program individuals.	Initially
Non-radiation oncology specialists can sometimes lend expertise in the area of target delineation for SBRT, given a deep fund of knowledge in the anatomy of various body sites. Examples of such specialists include neurosurgeons, pulmonologists, hepatologists, and oncologic surgeons.	

SUPPLEMENTAL MATERIAL

Practical Radiation Oncology (2011)

Table 5. SRS / SBRT-specific linac-related quality assurance requirements, to be performed in addition to the standard linear accelerator tests described in the AAPM Task Group 142 report.

Daily Tests	
Procedure	**Tolerance**
Laser localization	1 mm
Distance indicator (ODI)	2 mm, if available
Collimator size indicator – both jaws and MLC	1 mm
Winston-Lutz test	≤ 0.75 mm average
IGRT positioning / repositioning	≤ 1 mm
Imaging subsystem interlocks	Functional
Stereotactic interlocks – cone size, backup jaws	Functional
Monthly Tests – in addition to tests listed above	
Procedure	Tolerance
Winston-Lutz test – both cones and MLC, covering complete range of gantry, couch, collimator positions	≤ 0.75 mm average
≤ 1 mm maximum	
Hidden target test using SRS frame and/or IGRT system	≤ 1 mm
Treatment couch position indicators	1 mm / 0.5 degrees
Output constancy at relevant dose rates	2%
Annual Tests – in addition to tests listed above	
Procedure	Tolerance
SRS arc rotation mode	1 MU or 2%
1 degree or 2%	
X-ray MU linearity	± 5% (2-4 MU)
± 2% (≥5MU)	
Coincidence of radiation and mechanical isocenter	± 1 mm from baseline
Verification of small field beam data – output factors, depth dose, and off axis profiles for cones and MLC	± 1% from baseline
End-to-end localization assessment "hidden target test" using SRS frame and/or IGRT system	≤ 1 mm
End-to-end dosimetric evaluation using SRS frame and/or IGRT system	≤2%

Medical Physicist

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beam placement, and margin recommendation, and plan review to assure that the goals of the treatment directive are met.
2. Enters the approved plan information into the patient's chart and/or treatment management system.
3. Assists therapists with understanding the IMRT plan, and with treatment delivery as needed.

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1. The neurosurgeon participating in an SRS program must have completed an Accreditation Council for Graduate Medical Education (ACGME) approved residency program in neurosurgery, and must have obtained certification or be board-eligible in Neurosurgery by the American Board of Neurological Surgery (ABNS) or an equivalent national or international board. If the neurosurgeon's formal

Other Specialists

1. Other physicians may participate in the care of the patient undergoing SRS or SBRT by offering assistance derived from their own subspecialty training and expertise in the evaluation and treatment of the type of patient receiving SRS or SBRT.

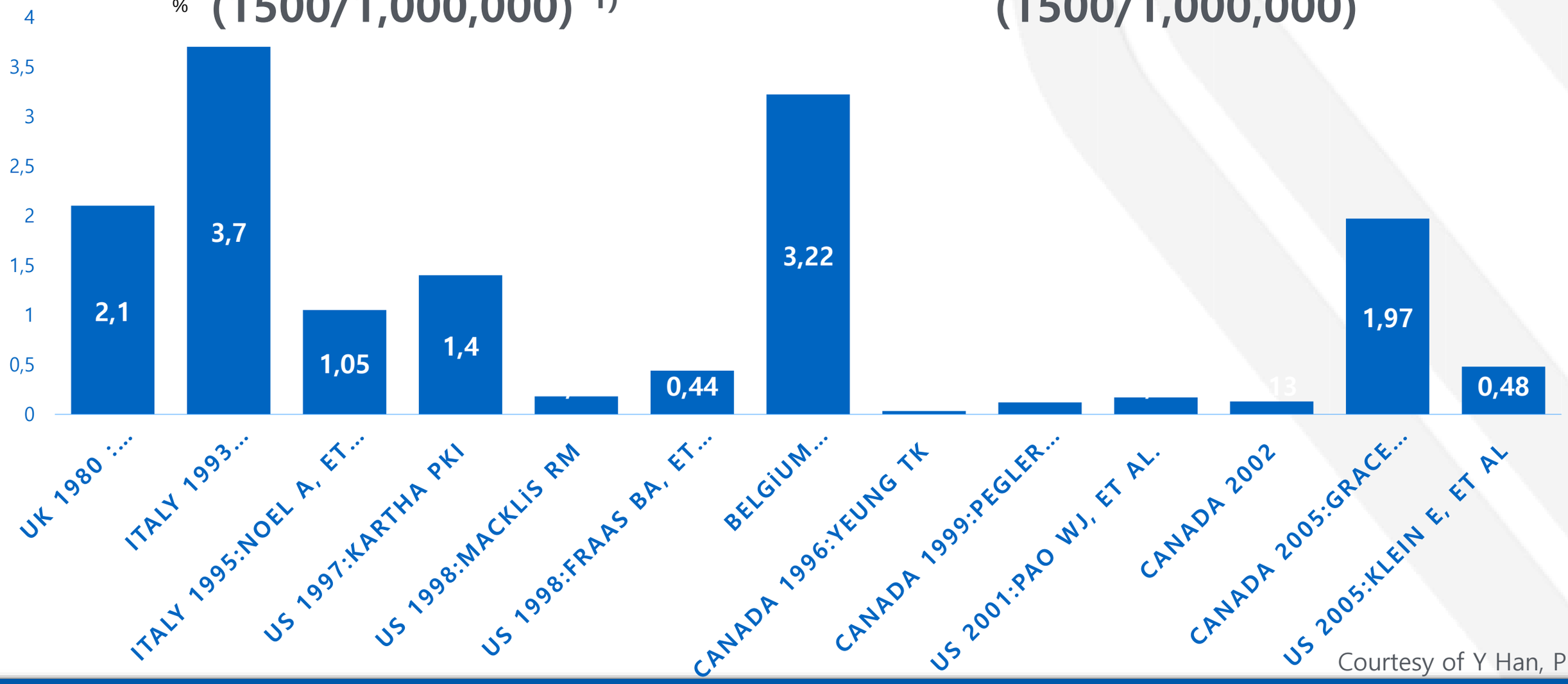
Radiotherapy is the safe?

The Risk of mild to moderate injurious outcome to patients:

0.15%
(1500/1,000,000) [1)]

Hospital admission rate for adverse drug reactions:

6.5%
(1500/1,000,000)



Courtesy of Y Han, Ph.D.

1) Radiotherapy Risk Profile: World Health Organization 2008.12

Can be fatal

The New York Times

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THE RADIATION BOOM

Radiation Offers New Cures, and Ways to Do Harm

By WALT BOGDANICH
Published: January 23, 2010

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REPRINTS

As Scott Jerome-Parks lay dying, he clung to this wish: that his fatal radiation overdose — which left him deaf, struggling to see, unable to swallow, burned, with his teeth falling out, with ulcers in his mouth and throat, nauseated, in severe pain and finally unable to breathe — be studied and talked about publicly so that others might not have to live his nightmare.

Enlarge This Image

For his last Christmas, Scott Jerome-Parks rested his feet in buckets of

Sensing death was near, Mr. Jerome-Parks summoned his family for a final 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.

Radiation Protection Dosimetry (2008), Vol. 131, No. 1, pp. 130–135
Advance Access publication 25 August 2008
doi:10.1093/rpd/ncn235

LESSONS FROM RECENT ACCIDENTS IN RADIATION THERAPY IN FRANCE

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Many accidents in radiotherapy have been reported in France over the last years. This is due to the recent legal obligation to declare to the national safety authorities any significant incident relative to the use of ionising radiation including medical applications. The causes and consequences of the most serious events in radiotherapy are presented in this paper. Lessons can be learned from possible technical dysfunctions, from human errors or organisational weaknesses as to how such events can be prevented. The technical aspects are addressed here: in particular, dosimetric issues.

방사선을 과다노출, 하복부에 괴사현상이 나타나는 후유증을 유발했다며 지난 2001년 5월22일 43억 여원의 의료사고 손해배상 청구를 한 장모씨(39·여·광주시 북구 일곡동) 등 13명의 원고에게 병원은 모두 18억여원을 지급하라고 10일 선고했다.

전남대병원에 내려진 손해배상액은 단일의료사고로는 국내 최고액이다.

재판부는 전남대병원이 환자에게 방사선 고선량 용법을 처치하면서 통상 국내 임상의학계에서 통용되는 1회 분할 조사량 및 총 조사량을 과도하게 초과했다고 밝혔다.

재판부는 전남대 병원의 이같은 잘못으로 인해 환자들에게 후유증을 초래하고, 이중 2명을 사망에 이르게 했다고 판시했다.

재판부는 환자들의 후유증에 대해 병원측이 의료진의 처치상의 잘못으로 인한 것이 아니라는 입증을 다하지 못한 이상 손해를 배상할 책임이 있다고 결정했으나 원고측의 청구금액이 과다하다고 판단해 원고 일부승소 판결을 내렸다.

이에대해 전남대병원은 "과다 조사가 결코 아닌 적법한 의료행위였다"며 항소의사를 분명히 했다.

한편 국내 임상의학계의 보고에 의하면 고선량 요법에 의한 내부 방사선 치료를 하는 경우 통상 300~500cGy를 주 2~3회 총 5~13회(총량 3천~3천500cGy) 조사하는 방법으로 시행하고있다.

또 1회 방사선 권장 분할선량은 500cGy, 한도는 통상 700~800cGy이하이며, 문헌상 보고된 최대량은 1천400cGy이나 전남대 병원은 당시 2천cGy를 조사한뒤 사고후 500cGy로 감량한 것으로 나타났다.

Courtesy of Y Han, Ph.D.

Accidents in Radiotherapy

Incidents	Author	Time Interv	Event	Total Pat	Outcome	Direct Causes
Poland	IAEA, Safety Report Series No.38, 2006	2001	Overdose	5	5 – Severe injuries	Failure of more than 1 layer of safety in electron accelerator (monitor chambers and interlock)
UK	McKenzie AL, British Institute of	1988	Overdose (+25%)	207		Teletherapy activity calculation error
UK	McKenzie AL, British Institute of	1982-1991	Underdose (-25%)	1,045		Misunderstanding of algorithm in Tx planning computer
Germany	IAEA, Safety Report Series No.38, 2006	1986-1987	Overdose (various)	86		Co-60 dose calculations based on erroneous dose tables, no independent checks
US	Ricks CR, REAC/TS Radiation Incident Registry, 1999	1944-1999	Overdose		13 – Deaths (OH:10, PA:1, TX:2) 1 Serious Injury (WA)	Incorrect calibrations, incorrect computer programming, equipment maintenance/repair negligence
US	Sickler M, St. Petersburg Times, 2005	12 months	Overdose (+50% or >)	77	19 - Unsafe level	Programming error using wrong formula in Tx planning computer, no independent second dose verification
Spain	IAEA, Safety Report Series No.38, 2006	1990	Overdose (+200 - 600%)	27	15: Direct Death s 2 :Deaths from complication	Error in maintenance if linac, procedures not followed, conflicting signals not analyzed, no beam verification procedures
UK	IAEA, Safety Report Series No.38, 2006	1999-1989	Over and under dose (-20 to +10%)	22		Error in identification of Cs-137, brachytherapy sources, no independent check of no independent check of source stength
Costa Rica	IAEA, Safety Report Series No.38, 2006	1996	Overdose (+60%)	114	17 - Deaths	Error in calibration of Co-60 unit, lack of independent beam calibration, recommendation of external audit ignored
Panama		2000	Overdose	28	Several - Deaths	Modified procedure for entry into Tx planning computer without verification
US	IAEA, Safety Report Series No.38, 2006	1989-1988	Overdose (+75%)	33		Computer file for use of trimmers not updated for new Co-60 source, no manual or independent verification of calculated Tx
Scotland	Scottish Ministers, Report of an Investigation, 2006	2006	Overdose (+58%)	1	1 - Death	software was upgraded. Old correction factor was applied to new calculation program.

Courtesy of Y Han, Ph.D.

Error rate with RT

- Events : 0.5%
- Serious incidents : 1 / 10,000 treated Pts.

Event Rates (%)

	Per Treatment	Per Course	Per Fraction	Per Field
Multiple-Center Series				
United Kingdom, 2006		0.04 (0.003)[a]		
Pennsylvania State, 2009	0.0025 (0.0006)[a]			
New York State,[b] 2009	0.06 (0.01)[a]			
Single-Institution Series				
Fraass, 1998	0.44	1.20		
Macklis, 1998		3.06		0.18 (0)[a]
Barthelemt-Brichant, 1999				3.22
Patton, 2003	0.17	3.3		
Huang, 2005		1.97	0.29	
Yeung, 2005		4.66	0.25	
French, 2006			0.32 (0.05)[a]	0.037 (0.005)[a]
Marks, 2007	0.10			

Source: Reproduced with permission from Marks LB, Jackson M, Xie L, et al., *PRO*, 2011;1:2–14.

[a] Estimated "serious" incident rate.

[b] NY state regions outside the metropolitan New York City area.

Error Type

Table 2. NYSDOH LINAC medical events — Error type (2001–2009).[a]

Type of Error	Number (%) (N=228)
Incorrect body part (set up, block, multi-leaf collimator)	104 (45.6%)
Incorrect patient	45 (19.7%)
Incorrect dose	35 (15.4%)
Incorrect energy	36 (14.5%)
Incorrect field size	20 (8.8%)
Absence of, or incorrect, treatment device	31 (13.6%)
Patient needing follow-up	34 (14.9%)

[a]Note: Error types add up to more than 228 and percentages add up to more than 100% because an error may be classified under 2 or more types – such as incorrect dose and incorrect patient.

Krishnamoorthy J, et al., Health physics. 2014;106(5 Suppl 2):S71-7.

