

“Lawsuit-proof” Your Radiation Oncology Practice

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In Brief

Radiation therapy lawsuits rank in the top third of all medical specialties with regard to claims made, claims paid, and damage amounts.¹ The most common claims are related to delayed injury to the spinal cord and/or intestine. Newer claims involve computer errors, wrongful interpretations of CT, MRI, and PET images used for radiation therapy target-volume planning, and lack of proper informed consent.

To safeguard against these types of claims, radiation oncology practices should implement a system for triple-checking critical steps such as setups, equipment calibrations, and prescription dose calculations. Double-check other aspects of care, including diagnosis, staging, the treatment plan, treatment simulation, and treatment and progress notes. For combined modality treatments, consider using a combined chemo-radiation consent form. These precautions generally “catch” the most serious and frequent mistakes.

According to the Physician Insurers Association of America (PIAA) almost seven claims are made per 100 radiation oncologists each year. Or, to look at it another way, every ten years one half of all radiation oncologists will be sued for malpractice. For claims paid in 2005, insurance averaged \$313,000 per claim settled or litigated. This 33 percent payout rate of claims made/claims paid is the highest of all the medical specialties.¹

Before your radiation oncology practice can develop preventative measures to safeguard against lawsuits, you must first understand *why* claims are made. As consultant lawyers for attorneys representing injured plaintiffs, as well as for defendant doctors and radiation facility administrators, we reviewed many malpractice cases over the past 30 years and identified two principal reasons for radiation oncology claims: 1) negligence in set-up, equipment calibrations, and dose calculations

and 2) a patient’s misunderstanding of the informed consent, especially with regard to delayed risks.²⁻¹⁵ Most often a plaintiff’s spinal cord paralysis,²⁻⁵ intestinal obstruction injury,⁶⁻⁹ or pelvic organ injury¹⁰⁻¹⁵ initiated the claims.

Claims most often occur within one year of treatment—although repair of the delayed injury usually takes place in two to three years. In other words, cancer patients will sue—whether or not their cancer has been cured and whether or not their injuries related to radiation treatment will eventually resolve with proper care.

All states have a statute of limitations that prevents claims usually after three years, but the clock only starts running when the patient realizes that the injury was caused by irradiation. This realization can happen years after the treatment. In addition, secondary malignancy related to irradiation can occur many years later, so your radiation oncol-

ogy practice must preserve its patient records well beyond what state laws minimally require.

While alternative dispute resolution (ADR) may be a better way to handle these types of claims, most patients are not made aware of the choice and instead choose to sue the healthcare provider. To help defend against such lawsuits, radiation oncology practices should implement the following processes.

Check and Re-check

Develop a system for triple-checking critical treatment steps and double-checking all other important steps.

Here’s how a typical check system might work. A dosimetrist performs the initial dose calculations, and the physicist performs the equipment calibrations. Radiation therapy technologists (RTTs) perform daily morning machine verification checks. A physicist double-checks all calculations, regularly checks calibrations, and yearly verifies equipment with national calibration standards published by the American Association of Physicists in Medicine (AAPM) and the American College of Radiology (ACR)—the vanguards of safety precautions. The radiation oncologists triple check all steps.

The initial treatment set-up and isodose plan is reviewed and approved by the physician. Any changes are documented with a status progress note explaining why the change was made. Before continuing further treatments, images and verification films are also reviewed and approved.

Document when the total given dose differs by more than 10 percent from the prescribed dose, or provide an explanation of why it does.

We suggest that radiation oncology practices triple-check these key steps:

- ✓ Informed consent
- ✓ Dose calculations

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- ✓ Equipment calibrations
- ✓ Treatment set-up verifications.

We suggest a double-check system for the following important steps:

- ✓ Diagnosis
- ✓ Staging
- ✓ The treatment plan
- ✓ Treatment simulation
- ✓ Radiation therapy treatment and progress notes.

Understand Informed Consent

A consent form is a legal contract, and a legal contract assumes that both parties understand the language. If a radiation oncologist does not fully explain and then ensure that the patient understands the explanation, the result is uninformed consent. In contract law, this consent may end up as a voided agreement. About one-third of all radiation oncology lawsuits claim “inadequate informed consent.” And remember, since informed consent is an active document, patients may revoke the contract at any time during treatments.

