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Erratum

The Directed Reading article “Managing Side Effects in Radiation Therapy Patients,” published in the Fall 2009 issue (Vol 18, No 2), contained an error. The last sentence of the first full paragraph on Page 117 should state that silver sulfadiazine is contraindicated for patients who are allergic to sulfa antibiotics, not to penicillin. We regret the error.
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This symbol indicates expanded content in the online edition of *Radiation Therapist* at www.asrt.org/publications.

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*ON THE COVER*

Nationally recognized artist Earl Keleny of Madison, Wisconsin, creates his vision of targeting radiation in the treatment of cancer. Mr Keleny also has illustrated covers for Radiologic Technology.
Earn Credit: Expand your knowledge with courses covering cutting-edge CE topics in radiation therapy and dosimetry.

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Get Inspired: Acquire new methods, improve your techniques and gain a renewed enthusiasm for your work!
Radiation therapy and medical dosimetry have come a long way in cancer treatment and patient care since 1992, when the first issue of Radiation Therapist appeared. Field intensity modulated radiation therapy, volumetric modulated arc therapy, image-guided radiation therapy — you name it — all of these technologies and more have improved the ability to target radiation and define tumor volumes while minimizing radiation to surrounding normal tissue and critical structures.

Despite impressive leaps forward in treatment planning and delivery, patient safety remains a top concern as increasingly complex technologies require more from radiation therapists and dosimetrist. Last November, the Health Care Industry Advisory Council Subcommittee on Patient Safety and Quality in Radiation Therapy met to discuss recommendations to improve and foster safety in radiation therapy. The special report on Page 81 summarizes the subcommittee’s recommendations, including ways workplace staffing, workplace culture, and applications training can help you fulfill your critical role in a culture of safety.

Although there have been countless changes in radiation therapy, the pages of Radiation Therapist haven’t changed much over the years. But spring, and change, is in the air. Now in its 20th year of publication, the Journal is still going strong, and in celebratory fashion, the spring issue kicks off a new design we hope you’ll enjoy.

With the new look comes exciting additions to our e-magazines, including videos to optimize your virtual learning experience. You’ll see a play-button icon at the beginning of articles with expanded content online. This digital issue of Radiation Therapist includes video discussions about radiation therapy tattooing procedures and a recap presented by Natasha Rosier, MBA, MHA, R.T.(R)(T), on the November 2011 HCIAC subcommittee meeting. Natasha joined the ASRT as radiation therapy coordinator in 2011 and has been an integral part of the Journal staff. We greatly appreciate her expertise and insight.

ASRT’s membership includes nearly 16 000 radiation therapists and medical dosimetrist to date, and that number only continues to grow. Thanks to the work you do, those fighting the battle against cancer — or helping a loved one through it — can believe in survivorship. Here’s to 20 more exciting years of growth and success in radiation therapy, and the hope that comes with it.

Kim Agricola, BS, is an ASRT scientific journal editor.

Go online to hear Kim’s overview of this milestone issue and check out other digital extras.
A Review of Literature: Learning Conditions of Radiation Therapists

Ronnie Garza Lozano, MSRS, R.T.(T)

**Background** Operation of the modern radiation treatment center, with new and changing treatment technologies, raises questions about workplace learning of radiation therapists. The role of radiation therapists is directed by the organizational system, and changes affecting this role are made in response to changes in the field. Literature on adult education and workplace learning elucidates the learning process of radiation therapists.

**Methods** A comprehensive literature search was performed to develop a theoretical platform suggesting that continuous learning among radiation therapists is influenced by organizational factors, departmental culture, and technological advances.

**Relevance** Optimal patient care and safety demand comprehensive knowledge of current radiation therapy practices. Supervisors have described the need to “think on your feet” in an environment where peer-to-peer training is the method most often used to share knowledge.

**Conclusion** Although organizations attempt to enhance the learning capacity of all employees, learning opportunities for radiation therapists are now fragmented and limited and adversely affect their problem-solving skills and clinical judgment. By extending existing research on knowledge transfer and knowledge management and by adopting a sociotechnical perspective, this study builds a theoretical foundation for this problem.

Operation of modern radiation treatment centers and current radiation treatment technologies have created a widening chasm between foundations of knowledge and radiation therapy practice. This widening chasm is occurring at a time when optimal patient care requires that radiation therapists be knowledgeable, skilled, and able to make independent clinical judgments. Two forces in the clinical workplace have created this chasm, each working against the other.

First, modern radiation treatment machines require fewer manual, hands-on operations. Radiation therapists now perform tasks with greater focus on technology operation and treatment software. In fulfilling this function, however, radiation therapists have been removed from the planning stages of treatment and from discussions about a patient’s medical history and current condition. This limited awareness affects the ability of radiation therapists to connect inventories of conceptual knowledge to their clinical work.

Second, advances in computerization have made radiation delivery systems more precise. Today, radiation beams are narrower and are delivered in smaller treatment volumes at higher doses in less time. Although this greater precision has reduced the margin for error, errors associated with smaller treatment volumes can be crippling and even fatal. Optimal patient care demands that radiation therapists be aware of these potential consequences and be able to prevent them.

Radiation therapists also must be aware of the limitations of the safety mechanisms built into radiation delivery systems. In current systems, treatment data are routed from a treatment planning computer system, typically located in a physics department, to a “record and verify” computer system located in the treatment unit. The amount of data transferred for a single treatment, including beam configuration and patient information, is much greater than the amount that can be transferred and verified manually. A major concern is that transferred data may be lost or altered because of incorrect default
settings in some record and verify systems.\textsuperscript{1} To prevent such occurrences, a quality assurance program is recommended, which adds another dimension to practice.\textsuperscript{2}

Before the chasm between conceptual knowledge and clinical practice can be bridged, it is important to understand the impediments to workplace learning that radiation therapists now confront. This literature review examines deskilling among health care professionals and selected theories on adult education and informal learning for radiation therapy.

**Methods**

The researcher performed a literature search of mainstream radiation therapy books and journals providing technical treatment delivery information. All of the publications, including those regarding adult learning, organizational learning, and knowledge management, were acquired using the education, management, engineering, and technology search engines accessed through the electronic library database at Texas State University in San Marcos. A search for supporting material also was collected through the ProQuest Dissertations and Theses database (ProQuest LLC, Ann Arbor, Michigan), which led to 2 dissertations. Key search terms included sociotechnical, technology, situated learning, tacit learning, explicit learning, knowledge transfer, organizational learning, systems learning, adult education, and workplace learning.

**Literature Review**

**Deskilling of Health Care Professionals**

Many social scientists have examined the effects of modern technologies on workers and society at large.\textsuperscript{3-9} In *Labor and Monopoly Capital: The Degradation of Work in the 20th Century*, Bravermann wrote that the introduction of mechanization and automation, in combination with modern management techniques, has led to the deskilling of workers in many economic sectors.\textsuperscript{3} The result has been a separation of the conception of a job from its execution. The traditional skill content of jobs was destroyed, and a homogenous, degraded working population was created.

Since Bravermann’s seminal work, concerns about the effect of technological changes and other factors on the practices of health professionals have emerged.\textsuperscript{10-12} Studies among physicians, nurses, and radiologic technologists have examined how technological innovations have adversely affected the skill sets and knowledge of these professionals.\textsuperscript{10,12,13} These studies include collaborative international research concerning communication, diagnosis, and other medical errors made during the process of entering and retrieving patient care information throughout hospital departments.\textsuperscript{11} The results of these studies offer insights into the effects of technological advances on radiation therapists.

**Deskilling of Physicians**

Ritzer studied the skills needed by physicians and other health professionals involved in diagnosis and how technology affected those skills.\textsuperscript{9} He found that medical technologies, specifically laboratory procedures and machines that aid in the diagnostic process, contributed to skill degradation.

**Deskilling of Nurses**

Rinard examined the effects of technology on nursing skills since World War II.\textsuperscript{10} She first analyzed the content of the *American Journal of Nursing* in 5-year increments to document the types of technological advances that had occurred during this period. These advances included new medical techniques and new drugs (1950-1960); new electronic machinery and specialized care units (1965-1981); and the introduction of new technologies to control, streamline, and predict care (1980-1996). Based on this classification of advances, she then analyzed how the nurse-authors responded to the technological changes. The separation of tasks entailed by the changes made many nurses fear that the hospital was turning into a “factory” and the nurse into a “technician.” Rinard also found that, as nursing moved into the realm of higher education, the differentiation between a “technical” nurse and a “professional” one depended on the ability of nurses to discuss tacit (how-to) skills in a social scientific jargon. She described changes in the nursing field as a deskilling process in the Bravermannian sense, making nursing “all hands, little head, and hardly any heart.”\textsuperscript{10}

**Deskilling of Radiologic Technologists**

Donahue studied the effects of new x-ray technologies on radiologic technologists.\textsuperscript{13} Her findings echoed
those of Ritzer, showing an increased division of labor because of separate licensing requirements for different machines. Some technologists work with mammography machines, others work only with computed tomography and magnetic resonance imaging machines, and still others are not allowed to use any of these machines. Along with the division of labor, new imaging technologies were believed to have limited the role of technologists in the imaging process, and thus could potentially alienate technologists from the work process and the product of their labor in the long term.

**Technological Challenges of Modern Radiation Therapy**

Significant advances in both hardware and software have contributed to innovations in the computer-controlled delivery of radiation treatment, such as proton radiation therapy. The Midwest Proton Radiotherapy Institute reports that dose distributions in proton radiotherapy are more sensitive to positional errors than those in conventional radiation therapy because of an additional dimension — depth. Radiation dose can be made to conform to the tumor to produce a beam that varies in shape to the same extent as the targeted tissue or tumor area in 3 dimensions. With multileaf collimation, very specific beam shapes consistent with the 3-D volume of the tumor may be produced. The high precision of beam shaping is reflected in the term “beam sculpting.” Using this sculpted beam, treatment plans require a very high radiation dose and smaller, stringent target-volume borders. Concentration has shifted from positioning the patient’s body to a more precise focus on organ movement — the fourth dimension in treatment planning. This illustrates the high degree of intended accuracy, where only the targeted tumor is exposed to a very high dose, leaving normal surrounding tissues unexposed to radiation.

To appreciate how a difference of only 2 mm results in rapid escalation of radiation dose, one must understand that treatment deviations with small field-size settings greatly affect the resulting dose output. The effect of the output intensifies with smaller field sizes and higher energies, measured in megavolts (mV = 1 000 000 volts). A 2-mm increase in volume increases the resulting dose-per-monitor unit by 2% and 3% for a 2 × 2-cm treatment area for 6-mV and 18-mV energies, respectively. These are typical treatment energies. The same 2-mm deviation for a 1 × 1-cm area changes the resulting dose per monitor unit by 15% and 16% for 6-mV and 18-mV energies, respectively.

**Models of Workplace Learning**

Various models of workplace learning have been proposed that may be applied, in whole or in part, to the environment in which radiation therapists currently practice.

**Organizational Learning**

All organizations actively create, capture, transfer, and mobilize knowledge to adapt to a changing environment, whether adopting new technologies or expanding information networks. A key aspect of this organizational learning is the interaction of individuals across an organizational hierarchy. Human resource development initiatives, therefore, focus on the multilevel structure of an organization and on ways to target learning to its different workgroups at a level appropriate for each. In other words, the organizational hierarchy determines the types of organizational learning activities that occur, who may participate, and the extent to which new knowledge is shared. This model of organizational learning, however, has been criticized for several reasons.

Senge, in his critique of organizations in the United States, argued that the traditional authoritarian, hierarchical structure fails to tap the capabilities of all workers fully and to recognize their capacities for learning. The traditional notion that the top levels think and the lower levels act on their directives is no longer sufficient for effective management. Senge claimed that organizations must promote learning among all their employees on a regular basis to maintain cohesion among departments, especially in a rapidly changing environment. Because people learn (not systems or management hierarchies), Senge places the individual at the center of organizations.

In a similar vein, Brooks critiqued the “technical rationality” model of organizational knowledge and learning described by Schön in *The Reflective Practitioner: How Professionals Think in Action*. Schön’s model, the learning of workers is tightly controlled and prescribed by those above them. In this hierarchy, scientists create knowledge, engineers and
Managers determine the ways to apply that knowledge, and semiskilled and unskilled workers enact the knowledge. In contrast, Brooks believes that knowledge belongs to the community as a whole, not to high-power individuals alone. The exclusion of low-power employees from the team-learning process, which is reflected in the cultural patterns of organizations in the United States, has serious implications for organizations competing in a diverse, technologically complex, and quickly changing global environment.

In her critique, Brooks also emphasized the importance of critical self-reflection to all learning (i.e., allowing individuals to examine their suppositions as they acquire new knowledge). According to many researchers, learning in context or in action is also important. These researchers asserted a direct relationship between participation in learning activities and professional role, identity, and practice. They all emphasized the interdependence of all hierarchies of employees within organizations.

Studies of knowledge transfer have focused on the interrelatedness of individuals within organizations and organizational factors that promote or impede learning. One factor is the willingness to share knowledge on a peer-to-peer basis. Another factor is the value an employee attributes to the training he or she receives. Burke calls these factors “transfer climate” and “utility of training” and argues that the linkage between these motivational variables and knowledge transfer outcomes need to be confirmed. In their evaluation of knowledge transfer in the context of human resource development, Kozlowski and Salas proposed a “levels of analysis” perspective to capture the interrelatedness of individuals, interventions, and organizational factors separately while maintaining the integrity of the system as a whole.

Relevance to Radiation Therapists

The role of radiation therapists is controlled by various sectors within the hierarchy of the organization that employs them. Because radiation therapy departments are also hierarchical, various factors affect the continuous learning of radiation therapists as a work group in a technologically complex and ever-changing work environment (see Figure 1). Although the goal of organizational learning is to increase the knowledge of all employees, the learning opportunities of radiation therapists have become limited as their role within the departmental hierarchy has become more restricted. Controlling the flow of knowledge, limiting opportunities for learning, and restricting participation can affect the problem-solving skills, clinical judgment, and professional identity of radiation therapists.

Systems Learning

From a systems perspective, the roles of employees within organizations are directed and driven by the organizational system (i.e., the whole), and changes affecting their roles and functions are implemented as a response to changes in an industry or field. In other words, the organization adapts internally to the pressures of external change; this adaptation, in turn, initiates the shifting of technologies and knowledge within the parts of the organization. Patton describes thinking within organizational systems as being focused on the whole while disaggregating the parts. In other words, the roles, functions, and behaviors of the parts are deconstructed and viewed only in relation to the whole. Sense believes the parts of organizational systems to be so interconnected and so interdependent that any simple cause-effect analysis within such systems distorts more than it illuminates. Consequently, learning within organizational systems or systems learning presents unique challenges.
Relevance to Radiation Therapists

The role of the modern radiation therapist is directed and driven by the whole; thus, the radiation therapist’s role changes in response to industry changes. Radiation therapy practice has been redefined within the hierarchical system of other departments that direct the radiation therapist’s work and control access to information through changing information networks and changing technology. The learning activities, individual participation, thinking capacity, and even professional identity of radiation therapists are interdependent on other parts of the organizational system.19

Situated Learning

Situated learning theory holds that the identities acquired by participation in communities of practice are continually evolving and are framed by the opportunities available within each community. Communities of practice refer to skilled groups, both professional and nonprofessional, that model an apprentice-to-master learning and working relationship. It is within these communities that individuals gain knowledge, progress through improvised opportunities from peripheral to full participation, acquire advanced skills, and assume the identity of a practitioner — all while gradually conceptualizing the practices of the community.26 Although participation is central to situated learning, many researchers agree that power dynamics within the workplace can adversely affect the participation of workers and that limited participation may prohibit workers from developing identities and practices unique to their roles.19,26,27

All types of learning require that we understand who we are and what our maximum potential is,28 and we must learn to speak and act in ways that make sense to the communities in which we live. Lave and Wenger describe this process as becoming “[a] whole person acting in the world.”26 Although sense of self plays a role, practitioner identity is acquired through the collective recognition and validation of the individual’s actions or practices by others within the community of practice.26 For this reason, Wenger considers practice in the context of situated learning to be a social phenomenon.29 Ibarra, from a social learning perspective, explained that situated learning also allows individuals to experiment with the practices that define their professional roles.39 They may adopt or adapt new practices based on the social context that provides structure and meaning to what they do.

Relevance to Radiation Therapists

Situated learning theory supports the supposition that the separation of radiation treatment planning, simulation tasks, and other forms of treatment preparation in the clinical workplace has marginalized the participation of radiation therapists.19,26,27 When work processes are separated into specific tasks and participation is limited to only a portion of a process, the interdependency of the employees who perform the separate tasks is greatly diminished. In this context, new generations of radiation therapists are unable to acquire the fund of knowledge and complete skill sets of their predecessors.

As specialized workstations and treatment consoles are introduced in the modern radiation treatment center, therapists are in jeopardy of becoming machine operators as a consequence of their fragmented job duties. They also are in jeopardy of losing their professional status and credentials because of their diminished job role and peripheral participation in the radiation treatment process. These current conditions restrict learning and severely limit the potential of radiation therapists as “therapists.” Their inability to rehearse, participate, and practice applications that actively link conceptual knowledge to their clinical work adversely affects their professional practice and identity and represents a significant step backward in the evolution of the credentialed radiation therapist.

Knowledge Management

The concept of knowledge management learning is embedded in some definitions of situated learning and is described with terms such as “knowing in action” and “knowing in practice.” The ability to perform daily tasks is achieved by acquiring knowledge of work processes.21,22 The concept of “knowing” connects the views of Lave and Wegner26 regarding professional practice with Schön’s21,22 concept of “knowing in action” and Polanyi’s31 concept of understanding “why” as well as “how” things work (the bigger picture).

Many theories of knowledge management begin with Polanyi’s views on “tacit” and “explicit” knowledge. A leading chemist of his day, Polanyi became disenchanted with the view of knowledge held by his
scientific contemporaries and developed a postmodern view of how individuals gain knowledge and share it. Polanyi argued the following points:

- Knowledge includes the element of knowing shared by communication. Language is a vital tool to share knowledge, but we can often know how to do things without either knowing or being able to articulate to others why what we do works.
- That we know more than we can tell expresses a breakdown in peer-to-peer teaching between a speaker and listener, with the speaker wrongly assuming that we all share the same history and work experiences. The listener receives only a limited version.
- There are 2 kinds of awareness: subsidiary awareness and focal awareness. Skillful, more experienced individuals with a rich knowledge inventory can focus on an overall objective, such as the optimal treatment of a patient, when using a tool (focal awareness) to achieve the objective. Less skilled individuals pay more attention to the tool and its mechanics (subsidiary awareness), focusing less on the overall objective.\(^{31}\)

Relevance to Radiation Therapists

The theories described use terms such as “knowing in action” and “knowing in practice.” These concepts build from experiential learning theory as it relates to reflective processes or reflection on action. The term “knowing” can be associated with Polanyi’s concept of understanding related processes with the ability to articulate “why” and “how” things work. High levels of efficient automation and computer systems have replaced manual, step-by-step processes that allowed a greater degree of tactile practice with rich opportunities for observing and connecting conceptual to applied relationships in the clinic. History shows that automation and certain health care management divides and limits knowledge, eliminating learning opportunities and teaching moments.\(^{3,10,13,32}\)

As a result of changes in treatment practice spurring from new technology, staff as well as students are seeing, doing, and understanding less. Staff and, consequentially, students may be less able to demonstrate, practice, or rehearse the ability to connect treatment practices with higher-level thought processes and critical thinking applications regarding treatment rationale. This trend has been described in historical publications in which the clinical setting is increasingly characterized as incorporating fragmented operational knowledge through simplified tasks.\(^{4,10,12,13}\)

Modern radiation therapists may learn new treatments by the “see one, do one” method only. New knowledge in this manner is void of the “knowing” element described by Polanyi\(^{31}\) and restricts awareness to the subsidiary awareness level. The more experienced radiation therapists have a richer stock of background and foundational knowledge gained from the previous “old school” years of application practiced through their work activities. The notion of “button pushers” — the potential degradation from “therapist” to “technician” — results from this subsidiary awareness phenomenon where the scope of learning remains limited to machine operation. Knowledge sharing among peers remains restricted to tacit knowledge, or “know how,” with less “know why” articulation ability.

