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Special Article

Safety considerations for IGRT: Executive summary

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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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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 Safely 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 interprofessional 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 interprofessional 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.

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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.

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References

1. Klein EE, Hanley J, et al. Task Group 142 report: Quality assurance of medical accelerators. *Med Phys.* 2009;36:4197-4212.
2. Yin FF, Wong JW, et al. TG-104: The role of in-room kV x-ray imaging for patient setup and target localization. College Park, MD: American Association of Physicists in Medicine. 2009.
3. ASRT. The practice standards for medical imaging and radiation therapy. Albuquerque, NM: American Society of Radiologic Technologists; 2011.
4. White E, Kane G. Radiation medicine practice in the IGRT era: New roles and new opportunities. *Semin Radiat Oncol.* 2007;17:298-305.
5. Potters L, Gaspar LE, Kavanagh B, et al. American Society for Therapeutic Radiology and Oncology (ASTRO) and American College of Radiology (ACR) practice guidelines for image-guided radiation therapy (IGRT). *Int J Radiat Oncol Biol Phys.* 2010;76:319-325.
6. Mills MD. Analysis and practical use: the Abt Study of Medical Physicist Work Values for Radiation Oncology Physics Services–round II. *J Am Coll Radiol.* 2005;2:782-789.
7. American Association of Physicists in Medicine. The Abt Study of Medical Physicist Work Values for Radiation Oncology Physics Services: Round III. http://www.aapm.org/pubs/reports/ABTIIIReport.pdf. Published March 2008. Accessed March 14, 2013.