

RADIATION THERAPY-BACKGROUND PAPER

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Medical Background

Radiation Therapy (RT) uses high-energy radiation to shrink tumors and kill cancer cells. X-rays, gamma rays and charged particles are types of radiation used for cancer treatment.

The radiation may be delivered by a machine outside the body, called external beam radiation therapy or it may come from radioactive material placed in the body near cancer cells, known as internal beam radiation or brachytherapy. Systemic radiation therapy uses radioactive substances that travel in the blood to kill cancer cells.

RT systems have become more complex and have been refined to better target the cancer and minimize surrounding tissue damage through “image guided radiation therapy” (IGRT) and “intensity modulated radiation therapy” (IMRT). The advanced systems rely on computer networks and electronic data storage.

About half of all cancer patients receive some type of RT during the course of their treatment. Many times this involves short, daily treatments for consecutive weeks or months. Consequently, offering access to services which is convenient for patients so they can continue in their daily activities has been a primary concern and correlates with the move towards integrated community based cancer care. This model allows patients to have access to all their care in an integrated, local setting. This works well for cancer care as there are many components to a treatment plan, e.g. the use of advanced imaging to guide radiation therapy and chemotherapy.

Costs

RT is very costly, and according to a 2010 analysis of Medicare data done by Thomas Jefferson University in Philadelphia, the number of patients receiving services grew 33% and the costs of therapy grew 156% from 1998-2008. Most of the increase in charges is attributed to the use of IMRT-which they report has grown 930% since its inception in 2002. A 2006 National Cancer Institute (NCI) report based on 2005 SEER data demonstrates that the majority of cancer costs are attributed to chemotherapy and not diagnostic advanced imaging or radiation therapy. Reports from Millman (2011) and Avalere Health (2012), demonstrate that physician based integrated cancer care is less costly than hospital based care.

Utilization

There have been concerns raised about the overuse of RT. There are allegations that without any need review RT centers can proliferate and increase utilization. This is of particular concern with advanced therapy (IMRT) when conformal radiotherapy (older RT) might be just as helpful. Dr Ronald Chen and others recently published a study in the *The Journal of the American Medical Association (JAMA, May 20th, 2013)* concluding that IMRT and conformal radiotherapy for prostate cancer were equivalent, despite the much higher cost for IMRT.

Quality and Safety

Equipment maintenance and dosage calculations are obvious quality and patient safety areas of concern but there are also broad quality implications for complex radiation therapy systems. RT requires highly trained, competent staff working in a well organized and monitored system of care that is driven by a quality improvement program. Accreditation and society practice guidelines have driven improvements in this area.

Accreditation

There are many accrediting options for RT. The American College of Radiology (ACR), the American College of Radiation Oncology (ACRO) and The Joint Commission (TJC) have programs as do other professional radiology groups. Regulations, such as Part 16, are used to set minimum standards that must be met for simple, straightforward items. Accreditation can then be used to address more complex situations that may involve clinical judgment, are rapidly changing or involve business aspects that drive utilization.

The DOH Bureau of Environmental Radiation Protection (BERP) recently amended Part 16 to require accreditation for RT. The ACR, ACRO and other professional organizations also offer optional practice guidelines for RT.

Federal and State Regulation

The federal Atomic Energy Act of 1954 authorizes the Nuclear Regulatory Commission (NRC) to regulate the use of radioactive materials. NYS, under this law, is an “agreement state” and as such the state agrees to adopt and enforce standards that are comparable or exceed the federal rules. The DOH (BERP) oversees the requirements of 10 NYCRR Part 16, the state regulations that comply with this. BERP is in the process of amending Part 16 to update the quality assurance provisions and require that RT providers be accredited by the American College of Radiology (ACR) or the American College of Radiation Oncology (ACRO) or another equivalent organization within 18 months of the effective date of the regulations. The regulations have been published in the state register and final adoption is anticipated in a few months.

RT is exempt from the federal Medicare Improvement for Patients and Providers (MIPPA) Act of 2008 (see Advanced Diagnostic Imaging paper). There has been pending legislation to include them but nothing has been enacted.

Most large states have standards for radiation safety in radiation therapy similar to NYS’s Part 16. Many have similar QA requirements as well, although NY has been a leader in the area of radiation safety. All providers using radioactive materials must comply with federal NRC requirements; however the vast majority of RT is done using linear accelerators (LINACs) and these generally fall under state regulatory authority.

CON/licensure in other states varies and must be clearly defined as some states include what NYS would identify as a “character and competence” review in licensure, but assert they do not have CON.

- New Jersey- Since 2004 LINACS removed from CON, licensure continued through policy (not a regulation). Licensing includes a character and competence review and physical plant requirements. There are no accreditation requirements.
- Connecticut- Non-hospital based LINACS require a CON. Licensure is not required for physician practices that have LINACS, but CON is. CON is primarily a need review, with some financial and access reviews and no architectural review. Architecture review is included in licensure.
- Massachusetts- Beginning in 2009 physician based operators could no longer apply for exemptions to “Determination of Need” (DON). Existing practices were grandfathered in over a 6 month period.

FACILITIES AND SERVICES REGULATED BY CON

Regulated Services	No. of States	States, Districts & Commonwealth
Radiation Therapy	23	AL, AK, CT, DE, GA, HI, IA, KY, ME, MA, MI, MS, MO, NH, NY, NC, RI, SC, TN, VT, VA, WV, DC

Source: AHPA, 2011; as found on the website of the National Conference of State Legislatures (NCSL)