Polanyi’s work suggests that continuing on this course of deskilling will lead to reduction in certain knowledge transfer among staff, with no conceptual recall and failure to rehearse simple application of concepts.\(^{31}\)

Sociotechnical Systems

The constructs of the sociotechnical system were established in the context of labor studies by the Tavistock Institute in London and the work of Trist et al in the 1950s.\(^{32-36}\) Trist suggested the term sociotechnical to describe a view that emphasizes the interrelatedness of the social and technological subsystems within an organization and the relation of the organization as a whole to the environment in which it operates.\(^{37,39}\) In other words, “the socio-technical system view contends that organizations are made up of people that produce products or services using some technology,” and that each “affects the operation and appropriateness of the technology as well as the actions of the people who operate it.”\(^{40,41}\) As technologies assume more work functions, humans abandon those functions and repeated rehearsal of the tasks associated with them. The result is a loss and a transfer of power from the human subsystem (ie, workers) to the technical subsystem (ie, technologies) through a loss of conceptual knowledge over time.

Adopting an action systems view, Ropohl\(^{42,43}\) argues that every new invention or tool that supports
human tasks represents a novel action function. In other words, there is no invention that would not also constitute a new pattern of human action at the same time. The effect is a change in the human subsystem. Furthermore, technical products or artifacts incorporate functions that originally had relied on human abilities, knowledge, and intentions. The functions and qualities of individuals are externalized and objectified within the technical system, which is generalized beyond the individuals. In sociology, “institutionalization” refers to the process of transindividual generalization of value and behavior patterns into a community.

Similarly, from a sociotechnical view, a community using and learning more technical functions and gaining technological innovations undergoes a process understood as “technical institutionalization.” Institutions, in an abstract sense, channel and shape the behavior of the individuals they employ and integrate them into a common culture, an effect called socialization. Previously, this happened mainly through human group interaction and communication, but in present-day organizations, technical products, tools, and social network systems exhibit the same socialization ability. When viewed in the context of the sociotechnical system, technical products extend their institutional power to the individuals engaged in goal-directed behavior that ideally leads to productivity. This process is referred to as “technical socialization.” Technical development, in effect, is equivalent to social change and influences group culture.

What workers eventually may lose is the information and processes built into the technologies. As we become more dependent upon technologies, their failure or loss can paralyze us as individuals or society as a whole. Knowledge that once was transmitted through human communication or the practice of traditional skills is appropriated by technical products. Although technical socialization brings enriched communication, collaboration, and productivity, workers essentially lose power.

Relevance to Radiation Therapists

Much research on sociotechnical systems focuses on information systems design and implementation. Because modern health care systems are so dependent on complex human organizational structures, they are suitable to sociotechnical analysis. Although information technologies seem to be crucial to the development of sustainable health services, every new health informatics application seems to generate an unanticipated consequence that may adversely affect patient care. A similar technological systems situation has become a primary concern with modern computer-assisted radiation treatment delivery systems.

Discussion

Radiation therapists work in a fast-paced, ever-changing environment that poses many challenges. As they have been empowered by sophisticated automated technologies to provide more precise treatments, a critical perspective resting on learning theories assert that their tasks have become fragmented and foundations of clinical knowledge jeopardized. Their function as caregivers is being appropriated by the very treatment delivery systems they now use. The mechanics and operational aspects of radiation delivery have, in effect, removed important elements from treatment that once fostered and demanded conceptual knowledge. Organizational structures and work processes also have been a limiting factor.

Maintaining competence in this highly technological environment is an ever-present demand for radiation therapists. What competence level is required depends on routine practices within the immediate workgroup of radiation therapists but more likely is set by the organizational (or departmental) hierarchy. Expectations with regard to conceptual knowledge also may vary, being strongly emphasized in some departments and less so in others. Radiation therapists customarily seek to maintain their competence by attending off-site continuing education programs, in-house clinical workshops, and on-site application training sessions or in-services. Peer-to-peer training, however, is the method used most frequently to share knowledge among radiation therapists who rotate between treatment machines. Anyone may seek training by his or her own initiative.

This paper presents the argument that forms of technology and automation create distance between treatment processes and forms of thinking and awareness. Even if manual procedures are no longer performed, radiation therapists still should maintain adequate conceptual knowledge, strong critical
Increasingly is characterized by simplified tasks that fragment operational knowledge. High levels of efficient automation and computer networks have replaced manual, step-by-step processes in radiation therapy that once allowed a greater degree of tactile practice with multiple opportunities to observe and connect conceptual to applied knowledge in the clinic. Organizational structure and management practices also divide and limit knowledge and thereby eliminate learning and teaching opportunities. As a result of changes in radiation delivery systems, staff radiation therapists and students are observing, doing, and understanding less. They are less able to connect applied treatment practices to treatment rationales.

**Implications for Continuous Learning**

Historical reviews of medical practices and studies of health professionals show that the clinical setting increasingly is characterized by simplified tasks that fragment operational knowledge. High levels of efficient automation and computer networks have replaced manual, step-by-step processes in radiation therapy that once allowed a greater degree of tactile practice with multiple opportunities to observe and connect conceptual to applied knowledge in the clinic. Organizational structure and management practices also divide and limit knowledge and thereby eliminate learning and teaching opportunities. As a result of changes in radiation delivery systems, staff radiation therapists and students are observing, doing, and understanding less. They are less able to connect applied treatment practices to treatment rationales.
Although this argument lacks validity through empirical research, the relevant theories and studies presented provide a level of evidence for its consideration. Clearly, additional research is needed in this area to confirm or disprove this analysis.

Implications for Policy
The modern radiation treatment center, as an organizational structure, must confront external pressures to remain competitive and to sustain a rapid rate of technological change. For this reason, learning remains a constant need. This review provides information that organizational decision-makers can use to understand sociotechnical dynamics and to identify possible gaps in workplace learning processes that can affect adoption of new treatment technologies.

For administrators seeking higher levels of organizational effectiveness, a crucial piece of this review to consider is how past knowledge is applied to current practices or how the fragmentation of information or ineffective peer-to-peer learning can hinder seamless transition to new practices.

Implications for Practice
Radiation therapists have varying levels of knowledge based on their work history and level of experience. Experienced radiation therapists are able to perceive treatment objectives fully by relying on a deep well of conceptual knowledge while adopting new work practices. Inexperienced radiation therapists must focus directly on learning new tasks at a fast pace as they attempt to “think on their feet,” a situation that makes it more difficult for them to tie conceptual knowledge to their work and maintain their ability for independent clinical judgment.

The adult learning theories examined in this review offer a perspective that lend credence to perceived knowledge gaps among practicing radiation therapists. By viewing all radiation therapists as potential experts and by understanding their need for effective methods of knowledge sharing, workplace learning dynamics may become a focus of future research.

Conclusion
Staff radiation therapists teach entry-level personnel and students by modeling the treatment delivery process. This type of knowledge translation encompasses tacit knowledge. Because learning in the clinical setting focuses primarily on operational knowledge, gaps in conceptual knowledge could develop over generations of radiation therapists. This possibility is underscored by theories of organizational learning, situated learning, systems learning, knowledge management, and sociotechnical systems.

Gaps in conceptual knowledge among staff radiation therapists may be transmitted to students working under their supervision as part of the learning process and may affect the practice of radiation therapy for generations to come.

Future research should test these assertions and, if confirmed, methods of workplace learning should be developed that will ensure optimal radiation therapy practice and patient care.

References
11. Ash JS, Berg M, Coiera E. Some unintended consequences of information technology in health care: the nature of patient...
Peer Review

Learning Conditions of Radiation Therapists

The ASRT is seeking members to serve on the Radiation Therapist Editorial Review Board. Appointees begin their terms Jan. 1, 2013, and serve a 2-year term. To be qualified, you must be a member of ASRT and have experience writing or editing professional materials. Strong preference will be given to a candidate who has published a peer-reviewed article.

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Variations in Tattooing Procedures Among Canadian Radiation Therapy Cancer Centers

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Background The vast majority of patients who receive radiation treatment are given small tattoos to distinguish their treatment site, which helps radiation therapists set up reproducible treatment. It is probable that the tattooing procedure varies between radiation therapy cancer centers and even between radiation therapists within a single center.

Objective To find out if procedural variations in radiation therapy tattooing exist among Canadian radiation therapy cancer centers.

Methods A unique information base was compiled consisting of the supplies and procedures used in the Canadian tattooing procedure. A survey composed of 27 questions addressing 6 main topics (baseline information, documentation, needles, ink, tattoo supplies, and infection prevention practices) was constructed and distributed to radiation therapy cancer centers across Canada, excluding Quebec.

Results Twenty radiation therapy cancer centers from 5 provinces responded. Results revealed many variations in the tattooing process among centers across Canada, even among centers in the same province. Some identified practices were not supported by related peer-reviewed literature researched at the time this article was written.

Conclusion This article outlines supply and process alternatives currently in practice to provide an initial research base for radiation therapy cancer centers seeking to revise their tattooing procedures.

Tattooing radiation therapy patients to delineate their treatment site has been practiced for many years, although the origins of the procedure are unknown. Tattoos are used to reproduce the original patient position from the patient’s simulation appointment for future treatments. Although radiation therapy tattooing has not garnered much attention in medical literature, it is an invasive process that affects many patients undergoing radiation therapy, some of whom are immunocompromised. Many therapists learn the tattooing procedure by watching a fellow therapist perform the procedure, and then perform the procedure under supervision until they are competent. The Canadian Association of Medical Radiation Technologists (CAMRT) risk management guidelines recommend gloving while tattooing, but they do not recommend supplies or procedures. Thus, radiation therapy tattooing can vary from 1 radiation therapy cancer center to the next, and may even differ between radiation therapists within a center. If every radiation therapy cancer center in Canada is performing tattooing, what procedural variations exist between them, if any?

With the exception of anecdotal evidence and Internet forums that address radiation therapy tattooing, the authors of this study identified a lack of literature on the topic, indicating a need for research. Specific tattooing procedures do not appear to be included in any available radiation therapy textbooks. Without a documented procedure to follow, the chance of spreading a nosocomial infection to a patient during the tattooing process may increase, as may the risk of needle-stick injuries. Additionally, without knowing what tattooing
supplies are in use, radiation therapy cancer centers must draw their own conclusions about what works and what does not. For this reason, the authors surveyed Canadian radiation therapy cancer centers about their tattooing supplies and documentation which, in turn, could provide a baseline of information to help centers make evidence-based clinical decisions concerning tattooing procedures. This survey was the first of its kind to investigate radiation therapy tattooing variations among Canadian centers.

**Literature Review**

Relevant studies and abstracts were identified by searching Ovid MEDLINE and the Cumulative Index to Nursing and Allied Health Literature, restricted to literature published from January 1995 to June 2009. Only articles that referred to radiation therapy tattooing were included for discussion. Unfortunately, very few articles were directly related to tattooing policies and procedures. The authors’ literature review revealed several important themes related to radiation therapy tattooing; however, these results were sparse and had not been followed up with subsequent research to prove or disprove initial findings.

Tattoos may cause patients stress and anxiety because the tattoo’s permanence reminds them of their cancer diagnosis and treatment.\(^4\)\(^,\)\(^5\) The tattoos given for treatments of the chest area may be particularly troubling because they are difficult to conceal along the neckline. One article suggested “alternative wording” in the form of “permanent dots,” which was believed to lessen the negative stigma that surrounded the patient’s perception of receiving tattoos.\(^5\)

Equally as damaging as the psychological trauma may be the allergic reaction experienced or blood-borne pathogens that could be acquired from tattoos. Allergic reactions to radiation therapy tattoos rarely have been documented, and only 2 instances were found in peer-reviewed literature.\(^\)\(^7\) Matera agreed that radiation therapy tattoo allergies may be underreported, and that diseases transmitted by this process are not described in available literature.\(^\)\(^7\) Many different diseases, such as hepatitis B, hepatitis C, human immunodeficiency virus, human papillomavirus, and mycobacterium, are discussed in medical literature as a result of commercial tattooing.\(^4\)\(^,\)\(^6\)\(^,\)\(^7\)

Specifically, the ink reservoir used to store radiation therapy tattooing ink when not in use has been singled out as a potential source of contamination.\(^7\)\(^8\)

Ink reservoirs are not the only supplies mentioned in the literature, but the list of supplies mentioned is short. India ink, a plain black ink normally sold in art stores, is commonly discussed.\(^4\)\(^,\)\(^5\)\(^,\)\(^7\)\(^,\)\(^8\) Although this type of ink is touted as nontoxic, it is not intended to be injected under human skin, and its sterility often is questionable.\(^7\)\(^4\) In radiation therapy cancer centers, the use of a small-gauge needle typically is indicated to deliver India ink into the dermal layer of a patient’s skin.\(^4\)\(^,\)\(^5\)\(^,\)\(^7\)\(^,\)\(^8\) One study was performed to determine whether fluorescent ink was a viable option for patients as a way to reduce the visibility of radiation therapy tattoos to the naked eye under normal light.\(^3\)

Ink and needles are the main supplies used to tattoo a patient, but radiation therapy textbooks only mention the use of tattoos as reference marks or give general guidelines without outlining a definitive procedure.\(^\)\(^4\)\(^,\)\(^8\)\(^,\)\(^9\)\(^,\)\(^10\) Upon reviewing all relevant literature, a lack of radiation therapy tattooing information was identified.

**Methods**

This study was conducted using survey research methodology. A survey comprising 27 questions was designed to obtain information on 6 main topics pertaining to radiation therapy tattooing:

- Baseline information.
- Documentation.
- Ink.
- Needles.
- Tattoo supplies.
- Infection prevention practices.

This study adheres to the ethical principles set out by the British Columbia Cancer Agency Research Ethics Board. An expedited review from this board was submitted and approved. The survey was distributed in an e-mail via SurveyMonkey (Palo Alto, California), an online survey tool, to 29 radiation therapy cancer centers across Canada, excluding the predominantly French-speaking Province of Quebec. Managers, clinical educators, and radiation therapy staff with the most proficient knowledge of the center’s tattooing procedure were invited to complete the survey. Of the 29 surveys e-mailed, 2 bounced back. Three weeks following the distribution of the survey, a reminder e-mail was sent to increase the
Variations in Tattooing Procedures

 número de respuestas. Los datos recopilados se evaluaron utilizando las herramientas de carga y análisis de SurveyMonkey.

La investigación realizada mediante el método de encuestas se consideró el método más apropiado debido a las limitaciones geográficas. Otras limitaciones incluyeron la incapacidad para observar procedimientos, la credibilidad de la información de los respondentes y la fiabilidad de las respuestas obtenidas. La fiabilidad podría haber sido comprometida en casos en que los respondentes no comprendieron lo que se les estaba pidiendo o respondieron basándose en la memoria en lugar de la información que proporcionaban de su manual de procedimientos de tatuaje de su centro.

Los autores no anticiparon algunas respuestas recibidas, sugiriendo que estas preguntas particulares estaban abiertas a interpretación. Los autores determinaron que estas respuestas no se enfocaron en lo que se les estaba pidiendo o implicaban que se confundía con lo que se les estaba pidiendo.

En lo que respecta a este método, las limitaciones incluyen que 5 de 10 provincias de Canadá no enviaron encuestas, y el nivel de conocimiento de los respondentes sobre el procedimiento de tatuaje variaba. Los resultados podrían mejorar a través de un muestreo de una muestra mayor y la adición de gráficos de encuestas para aumentar la claridad de las preguntas.

**Resultados**

**Información basal**

De las 29 invitaciones de encuesta enviadas a lo largo de Canadá, 20 encuestas se completaron y devueltas, con una tasa de respuesta de 74%. Veinte (55%) encuestas se recibieron de Ontario, 5 (25%) de Columbia Británica, 2 (10%) de Alberta, 1 (5%) de Manitoba, y 1 (5%) de Nuevo Brunswick. Los respondientes fueron animados a tener su manual de procedimientos de tatuaje y suministros con ellos mientras completaban la encuesta. Se supuso que todos los respondientes probablemente tendrían algún conocimiento de tatuajes, pero no se requirió que llenaran la encuesta con éxito. Ocho encuestas respondieron (50%) se identificaron como educadores clínicos; otros respondieron que se identificaron como coordinadores clínicos (15%), terapeutas de radiación (15%), superiores / administradores (10%) y terapeutas de recursos para la planificación (10%).

Para servir como una comparación para centros de radioterapia de cáncer en los Estados Unidos, la encuesta inquirió sobre la carga del paciente del centro (ver Figura 1). La mayoría de los centros (n = 13) estimaron que entre 6 y 10 pacientes fueron tatuados al día. Siete centros tenían una carga de pacientes más alta, mientras que solo 1 centro reportó que menos de 6 pacientes fueron tatuados al día.

**Documentación**

En general, se encontró variación con respecto a la presencia y claridad de la documentación formal relevante a técnicas de tatuaje de radioterapia. Dieciocho centros (90%) reportaron la presencia de un documento de tatuaje, 1 (5%) no tenía un documento en lugar, y 1 (5%) no respondió a esta pregunta. De los 18 respondientes que sabían cuándo se revisó o revisaron el documento, 16 (89%) afirmaron que se revisó dentro de los últimos 2 años. Los dos centros restantes lo revisaron en los últimos 7 años. Los motivos para hacer revisiones incluyeron:

- **Policy:** Reglamento: Una serie de instrucciones que deben ser respetadas (implica adherencia rígida).
- **Protocol:** Instrucciones que idealmente deben ser seguidas.
- **Procedure:** Un procedimiento para realizar una tarea.
- **Guideline:** Un esquema para realizar la tarea (implica adherencia sugerida).

Las respuestas varían en términos de importancia y formalidad de la documentación de tatuaje. Aunque 5 centros (25%) identificaron la documentación de tatuaje como un reglamento no negociable, 9 (45%) lo referían como un procedimiento informal, 3 (15%) lo referían como una guía, y 1 (5%) lo referían como un protocolo. De los 18 respondientes que sabían cuándo se revisó o revisaron el documento, 16 (89%) afirmaron que se revisó dentro de los últimos 2 años. Los dos centros restantes lo revisaron en los últimos 7 años. Las razones para hacer revisiones incluyeron:

- **Needle type** or a safety device changed (n = 3).
- The document was newly created (n = 2).
- Canadian Centre for Occupational Health and Safety concerns were addressed (n = 1).
Although all Canadian radiation therapy cancer centers reported the use of black ink to tattoo patients, many different ink brands and suppliers were identified (see Table 1). For example, 1 clinic reported that their pharmacy packages ink into 5 mL sterile vials and therapists discard the vials within 7 days of opening, whereas other centers reported the use of drawing ink from large vials obtained from art supply stores. One clinic used green ink to tattoo subsequent treatment reference points.

Concerning transfer of ink from container to the patient’s skin, the survey presented 4 different methods. Eight respondents confirmed syringes were used to transfer ink to the patient’s skin, 7 dabbed ink onto the patient’s skin, 3 used hollow needles, and 2 described dipping a sterile lancet into a single-use ink cap before tattooing the patient directly with the sharp point (see Table 2).