In a 2007 policy memo, the Centers for Medicare & Medicaid Services (CMS) said that the government could withhold payments in the absence of proper informed consent.¹⁶ To satisfy proper informed consent elements, providers must include discussion *and* documentation of:¹⁶

- Diagnosis and extent of disease
- Proposed treatment with risks and benefits
- All other reasonable treatment alternatives along with their risks and benefits
- Expected outcome when not receiving any treatment.

Informed consent problems alone rarely trigger lawsuits. Juries generally assume that the patient understood the benefits and risks explained—but only when those risks are documented. In other words, merely stating that the patient understood the risks, without spelling them out, is risky business.

But what about the discussion of all reasonable treatment options? The American Society for Therapeutic Radiology and Oncology (ASTRO)

surveyed cancer patients and found that while “64 percent of patients interviewed chose to undergo radiation therapy when it was presented as an option, 77 percent of the patients said radiation therapy was never presented to them by their surgeon as an option.”¹⁷ Physicians should explain reasonable alternative treatments—even the “no treatment” option. If a physician prefers to not inform patients about alternative treatments, he or she should offer to send the patient to another physician who can. Most payers now recognize a second opinion as a valid medical expense, and it strengthens the informed part of the consent.

Improve Your Informed Consent Process

Communication without patient understanding favors the plaintiff’s claim. So physicians should do their best to ensure understanding by always asking their patients questions such as:

- *Do you understand what was said?*
- *Can I explain anything better?*
- *Do you have any questions?*

Describe and record radiation risks and benefits clearly and in layman’s terminology. Directing patients and family members to websites such as ASTRO (www.astro.org) or ACR (www.acr.org) can provide additional information. Non-English speaking patients should have a translator present and have access to written materials available in their native language. Free online translation can be found at: www.freetranslations.com.

Nominal risks, such as temporary dry skin, need not be disclosed. However, moderate risks with higher frequency, such as red skin, hair loss, nausea, and diarrhea, should always be disclosed. Similarly, severe risks, even when a very low probability of occurrence exists, must always be disclosed. Severe risks can include bowel injury requiring surgery, irreversible brain or spinal injury, and secondary cancers years later when younger patients are treated with curative intent. In addition, chemotherapy

given close in time to irradiation adds treatment risks that need to be discussed with the patient.

As the severity of the risk increases so does the treating doctor’s duty of disclosure.

The final step in the informed consent process is to obtain signatures. The patient, a second person present during signing, and the physician who performed the informed consent must sign and date the document.

Computer-related Errors

Over the past ten years, radiation treatment of cancer has become a more integrated and networked specialty—much more complex. Today, computers calculate radiation doses using mathematical algorithms to find the best-configured plan for each individual. Medical radiation therapy physicists and dosimetrists control this process.

Unfortunately, these computers can fail. In 2001 a computer failed to correctly calculate doses, resulting in 28 patients being overdosed.¹⁸⁻¹⁹ Failure to double-check calculations manually before entering them into the treatment machine computer resulted in five of these 28 patients dying and half of the others developing serious in-field overdose injury complications.

Linear accelerator computers that control dose delivery can also fail. A software “bug” is an error in computer programming that prevents computer-controlled equipment from behaving as intended. In the early 1990s, software bugs in the Therac-25 linear accelerator allowed hardware safety interlocks to fail causing multiple deaths and injuries in the United States.²⁰

To protect against these types of computer-related errors, all critical computer calculations should be independently verified by three persons before treatment: dosimetrist, physicist, and physician.

Equipment calibrations must not exceed allowable standards. Physicists are responsible for ensuring the integrity of linac beam parameters: energy, flatness, symmetry, output, and constancy. Keep records of these data and the dates of performance. Any documented equipment problems must have repair dates recorded and saved for review.

