

Special Article

Safety considerations for IGRT: Executive summary

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Received 6 October 2012; revised 8 January 2013; accepted 13 January 2013

Abstract Radiation therapy is an effective cancer treatment that is constantly being transformed by technological innovation. Dedicated devices for fraction-by-fraction imaging and guidance within the treatment room have enabled image guided radiation therapy (IGRT) allowing clinicians to pursue highly conformal dose distributions, higher dose prescriptions, and shorter fractionation schedules. Capitalizing on IGRT-enabled accuracy and precision requires a strong link between IGRT practices and planning target volume (PTV) design. This is clearly central to high quality, safe radiation therapy. Failure to properly apply IGRT methods or to coordinate their use with an appropriate PTV margin can result in a treatment that is ‘precisely wrong’. The white paper summarized in this executive summary recommends foundational elements and specific activities to maximize the safety and effectiveness of IGRT.

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Supplementary material for this article (<http://dx.doi.org/10.1016/j.prro.2013.01.004>) can be found online at www.practicalradonc.org.

Conflicts of interest: Before initiation of this white paper all members of the White Paper Task Group were required to complete disclosure statements. These statements are maintained at ASTRO Headquarters in Fairfax, VA and pertinent disclosures are published with the report. The ASTRO Conflicts of Interests Disclosure Statement seeks to provide a broad disclosure of outside interests. Where a potential conflict is detected, remedial measures to address any potential conflict are taken and will be noted in the disclosure statement. Dr David Jaffray has received research grants from Philips Medical Systems, Elekta, IMRIS, GE, and RaySearch Laboratories. Dr Laura Dawson has received a research grant from Bayer and is listed on a licensing agreement with Raysearch. Dr Katja Langen has received research grants from Varian Medical Systems, Phillips Medical Systems, .decimal, and TomoTherapy/Accuracy. Dr Gikas Mageras has received research grants from Varian Medical Systems, and the National Institutes of Health. Dr Arno Mundt has received research grants from Varian Medical Systems, .decimal, VisionRT, and the National Institutes of Health. Dr Di Yan has received research grants from Elekta, Phillips Radiation Oncology System, Morphormics Inc, and the National Institutes of Health. The Task Group Chair as well as the chair of the Multidisciplinary Quality Assurance (QA) Subcommittee reviewed these disclosures and determined that they do not present a conflict with respect to these Task Group members’ work on this white paper.

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Introduction

This executive summary provides a brief description of the content of the report on safety considerations for image guided radiation therapy (IGRT) and is intentionally limited in length and content. Please see the full report published online only at www.practicalradonc.org. This abridged version is not intended to replace the full length report but rather to highlight key elements of the report. The full report provides additional background information for those less familiar with IGRT.

White papers on patient safety in radiation therapy

The full 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 June 23, 2012 and has been endorsed by the American Association of Physicists in Medicine, the American Association of Medical Dosimetrists, and the American Society of Radiologic Technologists. The document has also been reviewed and accepted by the American College of Radiology's Commission on Radiation Oncology. These organizations have a long history of supporting efforts toward improving patient safety in the United States.

This report is related to other published reports of the ASTRO white paper series on patient safety, including those on intensity modulated radiation therapy (IMRT) and stereotactic body radiation therapy (SBRT), and those still in preparation. There are sections of this report that defer to guidance in these reports.

Image guided radiation therapy

Highly tailored, patient-specific dose distributions can now be generated using 3-dimensional (3D) imaging and inverse planning techniques to design IMRT. The increased dose conformality heightens the need to assure accurate and precise localization of the target and normal structures prior to or during each treatment fraction, and has driven the integration of imaging technologies (and/or tracking systems) into the treatment room and onto the treatment machine. For the purpose of this paper, the activities associated with the use of these systems are referred to as image guided radiation therapy (IGRT). IGRT techniques can substantially reduce geometric positioning errors that can occur between treatment planning and delivery and enable clinicians to pursue

treatments that are more conformal. It also increases the reliance of these treatments on the IGRT system performance. Failure to assure this performance can result in treatments that are "precisely wrong."

Nature of safety concerns

IGRT is a method of assuring the geometric-targeting elements of the treatment for the individual patient as well as a method of maintaining a level of geometric targeting performance for a population of patients that allows confident use of smaller planning target volume (PTV) margins in the planning process. The use of smaller PTV margins is a delicate issue that requires strong coordination between the planning process and the image guidance activities at the treatment unit. Failure to reproduce the expected geometric accuracy and precision for which the plan was designed could result in an under-dose to the target or an over-dose to surrounding tissues. This feedback loop between the actions at the treatment machine and the planning process heightens the safety-related issues associated with IGRT. Specifically, the need for increased communication between the professions is heightened. A radiation therapist applying IGRT technology and a dosimetrist/physicist working with the radiation

Table 1 Recommendations to establish a foundation for safe and effective IGRT practices

Recommendation
1. Establish a multi-professional team responsible for IGRT activities.
2. Establish and monitor a program of daily, monthly, and annual QA for all new or existing IGRT sub-systems.
3. Provide device- and process-specific training for all staff operating IGRT systems or responsible for IGRT delivery.
4. Perform 'end-to-end' testing for all new IGRT procedures (from simulation to dose delivery) and document performance prior to clinical release.
5. Establish process-specific documentation and procedures for IGRT.
6. Clearly identify who is responsible for approval of IGRT correction decision and the process whereby this decision is made and documented.
7. Establish and document site-specific planning procedures; specifically, the procedure for defining PTV margins. Link these planning procedures to IGRT procedures.
8. Multi-professional peer-review of PTV volumes. Peer-review of GTV/CTV volumes by ROs.
9. Verify proper creation and transfer of IGRT reference data (PTV, OARs, DRRs, etc) to IGRT system.
10. Establish a reporting mechanism for IGRT-related variances in the radiation treatment process.