Error Type

- Pennsylvania

Table 2. Radiation Oncology Event Types Reported to the Pennsylvania Patient Safety Authority, June 2004 through January 2009

TYPE OF ERROR	NUMBER OF REPORTS	% OF TOTAL
Wrong dose	10	40%
Wrong patient	4	16%
Wrong location	3	12%
Wrong side	3	12%
Wrong setup	2	8%
Wrong treatment	1	4%
Wrong treatment device	1	4%
Equipment other	1	4%
Total	**25**	**100%**

Table 4. Medical Accelerator Event Types Reported to the Pennsylvania Department of Environmental Protection, February 2004 through January 2009

TYPE OF ERROR	NUMBER OF REPORTS	% OF TOTAL
Incorrect site	17	46%
Wrong patient treated	10	27%
Incorrect dosage	8	21%
Underestimated medical procedure duration	1	3%
Inattention to detail	1	3%
Total	**37**	**100%**

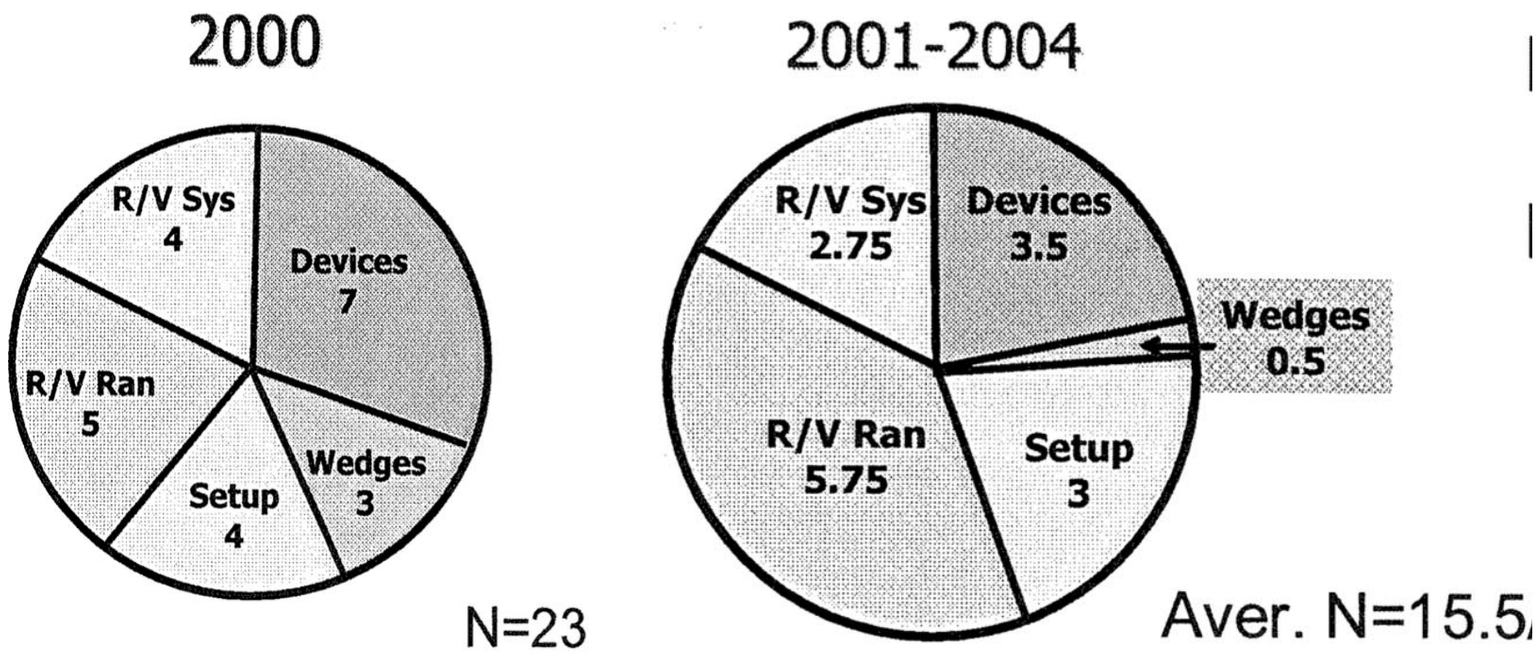
Source: Pennsylvania Department of Environmental Protection, Bureau of Radiation Protection. [reports of medical accelerator events]. E-mail to: Pennsylvania Patient Safety Authority. 2009 Apr 2.

Konski A, et al. *JACR* 2009;6:45-50.

Impact of new technologies

Table 1. "High-tech" vs. "low-tech" QA in radiation therapy.

Low-tech era	High-tech era
1. "Forward" treatment planning—intuitive and can be manually checked	IMRT "inverse" treatment planning—less intuitive and cannot be manually verified
2. Radiation therapist sets up patient based on data from a paper chart	Patient setup downloaded from computer file, auto patient setup by computer RV system
3. Treatment aids such as blocks and wedges can be checked manually, and have hardware interlocks	Treatment aids such as dynamic wedge and IMRT are invisible, and have software interlocks
4. First generation RV system checks human setup of patient and linac	Therapist checks computerized patient setup by RV system based on data from a paper chart
5. Patient setup confirmed via planar port films	Patient setup confirmed via digital imaging system and auto-registration software



Amols HI, *Health Phys* 2008;95:658-665.

Impact of new technologies

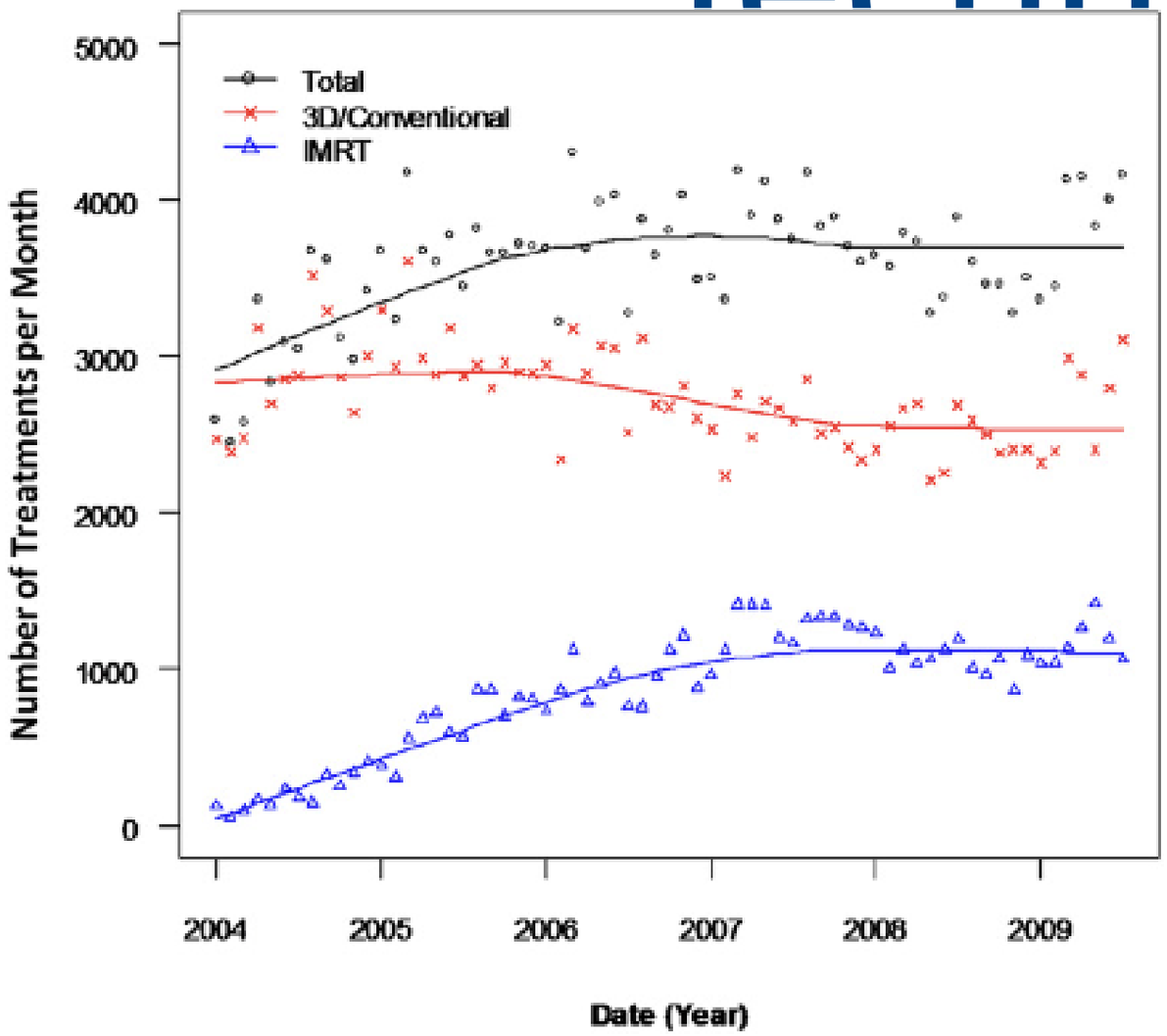


Fig. 1. Treatment volume over time with trend curves. Open circles denote total number of treatments per month; crosses, total number of 3D/conventional treatments per month; open triangles, total number of intensity-modulated radiation therapy (IMRT) treatments per month; solid lines, trend in number of treatments over time.

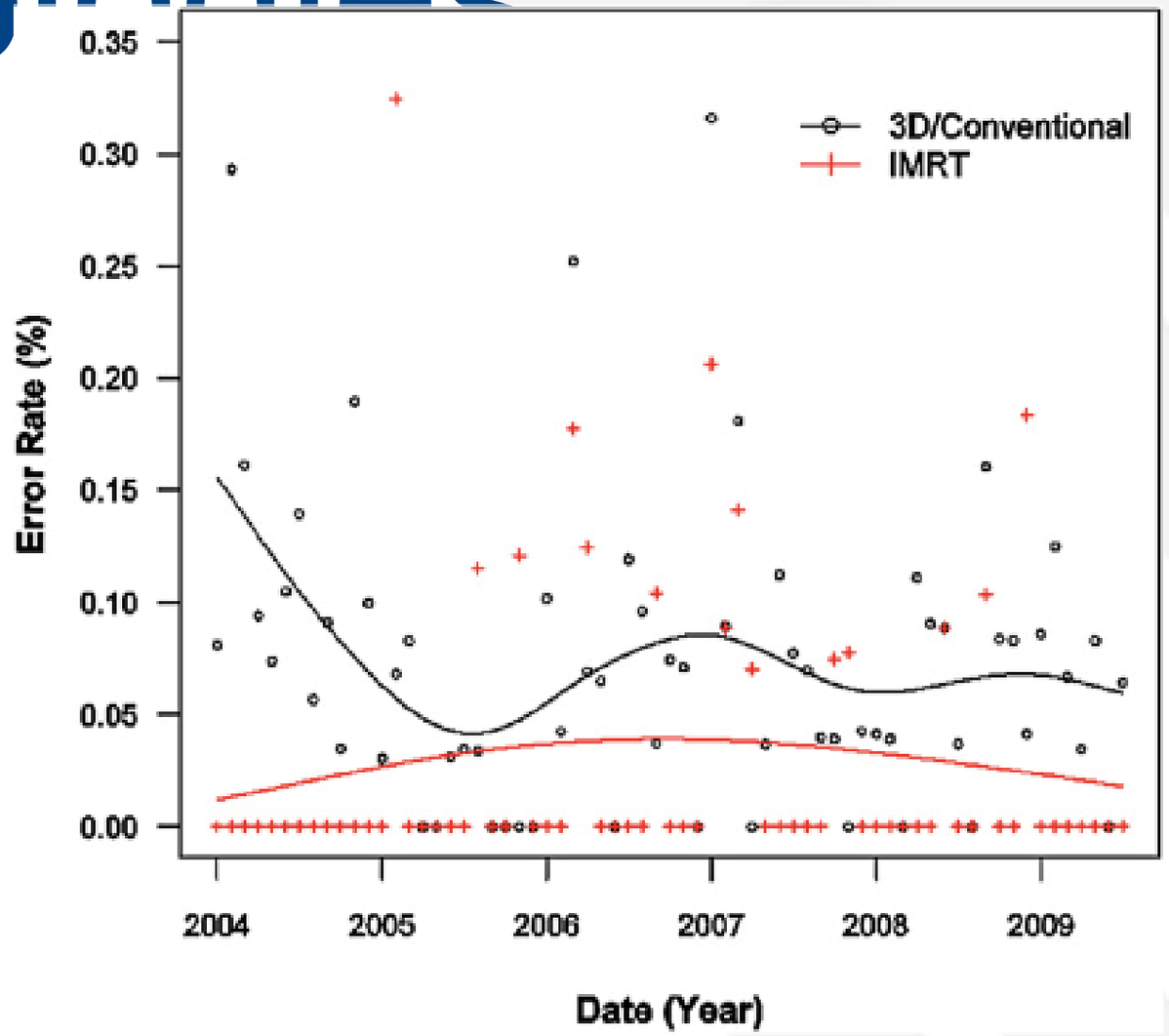


Fig. 2. Error rates over time with trend curves. Open circles denote error rate per month for three-dimensional (3D)/conventional treatments; solid black line, trend in 3D/conventional error rate over time; crosses = monthly error rate for intensity-modulated radiation therapy (IMRT); solid red line, trend in IMRT error rate over time.

Margalit DN, et al. Red 2011;81:e673-e679.

Impact of new technologies

- There was a lower error rate with IMRT compared with 3D/conventional RT .
- The types of errors differ significantly between IMRT and 3D/ conventional RT.
- QA processes must be uniquely adapted for each technique.

Table 5. Association between error type and treatment type

	Treatment type			
Error type*	3D/Conventional	IMRT	OR† (95% CI)	*p* Value
Data	38 (0.02%)	6 (0.01%)	0.50 (0.21, 1.19)	0.12
Setup	39 (0.02%)	3 (0.005%)	0.24 (0.08, 0.79)	0.02
Machine	25 (0.01%)	9 (0.02%)	1.14 (0.53, 2.45)	0.73
Accessory	30 (0.02%)	1 (0.002%)	0.11 (0.01, 0.78)	0.03
None	183608 (99.9%)	57787 (99.97%)		

Abbreviations: 3D = three-dimensional; CI = confidence interval; IMRT = intensity-modulated radiation therapy; OR = odds ratio.
* Four errors with unknown treatment type were excluded from the analysis.
† OR of each error type vs. no error for IMRT vs. 3D/conventional treatment.

Margalit DN, et al. Red 2011;81:e673-e679.

