

Safety considerations for IMRT: Executive summary

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This report on intensity-modulated radiation therapy (IMRT) is part of a series of white papers addressing patient safety commissioned by the American Society for Radiation Oncology's (ASTRO) Target Safety Campaign. The document has been approved by the ASTRO Board of Directors, endorsed by the American Association of Physicists in Medicine (AAPM) and American Association of Medical Dosimetrists (AAMD), and reviewed and accepted by the American College of Radiology's Commission on Radiation Oncology. This report is related to other reports of the ASTRO white paper series on patient safety which are still in preparation, and when appropriate it defers to guidance that will be published by those groups in future white papers. This document takes advantage of the large body of work on quality assurance and quality control principles within radiation oncology whenever possible. IMRT provides increased capability to conform isodose distributions to the shape of the target(s), thereby reducing dose to some adjacent critical structures. This promise of IMRT is one of the reasons for its widespread use. However, the promise of IMRT is counterbalanced by the complexity of the IMRT planning and delivery processes, and the associated risks, some of which have been demonstrated by the New York Times reports on serious accidents involving both IMRT and other radiation treatment modalities. This report provides an opportunity to broadly address safe delivery of IMRT, with a primary focus on recommendations for human error prevention and methods to reduce the occurrence of errors or machine malfunctions that can lead to catastrophic failures or errors. © 2011 American Society for Radiation Oncology. Reprinted with permission. *Practical Radiation Oncology*. [DOI: 10.1118/1.3600524]

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I. INTRODUCTION

This executive summary briefly describes the overall goals and content of the report on safety considerations for IMRT and is intentionally limited in length and content. Please see the full report published electronically at www.practicalradonc.org. This abridged version is not intended to replace the full length report but rather to highlight key recommendations of the report. Background information for those less familiar with IMRT is limited to the full report.

I.A. Scope of this document on patient safety

This report is part of a series of white papers addressing patient safety commissioned by the American Society for Radiation Oncology (ASTRO) Board of Directors as part of ASTRO's Target Safety Campaign. The full length document was approved by the ASTRO Board of Directors on February 14, 2011 and has been endorsed by the American Association of Physicists in Medicine (AAPM), American Association of Medical Dosimetrists (AAMD), and the American Society of Radiologic Technologists (ASRT). These organizations have a long history of supporting efforts toward improving patient safety in the United States.

This report is related to other reports of the ASTRO white paper series on patient safety, still in preparation, especially those on peer review and on image-guided radiation therapy (IGRT) since both of these areas have implications on the practice of IMRT. There are sections of the report that defer to guidance that will be published by those groups in future reports. Because this is the first report in the safety series, some of the concerns included in this report are not limited to IMRT.

IMRT provides increased capability to conform isodose distributions to the shape of the target(s), thereby reducing dose to some adjacent critical structures. This promise of IMRT is one of the reasons for its widespread use. However, the promise of IMRT is counterbalanced by the complexity of the IMRT planning and delivery processes, and the associated risks.

The New York Times reported on serious accidents involving both IMRT and other radiation treatment modalities.^{1,2} The full length report broadly addresses safe delivery of IMRT, with a primary focus on recommendations for human error prevention and methods to reduce the occurrence of errors or machine malfunctions that can lead to *catastrophic failures or errors*.

The full treatment team should be composed of individuals with proper credentials and training specific to radiation therapy for the simulation, treatment planning, QA, and delivery processes. Additional training specific to IMRT is important. See the full length report (Sec. I A, available

online only at www.practicalradonc.org) for a description of the responsibilities of IMRT team members: including radiation oncologists, medical physicists, dosimetrists (or treatment planners), radiation therapists, and administrative staff. Special attention should be paid to the roles of the physician and physicist; both board certified medical specialists who share responsibility for IMRT quality.

II. SAFETY CONCERNS

Tools and techniques that can be used by individual clinicians to reassess and strengthen the safety of their IMRT programs are presented in the full length document. Due to the complexity of IMRT delivery, we believe it is unsafe for IMRT to be delivered in emergent situations that would encourage staff to skip the needed quality assurance steps. And yet, clinical pressures can make it difficult to ensure support for this approach.

Hazards within an IMRT program can be broadly categorized as environmental or technical. Environmental concerns, that can affect all patient treatments, include the lack of standard operating procedures, haste, habituation, incomplete understanding or misuse of procedures/equipment, an inadequate QA program, and a lack of continuing staff education. While these hazards are not unique to IMRT, their impact may be greater due to the complexity of IMRT. Technical concerns that affect safety can include inadequate commissioning of the clinical IMRT program, inadequate validation of the accuracy of treatment delivery parameters, improper use of one or more parts of the planning and delivery process, and an inadequate investigation of discrepancies between treatment plan parameters and QA results.