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Chemo-radiation Cancer Treatment Consent Form

Patient Name: _____

Diagnosis: _____

Extent of Disease: _____

Probable Outcome without Treatment: _____

Alternative Treatments with Risks and Benefits: _____

Proposed Treatment and Benefit Goals: _____

POSSIBLE SIDE EFFECTS/RISKS:

Side Effect	Radiation Therapy Risks	Chemotherapy Risks
ANTICIPATED:	_____	_____
	_____	_____
	_____	_____
OCCASIONAL:	_____	_____
	_____	_____
	_____	_____
RARE BUT SEVERE:	_____	_____
	_____	_____
	_____	_____

Both columns apply for combined chemo-radiation (CRT).
All side effects may occur earlier and be more severe.

I have been informed and understand my diagnosis, outcome without treatment, alternative treatments, and proposed chemo-radiation treatments with risks and benefits explained to my satisfaction. _____ (initial)

I agree to try the above cancer treatments as presented to me. I also understand that any time I wish to stop treatments, I may do so. _____ (initial)

Patient or Guardian: _____ DATE _____

Witness: _____ DATE _____

Radiation Oncologist: _____ DATE _____

Medical Oncologist: _____ DATE _____

Imaging-related Errors

Visible tumor volumes may vary considerably depending on the imaging equipment used and the interpreter's expertise.²¹ The interpretation by the radiation oncologist should be consistent with the one performed by the diagnostic radiologist. Be sure to document both interpretations in the patient's medical record. If the interpretations differ, provide a written explanation for why they differ.

Most imaging mistakes result in either over-treatment of the tumor or under-treatment of the tumor. Misinterpreted gross tumor volumes, especially ones that overlap normal tissues, can cause delayed injuries. "Under-dosing" of the tumor or incomplete tumor treatment results in loss of chance for cure or survival. Some states now recognize "loss of chance theory" and allow monetary recovery for this portion of the patient's loss as "damages."

To reduce liability risks, practicing radiation oncologists should stay current with newer diagnostic imaging procedures and interpretations. Documenting consultations with the interpreting diagnostic radiologist improves accuracy, and can also help protect against liability.

Chemo-radiation Injuries

For cancers of the brain, head and neck, lung, gastrointestinal tract, genitourinary system, some lymphomas, and some soft tissue sarcomas, chemotherapy is commonly administered together with irradiation. The combined procedure is termed chemo-radiation treatment. Certain chemotherapy drugs can increase responsiveness of tumors to radiation, but they also can produce greater injury to normal tissue. In both acute and delayed chemo-radiation treatment, normal tissue toxicity is increased. To protect against liability, inform and educate patients about these increased risks.

Chemo-radiation causes increased side effects. For example, in a 2007 lawsuit, a woman treated concomitantly with cisplatin, paclitaxel, and irradiation to the chest for lung can-

cer, developed severe tracheobronchitis and esophagitis requiring hospitalization.²² Treatment with antibiotics, steroids, intravenous fluids with electrolytes, and a percutaneous gastric feeding tube helped her recovery. Attorneys for the patient argued that the combined chemo-radiation caused excessive injury that contributed to her increased pain, earlier demise, and excessive costs. The jury verdict and appellate courts decided otherwise, because the radiation oncologist and medical oncologist had both correctly explained the increased foreseeable risks. The defendant doctors in this case performed their duty of disclosure, and documented and witnessed it properly.

Because chemo-radiation treatment involves two specialties—medical oncology and radiation oncology—consider developing a combined consent form (see page 21) and have it signed and dated by all parties.

Be Proactive

Physicians, administrators, and office managers can help "law-suit proof" their radiation oncology practice. Establishing a system of triple- and double-checks is essential and ensuring adequate patient consent is critical to these efforts.

In the end, recognize that lawsuits are a reality that your practice may have to face. For economic reasons, some lawsuits will be settled out of court. In other words, it may be cheaper to offer a settlement than to proceed to trial. The upside of settlement is that it dismisses further medical-legal stress. The downside is that you must continually explain the mandated report to the National Practitioner Data Bank—Healthcare Integrity and Protection Data Bank. The American Medical Association (AMA) can be a resource for physicians, by offering tips to ensure report accuracy and to add rebuttal information. ☒

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