Impact of new technologies

Event	Task Name	1997				1998				1999				2000				2001				2002			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
1	Install 2 Varian linacs with MLC																								
2	Upgrade 2 Varian linacs with MLC																								
3	Upgrade 1 Varian linac with MLC																								
4	Replace 2 Varian linacs with MLC																								
5	Electronic programming: Record & Verify to Varian linacs																								
6	Install 2 Elekta linacs with MLC & motorized wedge																								
7	Install 1 Elekta linacs with MLC & motorized wedge																								
8	Manual programming: Record & Verify to Elekta linacs																								
9	Partial electronic programming: Record & Verify to Elekta linacs																								
10	Policy for motorized wedge programming: Elekta linacs																								
11	Electronic programming: Record & Verify to Elekta linacs + MLC																								

Fig. 1. Introduction of MLC and R&V systems at the Princess Margaret Hospital, 1997–2002.

Huang G, et al., *Red* 2005;61:1590-1595.

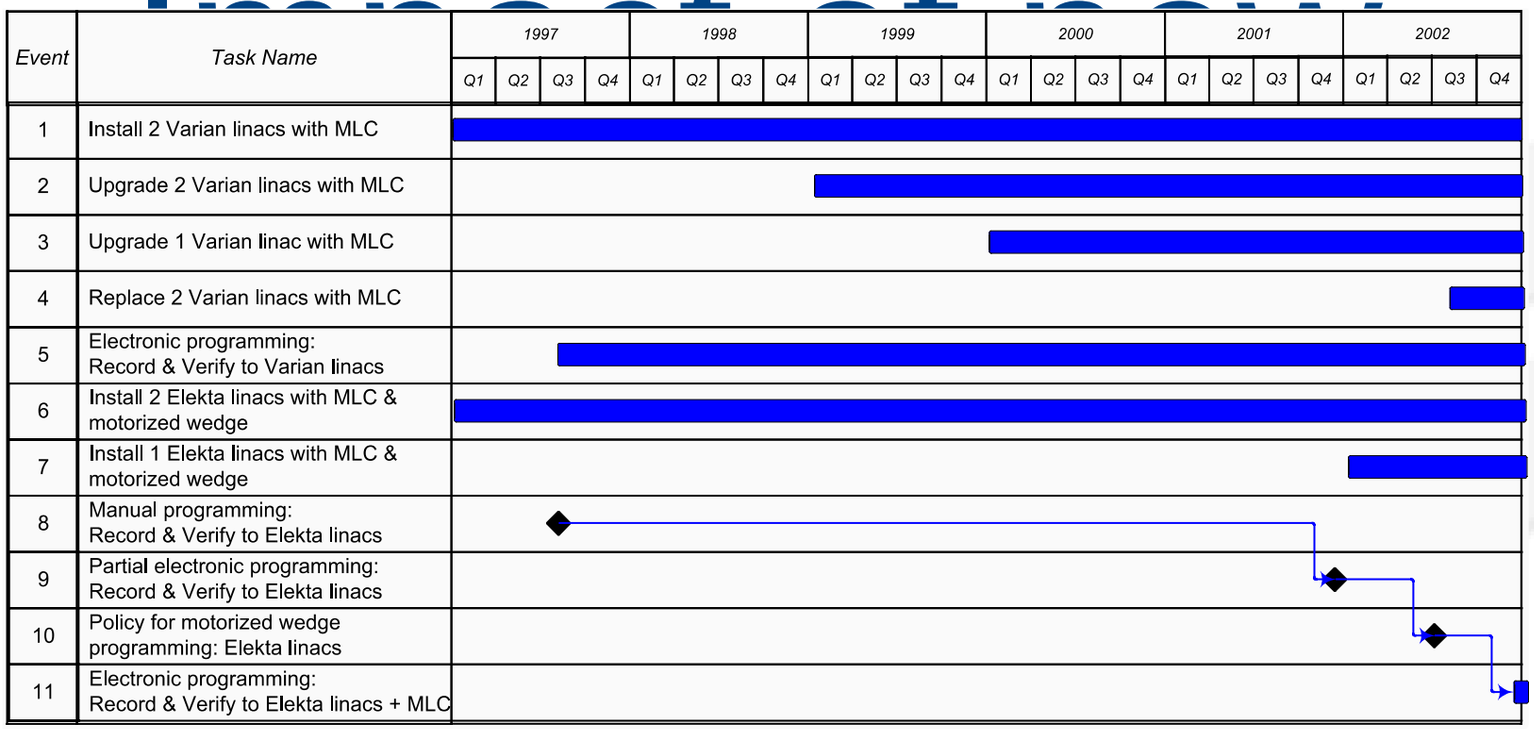


Fig. 1. Introduction of MLC and R&V systems at the Princess Margaret Hospital, 1997–2002.

Table 1. Radiation therapy error rates from 1997–2002

Year	Errors* (*n*)	Patient treatments (*n*)	Error rate per patient (%) (95% CI)†	Treatment volumes (*n*)	Error rate per treated volume (%) (95% CI)†	Fractions (*n*)	Error rate per fraction (%) (95% CI)‡
1997	63	4,880	1.29 (1.00–1.66)	5,935	1.06 (0.82–1.37)		
1998	65	4,967	1.31 (1.02–1.68)	7,400	0.88 (0.68–1.13)		
1999	85	4,492	1.89 (1.52–2.35)	6,959	1.22 (0.98–1.52)		
2000	91	4,179	2.18 (1.77–2.68)	7,018	1.30 (1.05–1.60)	41,548	0.29 (0.24–0.35)
2001	145	4,624	3.14 (2.66–3.69)	7,835	1.85 (1.57–2.18)	97,858	0.38 (0.34–0.42)
2002	106	4,994	2.12 (1.75–2.57)	8,155	1.30 (1.07–1.58)	101,781	0.21 (0.19–0.25)
Total	555	28,136	1.97 (1.81–2.14)	43,302	1.28 (1.18–1.39)	241,187	0.29 (0.27–0.32)

Abbreviation: CI = confidence interval.

* The same technical error occurring over >1 fraction is counted as one error.

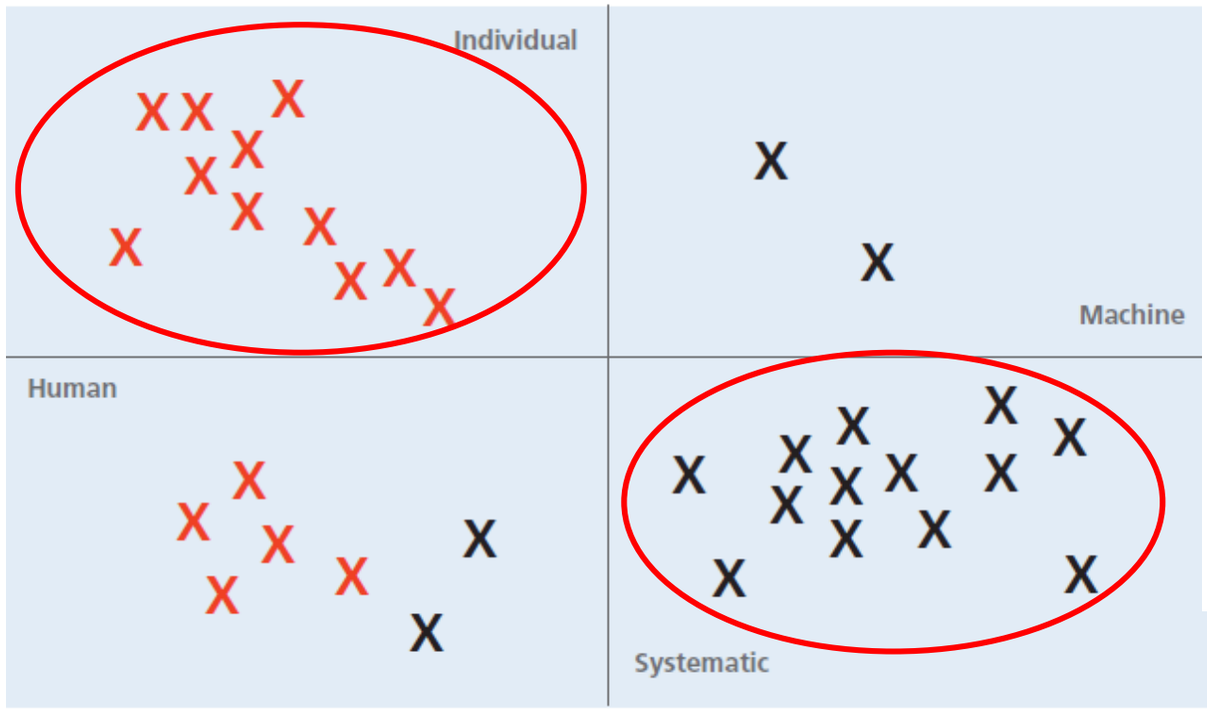
† Significant increase in error rate over time ($p < 0.001$).

‡ Each fraction delivered with an error is counted as a separate error.

Huang G, et al., *Red* 2005;61:1590-1595.

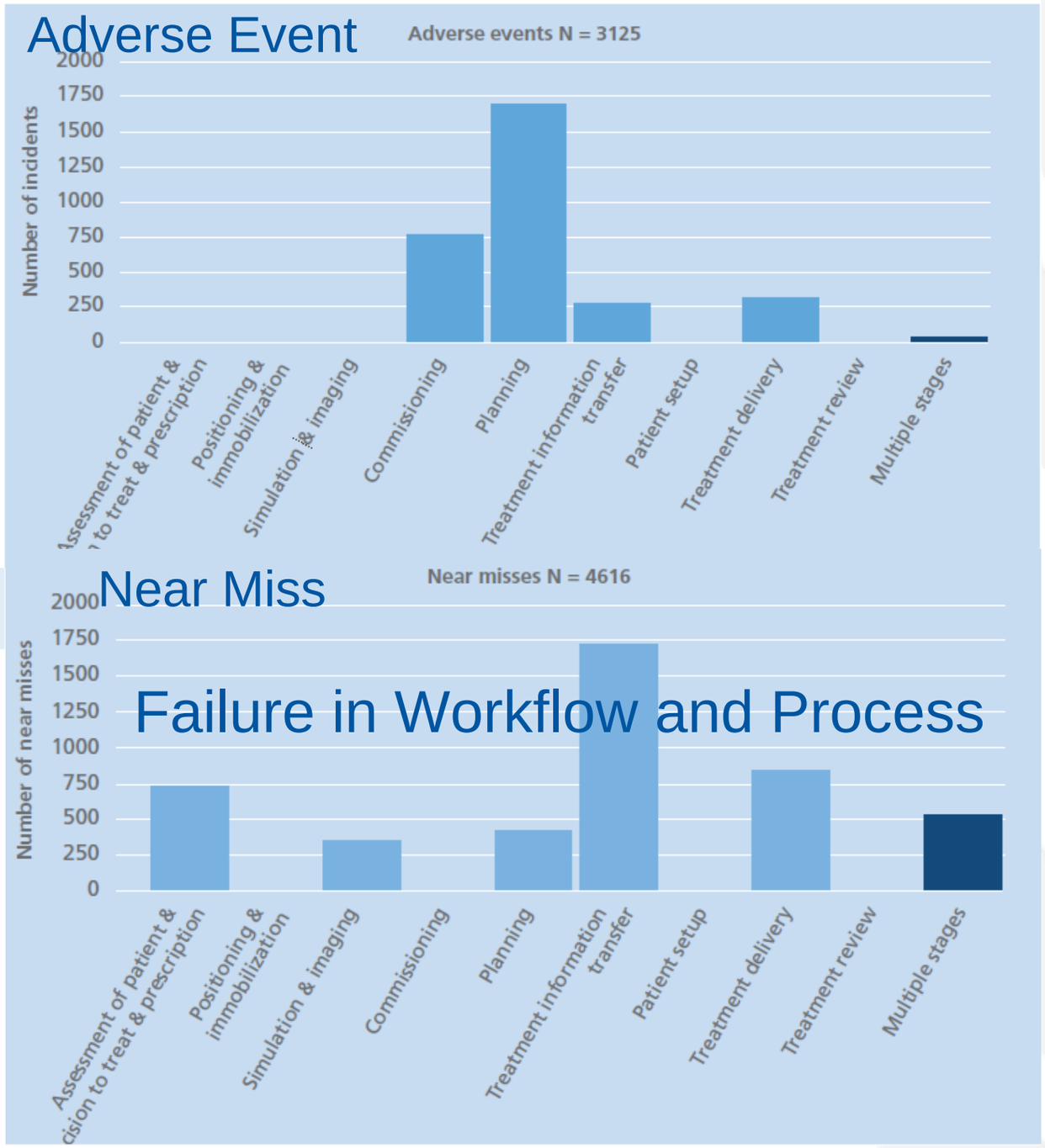
High Risk Area in Radiotherapy

Figure 3: A conceptual framework to prioritize high-risk areas in radiotherapy practice[1]