### Table 1

<table>
<thead>
<tr>
<th>Ink Suppliers</th>
<th>No. of Clinics</th>
<th>Ink Brands/Generic Name</th>
<th>No. of Clinics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy</td>
<td>5</td>
<td>India ink</td>
<td>11</td>
</tr>
<tr>
<td>Art store</td>
<td>5</td>
<td>Pelikan ink</td>
<td>2</td>
</tr>
<tr>
<td>Medical ink supplier</td>
<td>3</td>
<td>Koh-I-Noor</td>
<td>2</td>
</tr>
<tr>
<td>Tattoo ink supplier</td>
<td>2</td>
<td>Classic Colour Systems</td>
<td>1</td>
</tr>
<tr>
<td>Office supplier</td>
<td>1</td>
<td>Uncertain</td>
<td>3</td>
</tr>
<tr>
<td>Uncertain</td>
<td>3</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>

*This table accounts for only 19 clinics; 1 clinic did not respond.

### Table 2

<table>
<thead>
<tr>
<th>Transfer of Ink to Skin</th>
<th>No. of Clinics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syringe</td>
<td>8</td>
</tr>
<tr>
<td>Ink dabbed onto patient skin</td>
<td>7</td>
</tr>
<tr>
<td>Hollow needle dipped in ink</td>
<td>3</td>
</tr>
<tr>
<td>Lancet</td>
<td>2</td>
</tr>
</tbody>
</table>

- Consent documentation was added (n = 1).
- A patient education booklet was added (n = 1).
- Documentation for preparing a syringe was added (n = 1).
- Doctor approval was now needed for new tattoos within 5 cm of each other (n = 1).
- Single-use ink caps were implemented (n = 1).

Several of these reasons also had interesting backgrounds leading to the changes. One center added consent documentation because of legal concerns. At another center, the doctor’s approval became required when giving new tattoos less than 5 cm apart because an error had been made when a patient’s tattoos for a new treatment site and previously treated site were confused. At yet another center, single-use ink caps came into use because of infection control concerns, and a patient education booklet was added to tattooing documentation for patients who requested more information prior to going through the procedure. Syringe preparation was formally documented at a facility after a needle-stick injury was sustained during the tattooing procedure.

### Ink

Although all Canadian radiation therapy cancer centers reported the use of black ink to tattoo patients, many different ink brands and suppliers were identified (see Table 1). For example, 1 clinic reported that their pharmacy packages ink into 5 mL sterile vials and therapists discard the vials within 7 days of opening, whereas other centers reported the use of drawing ink from large vials obtained from art supply stores. One clinic used green ink to tattoo subsequent treatment reference points. Although the use of fluorescent ink was queried recently as an alternative to black ink for improved cosmetic results or for darker skin tones, no clinics reported the use of fluorescent ink.

Concerning transfer of ink from container to the patient’s skin, the survey presented 4 different methods. Eight respondents confirmed syringes were used to transfer ink to the patient’s skin, 7 dabbed ink onto the patient’s skin, 3 used hollow needles, and 2 described dipping a sterile lancet into a single-use ink cap before tattooing the patient directly with the sharp point (see Table 2).

### Needles

The implements used to pierce the patient’s skin during tattooing varied from simple syringes to “tattooing devices” originally intended for use by diabetics to check their blood glucose levels. Centers identified the tattooing implement and needle gauge they use to pierce the skin (see Table 3). When asked to describe the brand of implement used, half of all clinics (n = 10) preferred BD (Franklin Lakes, New Jersey),
Variations in Tattooing Procedures

Table 3

<table>
<thead>
<tr>
<th>Needle Gauges</th>
<th>No. of Clinics</th>
<th>Tattooing Implementa</th>
<th>No. of Clinics</th>
</tr>
</thead>
<tbody>
<tr>
<td>27 g</td>
<td>1</td>
<td>Syringe</td>
<td>10</td>
</tr>
<tr>
<td>26 g</td>
<td>1</td>
<td>Hand-held needle</td>
<td>8</td>
</tr>
<tr>
<td>25 g</td>
<td>5</td>
<td>Tattooing device</td>
<td>3</td>
</tr>
<tr>
<td>23 g</td>
<td>3</td>
<td>Lancet</td>
<td>1</td>
</tr>
<tr>
<td>22 g</td>
<td>2</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>21 g</td>
<td>1</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>18 g</td>
<td>5</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>16 g</td>
<td>1</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Uncertain</td>
<td>1</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>

They were allowed to identify more than 1 tattooing implement because different options were available.

2 centers preferred Owen Mumford (Woodstock, England), 2 used Covidien ([formerly Kendall], Mansfield, Massachusetts), and 1 center each used the brands EZ-Ject (Omaha, Nebraska), VanishPoint (Retractable Inc, Little Elm, Texas), and BAKSNAP (Domrex Pharma Inc, Laval, Quebec, Canada). Three clinics were unsure of the brand used at their facility.

Needle-stick injuries had occurred at more than half of the Canadian centers surveyed. Three centers identified 4 to 6 needle-stick injuries to staff in the past 5 years. However, the majority of centers (n = 14) identified 1 to 3 needle-stick injuries. Three centers chose not to answer the needle-stick inquiry. Interestingly, half of the respondents (n = 10) reported the use of safety-engineered recapping devices, whereas 8 denied their use. Two were unsure or did not answer. Of the respondents who did not use recapping devices, reasons included hospital policy against recapping, the use of retractable needles, and direct ejection of the contaminated sharp into a sharps bin.

Tattoo Supplies

The main survey question regarding various additional tattooing supplies allowed for as many supplies to be indicated as were used by each center. A short answer box also was provided for any supplies not included in the choices. The data displayed in Figure 2 charts the equipment most commonly used by 18 clinics. (Two survey respondents did not answer the question.) In addition to the supplies shown in Figure 2, 1 center noted in the short answer box that they used a multiuse ink vial with a self-sealing membrane in the lid, while another clinic used felt pens to mark the patient’s skin.

Infection Prevention Practices

Infection prevention practices in radiation therapy cancer centers across Canada are far from standardized. This section of the survey asked centers:

1. At what point during the tattooing procedure do you disinfect a patient’s skin? (What they use to disinfect skin was covered in the tattoo supplies question.)
2. When do you disinfect work surfaces?
3. When does hand washing occur?
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Table 4

<table>
<thead>
<tr>
<th>Frequency of Work Surface Disinfection and Hand Washing During Tattooing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Work Surface Disinfection</strong></td>
</tr>
<tr>
<td>-------------------------------</td>
</tr>
<tr>
<td>Between each patient</td>
</tr>
<tr>
<td>Daily</td>
</tr>
<tr>
<td>Weekly</td>
</tr>
<tr>
<td>As required</td>
</tr>
<tr>
<td>Not disinfected</td>
</tr>
<tr>
<td>No answer</td>
</tr>
</tbody>
</table>

4. Do you keep your supplies in open or closed containers?

Skin disinfection at some point in the procedure was indicated by 17 centers. One respondent specified that their patients’ skin is never disinfected during the tattooing procedure, and 2 centers did not answer this question. Work surface disinfection varied among clinics (see **Table 4**). The majority of centers disinfect their working surfaces with varying frequency, with the exception of 1 center that claimed never to disinfect work surfaces. All centers reported handwashing at some point during their tattooing procedure.

Finally, 7 respondents indicated they kept their tattooing supplies in closed containers, and 12 left them uncovered. The 19 responses to this question are due to an overlap in the response of 1 center that specified both open and closed containers are used to house their products.

**Discussion**

**Baseline Information**

Responses from 20 radiation therapy cancer centers across Canada identified considerable differences in all aspects of radiation therapy tattooing. Of the 27 surveys distributed, 20 were completed and returned for a response rate of 74%. Several provinces were underrepresented, or not heard from at all, because of the limited number of radiation therapy cancer centers throughout Canada. Centers that did not return a survey were located in the provinces Newfoundland, Nova Scotia, Prince Edward Island, and Saskatchewan. Of the responses received, 100% of centers from British Columbia (n = 5), Alberta (n = 2), Manitoba (n = 1), and New Brunswick (n = 1) returned completed surveys. This percentage cannot be calculated for Ontario (n = 11) because it is unclear how many centers existed in Ontario when the survey was conducted.

Each province has a unique cancer care program, which translates into varying job titles indicated by survey respondents. These dissimilar titles (e.g., clinical educator, manager, supervisor, and clinical coordinator) have several implications. Primarily, the knowledge level of tattoo procedures and supplies may vary between the different employment roles in each center. Staff directly related to patient tattooing may have been more knowledgeable of the supplies and methods used in the procedure. However, if respondents followed the survey instructions and had a copy of the center’s tattooing document with appropriate supplies nearby, their experience with the tattooing procedure should not have mattered to their responses.

When discussing their current patient workload, many centers in Canada claimed to tattoo an average of 6 to 10 patients each day, whereas 7 clinics tattoo more than 10, likely corresponding to larger centers. Conversely, 1 center indicated they tattoo 1 to 5 patients each day, which, in addition to their province (New Brunswick), led the author to believe this center is smaller than average.

**Documentation**

Only 1 radiation therapy cancer center did not have a formal tattoo procedure document. This finding is concerning because the CAMRT risk management guidelines states that “inadequate information or documentation to perform the requested task” constitutes a “major risk factor.” A detailed document with procedures supported by current literature should be available at all centers, and strict adherence should be encouraged. Adherence to such a document may
minimize risk of needle-stick injury to staff when tattooing patients.\textsuperscript{13,14}

The centers with documented tattoo procedures attributed varying degrees of importance to the document for reasons unknown. The degree of importance placed on the documents may reflect a center’s expectations of document adherence. A 2004 study of evidence-based medicine suggests that lack of adherence to recommended procedures may pose risks in health care.\textsuperscript{14} Once a document is in place, keeping it up to date is ideal to ensure consistent practice. Sixteen centers reported reviewing or revising their tattoo procedure document within the past 2 years. This is a positive finding, as literature on the subject states that “guidelines should be reassessed for validity every 3 years” and “should be updated when new information becomes available.”\textsuperscript{13} Of these 16 centers, 2 created a document that did not previously exist. This also is promising because it demonstrates that Canadian radiation therapists are beginning to formally put into words what so many therapists learn on the job by word of mouth and impromptu observational learning.

**Ink**

Ink brands and suppliers were not overly similar between centers, other than the fact that all centers used black ink (commonly known as India ink) to tattoo their patients. In addition, 5 centers reported that inks were obtained from the hospital pharmacy and thus ink supplier and brand information may not have been available to the respondent. One center reported the use of green ink for second-course radiation therapy tattooing to minimize confusion and errors associated with retreatment when a second set of treatment tattoos are within 5 cm of the first set.

The British Columbia Ministry of Health Guidelines for tattooing state that “all pigments should be chemically pure, nontoxic, and nonsensitizing.”\textsuperscript{17} In reality, very few inks are “chemically pure,” and “nontoxic” has never been fairly researched. Sensitivities have been seen from many different inks, even black India ink.\textsuperscript{6} The U.S. Food and Drug Administration is reviewing which inks are safe for tattooing, but no results are conclusive at this time.\textsuperscript{18}

Following the authors’ analysis of survey results, ink suppliers identified in the survey responses were contacted with questions regarding material safety data sheets and complete ink ingredients. The material safety data sheets for Speedball India ink (Speedball Art Products LLC, Statesville, North Carolina) stated: “This product has been evaluated by a Toxicologist only as per intended usage. DO NOT DEVIATE FROM INTENDED USE.”\textsuperscript{19} The intended use of Speedball India ink is for writing or crafts, as is the intended use for all inks with the exception of Classic Colour Systems (Albury, Australia), a tattoo supply company whose ink was used by 1 survey respondent. Tattoo ink composition is not federally controlled in Canada or the United States, and allergic reactions and other complications continue to occur.

These findings are alarming for several reasons. Ink being used for radiation therapy tattooing has not been evaluated for safety as a tattooing ink. Injection of such ink into the dermis (between the epidermis and the subcutaneous skin layers) may pose health risks to all patients. Although allergic reactions to black tattoo ink are rare, the prevalence of reactions to radiation therapy tattoos is unknown, as the duration between the administration of the tattoo and the patient’s start of treatment is approximately 2 weeks in some centers.\textsuperscript{6,20}

Radiation therapists are not in direct contact with the patient immediately following the administration of a tattoo, which provides no opportunity to assess signs of allergy or infection at the tattoo site. If tattoos do pose a risk of allergy or infection in current practice, the time between tattooing and the start of treatment may be sufficient for a reaction to subside.

The simplest way to transfer ink would likely reduce the chance of contamination. Thirteen centers stated they use the same device was to tattoo patients to transfer ink from a working container to the patient’s skin. Seven use a wooden stick to first dab ink on the skin before tattooing.

**Needles**

Tattoos become permanent when a needle or sharp object pushes ink into the dermis. Various devices are available for this purpose, but the most popular in Canadian radiation therapy cancer centers is the syringe. Needles and syringes produced by BD were used by 50% of centers (n = 10). Needle choice is most likely connected to the distributor that each center
uses for supply purchasing. In the authors’ experience, needle gauge (which denotes the diameter of the shaft of the sharp) is again determined by the needles or syringes already in use for other procedures at a center. Thus, there may be a variety of gauges used, as the survey results demonstrated. Thirteen centers used needles 21 gauge or smaller and 2 centers had the option of 2 different gauges (25 or 18, and 25 or 22). In studies relating needle gauge to patient pain perception, more pain was consistently felt with smaller needle gauges.\textsuperscript{17,22} To be clear, a smaller needle gauge actually corresponds with a larger diameter (21 gauge = 0.72 mm vs 16 gauge = 1.29 mm),\textsuperscript{23} thus smaller gauges will likely inflict more pain.

With our patients’ best interests in mind, we must balance producing a usable tattoo with the pain potentially inflicted. If a therapist can make functional radiation therapy tattoos with smaller needle diameters, patient discomfort will be lessened and, thus, is the preferred practice. Therefore, having the option of 2 different needle gauges seems superfluous.

Half of the reported needle brands (n = 10) were safety engineered to reduce needle-stick injuries; this is an important feature, which may reduce injuries to staff during this procedure.\textsuperscript{24} Two centers indicated that it was hospital policy not to, but when answering in the short answer box the term “recapping” was used. This response appears to relate to the wording of the question. The authors intended to determine the use of recapping devices, but perhaps recapping was seen in general terms. In this case, wording should have said “mechanical recapping device” to avoid ambiguity. Every center that answered the question regarding needle-stick injuries had at least 1 needle-stick injury in the past 5 years (3 reported 4 to 6 injuries), which speaks to the necessity of implementing strategies and devices aimed at reducing this number.

One center reported using the Autolet II Clinisafe (Owen Mumford Ltd, Woodstock, United Kingdom), an automatic bloodletting device used by diabetic patients to check blood glucose levels. The design of the device raised questions regarding a potential cross-contamination hazard when used on multiple patients. According to an Owen Mumford representative (Andy Coxon, written communication, October, 2009), the company does “not recommend the Autolet II for multi-patient use, as there is a possibility that cross-contamination of blood may occur on the platform, even when the needle is changed.”

**Tattoo Supplies**

In addition to being concerned with where ink comes from, how it is stored and dispensed are also important when addressing potential contamination issues. If a squeeze bottle with a replaceable cap is used to dispense the ink into single-use ink caps (small, disposable plastic containers used while tattooing a single patient), risk of contaminating the larger ink supply is decreased.\textsuperscript{17,25-27} Although 8 centers reported having single-use ink caps, only 6 stated that the tattoo ink was kept in an ink cap during the procedure. This discrepancy may have occurred because of a misunderstanding about what a single-use ink cap is.

As noted previously, the syringe was the most popular method of ink transfer from the ink cap to the patient’s skin. Using a wooden stick to dab ink on the skin was described by 7 centers. If wooden sticks are repeatedly inserted into the primary ink container after being in contact with a patient’s skin, they could contaminate the entire ink supply. Although the integrity of wooden sticks likely has never been tested by a radiation therapy department, it has been proven that “the microbiological quality of wood is difficult to control and sterilization by autoclaving may fail.”\textsuperscript{28} Additionally, if wooden sticks are left in an open container, environmental contamination of the sticks is possible.

After the tattoo is administered, excess ink is wiped off the patient’s skin using gauze or tissue, as indicated by 45% (n = 9) and 35% (n = 7) of respondents, respectively. Regardless of the type of material used to remove excess ink, Canadian tattoo industry standards state, “tissues or wipes to be used during tattoo procedures should be stored where they cannot become contaminated.”\textsuperscript{29}

**Infection Prevention Practices**

Fifteen centers require gloves on both hands prior to and during the entire tattooing procedure. Three indicated that gloves are worn for “tattooing only.” This finding is consistent with the CAMRT risk management guidelines, stating, “Gloves should be worn when giving injections or tattoos.”\textsuperscript{1} It was noted, however, that 1 clinic stated wearing gloves
was “optional.” The use of gloves protects patients from pathogens that may reside on a therapist’s hands, and protects the therapist from blood-borne disease possibly carried by the patient if his or her hands come in contact with blood and body fluids. Gloves also reduce the risk associated with needle-stick injuries. The Public Health Agency of Canada stated that “the volume of blood from a needle stick injury may be reduced by at least 50% when the needle passes through a glove.” Once gloves have been donned, 85% (n = 17) of centers reported disinfecting the patient’s skin with either alcohol (n = 18) or chlorhexidine (n = 1). Because 2 clinics did not respond, and 1 center denied disinfecting their patient’s skin at all before tattooing, the authors assumed that 1 clinic offered the option of both alcohol and chlorhexidine.

Respondents discussed placing tattooing supplies in stainless steel (n = 2) or plastic trays (n = 10) while tattooing patients. Having a tray that can be wiped down after the procedure is completed and making sure all disposable supplies have been thrown away reduces the risk of contaminating additional work surfaces with pathogens. Recommendations by the Ontario Ministry of Health state that tattoo supplies should be placed in stainless steel trays while tattooing patients.

When the tattooing procedure has been completed and gloves removed, a large proportion of responding clinics require hand washing (n = 13). Nine clinics reported that therapists wash their hands prior to donning gloves, with 1 clinic indicating that alcohol-based hand sanitizer is used. Hand washing is the most important method of preventing transmission of blood-borne pathogens and should be incorporated into every procedure where there is this potential. Literature reinforces hand washing after removing gloves.

According to the disinfection rates put forth by survey respondents, hospital policy for work surface disinfection is fairly random across the country. All but 1 center disinfected at least once per month (the center claimed never to disinfect their tattooing work surfaces). Nosocomial infections are an issue in many medical facilities and “the most common nosocomial pathogens may well survive or persist on surfaces for months and can thereby be a continuous source of transmission if no regular preventive surface disinfection is performed.” Disinfecting as recommended by hospital guidelines is important to reduce the transmission of pathogens when any medical procedure, including radiation therapy tattooing, is performed.

Based on the results of this initial study, several areas may warrant future research on radiation therapy tattooing. Two topics of importance are to determine the systemic effect on a radiation therapy cancer center when implementing changes to a tattooing procedure, and to analyze the costs and benefits of implementing a recommended best practice. Determining whether there is a risk of infection from current radiation therapy tattooing procedures may indicate what aspect of the procedure needs to be updated for enhanced safety.

**Conclusion**

Great variance has been shown in radiation therapy tattooing processes across Canada. Of the variations found, some tattooing practices include supplies and processes not supported by current literature. This study compiled information specific to Canadian radiation therapy centers to help them make decisions about tattooing procedures. These minor topics and procedures in cancer centers are sometimes forgotten when newer, more exciting technologies appear. However, it is necessary to continually improve in these areas because they are the foundation of exciting technological advancements.

**References**


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Prostate Cancer and Radiation Therapy

Bryant Furlow, BA

After completing this Directed Reading, the reader should be able to:
- Describe the epidemiology and pathobiology of prostate cancer.
- Summarize the screening, diagnosis, and staging of prostate cancer.
- Discuss the roles of radiation therapy in curative, adjuvant, salvage, and palliative prostate cancer management.
- Describe the emerging role of external-beam radiation therapy hypofractionation in prostate cancer treatment.
- Detail methodological problems with much of the available research on late radiation therapy toxicity.

