



PATIENT SAFETY INITIATIVE

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Potential Errors Associated with Radiation Therapy

Recently there has been extensive news coverage about overexposure to radiation during the use of computed tomography (CT) perfusion scans and linear accelerators. On January 24, 2010 the New York Times reported on two cases of fatal overexposure to radiation during cancer treatment. This Alert is to bring attention to this potential serious patient safety concern.

A CT scanner use x-rays to take numerous images as it rotates, usually around the brain or spine, creating detailed cross-sectional and three-dimensional images to help locate cancer.^[1] Linear accelerators (LINAC) are commonly used for external beam radiation treatments of cancer. LINAC uses microwave technology to accelerate electrons in the accelerator. These electrons then collide with a heavy metal target producing high-energy x-rays which are directed to the patient's tumor.^[2]

Radiation therapy is becoming more sophisticated and more complex. While there are many benefits in the use of radiation therapy, there are also potential problems.^[3] The complex hardware and software required for radiation therapy makes understanding the details of how the equipment works and its limitations difficult. The combination of the rapid technology development and the increase in patient volume may lead to a work environment that is more susceptible to errors.

Radiation therapy is highly regulated at the federal level by the Nuclear Regulatory Commission (NRC). Radiation and Radiation Oncology is regulated at the state level by the New Jersey Department of Health and Senior Services (NJDHSS) through the N.J.A.C.

8:43G-28. One of the requirements of this code is that all new or existing radiation oncology facilities are to be fully accredited by the American College of Radiology or the American College of Radiation Oncology and that this accreditation must be maintained thereafter.

Also in New Jersey, the Department of Environmental Protection administers the registration and inspections of all facilities that utilize medical diagnostic x-ray equipment. These facilities are required to conform to all the applicable radiation protection regulations codified at N.J.A.C. 7:28.

A study conducted by G. Haung et al. discovered that the rate of radiation therapy errors was low and that the majority of those errors had little or no clinical impact on the patient.^[3] These findings are similar to previous studies. The study did find that patients with multiphase plans, such as the head and neck or patients with tumor types with diverse anatomic locations, such as sarcoma and lymphoma are at a greater risk for errors. It was also found that use of beam-modifying devices was associated with an increased risk of error. There were a few errors associated with incorrect software programming intended to reduce errors and the manual transcription of treatment parameters. However, overall these errors were rare and had minimal if any impact on the patient.

The FDA is conducting an ongoing investigation of patients who may have been overexposed to radiation during CT scans and radiation treatment.^[4] In October 2009, the FDA issued an initial safety notification with recommendations.

The following are recommendations for facilities that provide radiation therapy:^[4]

- Review protocols and take special note of the dose indices (volume computed tomography dose index; $CTDI_{vol}$ in either milligray or mGy and dose-length product; DLP in either milligray-centimeter or mGy-cm) displayed on the control panels
- Review dosing protocols for all CT perfusion scans to ensure that the correct dose is administered
- Assess if any patient received excess radiation during radiation therapy
- Implement quality control procedures to ensure that dosing protocols are followed and the planned amount of radiation is administered
- If more than one study is performed on a patient during one imaging session, adjust the dose of radiation so it is appropriate for each study
- Review training procedures
- Implement systems to identify problems quickly
- The American College of Radiology recommends that all radiation plans undergo independent checks and require plans be signed by a radiation oncologist within one week of treatment initiation^[5]
- Joint Commission's National Patient Safety Goals state that at least two patient identifiers will be used when providing care to a patient^[6]
- Establish a reliable method for verification of external beam therapy, such as an in vivo dosimetry program that can be used as QA for machine calibration, planning dosimetry, and dose calculation, patient setup and influence of beam modifying components^[7]

Conclusion

Errors occurring during radiation therapy are rare and usually have little or no clinical impact on the patient. In New Jersey radiation therapy is highly regulated by the state and federal government. The equipment and radiation therapy providers must meet strict regulatory standards. An important way to reduce and eliminate potential overexposure of radiation to a patient is for facilities to remain diligent in the education of their staff, maintain and perform all checks and re-checks of the equipment and require that all radiation therapy plans have independent checks and sign offs before being administered to the patient.

The FDA and NJDHSS Patient Safety Reporting System require healthcare facilities to report deaths and serious injuries associated with the use of medical devices. For the FDA, report either to the device manufacture and/or to MedWatch online at <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm> or by phone at 1-800-FDA-1088. For NJDHSS, report to the Patient Safety Reporting System at www.state.nj.us/health/ps/.

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