Source: Dr. Claire Lemer, the WHO World Alliance for Patient Safety

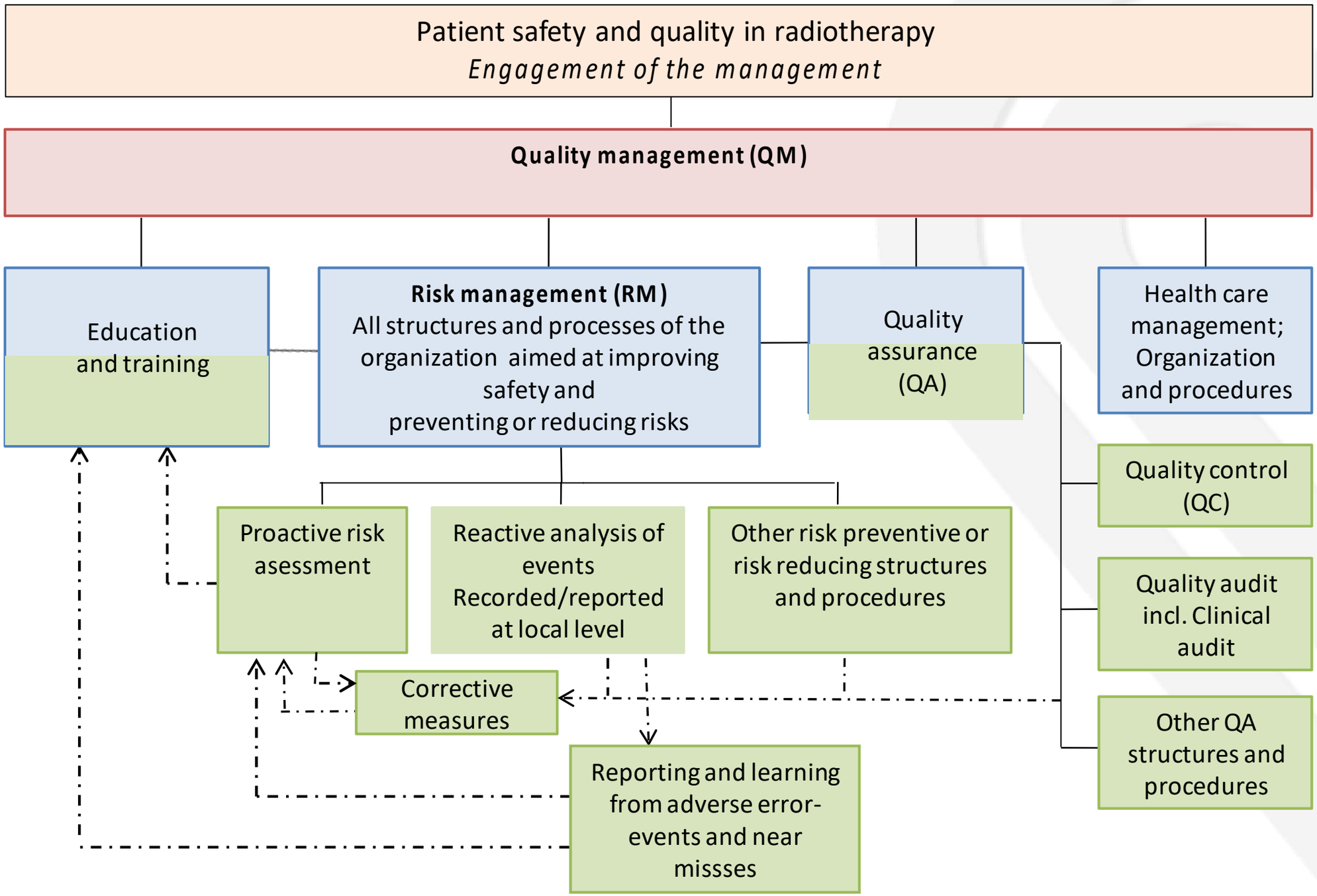
Figure 4: Radiotherapy incidents (1976-2007) by the stages of treatment process



Radiotherapy Risk Profile: World Health Organization 2008.12

Courtesy of Y Han, Ph.D.

Risk mitigation - Design



Risk mitigation - Design

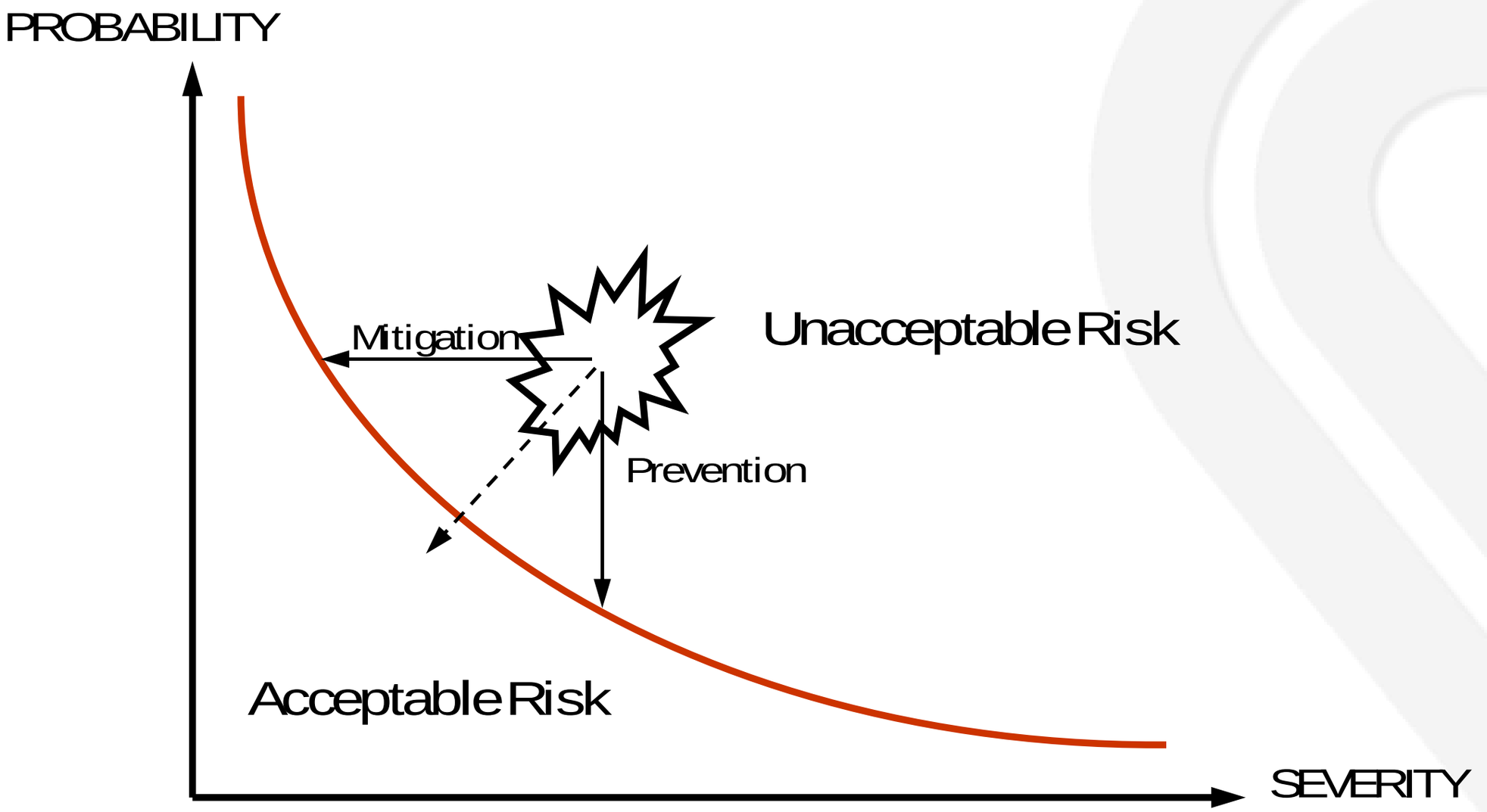
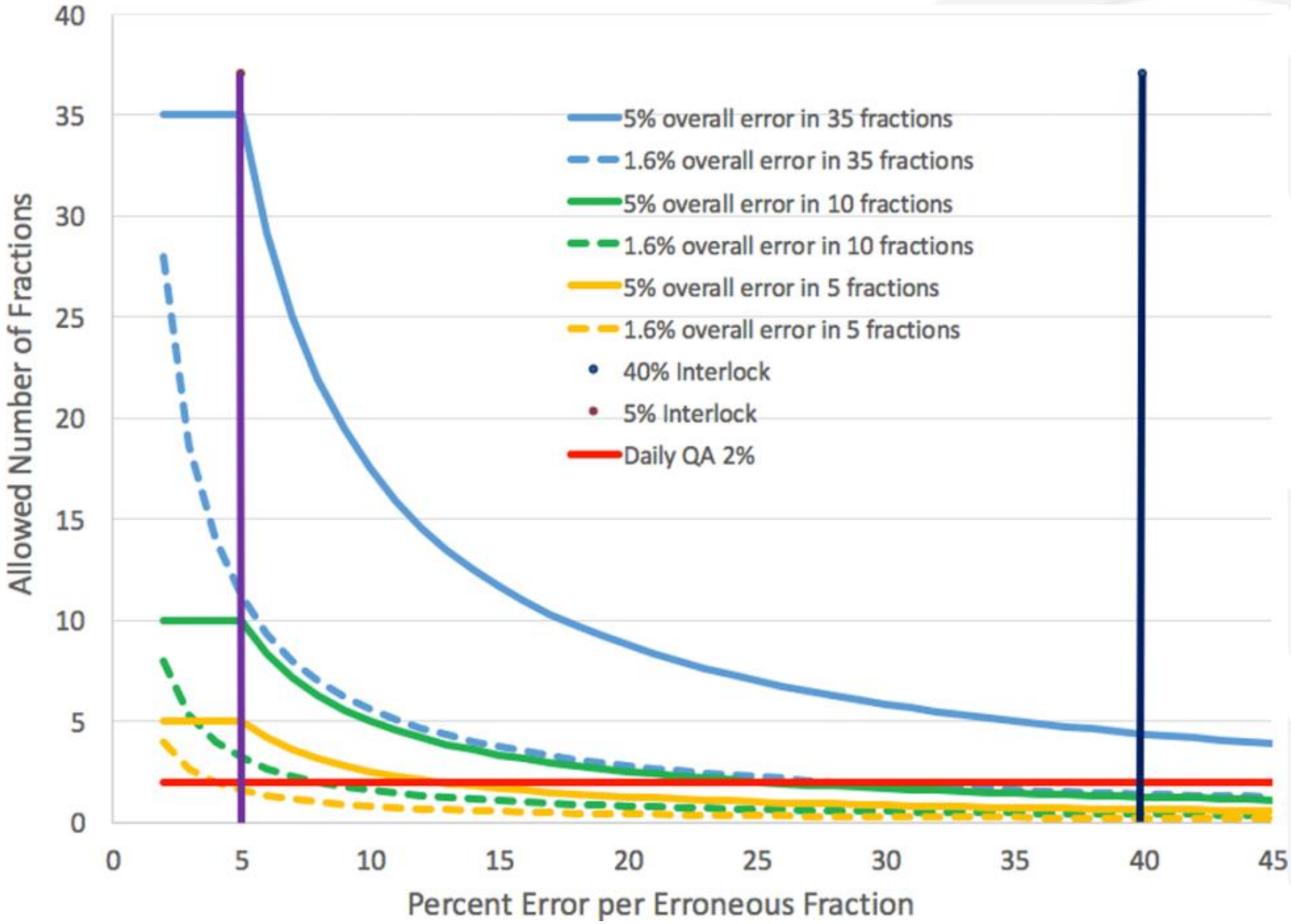


Figure 4.3. Relationship between severity and probability (Farmer Curve) indicating how to reach (via mitigation and prevention) the acceptable risk area.

Risk mitigation - Design



Risk mitigation - Process

- Eg. FMEA

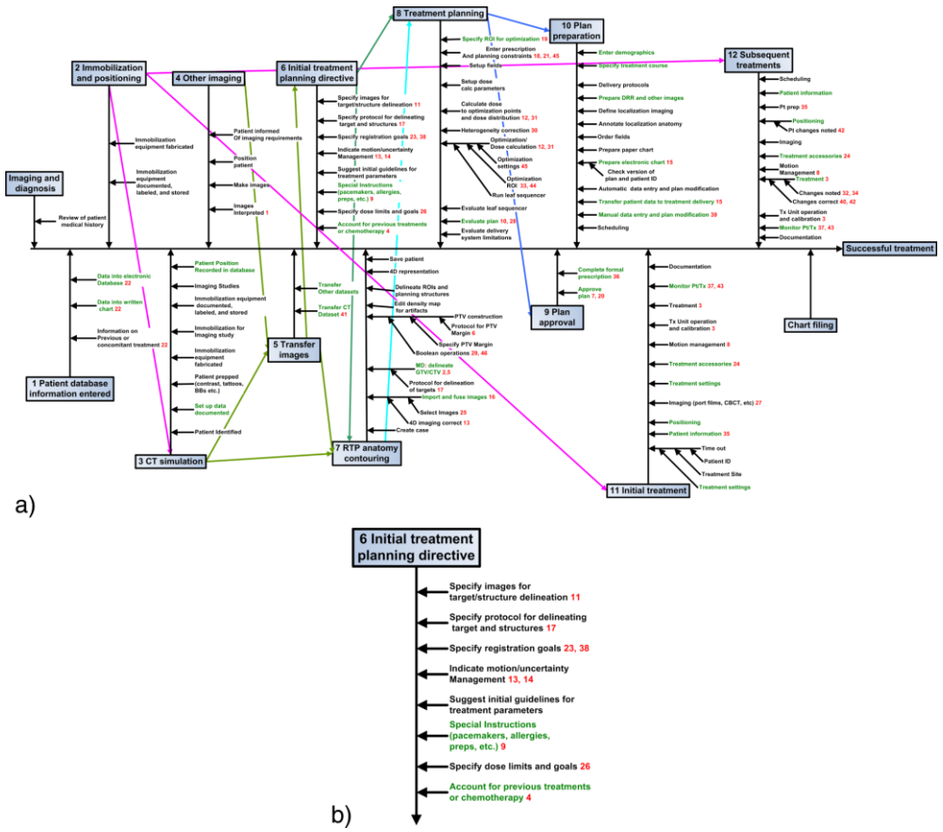


FIG. 2. (a) An IMRT process tree, (b) magnified view of the initial treatment planning directive branch. The red numbers indicate (hazard ranking) the most hazardous 20%–25% of the steps as indicated by high risk priority number values. Steps with high severity hazards are shown in green. [See text and Sec. VIII Ref. 64) for details.] A hazard is something that can cause harm. A risk is the chance, high or low, that any hazard will actually cause somebody harm.

TABLE II. Descriptions of the O, S, and D values used in the TG-100 FMEA.