Prostate cancer is a major and growing public health challenge in the United States. Prostate gland adenocarcinoma is the most frequently diagnosed non-skin cancer among U.S. men, and is described by many researchers and clinicians as “epidemic” in proportion. An estimated 217,700 cases of prostate cancer were diagnosed in 2010 and 32,000 people died of the disease that year in the United States, according to the National Cancer Institute. Nearly 1 in every 6 American men will experience prostate cancer at some point in his lifetime, and as of 2008, approximately 2.4 million living American men had prostate cancer histories. Worldwide, prostate cancer is the fifth most common cancer among men, killing an estimated 221,000 men each year.

Ethnic disparities exist in prostate cancer incidence and outcomes. African American men face a higher age-adjusted risk of developing prostate cancer than almost any other population in the world, for example, and are between 50% and 73% more likely overall to experience prostate cancer than white American men. Native American incidence rates are likely underestimated, and diagnoses in some Native American populations are frequently made only after tumors already have metastasized to bone and other organs.

In 1987, researchers at Stanford University in California published a clinical trial establishing the efficacy of the prostate-specific antigen (PSA) test for prostate cancer screening. As screening has become widely available and diagnostic techniques have advanced, detection of prostate malignancy has involved increasingly small tumors, the probable behavior and progression of which are difficult to predict, complicating treatment decision making and fueling controversies about the appropriate treatment of early-stage cancers.

Radiation therapy plays a crucial role in prostate cancer management.
Intensity-modulated radiation therapy (IMRT) and other newer methods can deliver higher radiation doses to the tumor while limiting dose to healthy tissues. However, IMRT use is not without controversy.

Patient age at diagnosis is an important factor in determining appropriate treatment strategies. Because prostate tumors grow slowly, tumor surveillance frequently is justified, particularly among elderly patients with early-stage, localized prostate tumors, who are generally more likely to die of other causes than prostate cancer. Critics claim that some urology practices have purchased IMRT equipment to take advantage of generous Medicare reimbursement rates and that these practices tend to overprescribe IMRT for elderly and low-risk prostate cancer patients. The reimbursement rates initially set for IMRT treatments of complex lung or head and neck tumors also apply to relatively simple prostate IMRT treatment, making radiation therapy potentially very profitable for urology practices. Opponents argue these reimbursement rates encourage overuse of IMRT for patients who may benefit from alternative treatments — including brachytherapy or tumor surveillance.

Critics contend that some smaller clinics use refurbished older models of radiation therapy equipment that may be more prone to failure and lack sufficient staff for adequate quality assurance. Whereas hospitals must meet certain accreditation standards, smaller clinics such as urology practices often do not face those constraints, and frequently have more serious staffing challenges than larger radiation oncology clinics. As of August 2011, an ongoing U.S. Government Accountability Office inquiry has focused on alleged overprescribing of IMRT by a small group of urology practices in New York, Texas, Florida, Pennsylvania, and other states. The American Society for Radiation Oncology (ASTRO) recently released new guidelines aimed at preventing radiation delivery errors with IMRT, including recommendations that address some of the staffing levels and planning coordination concerns raised by critics of urology IMRT practices. The American Society of Radiologic Technologists has endorsed the ASTRO’s recommendations, which emphasize the importance of credentialled radiation therapy team members trained specifically in simulation, treatment planning, quality assurance, and radiation delivery, using a number of radiation therapy modalities and techniques.

Despite concerns about an appropriate role for elderly patients and safety issues at some small clinics, radiation therapy is an excellent option to relieve pain or serve as an adjunct to treatment for thousands of prostate cancer patients each year, and will continue to play a central role in the treatment of prostate cancer.

This article relies heavily on published evidence-based systematic reviews and quantitative meta-analyses of data from multiple studies or datasets, and readers will be cautioned about methodological limitations in the research literature and resulting gaps in understanding of late radiation therapy toxicities.

**Epidemiology**

The median age of patients at time of prostate cancer diagnosis in the United States is 67 years, and more than 65% of cases are diagnosed in men older than 64 years. Less than 1% of cases are diagnosed in men younger than aged 44 years. The median age of cancer-specific death from prostate cancer is 80 years. Because risk rises sharply with age, the aging of the baby boomer generation is expected to bring sharp increases in incidence rates in the near future, such as a projected 300,000 diagnoses in U.S. men in 2015. The overall U.S. incidence rate for prostate cancer is 156 new diagnoses per 100,000 men per year — a rate that is expected to climb by more than 60% as the population ages.

The vast majority of cases (82%) newly diagnosed in the United States involve localized tumors, confined to prostate tissues. Another 11% of new cases are diagnosed after regional spread to pelvic lymph nodes already has occurred, and approximately 4% of cases are diagnosed after metastatic spread to distant organs. Approximately 3% of cases are diagnosed with undetermined stage.

The overall incidence rate for prostate cancer masks dramatic variation in the rates for different ethnic groups in the United States (see Table 1). African American men have the highest rates per 100,000, followed by white men, Hispanic men, and Asian men. Studies have not identified risk factors other than ethnicity to convincingly explain the elevated prostate cancer risk faced by African American men. Reported incidence rates for Native Americans, including Alaska natives, are the lowest in the United States, but this data must be interpreted cautiously because this population might not be classified properly. For example, hospital
susceptibilities, exposures to dietary or environmental carcinogens, and acquired genetic alterations. Several inherited genetic variants and mutations have been identified that might increase prostate cancer vulnerability and prostate tumor aggressiveness, including androgen receptor genes. There has been little agreement on genetic associations between studies; however, much more research is needed. Twin studies strongly suggest that underlying genetic factors contribute to prostate cancer risk, but have not yielded specific genetic targets. A first-degree relative’s diagnosis with prostate cancer is associated with more than a 2-fold increase in a man’s risk of developing the disease. Variants of prostate cancer with strong genetic components tend to occur among men who are 6 to 7 years younger than the typical age at onset, although they otherwise are clinically indistinguishable. Unusually high rates of prostate cancer among both Scandinavian and African American men — and the relative scarcity of prostate cancer among those of African ancestry living outside North America — have led some researchers to suspect that specific but as-yet unidentified prostate cancer genes that originated in Northern Europe today are over-represented among the descendants of enslaved African women who were sexually assaulted by Europeans during the trans-Atlantic slave trade, in which Scandinavians were integrally involved. Despite advances in screening, approximately 4% of men with recently diagnosed prostate cancer have metastatic disease. A review of the literature suggests that prostate cancer appears to involve the complex interaction of heritable susceptibilities, exposures to dietary or environmental carcinogens, and acquired genetic alterations. Several inherited genetic variants and mutations have been identified that might increase prostate cancer vulnerability and prostate tumor aggressiveness, including androgen receptor genes. There has been little agreement on genetic associations between studies; however, much more research is needed. Twin studies strongly suggest that underlying genetic factors contribute to prostate cancer risk, but have not yielded specific genetic targets. A first-degree relative’s diagnosis with prostate cancer is associated with more than a 2-fold increase in a man’s risk of developing the disease. Variants of prostate cancer with strong genetic components tend to occur among men who are 6 to 7 years younger than the typical age at onset, although they otherwise are clinically indistinguishable. Despite advances in screening, approximately 4% of men with recently diagnosed prostate cancer have metastatic disease.

Risk Factors

Age correlates with risk for many types of cancer, but prostate tissue appears to be particularly vulnerable to age-related cancer risk. Between age 40 and 90 years, the frequency of prostate cancer and benign prostatic hyperplasia increases dramatically, from less than 1% to more than 90%. Genetic damage accumulates throughout the lifespan, but the reasons for dramatic increases in prostate cancer risk between the fourth and ninth decades of life remain unclear.

As with most cancers, prostate cancer appears to involve the complex interaction of heritable susceptibilities, exposures to dietary or environmental carcinogens, and acquired genetic alterations. Several inherited genetic variants and mutations have been identified that might increase prostate cancer vulnerability and prostate tumor aggressiveness, including androgen receptor genes. There has been little agreement on genetic associations between studies; however, much more research is needed. Twin studies strongly suggest that underlying genetic factors contribute to prostate cancer risk, but have not yielded specific genetic targets. A first-degree relative’s diagnosis with prostate cancer is associated with more than a 2-fold increase in a man’s risk of developing the disease. Variants of prostate cancer with strong genetic components tend to occur among men who are 6 to 7 years younger than the typical age at onset, although they otherwise are clinically indistinguishable. Despite advances in screening, approximately 4% of men with recently diagnosed prostate cancer have metastatic disease. A review of the literature suggests that prostate cancer appears to involve the complex interaction of heritable susceptibilities, exposures to dietary or environmental carcinogens, and acquired genetic alterations. Several inherited genetic variants and mutations have been identified that might increase prostate cancer vulnerability and prostate tumor aggressiveness, including androgen receptor genes. There has been little agreement on genetic associations between studies; however, much more research is needed. Twin studies strongly suggest that underlying genetic factors contribute to prostate cancer risk, but have not yielded specific genetic targets. A first-degree relative’s diagnosis with prostate cancer is associated with more than a 2-fold increase in a man’s risk of developing the disease. Variants of prostate cancer with strong genetic components tend to occur among men who are 6 to 7 years younger than the typical age at onset, although they otherwise are clinically indistinguishable. Despite advances in screening, approximately 4% of men with recently diagnosed prostate cancer have metastatic disease.

### Table 1

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>New Cases per Year(^a)</th>
<th>Deaths per Year(^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All races</td>
<td>156.0</td>
<td>24.7</td>
</tr>
<tr>
<td>White</td>
<td>149.5</td>
<td>22.8</td>
</tr>
<tr>
<td>African American</td>
<td>233.9</td>
<td>54.2</td>
</tr>
<tr>
<td>Hispanic</td>
<td>107.4</td>
<td>18.8</td>
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<tr>
<td>Asian and Pacific Islander</td>
<td>88.3</td>
<td>10.6</td>
</tr>
<tr>
<td>Native American and Alaskan Natives</td>
<td>75.3</td>
<td>20.0</td>
</tr>
</tbody>
</table>

\(^a\)No. per 100 000 population.
cancer risk and prognosis, no specific genetic factors have yet been identified that convincingly explain ethnic disparities in prostate cancer incidence or outcomes. Ethnic differences in prostate cancer incidence rates don’t appear to be caused by population differences in physical activity levels, tobacco use, alcohol consumption, body mass, diet, occupational histories, sexual behavior, or sexually transmitted infections.\textsuperscript{17}

Lifestyle factors might not explain the different incidence rates among various ethnic groups, but some appear to affect prostate cancer risk and prognosis independently of ethnicity. These include obesity, tobacco use, and dietary factors.

Obesity increases prostate cancer mortality rates and recurrence, according to a recent meta-analysis of data from 16 studies.\textsuperscript{18} Obesity also might correlate with prostate cancer incidence after PSA levels are statistically controlled.\textsuperscript{19} Obese men have a significantly higher risk of high-grade disease and larger tumor volumes than non-obese men.\textsuperscript{20} Obesity also appears to correlate with inferior outcomes for both surgical prostatectomy and external-beam radiation therapy (EBRT).\textsuperscript{21} Obesity correlates with higher rates of tumor-positive surgical margins and organ motion during irradiation, and resulting radiation target miss rates appear to be a factor in relatively poor radiation therapy outcomes for obese patients.\textsuperscript{22}

Prostate cancer risk has been tied to physiologic correlates of obesity, as well, including higher systolic and diastolic blood pressure, higher uric acid levels, and higher fasting serum insulin concentrations.\textsuperscript{23} It is suspected that insulin promotes the growth of prostate tumors or modulates a complex and as-yet unclear relationship between androgens and prostate cancer.\textsuperscript{24,25,26}

Tobacco smoking is associated with increased overall and prostate cancer-specific mortality, and possibly recurrence.\textsuperscript{27,28} A meta-analysis of data from 24 cohort studies representing more than 21 500 prostate cancer patients reported that the number of cigarettes smoked per day or year correlates with prostate cancer risk — and that men who smoked at time of diagnosis had a higher risk of prostate cancer-specific mortality than former smokers.\textsuperscript{29} Heavy smokers had up to a 30% increased risk of prostate cancer-specific mortality.\textsuperscript{30} Tobacco smoking also increases the likelihood of compromised bowel function and control following radiation therapy for prostate cancer, possibly because tobacco toxins exacerbate vascular injury and tissue hypoxia and damage associated with irradiation.\textsuperscript{31}

Dietary factors for which there is evidence of involvement in prostate cancer prognosis include fish, red meat, and cow milk consumption. A recent meta-analysis of data from 4 cohort studies found a 63% reduction in prostate cancer-specific mortality related to fish consumption but no association between fish consumption and prostate cancer incidence.\textsuperscript{27} One study of 2576 men found that red meat consumption increased prostate cancer risk by 55% and may be tied to more aggressive tumors.\textsuperscript{32} However, a contract review of data from 15 studies of meat intake and prostate cancer, funded by the National Cattlemen's Beef Association, found no overall dose-dependent association between red meat consumption and cancer incidence.\textsuperscript{29}

Meta-analyses of data from case-control and cohort studies suggest that milk consumption also might increase prostate cancer risk, although possible mechanisms (eg, milk fats, calcium, or hormones) have not been identified.\textsuperscript{33,34} There is little compelling evidence that vitamin or mineral status, such as multivitamin consumption, increases or decreases the incidence or aggressiveness of prostate tumors.\textsuperscript{35,36} Low levels of dietary folate might increase prostate cancer risk, however.\textsuperscript{37}

Studies of alcohol consumption and prostate cancer risk have yielded mixed results, but a recent meta-analysis strongly suggested that heavy alcohol consumption increases the risk of this cancer — as it does with other types of cancer, including breast cancer.\textsuperscript{38}

Early reports of retroviral involvement in prostate carcinogenesis have not been confirmed. Veterans exposed to the defoliating pesticide known as Agent Orange during the Vietnam War have twice the rate of prostate cancer as men not exposed to Agent Orange, making these tumors reportedly more aggressive than normal, both before treatment and if they recur after treatment.\textsuperscript{39}

There is modest evidence that dietary and lifestyle factors can influence radiation therapy outcomes and side effects, as well. Soy isoflavones (a class of plant estrogen compounds such as the anticancer agent genistein) may sensitize cancer cells to radiation or protect healthy tissues from some forms of radiation damage, for example.\textsuperscript{40}
Functional Anatomy and Pathobiology

Prostate literally means “that standing before,” an apparent reference to the gland’s anatomic position immediately beneath the urinary bladder neck and at the base of the penis. Prostate also can be translated from the ancient Greek as protector or guardian, a descriptive allusion to the role of prostatic fluids in protecting sperm or the prostate gland’s enveloping of the urethra.

The prostate contains a complex network of canal-like vesicle ductules and ducts that secrete a complex mixture of water-soluble chemical constituents of the prostatic fluid that make up approximately 30% of the prostate’s volume. Prostatic fluids are alkaline and protect sperm from the acidity of the vaginal canal. Textbooks describe typical prostate size as that of a walnut, chestnut, apricot, and even a large plum, reflecting considerable individual variation in the size and shape of this gland. The prostate also changes size and shape throughout a man’s development and life span.

The prostate surrounds the urethra, immediately below the urinary bladder neck, anterior to the rectum, and behind the pubic bone (see Figure 1). The urethra converges with the seminal vesicles within the prostate.

Epithelial cells in the prostatic ducts produce lipids, protease enzymes (including PSA), prostaglandins, proteins, hormones, relatively large amounts of zinc, citrate, sugars, and cholesterol. Prostatic fluid mixes with seminal vesicle fluids and sperm from the testes, which are delivered via vas deferens tubes to the urethra to produce semen. These fluids provide energy and protection to spermatozoa as they traverse the vaginal canal to fertilize female ova. Sperm have poor mobility and rarely survive outside these fluids. During ejaculation, smooth muscles contract to empty vesicles’ fluids into the urethra, to expel seminal fluids from the penis.

Fascia, a fibrous connective tissue, covers almost all prostatic surfaces. Dense bundles of paired nerves and vasculature are situated on the sides of the prostate. These neurovascular bundles are frequently damaged during surgical removal of the prostate (radical prostatectomy), rendering the patient sexually impotent. Nerve-sparing surgical techniques have been developed to avoid damaging the neurovascular bundles and maintain patient sexual function.

The prostate is composed, broadly, of glandular and nonglandular fibromuscular tissues. The outer fibromuscular tissue layer is called the capsule. “Extracapsular tumor extension” is a term describing the spread of prostate cancer beyond the prostate to adjacent tissues.

The prostatic capsule is divided into 4 regions or “zones” (see Figure 2). These anatomic zones are:
- Central zone: A small, cone-shaped region encompassing the prostatic fluid storage ducts. This region represents up to 25% of the healthy prostate. Prostate cancers originating in the central zone are rare, but tend to be more aggressive. The central zone begins to grow among men after age 40 years.
- Peripheral zone: Represents up to 70% of the prostate in younger men. It is the posterolateral region of the gland, containing most of the secretory tissues. It is here that the vast majority — up to 80% — of prostate cancers first develop.
- Transition zone: Represents about 5% of the prostate cancer in younger men. This region, which encompasses the central urethra, grows slowly throughout the life span, particularly after age 40 years, and it is the region affected by benign prostatic hyperplasia. Hyperplasia and malignancies affecting the transition zone can compress or obstruct the urethra, complicating urination and ejaculation.
- Stroma: Also called the anterior zone, the stroma is a region of muscle and fibrous connective tissues at the front of the prostate gland.
A separate anatomic classification scheme for the prostate delineates visually discernable gross anatomic "lobes" that roughly correspond to the zones (see Figure 3).41 The anterior lobe corresponds to the transitional zone; a posterior lobe corresponds to the peripheral zone; a middle lobe corresponds to the central zone. Lateral lobes refer to the right and left halves of the prostate, running the entire length of the gland and encompassing all anatomic zones.41 Lateral lobes can be palpated during digital rectal examinations.

Pathobiology: Benign Prostatic Hyperplasia and Prostate Cancers

Benign prostatic hyperplasia (BPH) is common in older men and presents as difficulty urinating, frequent urination, or urinary hesitancy — difficulty with initiating urination. BPH — but not prostate cancer — frequently is treated with transurethral prostate ablation and stenting, or transurethral surgical resection of the prostate. Unlike prostate cancer, hyperplasia does not represent a malignancy that can spread to adjacent or distant tumors to disrupt organ function. Left untreated, however, hyperplasia can obstruct urinary flow entirely, which is a serious condition.

Prostate tumors usually grow more slowly than other common cancers, requiring up to 4 years to double in size.39 More aggressive hereditary forms of prostate cancer also exist, typically becoming symptomatic in men at younger ages than other prostate tumors.6

Approximately 95% of prostate cancers are adenocarcinomas.42 Although adenocarcinomas represent the most common form of prostate cancer, they are not the only type of cancer to affect the prostate. Small cell carcinoma and squamous cell carcinomas also occur, albeit rarely. Small cell carcinoma is the rarest form of prostate cancer, affecting approximately 1% of patients, but it is a cancer type that metastasizes aggressively and does not trigger increased PSA production, complicating screening and diagnosis.41 Transitional cell carcinomas originating in the prostatic urothelial lining also occur, representing about 4% of prostate cancers.7 39 42 Transitional cell carcinomas also are common in the bladder neck and bladder wall, but these cases are classified as bladder cancers rather than prostate cancers.39

Common presenting clinical symptoms of prostate cancer are associated with the obstruction or restriction of the urethral lumen by the enlarged prostate. Obstructed, painful, or weak urinary flow; frequent, interrupted, incomplete, or inconsistent urination; difficulty and inability to urinate can represent urethral obstruction caused by prostate tumors (or bladder neck tumors).39 Increasing frequency of urination during the night and straining to complete urination also are frequently reported. Kidney failure, abdominal, lower back, or pelvic pain, or blood in the urine or semen also can occur among prostate cancer patients.39 The severity of symptoms does not necessarily predict the aggressiveness or stage of prostate cancer, but the frequency of symptoms can indicate PSA and other testing for cancer.39

Prostate adenocarcinomas most frequently originate in the peripheral zone, but diagnosed tumors commonly involve other regions of the prostate as well. Small tumors initially occur in isolation within otherwise healthy prostate gland tissue. This is known as carcinoma in situ or prostatic intraepithelial neoplasia.
Hormones called androgens affect prostate growth and prostate tumor growth. In the prostate, stromal cells convert circulating testosterone into dihydrotestosterone (DHT), which has a much stronger affinity for androgen receptors than testosterone. DHT is involved in facial hair growth, male pattern baldness, and prostate growth. Androgen receptors are crucially involved in prostate tumor growth. DHT plays normal roles in prostate development and function, but it also can hasten the growth and progression of prostate tumors. As prostate tumors develop, however, they tend to become androgen independent or hormone refractory, meaning they no longer respond to hormone therapy. Luteinizing hormone-releasing hormone agonists are widely used in treating metastatic prostate cancer, though its clinical efficacy is unclear.