The responsibilities of members of the treatment team are defined in the report (see Table 2 in the full document; available online only at www.practicalradonc.org). Also, specific example process steps are presented including QA (Appendix 1 in full document; available online only at www.practicalradonc.org), and checklists (Appendix 2; available online only at www.practicalradonc.org), which may address ways to prevent or detect catastrophic failures for IMRT. The 54 process steps and 15 hand-offs between the personnel in the example workflow illustrate the critical need for clearly defined roles, and unambiguous/robust hand-offs (and means of communication) between personnel.

III. SUPPORTING A CULTURE OF SAFETY FOR IMRT: ENVIRONMENTAL CONSIDERATIONS

The departmental leadership establishes the foundation for patient safety and teamwork. While these elements are not unique to IMRT, we believe that they are crucial for ensuring a safe radiation therapy program, especially since IMRT requires additional equipment, personnel, and procedures for safety. The following considerations (discussed in detail in the full length document at www.practicalradonc.org) are important for creation of a culture of safety:

- Department members must trust each other³
- Administration must provide strong support for safety

- Event tracking, review, investigation, and follow up for events and near misses
- Appropriately qualified personnel and ongoing training
- Use of Standard Operating Procedures (SOPs)
- Defined roles and responsibilities for team members
- Strong communication among team members
- ACR/ASTRO Practice Accreditation
- Continuous quality improvements.

Each institution should customize procedures to reflect their own processes and resources but should have a basis founded in national or international guidance documents (Sec. IV) to create a program that explicitly incorporates patient safety. SOPs should be written and should empower individuals to halt planning or treatment when a problem is encountered allowing for proper investigation into the problem and then a decision regarding the best course of action to maintain patient safety. In the midst of a situation where adequate time is *not* allowed for performing all of the necessary QA steps prior to treatment, time pressures may stand in the way of identifying and resolving problems. The SOP should not permit staff to skip quality assurance steps.

Implementation of and adherence to detailed policies and procedures are necessary to avoid both quality errors and catastrophic failures. Details of what should be included in an IMRT SOP are in the full length document available online only at www.practicalradonc.org.

Figure 1 shows the complexity of the IMRT process as a series of process steps and review steps by members of the IMRT team. There are numerous situations, for example, a change in the patient geometry, that can lead to restarting the process from the beginning, which can cause pressures to skip or short-circuit QA procedures. Risks may also increase if inadequate time is allotted for, and in between, the various steps (e.g., image segmentation, written directive, planning, patient-specific QA). The full length report discusses many of these time considerations (with respect to safety) in detail.

IV. IMRT: GUIDANCE FOR QUALITY ASSURANCE: TECHNICAL CONSIDERATIONS

A summary of the existing guidance documents for IMRT is presented in the full length document (text and Table 3 available online only at www.practicalradonc.org). These earlier IMRT QA documents emphasized establishing a quality IMRT program and did not explicitly concentrate on the potential for catastrophic failures in IMRT delivery. In fact, several documents suggested that some QA efforts could be decreased or even eliminated after the accumulation of a stated amount of experience. *In this work, we acknowledge that certain types of catastrophic failures resulting from human error and/or equipment (hardware or software) malfunction might not be predictable based on past experience. In some situations, periodic testing alone may be inadequate for identifying these types of problems.*

The processes and tasks performed by the IMRT team are addressed with special attention to patient safety and to minimizing the potential for *catastrophic failures*. The full length document includes a detailed discussion of the following with respect to patient safety and quality:

- 4.2.1 Training
- 4.2.2 Commissioning an IMRT System
- 4.2.3 Establishing a QA Program
- 4.2.4 Pre-treatment IMRT QA program
- 4.2.5 Monitoring the IMRT Program

Each institution should have clear criteria for a pass or fail of the IMRT patient-specific IMRT QA technique. There is interinstitutional variation in the *content* of pretreatment IMRT QA, as well as the equipment and software used. There is no formal consensus on the desired/required level of agreement between the planned or expected calculation and the measured data for patient-specific IMRT QA. Also, the impact of failing to meet a given set of criteria on these patient-specific measurements is often not explicitly addressed (e.g., remeasure the fields, generate an alternate plan, estimate the clinical impact qualitatively, etc). Therefore, further guidance is needed from national organizations in each of these areas.