Rank	Occurrence (O)		Severity (S)		Detectability (D)
	Qualitative	Frequency in %	Qualitative	Categorization	Estimated Probability of failure going undetected in %
1	Failure unlikely	0.01	No effect		0.01
2		0.02	Inconvenience	Inconvenience	0.2
3		0.05			0.5
4	Relatively few failures	0.1	Minor dosimetric error	Suboptimal plan or treatment	1.0
5		<0.2	Limited toxicity or tumor underdose	Wrong dose, dose distribution, location, or volume	2.0
6	Occasional failures	<0.5			5.0
7		<1	Potentially serious toxicity or tumor underdose		10
8	Repeated failures	<2			15
9		<5	Possible very serious toxicity or tumor underdose	Very wrong dose, dose distribution, location, or volume	20
10	Failures inevitable	>5	Catastrophic		>20

Risk mitigation

frontiers in ONCOLOGY

ORIGINAL RESEARCH ARTICLE
published: 16 December 2013
doi: 10.3389/fonc.2013.00305

Incident learning and failure-mode-and-effects-analysis guided safety initiatives in radiation medicine

Ajay Kapur*, Gina Goode, Catherine Riehl, Petrina Zuvic, Sherin Joseph, Nilda Adair, Michael Interrante, Beatrice Bloom, Lucille Lee, Rajiv Sharma, Anurag Sharma, Jeffrey Antone, Adam Riegel, Lili Vijeh, Honglai Zhang, Yijian Cao, Carol Morgenstern, Elaine Montchal, Brett Cox and Louis Potters

Department of Radiation Medicine, North Shore-LIJ Cancer Institute, Hofstra North Shore-LIJ School of Medicine, New Hyde Park, NY, USA

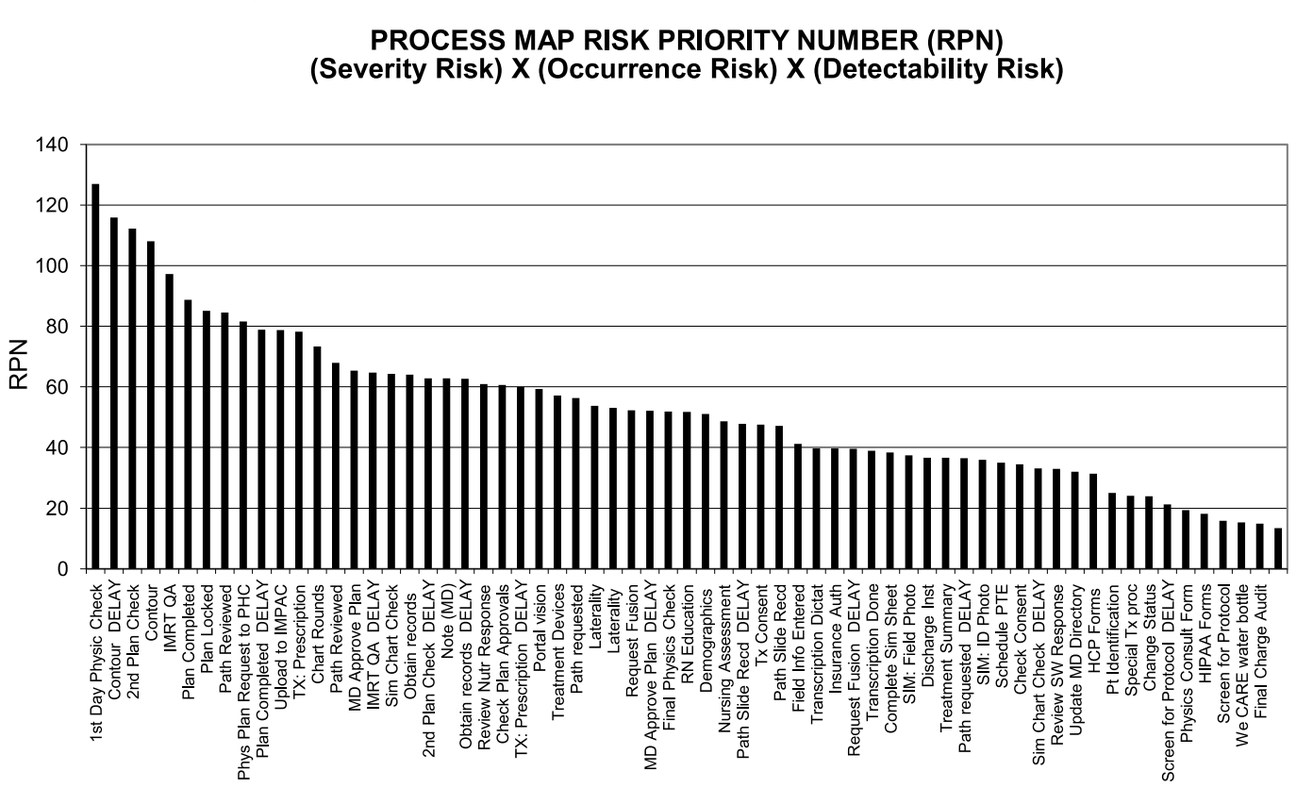


FIGURE 2 | Composite risk probabilities of failure-modes from combined components of risk elements. Based on inputs from all staff members.

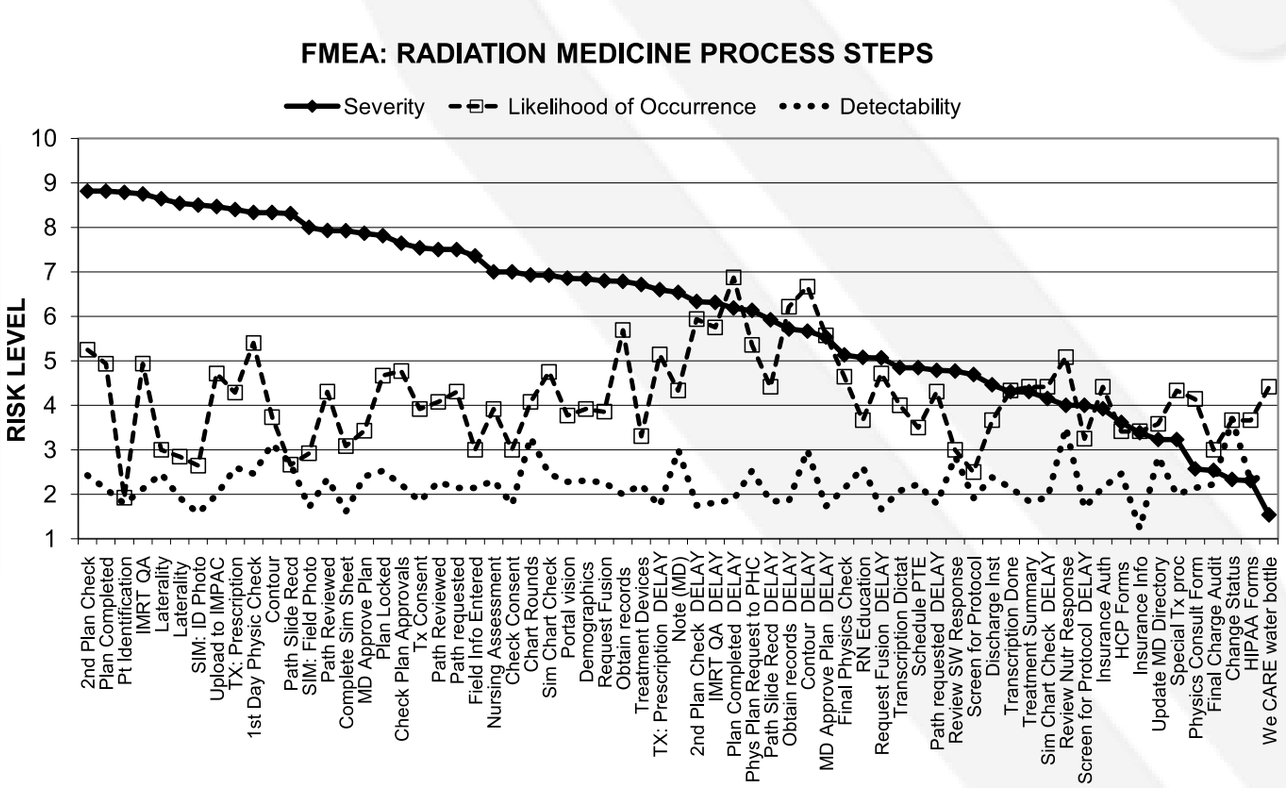


FIGURE 1 | Decomposition of our process-map in radiation medicine into three components of risk levels based on prospective failure-mode analysis.

Kapur A, et al *Frontiers in Oncology* 2013;3.

Risk mitigation

frontiers in ONCOLOGY

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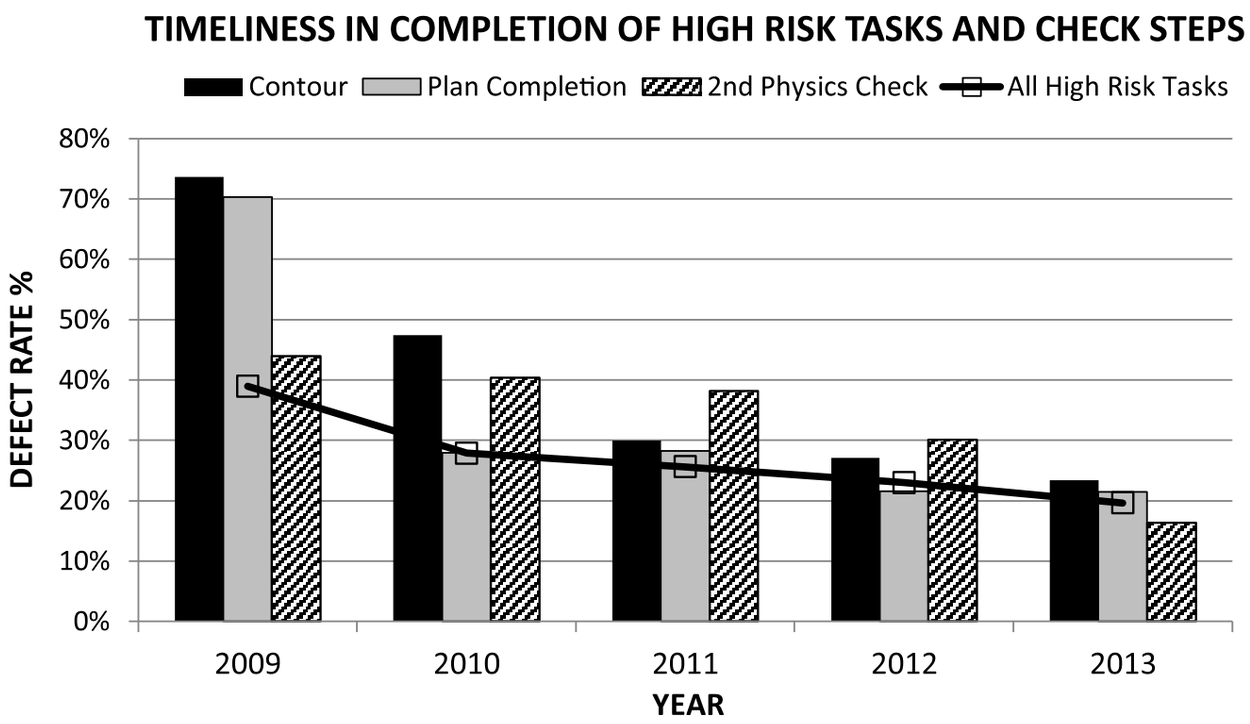

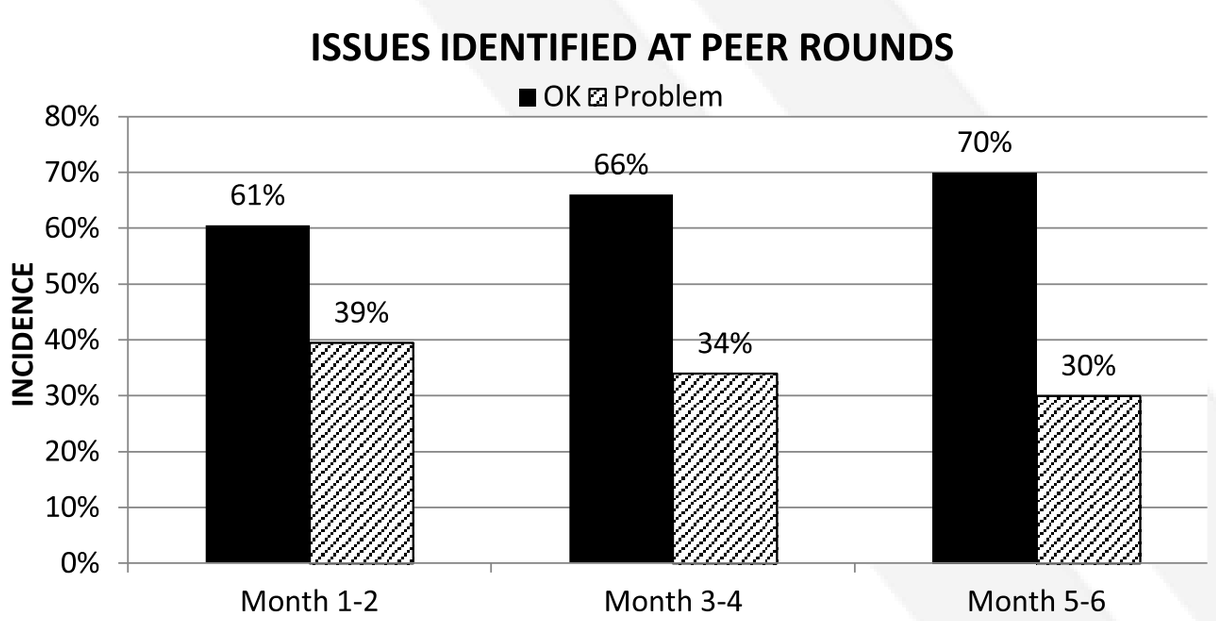

Kapur A, et al *Frontiers in Oncology* 2013;3.