**Screening and Diagnosis**

Improved early detection frequently is credited for a sharp decline in late-stage prostate cancer diagnoses made since the 1980s, because tumors often are identified earlier in their development. Between 1988 and 2003, the age-adjusted incidence rate for newly diagnosed advanced prostate cancers dropped by more than 6% a year, and 5-year survival rates climbed markedly during those years, from 41.6% to 62.3%. Little data is available for the systematic study of the role of PSA testing in increased incidence rates, however, and a recent meta-analysis of data from 5 randomized controlled clinical trials representing more than 341,000 men did not find that cancer screening significantly decreases prostate cancer-specific mortality rates overall. Survival benefits from screening might require more than a decade to appear, raising questions about the efficacy and justification of screening for men with life expectancies shorter than 10 remaining years.

Digital rectal examination is the most common clinical test of prostate size. The examination involves a clinician placing a finger into the patient’s rectum and palpating the prostate through the rectum’s anterior wall. The healthy prostate feels smooth and symmetrical. Relative size frequently is classified by clinicians and medical school students to help them envision what they are feeling during a rectal examination using sports balls as ascending size categories: golf ball, racquet ball, tennis ball, and baseball. Prostate tumors present as asymmetric bumps that are hard, much like a finger knuckle.

By screening with digital rectal examination and PSA blood tests at the same time, the clinician can provide an initial assessment of the relative size and pathophysiology of the prostate. The American Cancer Society recommends annual PSA and digital rectal examination for men aged 50 years or older. Men at highest risk — African Americans or men with a first-degree relative who has been diagnosed with prostate cancer before age 65 years — should begin testing at age 45.

The average age of patients at diagnosis also has declined by nearly 5 years since screening became widespread in the United States. Screening remains controversial, however. Some prostate cancers do not progress to a point that they threaten the patient’s health, and critics have pointed out screening that leads to biopsy can lead to overdiagnosis, anxiety, and even unnecessary treatment of men who would never have become symptomatic. This might be particularly true in younger men.

Elevated PSA levels are not specific to prostate cancer, and can instead indicate BPH or prostatitis, which is inflammation of the prostate that sometimes is caused by bacterial infection. Approximately 10% of men undergoing PSA screening have elevated PSA levels, and only 33% of those with elevated PSA levels eventually receive prostate cancer diagnoses.

The probability of a prostate cancer diagnosis increases with PSA levels. There is no specific “normal” PSA level, although many clinicians have long described results lower than 4.0 ng/mL as normal. However, 15% of men with PSA levels lower than 4 ng/mL are diagnosed with prostate cancer. Of these, about half have low-risk disease, yet still are treated with radiation therapy or radical prostatectomy.

Digital rectal examination and PSA results may be followed up with diagnostic imaging examinations to locate and characterize probable tumors, but only biopsy can definitively diagnose prostate cancer. Clinical history and screening typically are followed by fine-needle transrectal biopsy with ultrasonography guidance for cancer grading. Biopsy samples are examined and evaluated to identify and assign a Gleason score, and for tumor markers associated with androgen independence and tumor stage. Diagnostic imaging with transrectal ultrasonography, computed tomography, magnetic resonance (MR) imaging, or nuclear bone scintigraphy are additional confirmatory
Differentiated tumors (ie, Gleason scores of 4 or lower) are slow growing and cells appear similar to normal prostate cells, whereas moderately differentiated, intermediate-grade tumors (ie, Gleason scores between 4 and 7) may behave aggressively or like a low-grade tumor. Poorly differentiated or high-grade tumors (ie, Gleason scores higher than 7) are aggressive, recur as more aggressive cancers, and tend to be larger than lower-grade tumors.

Staging determines the probability or possibility of cure. The widely used TNM Staging System, a cancer classification system developed by the American Joint Committee on Cancer and the International Union Against Cancer, reflects primary tumor size, lymph node involvement, and metastasis to distant organs (see Figure 5).

Using the Staging System, the primary tumor is assigned a T score of 0 to 4, with several possible subdivisions:

- **T0** – Indicates no sign of a tumor.
- **T1** – Although a tumor is present, it cannot be detected clinically or with diagnostic imaging. Subdivisions of T1 are based on the percentage of cancer found in resected prostate tissue or if the tumor was detected by fine-needle biopsy.
- **T2** – The tumor is palpable, but has not spread beyond the prostatic capsule. Subdivisions of
T2 are based on the presence of the tumor in a prostate lobe or whether the tumor is palpable in both lobes.
- T3 – The tumor extends beyond the prostatic capsule. Subdivisions of T3 depend on whether the tumor has invaded 1 or both seminal vesicles.
- T4 – The tumor has invaded tissues adjacent to the prostate.9

The pelvic lymph nodes are evaluated to arrive at the N score:
- NX – Lymph node involvement cannot be evaluated.
- N0 – The tumor has not spread to the regional lymph nodes.
- N1 – The tumor has spread to the regional lymph nodes.9

Metastatic spread is designated by the following M scores:
- MX – Metastasis cannot be evaluated.
- M0 – There is no metastasis to nonadjacent organs.
- M1 – Distant metastasis is present.9

Prostate cancer staging frequently also incorporates a grade (G), reflecting Gleason scores:
- GX – Grade cannot be assessed.
- G1 – Gleason score 2 to 4 (tumor is well differentiated and very similar to normal tissue).
- G2 – Gleason score 5 to 6.
- G3-4 – Gleason score 7 to 10 (tumor is poorly differentiated).9

TNM staging and Gleason scores can then be combined into 4 overall stages, reflecting increasing patient risk (see Table 2).

Prostate cancers also can be described simply as low risk, intermediate risk, or high risk, using PSA levels, Gleason score, and TNM staging:
- Low risk: PSA < 10 ng/mL, Gleason < 7, T2a or lower.
- Intermediate: PSA = 11 ng/mL to 20 ng/mL, Gleason = 7, T2b or T2c.
- High risk: PSA > 20 ng/mL, Gleason > 7, T3 or T4.48

**Treatment**

Treatment options vary by tumor stage and risk, patient age, and other factors. The literature disagrees on treatment outcomes, but generally agrees that if prostate cancer is detected and definitively treated before tumors have penetrated the prostatic capsule, most patients have favorable prognoses, with a 15-year prostate cancer-specific mortality rate of only 12%.49

Patients should always be informed of the full range of treatment options, including watchful waiting and active surveillance, and the potential adverse effects of each treatment option. Critics allege that some small urology clinics that provide radiation therapy might fail to inform patients of treatment options other than radiation therapy.4

EBRT, brachytherapy, and radical prostatectomy are the methods generally used to treat localized prostate cancer. Clinical data that directly compares the 3 treatment types is lacking. Clinical trials such as the ProtecT trial in the United Kingdom are underway to compare outcomes for men with PSA-detected prostate cancer who are treated with prostatectomy, radiation, or active surveillance.49
Clinical trial data in the United States has raised doubts about significant survival benefits for prostatectomy among low-risk prostate cancer patients. Authors of a recent systematic review of 75 studies of radiation therapy for localized prostate cancer found that the absence of high-quality comparative research data means it is difficult to compare use of radiation therapy with surveillance only for low-risk tumors. Nevertheless, radiation therapy and prostatectomy are widely believed to be similarly effective, although systematic study of clinical outcomes is complicated by differences in patient populations undergoing various treatment strategies. The prospective, randomized Scandinavian Prostate Cancer Group 7 trial found a significant 10%–10-year overall survival advantage from using hormonal therapy plus radiation therapy compared with hormonal therapy alone (39.4% vs 29%).

The vast majority of newly diagnosed prostate cancer cases in the United States involve localized tumors, but primary therapy can fail if tumors become resistant to a given treatment or recur. After successful treatment of localized cancer, men with prostate cancer undergo surveillance for 10 years using PSA tests and, if PSA begins to increase, digital rectal examination, diagnostic imaging, and biopsy.

**Watchful Waiting and Active Surveillance**

Watchful waiting and surveillance frequently are treated as synonyms, but some authors differentiate between the terms, reserving “watchful waiting” for patients who are not candidates for curative therapy, but who might at some point be prescribed palliative treatment to control symptoms.

Localized prostate adenocarcinoma progresses slowly, and active surveillance frequently is justified only before symptom onset. One-third of men with low-stage tumors show evidence of tumor progression within 3 years of diagnosis. Active intervention is indicated if PSA levels double in fewer than 3 years or a repeated biopsy indicates grade progression.

Despite higher follow-up costs than other treatment strategies, active surveillance is the most cost-effective strategy for low-risk prostate cancer patients.

**Hormonal Therapy**

Management options for locally advanced prostate cancer can include more conservative androgen deprivation therapy rather than radical prostatectomy. Hormone therapy uses pharmacotherapies or castration surgery to prevent DHT from reaching tumor cell androgen receptors. DHT blockade can halt tumor growth, but is not considered curative because tumors become androgen independent within 1 or 2 years after the start of therapy. Hormonal therapy can be combined with radiation therapy to reduce the risk of recurrence, however. Unlike radical prostatectomies, hormonal therapies are indicated for advanced cancers that have escaped the prostatic capsule. When hormonal therapy fails, chemotherapy agents such as doxorubicin, 5-fluorouracil, or cyclophosphamide might be attempted.

**Radical Prostatectomy**

Prospective randomized clinical trial data suggest that radical surgical resection of the prostate (prostatectomy) offers better prognosis for patients with localized prostate cancer than does watchful waiting. Patients with life expectancies exceeding 9 years and who are in good general medical condition usually are considered as candidates for prostatectomy for stage T1 and T2 tumors.
Radical prostatectomy can be effective when tumors have not spread outside the prostate capsule. Adjuvant radiation therapy can improve survival by targeting undetected cancer cells not removed with the prostate during the resection. Radical prostatectomy can be performed as an open surgery or a laparoscopic procedure, although the latter is uncommon in the United States.

Cryotherapy

Cryotherapy and high-intensity focused ultrasound (HIFU) are nonsurgical tissue ablation modalities that have been adopted at some clinics but are not yet widely accepted as standard treatments for prostate cancer.

Ultrasoundography-guided percutaneous cryoablation freezes prostate tumor tissue to -302°F using argon gas and metal rods. Water within the tumor cells freezes, destroying cell wall and internal cell structures and killing tumor tissue. Early data suggested a 10-year recurrence-free survival rate for cryoablation that is superior to surgery and radiation. However, relatively little clinical trial or survival data has been published, and the few subsequent reviews published have not identified sufficient data to evaluate this modality definitively as a primary treatment for prostate cancer.

High-Intensity Focused Ultrasound

Manufacturer-sponsored research in the medical literature has described HIFU as an alternative to ionizing radiation and surgery to treat prostate cancer. Sound waves heat and destroy targeted tumor tissue without harming the patient’s healthy tissues. Few controlled clinical trials or survival data have been published on the technique, however. A recent systematic review of 29 studies on HIFU as a primary treatment for prostate cancer found HIFU studies to be of low quality and that widespread adoption of HIFU as a treatment modality for this cancer is unjustified.

Radiation Therapy

Radiation therapy plays a crucial role in curative, adjuvant, salvage, and palliative management strategies for prostate tumors of all stages. Both EBRT and brachytherapy with radioactive implants are used to treat prostate cancer. Radiation therapy delivers therapeutic doses of radiation to malignant tissues at levels sufficient to kill tumor cells while minimizing irradiation of healthy tissues. The goal of radiation treatment is to control tumor growth or to manage symptoms of tumors that can’t be eradicated.

No randomized prospective clinical trial data directly comparing EBRT and prostatectomy treatment strategies have been published to date. The clinical literature has reported on each treatment separately, however, and suggests comparable outcomes for patients with low-risk to intermediate-risk prostate cancer.

Total radiation doses exceeding 72 Gy over the course of treatment appear to provide superior rates of recurrence-free survival. Just 20 years ago, prostate cancer usually was treated with total radiation doses lower than 70 Gy, but doses up to 80 Gy now are routinely and safely administered. Curative and adjuvant radiation therapy for localized tumors is common, and radiation therapy frequently is used as a salvage therapy for tumor recurrence after radical prostatectomy surgery. Cure is not possible with metastatic disease but radiation can nevertheless offer palliative care and pain relief.

Imperfect radiation targeting of cancerous tissue is a basic limitation of radiation therapy. If tumor tissue could be completely and exclusively targeted, radiation therapy could yield near-complete local tumor control without harm to patients. Radiation scatter, patient movement and targeting errors, individual variation in patient anatomy, and tumor contours ensure that some degree of dose-limiting irradiation of nontarget tissues is unavoidable. Recent advances in EBRT have reduced irradiation of nontarget tissue through improved targeting and reduced safety margins, while improving dose delivery to tumors. Nevertheless, ionizing radiation always poses some level of risk. Acute toxicity usually manifests within 1 month, and late adverse events become evident between 6 months and 24 months following treatment. Toxicity from prostate cancer radiation therapy usually involves irradiation and scarring of organs adjacent to the prostate, including the rectum, colon, bowel, and bladder.

Radiation therapy plays a role in treating prostate cancer for patients with various stages of the disease. The purpose of radiation therapy can be curative, adjuvant, prophylactic, salvage, and palliative. The goal of curative radiation is to eradicate tumors and risk of subsequent recurrence. The vast majority of research and
major technical advances in prostate cancer radiation therapy has been devoted to better understanding and improving curative radiation.

Adjuvant radiation therapy within 6 months of prostatectomy can reduce the risk of failure or recurrence. Several large randomized clinical trials support adjuvant radiation with prostatectomy when tumors have positive surgical margins, seminal vesicle involvement, or tumor extension beyond the prostatic capsule. Adjuvant postsurgical radiation therapy with 60 Gy to 65 Gy upon the patient’s recovery of urinary function following prostatectomy reduces 5-year failure and recurrence by as much as 20%. Fewer than 4% of patients receiving adjuvant radiation experience significant urinary tract toxicity symptoms. Immediate adjuvant radiation can improve 15-year metastasis-free survival rates over delayed (salvage) radiation therapy with at least 66 Gy by up to 12%.

Prophylactic pelvic lymph node irradiation also can be performed on patients with localized prostate cancer to prevent metastatic spread. Prostate cancer recurs in 15% to 25% of men after definitive treatment for localized disease. PSA monitoring helps detect treatment failure or tumor recurrence. In cases of tumor recurrence, PSA levels initially are low and then resurge; in treatment failure, PSA levels remain at pretreatment levels or climb after primary treatment. Both phenomena are referred to as biochemical failure.

Most men experiencing biochemical failure after prostatectomy have local or regional recurrence. All patients whose cancers recur and develop into metastatic disease experience biochemical failure. Although not all men with biochemical failure have life-threatening tumor progression, it is difficult to predict tumor behavior. Risk factors for metastasis most likely include:

- A rapid PSA doubling time after treatment.
- A brief period of disease-free status after treatment.
- Tumors with Gleason scores higher than 7.

Patients who have biochemical failure frequently receive salvage radiation therapy. Hormonal therapy, alone or in combination with salvage radiation therapy, frequently is administered after prostatectomy failure or postsurgical recurrence, particularly in moderate-risk or high-risk patients.

Some authors have argued that salvage radiation therapy initiated as soon as possible after the detection of recurrence can offer effectiveness equivalent to that offered by adjuvant radiation therapy. However, the empirical salvage radiation therapy literature appears to offer little conclusive evidence of improved control of local recurrence, metastasis, or survival. Salvage therapy modalities after primary treatment with EBRT can include brachytherapy, surgery, HIFU, or cryotherapy. Palliative hormonal therapy can alleviate symptoms but is not considered curative. After surgery fails, radiation therapy is a common salvage option for local recurrence.

Large and extensive localized prostate tumors, pelvic lymph node involvement, and metastatic prostate cancer tumors in distant organs are often extremely painful. These high-risk cancers frequently cause blood in the urine, restricted or obstructed urinary flow, and edema of the legs. These symptoms can be alleviated with palliative radiation therapy at doses of 50 Gy to 60 Gy. Metastatic disease pain can be alleviated in most patients by treating the metastatic site as little as 30 Gy delivered over 14 days. Bone metastases are treated with localized radiation, although pain from extensive skeletal metastases can be treated more effectively with intravenous administration of strontium-89 or samarium-153 radioisotopes.

**Brachytherapy**

Brachytherapy plays an expanding role in prostate cancer treatment. The therapy consists of transperineal placement of radioactive beads or “seeds” under transrectal ultrasonography guidance. Patients with low-risk to intermediate-risk prostate cancer are treated with permanently implanted low-dose seeds; those with intermediate-risk to high-risk cancer receive temporary implants of high-dose seeds in combination with EBRT. Low-dose rate (LDR) brachytherapy typically uses iodine-125, with a half-life of 59.4 days, or paladium-103, with a half-life of 17 days. LDR brachytherapy alone is not appropriate for patients with stage T3 prostate tumors and high-dose rate brachytherapy should be used only as a monotherapy in the context of clinical trials. History of transurethral resection, restricted urination, and contraindications for general anesthesia are contraindications for prostate cancer brachytherapy.

LDR brachytherapy for localized prostate cancer yields 5-year recurrence-free survival rates comparable to those seen with radical prostatectomy, but with
Directed Reading

Furlow

accommodate patient and prostate movement, and daily setup inconsistency.

- **Treatment volume**: The entire volume receiving a planned isodose, including all volumes receiving planned irradiation.  

Even small variations in patient setup, rectal air and fecal volumes, and bladder filling can cause variation in prostate position from day to day and affect volumes and treatment plans.  

Patient respiration also can cause prostate motion during delivery of a given treatment fraction. In one study, respiration caused “negligible” motion (< 3 mm) in 69% of patients, but prostate movement varied considerably among patients, and respiration can displace the prostate by as much as 10.6 mm.  

Obesity appears to correlate with increased prostate motion, potentially contributing to obese patients’ relatively poor radiation therapy outcomes.

**IMRT in the supine and prone positions yields similar levels of prostate motion, which on average are < 3 mm.**

Endorectal balloons help to immobilize the prostate (see Figure 6). Studies of balloon immobilization’s clinical benefits are relatively few and inconsistent. A 2010 systematic review cautioned that while balloons are well tolerated, and limited data suggests they reduce irradiation of anorectal wall tissues, little data is available on clinical outcomes.

**Advanced Modalities**

Three advanced techniques in EBRT planning and delivery (3-D CRT, IMRT, and IGRT) have been developed to deliver radiation dose to tumor volumes with increased precision, maximizing irradiation of tumors while sparing healthy nontarget tissues beyond treatment volume (see Figure 7).

Dose escalation using advanced EBRT techniques should significantly improve biochemical control. Randomized clinical trials suggest up to a 20% improvement in biochemical control with gross tumor volume dose escalation by 8 Gy to 10 Gy (from total doses of 64 Gy to 70.2 Gy, to 74 Gy to 79.2 Gy) and an 8% improvement in 10-year recurrence-free survival rates.