Until formal guidance is available, we recommend that users establish acceptance criteria that they have determined will identify plans that should fail the QA check. For example, users should deliberately create plans with known errors such as the incorrect fluence for regions of high or low dose across the irradiated volume and/or critical structures, plans with one field with a rotated collimator or an incorrect fluence distribution, and other discrepancies that should be identified by the QA method. The IMRT QA criteria should be established using tests of the most highly modulated fields that are seen in the local clinic.

The full length report includes a summary of the primary recommendations, tasks, and assigned personnel to guard against catastrophic failures for IMRT, primarily concentrating on MLC-based delivery systems since they are the most common (Table IV).

V. COLLABORATION BETWEEN USERS AND MANUFACTURERS TO IMPROVE IMRT SAFETY

Improvements in IMRT equipment and methods to enhance patient safety are needed and would be facilitated by collaborative efforts between manufacturers, users, and regulatory agencies such as the United States Food and Drug Administration. The full length report includes a detailed list of possible improvements including:

- A. Methods to directly and independently verify/validate patient plan and treatment data on the treatment machine prior to, during, and after radiation delivery.
- B. Provision of safety measures in the IMRT workflow such as communication features, checklists, data integration, and tracking.
- C. Integration of IMRT subsystems and QA procedures
- D. Human interaction with equipment.