Risk mitigation - Standardizin
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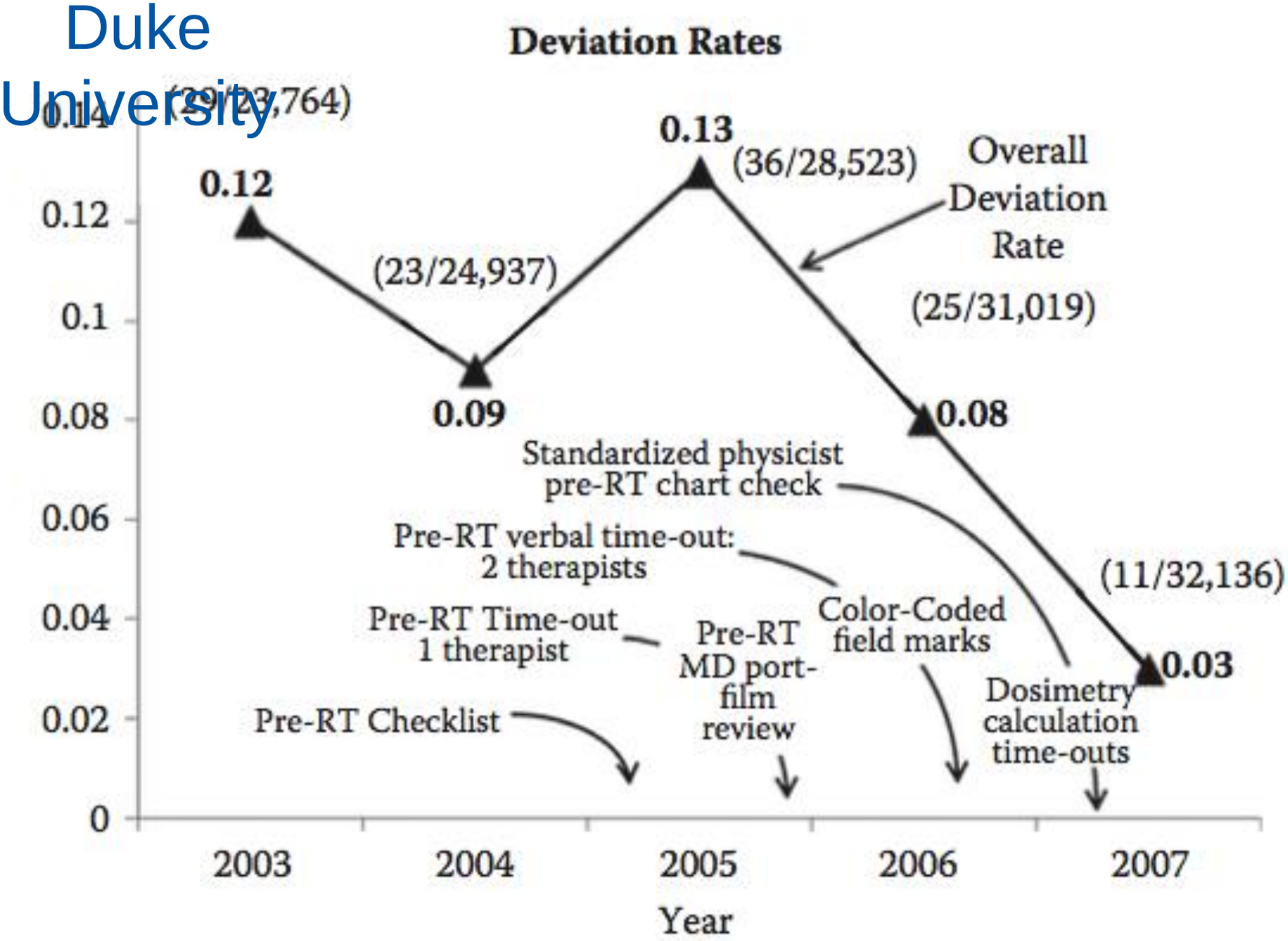
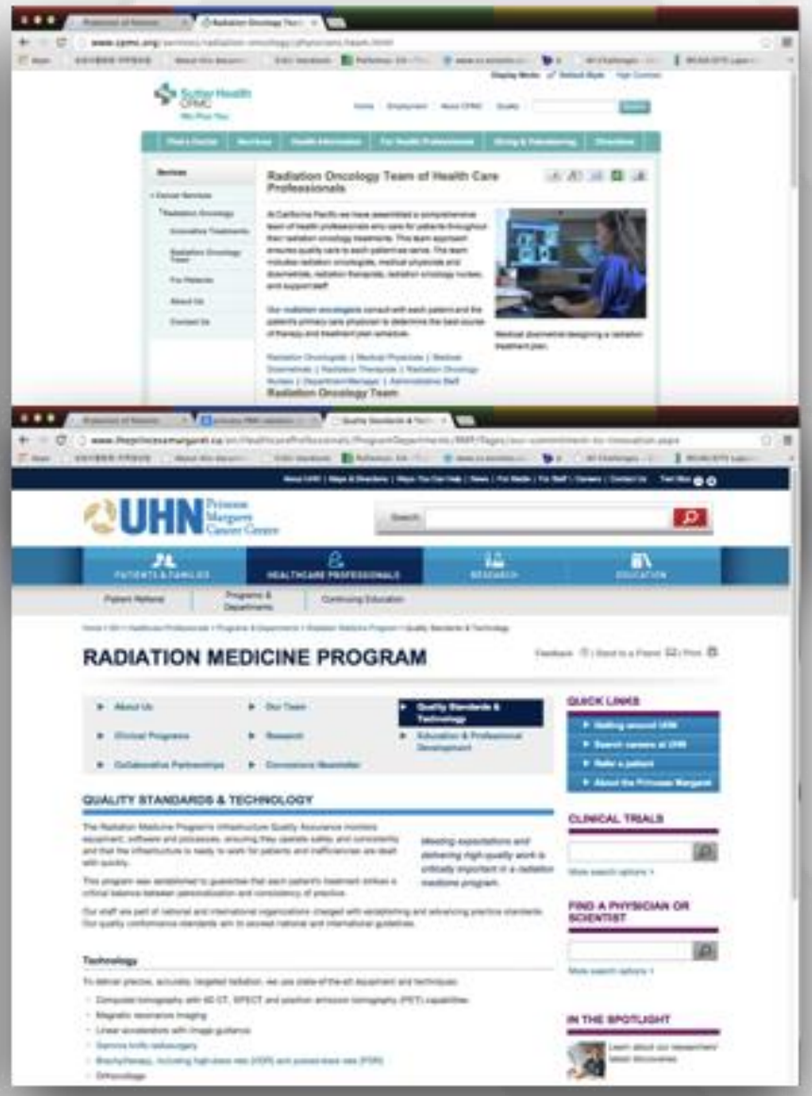
Duke University

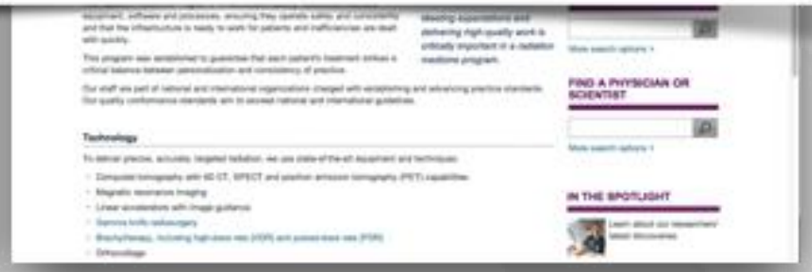


Adapted from ASTRO presentation; Marks L, et al. 2008

Perception Change for Patient Safety



Perception Change for Patient Safety



Risk mitigation – Reporting and Culture

Radiotherapy incidents

Trend analysis of radiation therapy incidents over seven years

Jean-Pierre Bissonnette *, Gaylene Medlam

Radiation Medicine Program, Princess Margaret Hospital, Toronto, Ontario, Canada

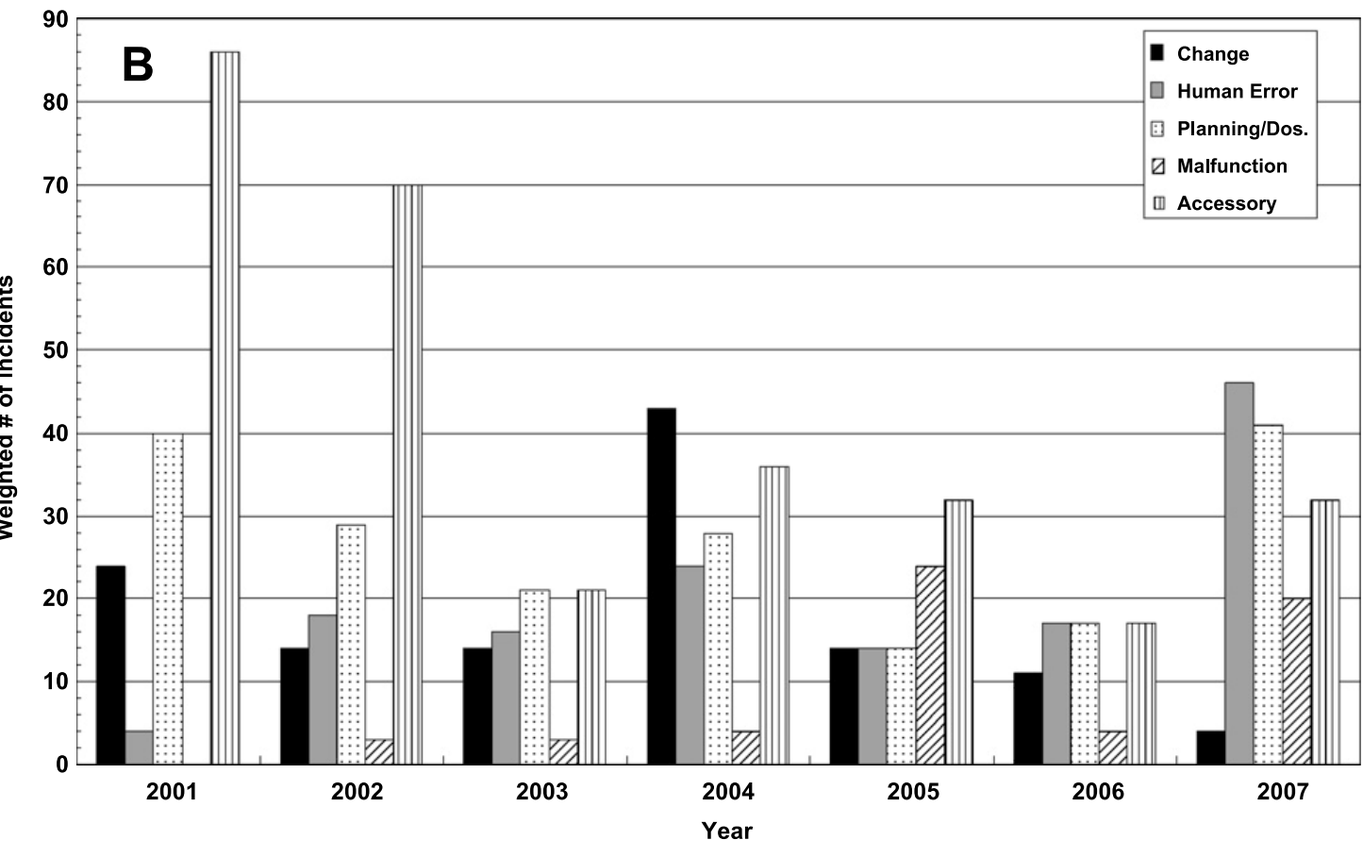


Fig. 4. Distribution of incidents sorted by generic cause, weighted by severity score.

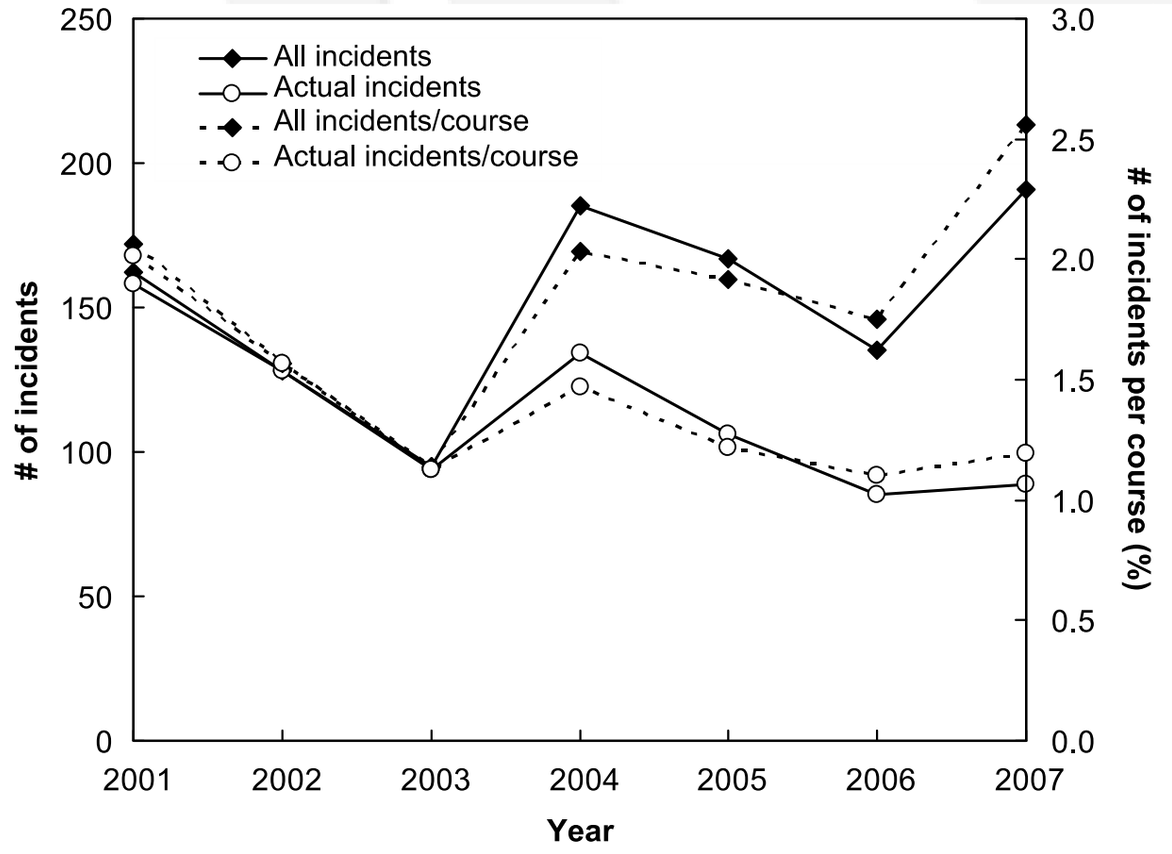


Fig. 1. Annual number of incidents and incident rates. Actual incidents are those that were not declared as near misses. Near misses were only sporadically reported until 2004.

Risk mitigation – Reporting and Culture

- Survey with Good catch program
  - 84% of respondents (100% of physicians) agreed that the good catch program enhances patient safety mindfulness.
  - Only 5% reported being dissuaded by a physician, supervisor, or peer from submitting good catches.
- Incident learning system can enhance patient safety mindfulness and promote a safety culture.