Targeting errors during irradiation are potentially more serious with advanced EBRT techniques because of the higher planned doses for gross tumor volume tissues, requiring careful attention to practice standards and institutional protocols on behalf of radiation therapists.
Conformal Radiation Therapy

Improvements in radiation treatment planning software that uses 3-D CT imaging reconstruction of target and adjacent anatomies allowed the more precisely targeted radiation delivery strategy known as 3-D CRT, which has been considered the standard for prostate cancer radiation therapy since the 1990s. Whereas traditional 2-D EBRT planning relies on a conventional simulator with standardized beam configurations and bony anatomic landmarks from planning radiographs, 3-D CRT uses volumetric planning image reconstruction. Target prostate anatomies, seminal vesicle tissue, and adjacent normal organs and tissue are delineated or outlined on each CT slice, allowing highly conformed targeting and safety margins that reflect planned dose and patients’ internal organ motions. Clinical tumor volume margins usually range from 0.55 cm to 1.0 cm. Common beam configurations include a 4-field “box” followed by a 6-field technique. Multileaf collimator settings and cerrobend alloy blocks are used to conform each field to the radiation therapy plan.

ASTRO’s outcomes committee conducted a systematic review, published in 2005, that supported 3-D CRT’s anticipated superiority over 2-D EBRT for treating prostate cancer because of reduced acute urinary and gastrointestinal toxicity, late toxicities, improved local tumor...
control, and disease-free survival rates. A separate systematic review by European researchers, published in 2006, supported a positive relationship between 3-D CRT radiation dose and outcomes, including patient survival rates. Authors of both studies noted the relatively small number of high-quality clinical studies and resulting gaps in the database, however. Both teams called for large, randomized clinical trials.

3-D CRT entails intrinsic risks or planning errors, particularly the potential for complacent over-reliance on planning images that might not display the true probable extent of disease extension based on tumor volumes and placement within the prostate. Prostate motion caused by respiration or poor patient immobilization also can compromise delivery of planned fractions between treatment sessions. 3-D CRT setup inconsistencies or prostate motion can increase dose to nontarget tissues by up to 5%. IGRT, also known as 4-D radiation therapy, has been developed to overcome motion challenges.

**Intensity-Modulated Radiation Therapy**

IMRT is inherently more complex than conventional EBRT. Introduced following development of 3-D CRT, IMRT typically uses 5 to 8 different beam angles, with multileaf collimator settings changing during field irradiation to shield some anatomy during treatment. This creates graded dosing within treatment volumes and maximizes dose delivery to the gross tumor volume (see Figure 8). Steeper dose gradients with IMRT mean that when delivery plans are properly executed, much higher gross tumor volume doses are possible while sparing nontarget tissues (see Figure 9). Dose escalation up to 80 Gy to 86 Gy in target tissue is possible — yielding favorable 5-year recurrence-free survival rates of 98% for low-risk patients with localized prostate tumors. A 2010 systematic review of data from 13 studies representing more than 5700 patients supports use of IMRT for patients with moderate-grade or high-grade prostate tumors. The technique can treat these cancers with excellent sparing of rectal tissues from unnecessary irradiation.

Targeting errors when performing IMRT are potentially more serious than with conventional EBRT because of the higher planned doses for gross tumor volume tissues. Radiation therapists, along with all radiation oncology staff, must exercise extreme caution and strictly observe quality assurance practices to avoid inadvertent irradiation of nontarget tissues. Clinical tumor volume doses must not be delivered to other treatment volume or nontarget tissues, because these treatment doses are well above acceptable doses for these healthy tissues; setup inconsistencies between fractions can increase dose to nontarget tissues by 5% to 15%.

ASTRO has released new guidelines for IMRT safety, describing recommended practices and emphasizing the importance of careful coordination and communication between team members through the many planning, simulation, and delivery steps. ASTRO recommends at least 2 radiation therapists be present for every IMRT procedure, and some researchers recommend a minimum of 3 therapists. One radiation therapist should read checklists, while another therapist checks the equipment and settings, patient information, treatment site, and patient positioning. This information must be confirmed for each IMRT procedure; equipment settings and treatment doses must always be confirmed using the treatment plan, and “forced time-outs” should be observed. Improved targeting with IMRT allows for clinical target volume dose escalation over 3-D CRT doses without increased toxicities. A study of 271 patients with localized prostate tumors treated with 68.4 Gy using low-dose 3-D CRT and 145 patients with localized tumors treated with 75.6 Gy total dose using IMRT, found significantly better 5-year control rates for prostate cancer in patients treated with IMRT (74%) than for those treated with 3-D CRT (60%), despite equivalent acute and late urinary and bowel toxicities.

A study of 729 patients with low-risk localized prostate cancer found that IMRT (total dose 81 Gy) is associated with significantly lower late urinary toxicity rates than brachytherapy (total dose 144 Gy), but at the cost of significantly inferior 7-year relapse-free survival rates (95% for brachytherapy; 89% for IMRT).

**Image-Guided Radiation Therapy**

IMRT’s steep dose gradients mean that targeting errors can yield increased risks of toxicity to inadvertently irradiated nontarget tissues. Traditionally, prostate and pelvic organ motion has been controlled using external immobilization equipment or intrarectal balloons. IGRT uses precise CT imaging to delineate target volumes and better accommodate intrafraction prostate movement,
such as that caused by patient respiration. CT alone can poorly display tumors within prostate tissue or delineate prostate tissue boundaries from fascia and muscle tissue. Fusing CT images with sonograms, MR images, MR spectroscopy, or positron emission tomography (PET) are techniques under development to improve IGRT precision. MR spectroscopy and PET-CT appear to display high Gleason-score regions of prostate cancer with sensitivity, which should allow the development of focal IMRT/IGRT dose escalation.

Patient setup variations, changes in rectal air composition or fecal volumes, urinary filling of the bladder, and respiration can cause variation in prostate position from day to day and motion during treatment. Guidance imaging is performed in the treatment rooms immediately before daily irradiation sessions. Fiducial markers are used for online positioning confirmation and correction.

IGRT requires careful, close coordination between experienced radiation oncologists, radiologists, dosimetrists, and radiation therapists.

**Proton Beam Therapy**

Proton beam therapy is an emerging radiation therapy technique for prostate cancer under clinical study. Protons are positively charged, relatively large-mass particles that can deliver high radiation doses of up to 82 Gy to the tumor with little beam broadening or side scatter, reduced surface doses, and no “exit dose” of radiation beyond the tumor in the beam path. As a result, lateral beam irradiation of the prostate capsule should minimize exposure to nontarget healthy tissue and reduce the risk and severity of acute and long-term adverse effects. The expected benefits of proton therapy are clearest for tumors close to the skin surface.

Brass apertures delineate the irradiated field. Proton beams are delivered laterally but might not be appropriate for irradiation of tumors affecting the seminal vesicles because of relatively high incidental irradiation of the rectum when the vesicles are targeted. Opening a proton therapy facility requires an initial investment of more than $225 million and there are not many proton beam machines available. Therefore, relatively few prostate cancer patients have been treated with proton-beam radiation and little empirical data is available from which to compare outcomes with those of other radiation therapy techniques and modalities. The few published reviews have been fairly discouraging, offering scant evidence of any advantage over conventional
radiation therapy procedures for cancer in terms of survival rates, tumor control, or toxicity.  

**Toxicity and Adverse Effects**

Ionizing radiation always entails some degree of risk, and radiation therapists always should adhere to the ALARA (as low as reasonably achievable) principle when irradiating healthy tissue. Ideally, irradiation of non-target tissue would be avoided altogether, but targeting inaccuracy and uncertainties about tumor margins and micrometastases make this goal rarely if ever practically achievable. Advances in planning and targeting, and the resulting increases in radiation doses delivered to tumor tissue, mean that unintended irradiation of healthy tissue, when it occurs, is more likely to cause tissue damage and symptomatic complications.

The risks of transient acute toxicity of urinary and bowel tissues have little effect on patients’ treatment choices. Skin irritation, fatigue, mild diarrhea, rectal pain, fecal urgency, painful urination, or urinary urgency can all represent mild acute signs of radiation toxicity.  

Long-term adverse events are considered more important. Rare late events for radiation therapy include gradually progressing sexual impotence up to 10 years after treatment, moderate or severe urinary leakage, urethral restriction, and rectal or bladder perforation.  

Even at higher doses, IMRT appears to offer acute and late toxicity rates equivalent to those from 3-D CRT and late toxicity rates equivalent to or lower than effects from brachytherapy.  The risk of late bleeding complications can be reduced with prostate immobilization using intrarectal balloons, but early support for this technique has not been confirmed with large randomized clinical studies.  Both IMRT and 3-D CRT should be used with caution in men receiving anticoagulation therapy (eg, warfarin or clopidogrel).  

The 4-year risk of serious bleeding complications following IMRT or 3-D CRT was significantly higher for men on anticoagulation therapy than patients not on anticoagulation therapy (15.5% vs 3.6%).  

Intrarectal balloons might not prevent late bleeding complications in patients taking anticoagulants.  

Anorectal toxicity, fecal dysfunction, chronic urinary dysfunction, and sexual impotence represent the greatest effects of treatment on quality of life for prostate cancer survivors. Theoretically, more accurate targeting of tumor tissue and sparing of healthy nontarget tissue by 3-D CRT and IMRT should yield reductions in rectal and urinary sequelae. The proportion of late events that can be attributed to irradiation is unclear because comorbidities such as BPH and diabetes are common in prostate cancer patients, and because there are widespread methodological problems in the radiation therapy toxicity research literature. For example, few studies have included pretreatment measures of functional status and patient-reported outcomes or complaints. Baseline studies strongly suggest that patients who have prostatectomies, brachytherapy, and EBRT have significant differences in respective baseline rates of sexual dysfunction; about 37% of radiation therapy patients have baseline sexual dysfunction before treatment, compared with 14% of men undergoing surgery. This is likely because men with prostate cancer who have radiation therapy tend to be significantly older as a group than those who have surgery only; those who undergo radiation therapy also tend to have more comorbidities. The literature shows that smokers more frequently seek radiation therapy than surgery. Failing to control for these baseline differences statistically can create the illusion of modality-related adverse outcomes for patients.  

Worsening fatigue in patients following radiation therapy plus hormonal therapy occurs at the same rate as following hormonal therapy alone. Transient acute urinary complaints increase with EBRT, but evidence from 2 large clinical trials has shown that 5 years after radiation therapy, urinary symptoms are rarer and less severe than reported at baseline, before treatment.  

A recent systematic review of 40 published studies of fecal incontinence after radiation therapy of the prostate found tremendous variability in reported incontinence after irradiation — from less than 2% to 58% of affected patients in a given study — but the absence of baseline pretreatment data in most studies left the authors unable to offer a meaningful interpretation of the available incontinence data. A similar recent analysis of 22 studies of EBRT found little evidence for a relationship between EBRT dose and urinary dysfunction.  

It is not currently possible to estimate individual patients’ risks of long-term adverse effects following radiation therapy for prostate cancer. However, suspected risk factors for late toxicity include tobacco smoking status, diabetes, and baseline pretreatment bowel complaints.
Secondary Cancer Risk

Secondary cancers are of concern following radiation therapy for prostate cancer, particularly for patients with life expectancies exceeding 10 years. Traditional 2-D EBRT — but not IMRT, 3-D CRT, or brachytherapy — appears to be associated with increased risk of bladder cancer, lymphoproliferative disease, and sarcomas.97

However, the relationship between some tumor risks and radiation therapy is not simple or straightforward. Rectal cancers do not appear to be caused by prostate radiation therapy, and actually may be more common among prostate cancer patients who do not undergo treatment than among those who do receive radiation therapy — although it is unclear why this may be the case.88 There is evidence that EBRT can increase the risk of rectal, bladder, and pelvic cancers, but these risks might be low — about a 1% increase in absolute risk of rectal cancer 15 years after EBRT, for example.98,99 Postradiation therapy surveillance for colorectal cancers allows resulting tumors to be detected early in their development.

Emerging Techniques

Research is under way that could represent major changes in prostate cancer and the roles radiation therapy can play in treating the malignancy. For example, some recent research data suggests that HIFU might be more effective than radiation therapy in treating many patients with early-stage prostate tumors.80 Large clinical trial data is required to confirm effectiveness of this treatment modality.

Hypofractionation

New treatment schedules have been proposed for prostate radiation therapy, and are undergoing clinical trials.91,92 The efficacy of radiation therapy is tied not only to the total therapeutic dose delivered, but also to tissue radiosensitivity and fraction. The radiosensitivity of prostate tumors and risk to adjacent organs has prompted calls by some researchers for hypofractionation — the use of large radiation doses per fraction (eg, 2.63 Gy per dose fraction, escalated from traditional 1.8 Gy to 2.0 Gy fractions) — to better exploit the higher radiosensitivity and maximize the chances for cure.92 Hypofractionation could reduce the number of patient visits required to complete radiation therapy, reducing inconvenience to the patient and medical costs. A hypofractionated boost or dose escalation following traditional-fraction radiation schedules also is undergoing clinical study.99 Preliminary data from a small prospective clinical trial of 472 high-risk patients reported that EBRT followed by a high dose-rate brachytherapy boost yielded improved 10-year tumor control rates and reduced risk of metastasis.99

Extremely hypofractionated 1-week stereotactic body radiation therapy regimens are undergoing clinical testing, as are investigational stereotactic hypofractionation treatments that use software modeling of patient respiratory motion and imaging checks to guide a robotically adjusted linear accelerator system.71

Canadian researchers have begun preliminary studies of hypofractionated EBRT as a monotherapy for intermediate-risk prostate cancer.94 Critics have cautioned, however, that it is too soon to begin using hypofractionation regularly outside of dose-escalation salvage therapy settings. Some authors question that prostate tumor cells are consistently more radiosensitive.92 Radiosensitivity also varies among cancer cells within tumors — the basis for the rapid loss of tumor radiosensitivity. Individual differences in patients’ tumor radiosensitivity, or even differences in the distribution of tumor cell radiosensitivities in a given patient’s tumors, could dramatically erode the asymmetry between radiosensitivity of healthy and malignant cells, and hence the expected benefit-to-risk ratio of hypofractionated radiation therapy.86 Radiosensitivity heterogeneity among cells within tumors remains poorly understood, leading some researchers to question the seeming promise of hypofractionation.91

A 2011 review of data from more than 5900 patients indicates that prostate cancer tissue is consistently more radiosensitive than rectal or bladder tissue and unaltered by hormonal therapy — supportive evidence for the theoretical utility of hypofractionation.95 But clinical trial data from 1 study suggests that biochemical recurrence rates following hypofractionation regimens actually are somewhat worse (60% vs 53%) than conventional fractionation schedules.92 Given the higher risk to healthy tissues posed by higher fraction doses, clinical trials must be completed before the relative benefits of different fractionation schedules can be known.

Radiosensitization Therapy

Some substances might increase the radiosensitivity of tumor tissue and offer partial protection from
Improved Prostate Immobilization

Improved IGRT is expected to mitigate prostate motion challenges and allow for significant advances in focal dose escalation and hypofractionation. These improvements could be complemented, as well, by advances in immobilization techniques. Radiofrequency transponder implantation might allow precise real-time tracking of prostate displacement, for example. Prostate-immobilizing intrarectal balloons continue to undergo development, including testing of balloons equipped with real-time dose-measuring equipment to track rectal wall irradiation and improved balloon designs for more reliable prostate immobilization and rectal sparing.

Conclusion

With advances in EBRT — particularly IGRT — radiation toxicities and sequelae are expected to decline while irradiation of gross tumor volumes increases to more effective, curative doses for localized prostate tumors. If IGRT and proton beam radiation therapy fulfill expectations, these could become as widely used — or even supplant — IMRT. The development of MR spectroscopy and PET-CT-IGRT should allow even more precise focal radiation dose escalation within cancerous prostate tissues, and resulting improvements in prostate motion accommodation should further improve patient outcomes, perhaps even more so for obese patients. Identifying optimal escalated doses to gross tumor volume and targeting error rates or risks will become increasingly important for balancing curative goals with minimized toxicities as focal targeting becomes more precise and reliable.

When properly performed, complex planning and coordination are effort intensive but should yield continuing improvements in prostate cancer patient prognosis and quality of life in the near future. The arrival of these advances in EBRT come at a critical point in the history of prostate cancer in the United States, as population demographics indicate spikes in incidence rates are beginning to crest.

References


radiation damage to healthy tissues. The use of statins (reductase inhibitors) appears to render prostate tumors more vulnerable to irradiation, for example. Studies have shown that statin use could markedly reduce the risk of recurrence after prostate cancer radiation therapy by as much as 57%. Concurrent administration of statins and high-dose EBRT (81 Gy) for high-risk patients with T1 to T3 prostate tumors is associated with significant improvements in recurrence-free survival rates. Critics have cautioned, however, that participants in this study who received statins had better baseline characteristics than those in the study who did not receive statins, and that it is unclear whether this potential source of systematic bias was adequately corrected in statistical analysis.

Adenovirus-vector gene therapy also might improve the efficacy of prostate cancer radiation therapy. Preliminary data suggests possible radiosensitizing or radioprotective characteristics for some plant phytochemicals. Celastrol, a plant-derived proteasome inhibitor, might render human prostate cancer cells more radiosensitive in xenografted mice, for example. Studies also have shown that soy isoflavones inhibit gene transcription and downregulate genes involved in tumor prostate survival and growth, along with angiogenesis. Soy isoflavones also are antioxidants that could reduce the severity of some adverse effects of radiation therapy. There is some preliminary evidence, however, that genistein could promote tumor metastasis.

Large randomized clinical trials are needed to determine whether soy isoflavones protect nontarget tissues from radiation without promoting the distant spread of existing tumors. The combination of IGRT-like delivery precision and radiosensitivity-modulating biotechnologies could move radiation therapy closer to the ultimate goal of maximal radiation of gross tumor volume and no irradiation of healthy nontarget tissue. A preliminary study of radiosensitivity in the cells of 99 individuals found dramatic radiation-induced production of a cell-suicide enzyme (caspase) with levels of the compound jumping by between 120% and 720%. Silencing 5 caspase-associated genes rendered cells significantly more radiosensitive, suggesting that gene therapy could potentially modulate the radiosensitivity of tumors and adjacent, nontarget tissues during radiation therapy.

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30. Qin LQ, Xu JY, Wang PY, Kaneko T, Hoshi K, Sato A. Milk consumption is a risk factor for prostate cancer.
Furlow


 directs reading quiz

prostate cancer and radiation therapy

1. An estimated _______ men were diagnosed with prostate cancer in the United States in 2010, and 32,000 died of the disease.
   a. 199,700
   b. 213,700
   c. 217,700
   d. 221,700

2. Critics of small urology practices argued that some patients who receive intensity-modulated radiation therapy (IMRT) treatment would benefit from:
   1. brachytherapy.
   2. cryotherapy.
   3. tumor surveillance.
   a. 1 and 2
   b. 1 and 3
   c. 2 and 3
   d. 1, 2, and 3

3. The median age at diagnosis for United States men with prostate cancer is _______ years, and less than 1% of cases are diagnosed among men younger than age _______ years.
   a. 57; 44
   b. 67; 44
   c. 57; 54
   d. 67; 54

4. Of newly diagnosed prostate cancers in the United States, _______ % involve localized tumors, confined to the prostatic tissue.
   a. 62
   b. 72
   c. 82
   d. 92

5. Cancer rates for _______ are likely underestimated because of wrongly recorded race or ethnicity in medical records.
   a. whites
   b. African Americans
   c. Hispanics
   d. Native American

6. Lifestyle factors that contribute to prostate cancer risk independently of ethnicity include:
   1. obesity.
   2. dietary factors.
   3. tobacco use.
   a. 1 and 2
   b. 1 and 3
   c. 2 and 3
   d. 1, 2, and 3

*Your answer sheet for this Directed Reading must be received by the ASRT on or before this date.
7. _______ is suspected to promote prostate tumor growth.
   a. An androgen receptor
   b. Insulin
   c. Dihydrotestosterone
   d. Alcohol

8. Prostate ductules secrete prostatic fluid mixtures that normally make up approximately _______ % of adult prostate volume.
   a. 20
   b. 30
   c. 40
   d. 50

9. Although rare, tumors originating in the prostate’s _______ zone tend to be more aggressive than those originating elsewhere.
   a. central
   b. transition
   c. peripheral
   d. anterior

10. The vast majority of prostate cancers first develop in the _______ zone.
    a. central
    b. transition
    c. peripheral
    d. anterior

11. _______ frequently is treated with transurethral prostate ablation and stenting.
    a. Small cell prostate cancer
    b. Prostatic transitional cell carcinoma
    c. Localized prostate adenocarcinoma
    d. Benign prostatic hyperplasia (BPH)

12. By far, the most common form of prostate cancer is:
    a. small cell carcinoma.
    b. squamous cell carcinoma.
    c. transitional cell carcinoma.
    d. adenocarcinoma.