GTV/CTV, gross tumor volume/clinical target volume; IGRT, image guided radiation therapy; PTV, planning target volume; OARs, organs at risk; QA, quality assurance; ROs, radiation oncologists.

oncologist to develop a robust treatment plan need to be confident that the expected precision and accuracy are actually achieved. The various points of failure that raise safety concerns in IGRT are illustrated in Fig 1 (available online only at www.practicalradonc.org) and briefly described in the caption. These are expanded upon in the full report. The full report also identifies foundational elements that should be in place to assure well-placed confidence in IGRT technology. This list is presented in an abridged form here in Table 1. Additional activities that can be used by individual clinics to reassess and strengthen the safety of their IGRT practices are presented in the full length document. Some of the key considerations affecting the safety of IGRT practice are briefly outlined below.

Commissioning and continuing quality assurance of IGRT technologies

A substantial body of literature on commissioning and quality assurance (QA) of IGRT systems is available for the community. These address both the general principles of IGRT as well as provide technology-specific guidance. Clinical programs should follow the general guidelines of TG-142 on medical accelerator QA, which includes a section that provides guidelines specific for planar and cone beam kV and MV imaging and lists daily, monthly and annual QA tests and their respective tolerances.¹ These should be supplemented by those recommended in IGRT technology-specific task group reports of the American Association of Physicists in Medicine.

The link between the PTV margin and IGRT practice

IGRT systems are capable of accurately targeting unambiguous objects to submillimeter levels, especially in phantom-type studies. However, this will not be achieved in the clinical context. Image registration of actual patient anatomy, variations between observers, and imperfect corrections will result in delivery that is less precise and less accurate than that shown in phantom studies. It is the accuracy and precision that can be obtained during clinical use that should be considered in the design of the PTV margin. Clinics need to focus on the link between the PTV margins used in treatment planning and the performance and application of the technology in the treatment room. This requires greater communication between the radiation oncology professions in the clinic and is supported by the creation of an "IGRT team," including medical physicists, medical dosimetrists, radiation therapists, and radiation oncologists.

Protocols for image acquisition and interpretation

IGRT needs to be performed under the direction of commissioned procedures to assure the clinical use of the system continues to be consistent with that characterized during commissioning. These protocols should address every facet of the IGRT procedure, including the imaging technique, imaging dose, definition of structures (normal and target), alignment methods, action thresholds (translate/rotate), decision-making process, and documentation.² These protocols are best designed by the IGRT team, where the needs of the clinician, operational concerns of the therapist, and technical guidance of the medical physicist can be expressed and addressed.³

Education, training, and human resources

IGRT technologies and practice bring a great deal of additional information into the radiation therapy treatment (RTT) process. In contrast to the pre-IGRT era, RTTs at the treatment unit may find that they handle more volumetric imaging data (eg, >20 cone-beam CT, ultrasound, or megavoltage CT scans) each day than does any other profession within the program. In addition, these images each require analysis and a decision that affects patient treatment. Operating the imaging systems, interpreting of volumetric images, and making image-guidance decisions push the limits of the existing training curricula of all professions involved: radiation therapists, medical dosimetrists, oncologists, and medical physicists. In addition, it also raises new challenges in terms of inter-professional dependencies and dialog.⁴ Appropriate staffing levels are also a critical part of a program's safe deployment of IGRT technology, requiring additional medical physics staffing for the commissioning, implementation, on-going QA, and operational stages.⁵⁻⁷ Staff requirements should be reviewed when it is decided IGRT equipment is to be purchased and should examine the additional time required for the quality control testing of IGRT systems, as well as the time required for daily decision-making processes during IGRT practice.

Summary

IGRT is a powerful tool that enables radiation oncologists to further increase the conformality of radiation delivery. It is time and resource intensive and heightens the need for process-oriented thinking and inter-professional communication. The safe application of IGRT technology is not limited to the operation of the

technology at the treatment unit. It extends back to the treatment planning process where treatment plans are developed under the assumption that IGRT performance will be present at the time of treatment. The recommendations in the full length report are intended to provide guidance to aid clinics in implementing the foundational elements for safe use of IGRT. These include both programmatic components and patient-specific efforts. In addition, a number of recommended activities are presented to educate and engage various stakeholders on the opportunities to assure the safe use of IGRT. Finally, it is expected that there will be further advances in IGRT technology and the establishment of a sound foundation will assure these technologies are safely deployed in the clinic.

Acknowledgments

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

The IGRT white paper was reviewed by 9 experts from the field of image guided radiation therapy. In April 2012, the IGRT 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. All the comments were reviewed by the entire writing group and appropriate revisions were incorporated into the paper with group consensus.

ASTRO white papers present scientific, health, and safety information, and may 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 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.

This white paper was prepared on the basis of information available at the time the writing group was conducting its research and discussions on this topic. There may be new developments that are not reflected in this white paper and that may, over time, be a basis for ASTRO to consider revisiting and updating the white paper.

We thank the reviewers who took on the challenge of providing a comprehensive review of an earlier draft of this document. These reviewers provided their responses within a limited time frame to support the timeliness of the report. Their comments and suggestions were invaluable. We respectfully acknowledge Larry Marks, MD, Jim Galvin, PhD, and Albert Blumberg, MD. We also thank the many reviewers who took the time to comment during the public comment period. All comments were reviewed and further changes were incorporated as determined to be appropriate. Finally, we thank Tinisha Mayo of ASTRO, who supported our writing group throughout the process.

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