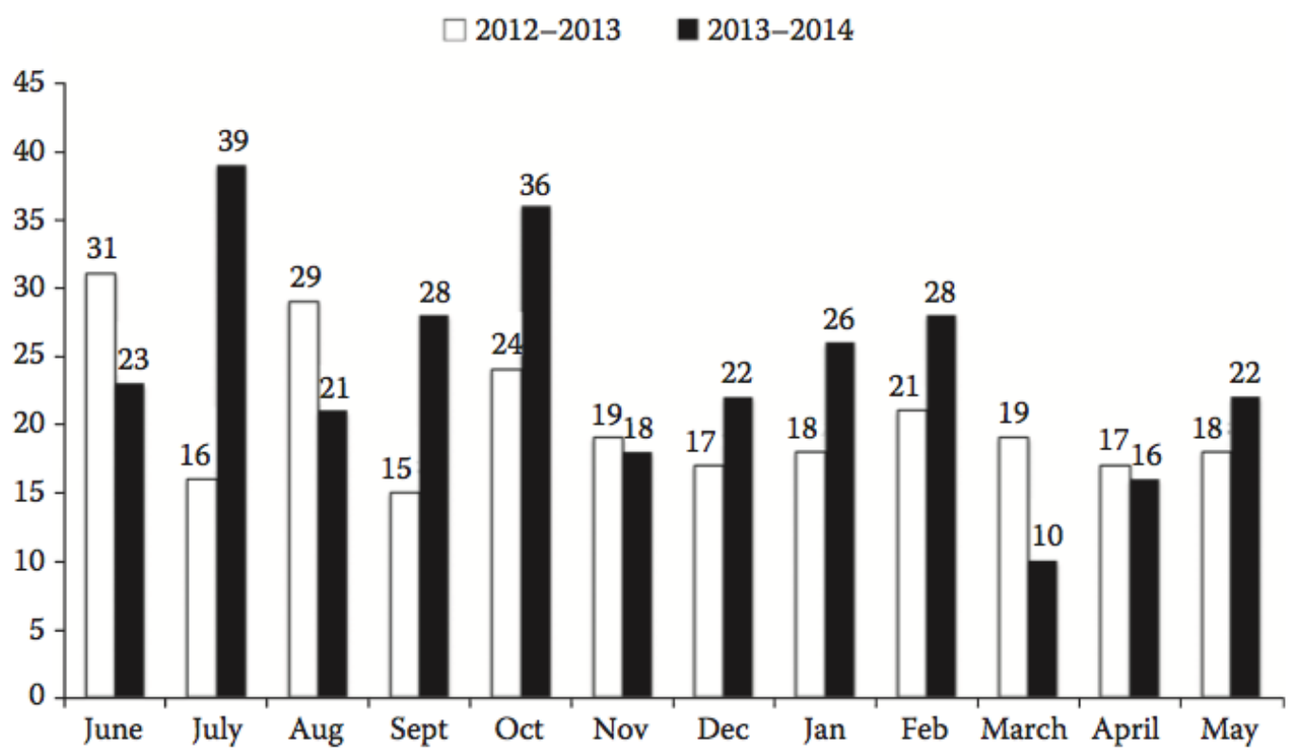
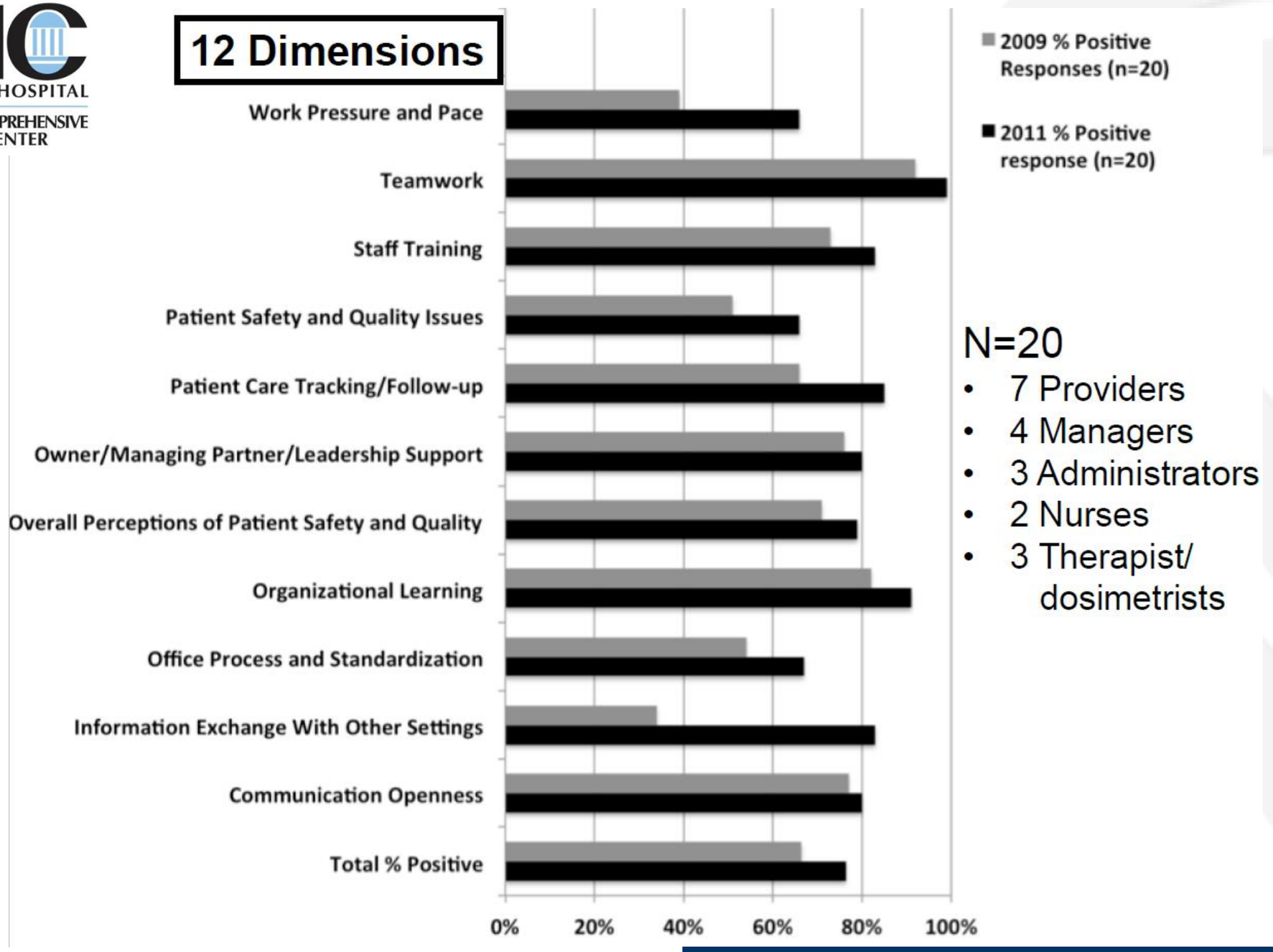


FIGURE 6.9
Number of submitted good catches per month.

Improvement of Patient Safety Culture

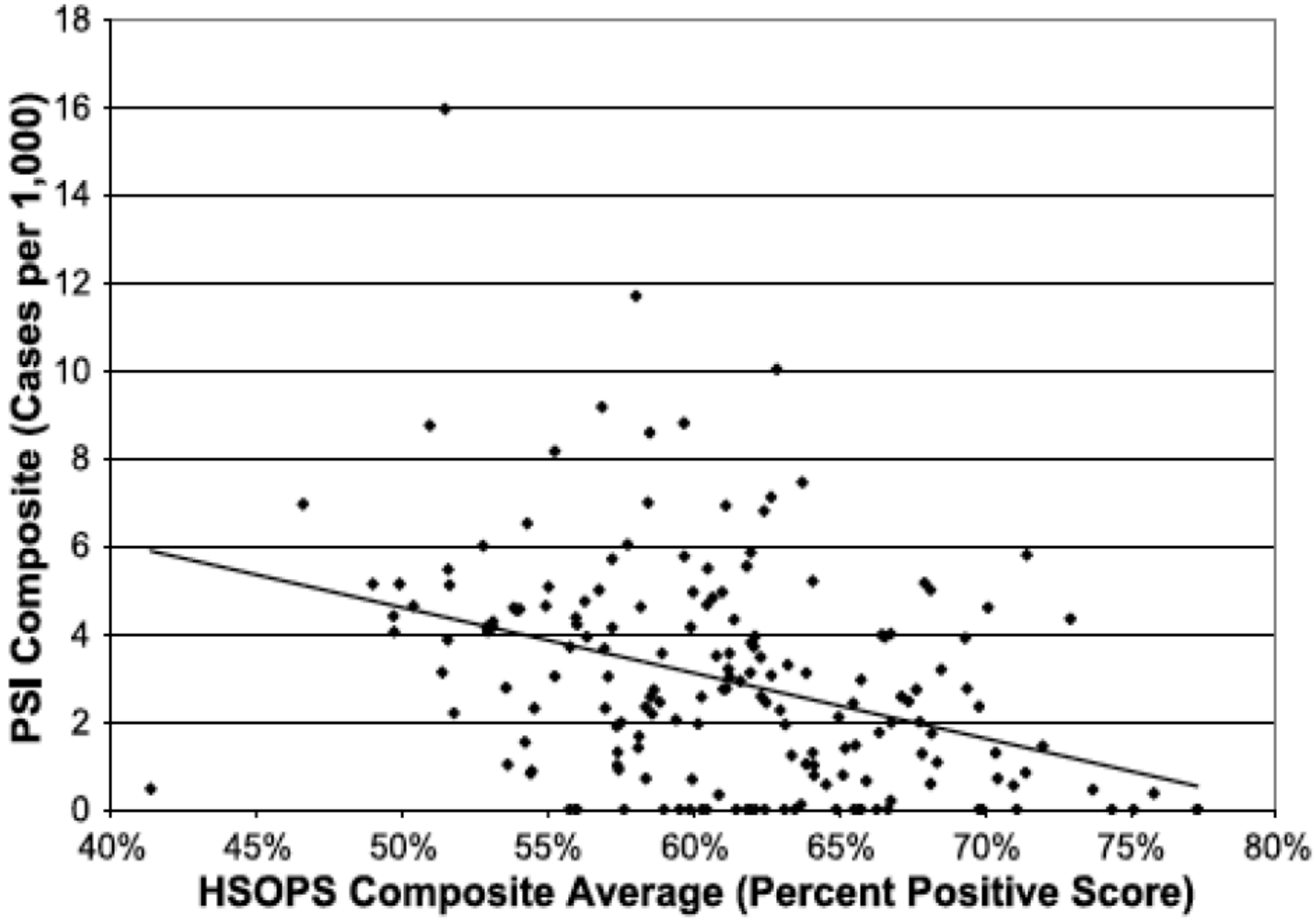
UNC N.C. CANCER HOSPITAL
LINEBERGER COMPREHENSIVE CANCER CENTER



N=20
- 7 Providers
- 4 Managers
- 3 Administrators
- 2 Nurses
- 3 Therapist/ dosimetrists

AHRQ Advancing Excellence in Health Care http://www.ahrq.gov/qual/patientsafetyculture/

Improving Safety Culture Reduces Complicates



179 Hospitals, 56,480 staff respondents

Mardon RE, et al., J Patient Saf. 2010.

(*J Patient Saf* 2010;6: 226–232)

Culture of Safety

- Climate of blame and punishment

  “We have tried to create culture, environment, and infrastructure to allow all individuals (staff members and patients) to develop an understanding of safety mindfulness and to feel comfortable in openly speaking about errors and suboptimal systems.”

Culture of Safety

Some people voiced, “I don’t want to report ‘errors’ because I don’t want to get into trouble.”

Table 2 Perceptions regarding overall communication and comfort in reporting errors