13. Elevated prostate specific antigen (PSA) levels can indicate:
    1. BPH.
    2. prostate cancer.
    3. prostatitis.
    a. 1 and 2
    b. 1 and 3
    c. 2 and 3
    d. 1, 2, and 3

14. According to the Directed Reading, _______ % of men with PSA levels lower than 4 ng/mL are diagnosed with prostate cancer.
    a. 5
    b. 10
    c. 15
    d. 20

15. A patient with PSA levels of 15 ng/mL and a Gleason score of 7 is considered _______ risk.
    a. low
    b. intermediate
    c. high
    d. metastatic

16. Some authors reserve the term _______ for patients who are not candidates for curative therapy but who may be prescribed palliative treatment to control symptoms.
    a. active surveillance
    b. watchful waiting
    c. salvage therapy
    d. adjuvant radiation

17. Hormonal therapy does not help reduce prostate cancer recurrence, even when used in conjunction with radiation therapy.
    a. true
    b. false

continued on next page
18. Total radiation doses exceeding _______ Gy over the course of therapy appear to yield superior rates of recurrence-free survival for prostate cancer patients.
   a. 52
   b. 62
   c. 72
   d. 82

19. Prostate cancer radiation therapy toxicity usually involves irradiation and scarring to which of the following organs?
   1. rectum
   2. colon
   3. kidneys
   a. 1 and 2
   b. 1 and 3
   c. 2 and 3
   d. 1, 2, and 3

20. Adjuvant postsurgical radiation therapy is undertaken within _______ months following prostatectomy.
   a. 3
   b. 4
   c. 5
   d. 6

21. In treatment failure for prostate cancer, PSA levels:
   a. continue to decline.
   b. start out low and then resurge.
   c. remain at pretreatment levels or climb after treatment.
   d. increase rapidly after treatment.

22. In the 1990s, _______ became the standard radiation therapy choice for prostate cancer treatment.
   a. 2-D external-beam radiation therapy (EBRT)
   b. 3-D conformal radiation therapy (CRT)
   c. IMRT
   d. proton therapy

23. _______ tumor volume encompasses gross tumor volume, plus a safety margin of visually normal tissue that might include subclinical extensions of the primary tumor.
   a. Gross
   b. Clinical
   c. Planning
   d. Salvage

24. Clinical tumor volume margins usually range between 0.55 cm to _______ cm in 3-D CRT.
   a. 1.0
   b. 1.5
   c. 1.75
   d. 2.0

25. Intrinsic risks or planning error from 3-D CRT include:
   1. over-reliance on planning images.
   2. prostate motion.
   3. poor patient immobilization.
   a. 1 and 2
   b. 1 and 3
   c. 2 and 3
   d. 1, 2, and 3

26. Steeper dose gradients with IMRT mean that _______ are possible while _______.
   a. lower dose volumes; also striking more nontarget tissues
   b. higher dose volumes; sparing nontarget tissues
   c. equal dose volumes; sparing nontarget tissues
   d. lower dose volumes; also sparing nontarget tissues

27. American Society for Radiation Oncology guidelines recommend at least _______ radiation therapist(s) be present for every IMRT procedure.
   a. 1
   b. 2
   c. 3
   d. 4

continued on next page
28. _______ alone can poorly identify tumors within the prostatic capsule and prostate tissue boundaries, from associated fascia and muscle tissue.
   a. Positron emission tomography
   b. Computed tomography
   c. Magnetic resonance imaging
   d. Magnetic resonance spectroscopy

29. _______ can deliver radiation doses of up to 82 Gy to gross tumor volume with little beam broadening or side scatter.
   a. 2-D EBRT
   b. 3-D CRT
   c. IMRT
   d. Proton therapy

30. According to the Directed Reading, men with prostate cancer who receive _______ tend to be significantly older as a group than those who have _______ only.
   a. radiation therapy; hormonal therapy
   b. radiation therapy; surgery
   c. surgery; hormonal therapy
   d. surgery; radiation therapy
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Directed Reading Evaluation
Prostate Cancer and Radiation Therapy

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○ Education ○ Magnetic Resonance ○ Mammography ○ Nuclear Medicine
○ Quality Management ○ Radiation Therapy ○ Radiography ○ Research
○ RIS/HIS/Information Systems ○ RN ○ Sonography ○ Other

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○ Certificate ○ Bachelor's degree ○ Doctoral degree (e.g., Ph.D. or Ed.D.)

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○ Too long ○ Somewhat long ○ Just the right length ○ Somewhat short ○ Too short

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Prostate Cancer and Radiation Therapy

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1 ○ ○ ○ ○ ○  11 ○ ○ ○ ○ ○  21 ○ ○ ○ ○
2 ○ ○ ○ ○ ○  12 ○ ○ ○ ○ ○  22 ○ ○ ○ ○ ○
3 ○ ○ ○ ○ ○  13 ○ ○ ○ ○ ○  23 ○ ○ ○ ○ ○
4 ○ ○ ○ ○ ○  14 ○ ○ ○ ○ ○  24 ○ ○ ○ ○ ○
5 ○ ○ ○ ○ ○  15 ○ ○ ○ ○ ○  25 ○ ○ ○ ○ ○
6 ○ ○ ○ ○ ○  16 ○ ○ ○ ○ ○  26 ○ ○ ○ ○ ○
7 ○ ○ ○ ○ ○  17 ○ ○ ○ ○ ○  27 ○ ○ ○ ○ ○
8 ○ ○ ○ ○ ○  18 ○ ○ ○ ○ ○  28 ○ ○ ○ ○ ○
9 ○ ○ ○ ○ ○  19 ○ ○ ○ ○ ○  29 ○ ○ ○ ○ ○
10 ○ ○ ○ ○ ○  20 ○ ○ ○ ○ ○  30 ○ ○ ○ ○ ○

No Photocopies Accepted
Radiation therapists have a pivotal role in ensuring accurate, quality patient care. Error reporting and reduction have always been critical in radiation therapy and are no less important as technology and treatment planning become increasingly complex. Yet, despite medical advances and changes in radiation therapy practice, error reporting has not been a widespread activity or expectation. This article reviews the literature regarding radiation errors and discusses error reduction recommendations that directly affect the role of the radiation therapist and can help decrease risk of error.

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After completing this article, readers should be able to:
- Recognize systems rather than single actions that cause a majority of errors in radiation therapy.
- Explain the importance of reporting errors and near misses.
- Discuss the recommendations that resulted from a 2010 milestone radiation safety and error prevention meeting.
- Understand ways the radiation therapist can contribute to a culture of safety.

Dr CJ Karzmark, a former American Association of Physicists in Medicine president, once remarked that radiologic technologists “who are most directly involved with machine operation, provide the most important first line of defense against accidents.” The greatest accidents in the history of radiation therapy occurred long before The New York Times hit newstands in 2010 with a series of articles that addressed recent cases of radiation overdose at several hospitals in the United States. Between June 1985 and January 1987, a series of overdose errors occurred using Therac-25 linear accelerators (Atomic Energy of Canada Ltd, Ontario), baffling the equipment users, manufacturer, and the radiation therapy community. The accidents are known as “Malfunction 54” after the fault message that appeared on the Therac-25 panel when the errors occurred; the message was neither explained nor mentioned anywhere in the equipment user manual. Eventually, it was discovered that the accidents occurred when operators incorrectly entered photon or electron data for their patient’s treatment and, after realizing their mistake, corrected the data in the last several seconds before starting treatment. The patients then were treated while the beam-flattening filter and scanning foil were both positioned out of the primary beam. Although an operator mistake triggered the errors, the Therac-25 lacked hardware safeguards against software errors. As a result, despite the operator’s corrections to the treatment information in the final seconds of data input — and despite the Therac-25 displaying the corrected data — the computer had already programmed the data originally entered, not the last-minute corrections.

The Malfunction 54 accidents occurred at 5 different medical sites in the United States and involved 6 individual patients who suffered serious side effects, including limb paralysis and, in some cases, even death. Because the errors at the first
site were not immediately broadcast to other sites, the error continued. As a pattern of recurrence became apparent, an investigation into the cause of the errors was initiated with the vendor’s reluctant participation. It would have been easy to label these errors as either operator or software error, but as Leveson and Turner indicated in their investigative report, it was a systems error—not a single error—that led to these incidents. A national reporting system is essential to prevent a significant error at 1 radiation therapy center from occurring at other centers.

Manufacturers and equipment users must work together to identify and evaluate equipment and software safety risks. Because errors are generally systems errors rather than single errors, systems need to be evaluated and procedures implemented to reduce errors. Software cannot be solely responsible for safety, and hardware backups are an essential component of the safety program. Software will never be without errors. It cannot be tested in all situations that match the environments in which it will be used.

Many lessons learned from the Malfunction 54 tragedy were applied in radiation therapy practice. Several user groups were developed and a reporting system for significant errors was established. Years passed with no similar serious errors reported and, again, complacency became the norm. Since 1987, however, all areas of medicine have become increasingly complex with technological advancements, changing the way medicine—including radiation therapy—is practiced today. Diagnostic images not only capture more anatomic detail, but also display cellular function with the use of positron emission technology. Advances in diagnostic radiology have resulted in changes to radiation therapy, and technological advances in radiation therapy equipment and treatment planning computers have allowed more focused and complex treatments to deliver even higher doses to tumors in fewer fractions. Now, patient treatment information travels between more radiation therapy staff and computer systems than ever before, creating an environment ripe for even more errors. Unfortunately, national reporting of radiation therapy errors and near misses is not undertaken except in cases of significant events.

The New York State Department of Health introduced a mandatory adverse reporting system in 1985 that continues to be in effect today. This robust reporting system allowed researchers for The Harvard Medical Practice Study I and Study II to examine the incidence and nature of adverse events from medical care in general for 31,429 patients in 1984. In the first study the researchers calculated the incidence of adverse reactions, identified the risk factors, and determined the adverse events caused by negligence. The second study focused on the types of errors and the degree of resulting injury or disability. The researchers concluded that the causes of adverse reactions should be identified and methods of error reduction developed. The results of the 2 studies demonstrated that error reporting systems are essential for comparison of incidents and the information was used widely and influenced numerous changes in medical care. In addition to its mandatory incident reporting system, New York has a central registry of reportable radiation events, which has yielded excellent information for people identifying the error rate in radiation therapy.

**Safety in Radiation Therapy**

Following The New York Times articles reporting the accidents in radiation overdose, the radiation therapy community was rocked by the magnitude of the problem and the resulting human suffering. As Marks et al noted, errors “also stem from fundamental changes” in the profession because of major technological advances that changed the way radiation therapy is now conducted. For example, radiation therapists no longer use 1 control panel to dial in the monitor units or check the field position by looking at the field on the skin. The New York Times articles were an unmistakable signal that a new method of ensuring patient safety is needed.

In June 2010 the American Association of Physicists in Medicine and the American Society of Radiation Oncology (ASTRO) sponsored “Safety in Radiation Therapy — A Call to Action,” an international meeting attended by professional organizations and experts within and outside the radiation therapy profession. The meeting brought together clinicians, equipment manufacturers, regulators, hospital administrators, and public interest groups to discuss new methods of error prevention, and resulted in 20 recommendations to promote patient safety (see Box 1).
Error Reporting

Although radiation therapy treatment is very safe, steps must be taken to reduce the occurrence of errors, which can result in serious injury and even death. A number of studies have been conducted to determine the frequency and types of errors that occur in specific departments.13-16 One of the many challenges of conducting error incident studies is that no well-established definition of error exists in radiation therapy.17-19 Error terms found in the literature include reportable events, adverse events, near misses, minor and major errors, clinically significant errors, and defined levels of errors. The World Health Organization World Alliance for Patient Safety developed a taxonomy system, contained within the International Classification for Patient Safety, that provides definitions of key error terms (see Box 2).19 It is clear that a universal taxonomy would be helpful moving forward to compare the effectiveness of departmental quality assurance programs more easily.

The limited scope of error reporting in radiation therapy literature presents another challenge when conducting incident studies. Although many departments have an internal system for reporting errors and near misses, the information is seldom reported in the literature unless the error is clinically significant.

Identifying adverse events is important for incident comparisons among radiation therapy departments, but it does little to explain how the errors occurred.

---

Box 1

**Patient Safety Recommendations**

1. As the complexity of treatment devices increases, control over the devices should be simplified. This recommendation calls for a simplification of the computer interfaces and a reduction in the number of monitors and computers found in many radiation therapy workspaces.

2. Radiation therapists’ workspaces should be designed according to principles of human factors engineering (ie, designing products and equipment based on an understanding of human characteristics), such as using the same type of number system on the keyboard as found on the phone. The design of the workspace also should prohibit distractions and interruptions.

3. Return control to point of care. Therapists can no longer look at the light field on the skin to determine if the field being treated is appropriate. With immobilization and multileaf collimators, the light field on the skin doesn’t provide a “second check” of the treatment field. Therapists should always have the ability to stop a treatment if they believe something is not correct.

4. Provide improved early warnings. Processes and procedures should be in place for all faults. A system should be in place to identify the cause and provide a means to correct the situation when faults or warnings occur.

5. Vendors should quickly and intelligently address concerns reported by physicists and other members of the treatment team.

6. Hold user group meetings. User group meetings allow communication between vendors and users. It is important for radiation therapists to be involved in these meetings to provide input because, as the end users of the products, therapists can identify any problems and provide suggestions for improvement, leading to safer operation.

7. Simplify the billing process. The radiation therapist should not be burdened with billing duties while overseeing patient treatments.

8. Develop recommended staffing levels.

9. Perform error analyses. Radiation therapy facilities should employ techniques such as failure mode effects analysis and root-cause analysis to identify potential sources of error and correct errors when they occur.

10. Develop error reporting systems in radiation therapy.

11. Expect a covenant and commitment to safety from the treatment team.

12. Any member of the team can declare a time-out, which occurs when an individual is not comfortable with a certain aspect of the treatment.

13. Checklists should be employed.

14. Audits should be performed.

15. Facility accreditation should be attained.

16. Standard operating procedures should be available and revised as necessary.

17. Patient safety should be a competency.

18. Safety champions should be present.

19. Treatment team qualifications must be consistent and recognized nationally.

20. The U.S. Food and Drug Administration review process of radiation therapy equipment should be improved.
ASTRO developed a 6-point action plan to improve the quality and safety of radiation therapy for patients. This plan includes creating a national, anonymous, and nonpunitive database for error reporting with a comprehensive analysis of the error events. The database would not only allow for error comparisons, but could prevent the recurrence of serious events once the first occurrence of the errors are reported. Further, equipment failure reports would signal to vendors that swift attention, communication, and analysis are needed for timely solutions.

**Contributing Factors to Errors**

Certain factors increase the likelihood of error and will continue to contribute to errors in an organization or department until they are identified. Thus, radiation therapy departments should be aware of the effect of contributing factors, be ready to identify those that may occur in their work environment, and take caution to avoid them. Common contributing factors to error include:

- Lack of a safety culture in an organization.
- Complacency among staff.
- Over-reliance on technology.
- Rushing a patient through treatment.
- Getting behind schedule.

**Box 2**

**Key Error Terms**

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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</thead>
<tbody>
<tr>
<td>Error</td>
<td>Failure to carry out a planned action as intended or application of an incorrect plan.</td>
</tr>
<tr>
<td>Reportable circumstance</td>
<td>A situation in which there is significant potential for harm, but no incident occurs.</td>
</tr>
<tr>
<td>Near miss</td>
<td>An incident that does not reach the patient.</td>
</tr>
<tr>
<td>No harm incident</td>
<td>An incident that reaches a patient but produces no apparent harm.</td>
</tr>
<tr>
<td>Harmal incident (adverse event)</td>
<td>An incident that harms a patient.</td>
</tr>
<tr>
<td>Harm</td>
<td>Any impairment of structure or function of the body, or any deleterious effect that arises from the impairment. Harm includes disease, injury, suffering, disability, and death.</td>
</tr>
<tr>
<td>Adverse reaction</td>
<td>Unexpected harm resulting from a justified action where the correct process was followed for the context in which the event occurred.</td>
</tr>
</tbody>
</table>
Complacency

In a highly technological profession in which serious errors rarely occur, it is difficult to maintain a high level of vigilance. Individuals forget to be afraid of the dangers inherent in the work they accomplish.\textsuperscript{23,24} Additionally, instead of focusing on the treatment at hand, a therapist may be thinking about the next patient or an event later in the day. This complacency and lack of focus does not contribute to the development of mitigating factors. An organization operating in a culture of safety can prevent complacency and lack of focus by continuously studying procedures and processes and looking for potential errors.

Over-reliance on Technology

Although technology reduces the risk of some errors, it introduces opportunities for others to occur. Technology depends upon accurate input, error-free transfer of information through multiple systems, and complete understanding of the systems involved. It is impossible to test the software for all of the environments and conditions in which it will be used. Without a systematic process in place to double-check the output, accidents will continue to occur. A healthy distrust of computers is essential to maintain an environment of checks and double-checks.\textsuperscript{6,8,12,17}

Table 1

<table>
<thead>
<tr>
<th>Error Reduction</th>
<th>Mitigating Factors</th>
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</thead>
<tbody>
<tr>
<td>Contributing Factors</td>
<td>Mitigating Factors</td>
</tr>
<tr>
<td>(Risk of error increases.)</td>
<td>(Risk of error is reduced.)</td>
</tr>
<tr>
<td>Rushing</td>
<td>Redundancy of checks</td>
</tr>
<tr>
<td>Miscommunication</td>
<td>Time-outs</td>
</tr>
<tr>
<td>Ambiguous written or oral directives</td>
<td>Barcodes for patient identification</td>
</tr>
<tr>
<td>Unique treatments</td>
<td>Barcodes for accessories</td>
</tr>
<tr>
<td>Changes to treatments</td>
<td>Independent verification</td>
</tr>
<tr>
<td>Distractions</td>
<td>Audits</td>
</tr>
<tr>
<td>Unclear standard operating procedures</td>
<td>Checklists</td>
</tr>
<tr>
<td>No procedures</td>
<td>Port films</td>
</tr>
<tr>
<td>Organizational culture</td>
<td>Competency verification</td>
</tr>
<tr>
<td>Improper training</td>
<td>Clear verbal communication</td>
</tr>
<tr>
<td>Lack of training</td>
<td>Clear written communication</td>
</tr>
</tbody>
</table>

- Unique treatment situations.
- Interruptions and distractions.
- Ineffective communication.
- Improper training or lack of training.
- Poor workplace design.
- Fault fatigue.
- Nonworking audio or visual monitors.
- Lack of therapist rotation schedules.