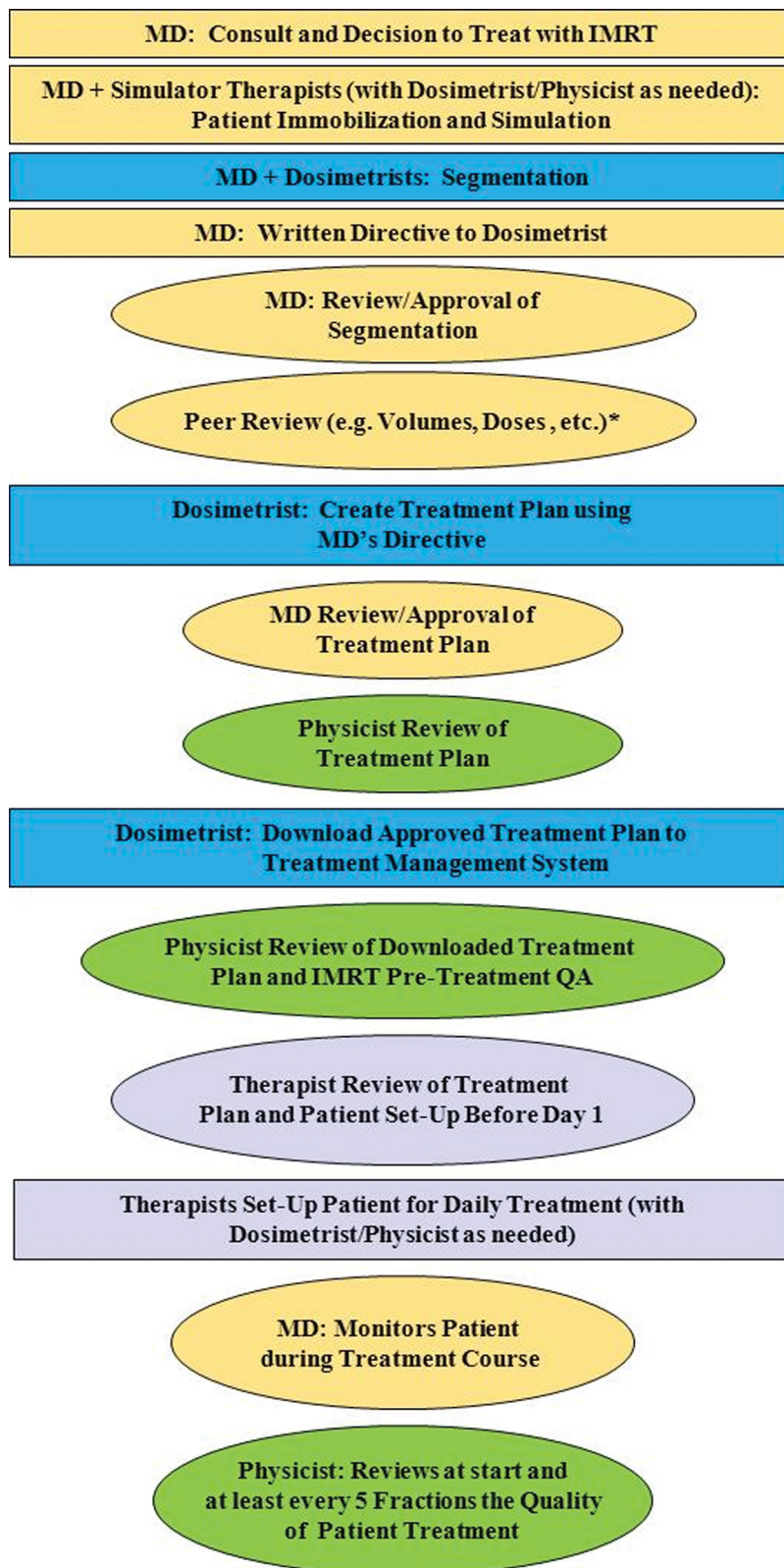


FIG. 1. An abbreviated diagram of the process (boxes) and review (ovals) steps for IMRT planning for an individual patient.

Successful improvements to existing/future systems will require joint efforts by the users, vendors, and regulators. The prioritization, implementation, testing, and commercial release of any improvements should be a partnership between users, manufacturers, and regulators.

VI. SUMMARY

IMRT is time and resource intensive. Environmental and technical concerns need to be addressed to improve patient safety. Timely treatment is important, but undue pressure and real-time changes to the treatment plan can lead to

TABLE IV. Recommendations to Guard against Catastrophic Failures for IMRT.

Recommended tests and procedures	Person who performs task	Primary review responsibility	Second review
Halt a procedure if the operator is unclear about what is being done.	All	All	All
Verify the patient information, treatment site, and prescription	All	All	All
Verify correct positioning of the high dose region of isodose plan relative to targets	Dosimetrist	Physician	Physicist
Verify the recording of reference and shift information from the planning scan in patient chart (electronic or paper)	Dosimetrist	Physicist	Therapist
Assess pretreatment localization/portal images with respect to corresponding reference images before first treatment; physician determines frequency of IGRT techniques (4)	Dosimetrist exports reference images from treatment planning system	Physician	Therapist
Verify that the correct version of the patient's treatment plan is approved, sent to treatment management system, and used for patient-specific QA	Dosimetrist exports from the treatment planning system	Physicist	Therapists confirm against prescription for each treatment; physician prescription should specify the physician approved plan
Before the first treatment or for any change in treatment, perform patient-specific QA to guarantee that data transfer between systems is correct before patient treatment begins	Physicist, dosimetrist, therapist or physics assistant	Physicist	Therapists confirm that only fully approved plans are used for treatment
Perform a complete chart check including review of information in treatment management system prior to the start of any treatment and after any change in treatment before changes are used for treatment Visually review field apertures in treatment management system Perform a check of dose to verify TPS calculation (measurement or calculation using DICOM export of data from RTP system)	Physicist	Therapist	
Perform a time out prior to treatment delivery.	Therapist	Second therapist	
Perform a check of treatment parameters before start of and during first treatment against a fixed version of the treatment plan Includes visual verification of field apertures during first treatment and after any change in treatment At each fraction, verify motion of leaves (if MLC delivery) and total monitor units	Dosimetrist exported from TPS; verified by physicist	Therapist	Second therapist
Perform end-to-end testing to guarantee transfer of data among all systems involved in imaging, planning and dose delivery (periodically and after any software or hardware changes)	Physicist, therapist, or physics assistant	Physicist	Second physicist to review

errors. The report suggests use of a “forced time out” to assure adequate time to perform reviews/QA at key points in the process. Team members need to acknowledge that initiation of treatment may need to be delayed to allow time for necessary quality assurance checks and subsequent investigations of problems.

The recommendations in the full length report are intended to provide guidance to aid clinics in avoiding catastrophic errors and to improve the safety and quality of care for patients receiving IMRT. It is expected that there will be further developments with respect to the evaluation of IMRT programs for accreditation, and that new guidance documents will continue to enhance the quality and safety of IMRT use.

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Quality Committee of the American Society for Radiation Oncology (ASTRO) as a part of ASTRO's Target Safety Campaign. The IMRT white paper was reviewed by eight experts from the field of IMRT. In December 2010, the IMRT white paper was posted for public comments for 4 weeks. We received comments from physicians, physicists, therapists, and representatives from radiation therapy manufacturers, including general and specific comments from the American Association of Physicists in Medicine (AAPM). All the comments were reviewed and discussed by the entire writing group and appropriate revisions were incorporated in the paper with group consensus. ASTRO white papers present scientific, health, and safety information and to some extent reflect scientific or medical opinion. They are made available to ASTRO members and to the public for educational and informational purposes only. Any commercial use of any content in this white paper without the prior written consent of ASTRO is strictly prohibited. Adherence to this white paper will not ensure successful treatment in every

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