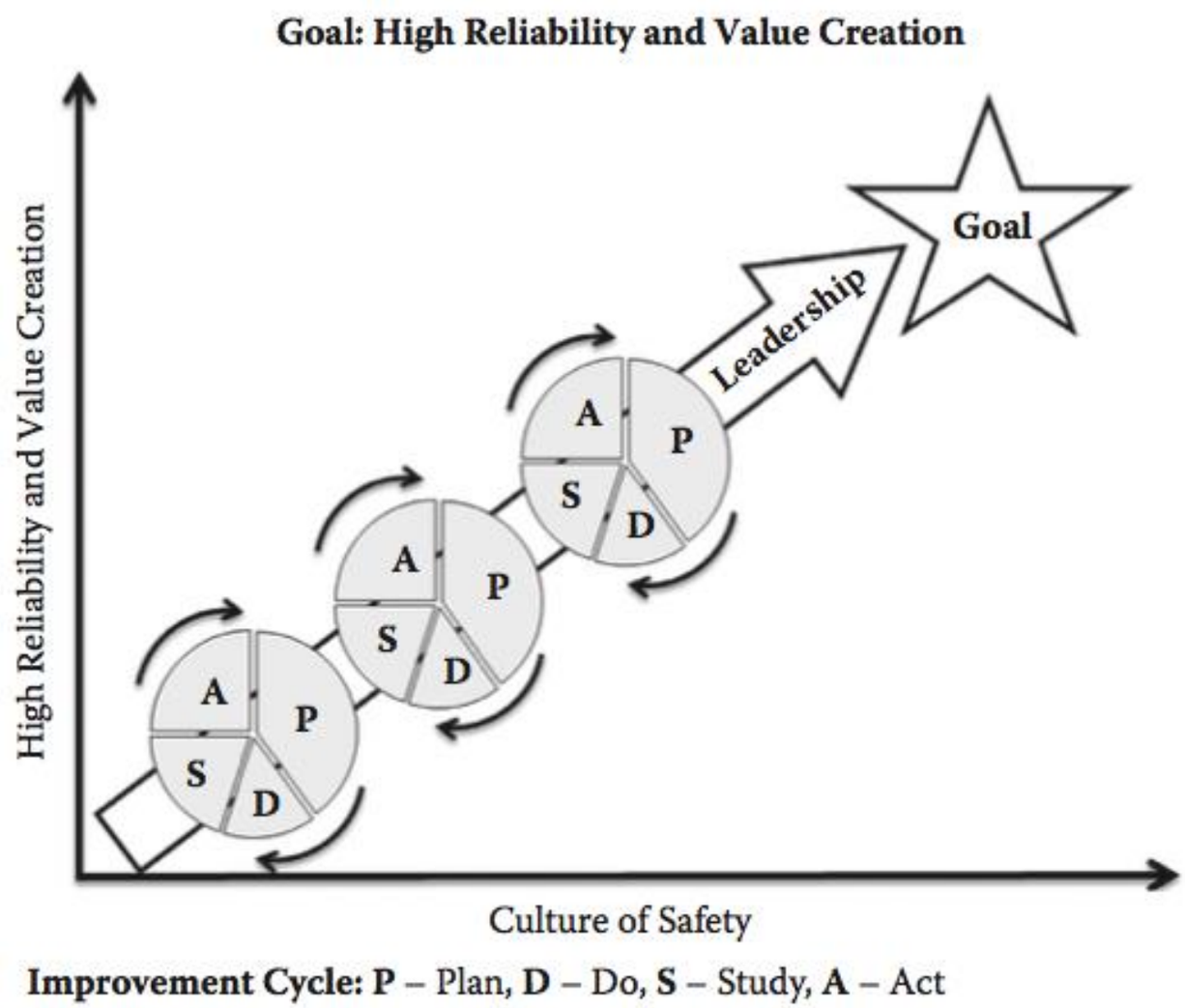
Survey questions	Strongly disagree n (%)	Disagree n (%)	Neutral n (%)	Agree n (%)	Strongly agree n (%)
The overall communication between me and the physicians in my department is good.					
Therapists	13 (4)	15 (4)	37 (10)	97 (27)	194 (55)
Dosimetrists	5 (3)	9 (5)	8 (4)	41 (21)	127 (67)
The overall communication between me and the dosimetrists and physicists in my department is good.					
Therapists (with dosimetrists)	14 (4)	9 (3)	20 (6)	78 (22)	230 (65)
Dosimetrists (with physicists)	7 (4)	3 (1)	13 (7)	30 (16)	137 (72)
The overall communication between me and the administrators in my department is good.					
Therapists	33 (9)	35 (10)	55 (15)	97 (27)	136 (38)
Dosimetrists	13 (7)	13 (7)	38 (20)	51 (27)	75 (39)
The overall communication between the radiation therapy/medical dosimetry staff and the physicians in my department is good.					
Therapists	14 (4)	23 (6)	45 (13)	116 (33)	158 (44)
Dosimetrists	6 (3)	10 (5)	7 (4)	48 (26)	114 (62)
The overall communication between the radiation therapy and medical dosimetry staff and the dosimetrists and physicists in my department is good.					
Therapists (with dosimetrists)	10 (3)	17 (5)	37 (10)	93 (26)	198 (56)
Dosimetrists (with physicists)	5 (3)	6 (3)	10 (5)	33 (18)	131 (71)
The overall communication between the radiation therapy and medical dosimetry staff and the administrators in my department is good.					
Therapists	35 (10)	37 (10)	82 (23)	92 (26)	110 (31)
Dosimetrists	13 (7)	13 (7)	36 (20)	55 (30)	67 (36)
I am encouraged to report errors in the clinic.					
Therapists	8 (2)	8 (2)	25 (7)	37 (11)	277 (78)
Dosimetrists	6 (3)	1 (1)	11 (6)	16 (8)	156 (82)
I am comfortable reporting errors in the clinic.					
Therapists	18 (5)	18 (5)	29 (8)	53 (15)	236 (67)
Dosimetrists	5 (3)	5 (3)	7 (3)	25 (13)	148 (78)

~18%

Jessica A. Church, Pract Radiat Oncol 2013.

Culture of Safety

- Safety culture can be increased by leadership only.
- Leadership
  - should suggest an exact goal for each role of staff (e.g. M.D., Physicist, RTT, and so on).
  - should organize process, role of staffs, and communication well.



Patient Safety in SMC

- Patient Safety Committee from 2014.
- Reporting System: Good Catcher
- Regular Meeting at Every Month
  - Review of all events
  - Risk Analysis
  - Modification of Protocols and Procedures
- Education 2 times a year
- Share the Critical Events Immediately

Modification of Work Flow

1. CBCT

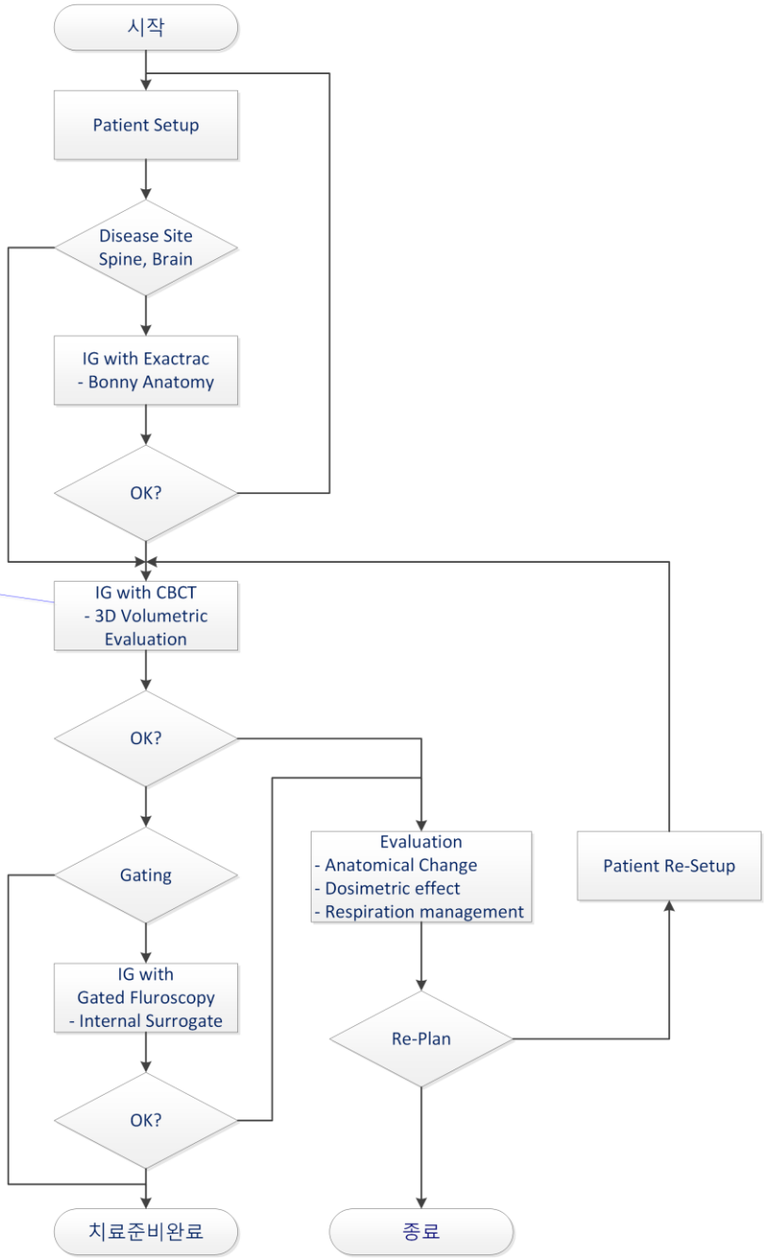
For Brain SRS

- Mode: Standard Brain or High Quailty Brain
- Full Fan, Slice Thickness 1 mm

For Other Sites

- Mode: Pelvis
- Half Fan, Slice Thickness 2.5 mm

2. 치료실 방사선사 수행 후, 주치의 확인



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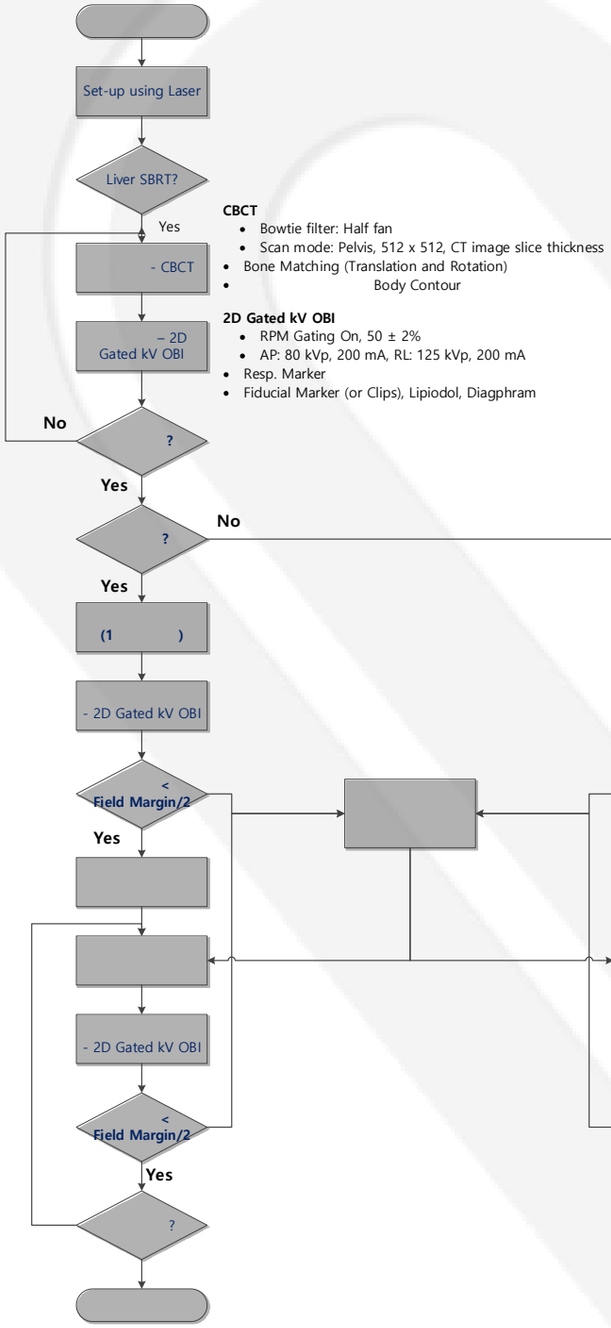
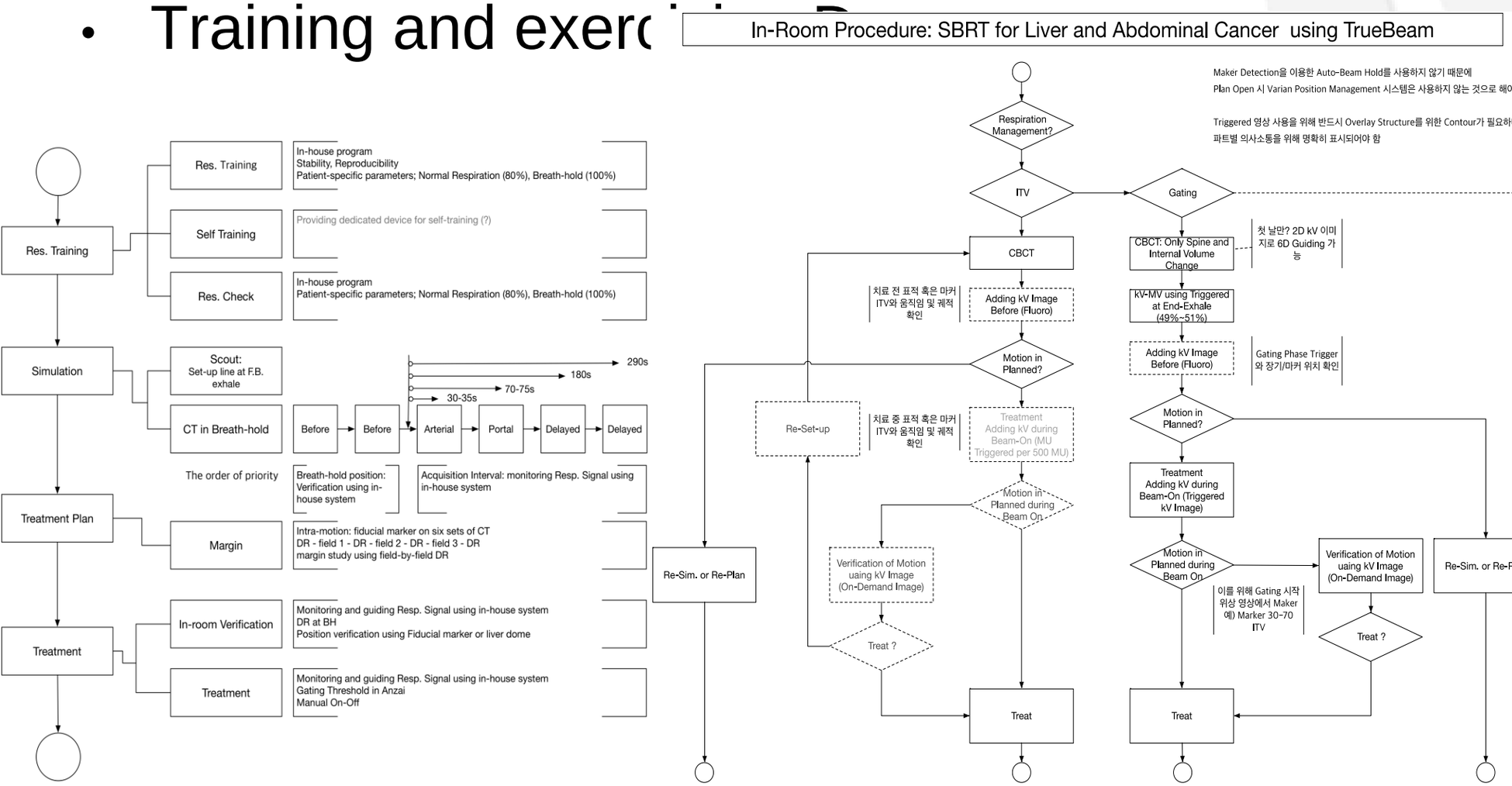


Before Clinical Implementation of New Machine and New Techniques

- Determining Workflow and role of the Physicians, Physicists, and RTT
- Training and exerc



Summary

- Need to secure justification through prospective research that is appropriate for domestic situation.
- Need to secure optimization for domestic situation
- Recently, the application and application of quality control to the treatment process have been actively studied.
- Development of optimization method including workflow optimized for individual institution is required.
- It should be applied in consideration of the financial resources of individual institutions including human resources in a domestic harsh environment.
- Efforts to raise safety culture.

Thank you.