Organizational Culture

A complacent, status quo organizational culture encourages a similar work ethic among employees. Reporting systems, if present, are focused on quick fixes and include finger pointing, blame, and punitive actions. An organization that embraces a safety culture encourages team members to actively engage in safety activities and promotes actions and meetings that lead to a safer environment for employees and patients. In a culture of safety, error reporting is the norm, and is both nonpunitive and anonymous. Reporting errors is also a professional obligation mandated by the American Registry of Radiologic Technologists in No. 22 of the Rules of Ethics, which applies to all medical imaging professionals and includes “the duty to report ... whether or not the patient suffered any injury.”\textsuperscript{22} However, a safety program will fall short of its objectives without the support of the administration. Policies and procedures need to be complete, clear, and understood by all users. They should be routinely evaluated to determine if they are still appropriate.\textsuperscript{19}
Error Prevention in Radiation Therapy

Rushing

Error rates and stress levels of radiation therapists and medical dosimetrists increase when a patient is hastened to treatment before all of the information is available. In the rush to complete treatment, a thorough, careful check of all patient information prior to starting treatment is circumvented. In addition, risk of error is introduced when a treatment machine breaks and patients are transferred to another machine. The alternative machine may be over-scheduled and pushed beyond capacity, and there may be numerous radiation therapists passing through the treatment area. Rushed treatment may result in confusion, distraction, and interruption.14,19

Unique Situations

The risk of error increases if a therapist is working with an unfamiliar patient treatment plan that requires new calculations and transfer of immobilization and setup devices. Any time a unique treatment plan or setup is prescribed, the probability of error increases. Ambiguous communication or a lack of communication about the specific unique treatment characteristics compounds risk of error.10 An example would be setting up a particular patient using positioning devices or sponges that are not normally be used for similar patients being treated for the same disease.

Interruptions

Distractions interrupt the radiation therapist’s focus, increasing the likelihood that he or she will make an error. Some examples of distraction include talking to a treating therapist about information not pertinent to the patient being treated, noise distractions occurring near the workspace, and answering phones during the treatment process.20

Ineffective Communication

Miscommunications and ambiguous communications can lead to significant errors and can occur at any stage of the treatment process. Assumptions often are made when communication is not clearly understood, and those assumptions may result in errors. For example, a shift error could occur when 1 individual indicates a shift direction of the table and another individual mistakes it for a shift of the patient position in the anterior/posterior direction.

Insufficient Training

Lack of training or improper training can occur in many areas of radiation therapy, such as inadequate training on the operation of new equipment, new accessories, or immobilizations devices (eg, moving from port films to image-guided radiation therapy). For the most part, therapists are expected to learn image registration on the job, but this lack of sufficient training has been implicated in a number of errors. Everyone in the department also should be aware of any newly established procedures and what their expected effect will be.16,20

Workspace Design

When delivering treatment, it is the therapist’s job to monitor the patient closely at all times. In addition, the therapist is responsible for checking the treatment parameters to ensure the equipment is operating accurately and delivering the dose prescribed. When there are 4 to 7 monitors to observe, some aspect of the treatment may go unobserved. The situation is exacerbated when the therapist also is required to complete billing procedures. A workspace cluttered with charts, paperwork, and other extraneous items makes it difficult to perform the multiple tasks at hand.12,20,25

Fault Fatigue

The term “fault fatigue” was introduced after the Malfunction 54 investigation. When the tolerance limits of a machine are set so narrowly that machine faults occur frequently, the therapist may begin to ignore the fault messages. It is similar to crying, “Wolf!” Before fault fatigue sets in, the appropriate physicist should be notified so the tolerances can be reviewed. Therapists need to know what each fault signifies and policies to manage each fault individually should be established.6

Nonworking Audio or Visual Monitors

Radiation therapists rely heavily on audio and video technology to monitor patient treatment. Therapists should never treat when neither technology is working.6 At 1 of the centers that experienced Malfunction 54, for example, a broken audio monitor and unplugged video monitor prevented a therapist from seeing that a patient was trying to get off the treatment table after receiving a massive dose of electrons. The therapist continued the treatment, not having realized a dose of radiation had
already been delivered. The next dose of radiation hit the patient on the arm before the patient managed to get off of the table. Had the therapist been able to see and hear the patient, the second exposure could have been prevented.

Error Management

Reporting errors is the norm in a culture of safety. Unreported errors cannot be evaluated in the context in which they occurred. Therefore, any related causes in the system will not be identified, making it difficult to prevent similar errors. Also critical to a culture of safety is managing errors as soon as they are reported. One of 2 primary approaches to error management, the single event approach or the system approach, can be performed. The single event approach focuses on a single error event or individual, whereas the systems approach looks at “errors as consequences, not causes.”

Scheduling

Adherence to the daily schedule often seems obsessive. Getting behind schedule often creates anxiety, frustration, and a need to rush to catch up. If the schedule becomes the major guiding principle, patient safety always will be pushed aside. The pressures of a hectic workday schedule commonly contribute to error and must be reviewed with respect to the increasing complexity of today’s radiation therapy environment.

Therapist Rotation Schedules

Rotation schedules should be examined in light of the complexity of newer machines. It is important that therapists rotate to different machines to remain flexible and competent. Another benefit to rotation is that a new treatment machine operator, observing with fresh eyes, may catch errors overlooked by the machine’s previous operators. Regardless of the rotation schedule used, an experienced therapist must remain on the machine until the newly rotated therapist gains competence and experience.

Single Event Approach

The single event approach to error management is the most commonly used method in radiation therapy — and medicine in general — to evaluate errors and implement corrective action. This limited error management approach does not take into account contributing factors or errors that may have led up to the outcome error; rather, a single error or individual is blamed, and corrective action is focused on that 1 cause or person. In addition, mitigating factors are not identified. Although this error management approach may help reduce single error events, it will not effectively reduce similar errors in the future. The errors within the system will remain in the system, ensuring the recurrence of the event.

The single event approach is also a punitive system; the individual who performed the final steps in a process is most often identified as the cause of the error, creating reluctance among staff to report errors for fear of corrective action. The finger pointing and blaming nature of the single event approach has a significant negative effect on the individuals involved and on the dynamics of a radiation therapy department. It is important to remember that even the most competent, caring, and professional therapist can make an error and that most errors are unintentional.

Systems Approach

The systems approach to error management focuses not on who was found responsible for making the error, but on how and why the error occurred, including why the safety measures in place did not prevent the error. This approach requires an in-depth analysis of the system as a whole and a risk analysis of each step in the treatment process. The systems approach examines the error event, errors that may have occurred at other stages in the process, and contributing and mitigating factors. This approach is based on a nonpunitive system of error reporting and encourages trust among the team members. The systems approach operates within a culture of safety that places high expectations of competence for each individual on the team. For this reason, this error reduction method does not protect workers who consistently fail to follow procedures or demonstrate a deliberate trend of incompetence.

The Swiss Cheese Model of System Accidents

Cancer treatment consists of several steps that may be subject to error, from biopsy, histology determination, and staging to the type of treatment offered. After the patient enters radiation therapy, an entirely new set of possible errors can occur at any phase in the treatment
Reason noted that a culture of safety can be engineered to reduce errors successfully: “An ideal safety culture is the ‘engine’ that drives the system toward the goal of sustaining the maximum resistance toward its operational hazards, regardless of the leadership’s personality or current commercial concerns.”

A culture of safety fosters values, beliefs, attitudes, policies, and procedures that enhance safety. An organization with a safety culture is one in which all members have knowledge of and a constant awareness of the hazards present. Once individuals in the organization become complacent to the hazards, safety is threatened. Because radiation therapy departments do not commonly experience adverse events that result in serious patient harm or injury, it is difficult to maintain a heightened sense of awareness. A department operating under a culture of safety focuses not only on actual events, but also on potential errors. A culture of safety is characterized as:

- An informed culture.
- A reporting culture.
- A learning culture.
- A just culture.
- A flexible culture.

In an informed culture, the organization collects and analyzes data concerning errors that have occurred and uses that data to determine potential errors. This is especially important in radiation therapy departments where errors are not frequent. An informed culture keeps safety at the forefront by continually respecting the damage that can occur if radiation therapists are allowed to become complacent. Studies are conducted.
on potential errors, data collected, and results shared with all members of the team.

A reporting culture creates an environment in which people are not afraid to report errors or near misses and, in fact, reporting errors is the norm. Individuals who do not report errors are subject to punitive action. Confidentiality and the knowledge that the information presented will be taken seriously and acted upon are essential if a culture promoting safety is to be established. Reporting errors only to have them ignored or put on the back burner will tire the reporter, who will eventually give up.

A learning culture is one in which each individual on the team — and the organization as a whole — is able to learn from mistakes and make the changes necessary to reduce the chance of mistakes in the future. In a just culture, individuals are not punished for unintentional acts; rather, those who act outside of the culture by engaging in reckless, unsafe acts are punished. Every organization has employees who bend the rules or believe the rules are not meant for them. If these individuals are not punished for their lapses, morale suffers and the credibility of management is undermined. Ignoring the acts of these individuals condones the unsafe behavior.

Finally, an organization with a flexible culture is one in which each team member has the ability to adapt to changing demands. A leadership that models high standards through communications and actions is critical to a culture of safety. Leaders must not only model the expected behaviors, but they also must hold themselves to a standard higher than their expectations of those they lead.

### A Systems Approach in Action

Using a systems approach to evaluate actual errors, Ostrom et al analyzed 7 misadministration errors. The errors were selected specifically to reflect a sample of representative events that would provide useful information for Nuclear Regulatory Commission-regulated state licenses. The events included:

- A high-dose radiation treatment in which an error occurred while programming the after-loading equipment.
- A cobalt 60 treatment that resulted in an unauthorized field shift.
- A low-dose brachytherapy treatment in which the source size did not match those needed for the applicator used.
- A patient scheduled for a thyroid scan being given enough iodine 131 for a thyroid whole body scan.
- Radioactive ribbons being taped to a patient’s abdomen when the ribbons fell out of the catheters.
- A prostate implant using incorrectly calculated iridium 192 source strength.
- A high-dose radiation procedure in which the wire broke and was left in the patient.

The consequences of these errors ranged from minor with no observed effects to a contributing factor in the patient’s death. Long-term side effects were not studied.

Direct causes (ie, events or actions that directly result in the error) and contributing factors were identified for each error. It is interesting to note that multiple direct causes for each error event were identified. A common direct cause in each of the 7 error events according to Ostrom et al was insufficient organizational policies and procedures to address the specific treatment procedures. Other direct causes identified in a majority of the cases were:

- A lack of radiation safety officer or medical physicist oversight.
- A lack of supervision of those involved in the procedures.
- Inadequate training and experience of those involved in the procedures.
- A lack of communication among those involved in the procedures.
- Errors of judgment and interpretation on the part of those involved in the procedures.
- Hardware failures.

The common contributing factor identified in each case was a recent change or a unique procedure. Other contributing factors included organizational factors, incorrect labeling, hardware incompatibilities, and poor workplace design.

Ostrom et al also investigated whether any mitigating factors were present and found that in all cases there were no procedures in place that would have prevented the error prior to treatment delivery. Four of the 7 organizations had mitigating factors, but only 2 had systematic procedures in place to detect errors. None of these mitigating factors would have prevented the error prior to treatment delivery. The researchers also assessed the
corrective action plans submitted to the Nuclear Regulatory Commission at the time the error events were reported and found that the action plans focused on the direct cause and lacked a system evaluation.\(^\text{23}\)

Had these errors been evaluated according to the single event approach, the most readily apparent direct cause would have been identified and actions taken to remedy that single cause. However, a single event approach would not be helpful in preventing future errors in every case. As evidenced by the additional information gleaned by the researchers, using a single event approach would have missed important information that indicated problems within the system (see Box 3).\(^\text{20,24}\)

Chan et al conducted a study in Canada that evaluated a radiation therapy treatment delivery system and found human engineering factors also can help reduce errors and improve safety when applied to radiation therapy systems.\(^\text{25}\) A workflow analysis of a treatment delivery system was performed, followed by a redesign of the system’s interface components according to a user-centered approach. Sixteen radiation therapy students then participated in a usability test of the redesigned system to help the researchers identify any human factor issues that might lead to errors in the check process before treatment delivery.

Prior to the redesign, there were policies in place for the various checks that needed to be performed, but they were not reinforced. Compliance to the policies depended on the radiation therapists’ decision to follow the policies and whether any distractions or time pressures existed. The redesigned system included highlighted important information, checklists to enforce policies, and fewer key strokes. Questionnaires were distributed to the 16 radiation therapy students to solicit information about the redesign, and researchers determined from the responses that the participants were satisfied with the redesigned system. The redesign was found to reduce all but 1 of the more common errors that occurred during the check process prior to treatment. Further study was indicated for possible table shift errors leading to incorrect isocenter alignment.\(^\text{25}\) The study demonstrated how a culture of safety is possible with investigation into errors and a focus on the individual procedures that compose a radiation therapy delivery system.

In a similar study by Klein et al, errors that occurred at 1 center were identified over a 30-month period.\(^\text{21}\) The researchers also evaluated policies, procedures, and the effect of the record and verify system. Using the Swiss cheese model, the researchers identified pathways for each error indicating at which level the failures occurred. Some of the pathways found in connection with the occurrence of the “shift errors” included:

- The dosimetry staff incorrectly completed an information sheet concerning shift. Incorrect table coordinates were calculated and entered. Note that this error could have been avoided if the treatment plan was completed before treatment commenced and a direct DICOM transfer, including table coordinates, were made.
- A physics staff member failed to check shift instructions filled out by the dosimetrist.
- The therapist staff did not check a digitally reconstructed radiograph to ensure shift had been made correctly.
- The diode did not facilitate error discovery.
- The port film was reviewed by a physician who discovered the error, and it was corrected before subsequent fraction.\(^\text{21}\)

**Box 3**

**Lessons Learned From Study**\(^\text{24}\)

1. Policies and procedures must be clear and address communication pathways among team members.
2. Implementation of an effective Nuclear Regulatory Commission quality management program has the potential to reduce errors.
3. Involvement of the radiation safety officer and medical physicist is essential to implement and effectively operate a radiation safety program.
4. Changes or unique treatments are at an increased risk for errors.
5. Hardware failures are rare but can be mitigated with adequate staff training, procedures, and a culture of safety.
6. A systems approach to identify and reduce future errors is more effective than a single event approach.
7. Systematic processes must be in place to mitigate errors.
8. Individuals involved in treatment must be properly educated for the procedures they deliver and educated about radiation safety and emergency procedures.
9. Redundancy for all aspects of the procedure, including patient identity, is a key mitigating factor.
In the pathway example above, the authors identified mitigating factors, process breakdowns, and needed changes. By identifying the pathway to the error, policies could be changed or developed, further training instituted, or backup safety measures implemented. The pathways also could be evaluated and categorized according to frequency, longevity, and dosimetric impact. Frequency refers to the frequency with which the error occurs; longevity indicates the number of treatments that could occur before error discovery; and dosimetric impact refers to the severity of the error in terms of patient safety. Using this categorization, it is easier to identify errors that may occur less frequently but possess longevity and high dosimetric impact, which allows for identification and examination of the most serious errors.

The Therapist’s Role in Quality Assurance

In a majority of radiation therapy departments, staff therapists do not have significant input about the selection or purchase of treatment machines. Before the equipment arrives, 1 or 2 individuals typically are sent for training and are expected to train the other therapists. Or, an applications specialist might visit the department to train the therapists who will be working on the machine. Generally, because this training does not include all of the therapists in the department, those who receive the applications training are expected to provide their colleagues with on-the-job training concerning proper operation of the new equipment.

In addition to this type of on-the-job education, workspace design and confusing computer interfaces may be significant contributing factors in error propagation. Even if the computer interface is unnecessarily repetitive, not user-friendly, and not intuitive, the therapists still are expected to adapt and learn how to work with the system. A typical workstation, previously only a console and a monitor, now may consist of several computers and keyboards with 4 to 7 monitors that need to be observed and evaluated.

Therapists must be active participants in simplifying the devices used in the administration of the treatment. By identifying factors that contribute to errors and providing input to quality assurance committees and vendors about design flaws or needless interface complexities, therapists can help engineer safer workstations that provide a more user-friendly environment and reduce errors.

Conducting a Quality Assurance Study

Because radiation therapists are the final defense against errors reaching the patient, they are in a prime position to conduct quality assurance or error studies. Often they are the individuals who first catch near misses and errors. Consider a hypothetical situation in which department Y discovers that thermoplastic facemasks have not been fitting patients consistently and this has resulted in difficulty during setup and in image registration. The therapists in department Y can take specific steps to identify, evaluate, and create changes to reduce the problem.

Identifying the Error

The first step in conducting a quality assurance study requires identifying the near miss, error, potential error, or procedure needing improvement. In the hypothetical scenario described, the therapists in department Y have identified a procedure they believe requires improvement. The thermoplastic facemasks must fit patients consistently to promote more efficient setup and image registration. In this situation, the thermoplastic facemasks are not consistent because they are tight-fitting for some patients and loose-fitting for others.

Gathering Error Data

Therapists can accomplish this step by gathering data from charts or digitally reconstructed radiographs of patients already treated, or patient treatment data can be gathered over a period. A simple checklist of the required information is an effective data collection tool that enables all members of the therapist team to assist in the data collection. Having input from all members of the team ensures an adequate amount of information is collected. In the case of department Y, it would be easy to collect data in an ongoing manner, but enough data must be gathered to determine if the inconsistency in facemask fittings could result in treatment errors and whether they increase the treatment time.

Data collected could include face mask identification, patient gender, treatment type, treatment times to determine if a longer setup and treatment time is required when face masks don’t fit, and patients’ comments about
the fittings. A clear description of the masks that don’t fit properly also would be useful to help analyze the data to determine if there are recurring issues.

Analyzing Error Data

After enough data is gathered, it can be grouped or categorized. For example, in grouping its data, department Y might find that 29 of 36 thermoplastic facemasks used over a period of 3 months did not fit properly, resulting in an average of 6 minutes of additional treatment time. If data concerning the increased treatment time is collected, the problem could be traced to the facemasks not fitting.

Evaluating Causes and Contributing Factors

Evaluating the causes and contributing factors can be accomplished using multiple methods. The data can be presented at a staff meeting for discussion about possible causes and contributing factors that led to the error. It is important to avoid jumping to conclusions about possible causes and rushing to implement solutions. If the actual cause or causes are not identified correctly, the problems will continue.

In the case of department Y, procedures for thermoplastic facemask construction may need to be reviewed or developed, and the construction should be observed by all staff members who construct facemasks. Some potential causes of the inconsistent fittings could be a changing water temperature that is not set to the manufacturer’s specifications, a lack of tools to construct the facemasks properly, or a lack of or noncompliance with procedures for constructing the masks. Contributing factors might be time constraints, scheduling difficulties, or a lack of information about the particular system used.

Determining a Solution

Multiple solutions might be needed to correct the problem. Procedures may need to be changed, updated, or developed; equipment may need to be updated or purchased; or training could be increased. For example, department Y may decide to provide more training in thermoplastic facemask construction, and invite the manufacturer to provide a presentation and demonstration.

Implementing the Solution

When a solution has been determined, it is important to garner support and buy-in from all team members so the solution is implemented fully. The plan for implementation — including how and when the solution should be implemented — needs to be clear and understood by everyone involved in the process. Department Y may decide that peer reviews will be conducted to ensure everyone involved with facemask construction follows correct procedures and the end solution is within tolerance levels.

Evaluating the Outcome

Once the solution plan is implemented fully, data must once again be gathered to ensure the problem has been corrected. Further research is required if the data does not show improvement. When the problem is solved, the information gathered and lessons learned should be shared with a national audience. Publication most often provides the widest audience, but presenting the information at a national level such as at a conference is also an appropriate and effective vehicle for sharing.

Mitigating Factors

As discussed earlier, mitigating factors are the procedures and processes in place specifically to reduce the risk of errors. Examples of mitigating factors include:

- Redundancy of checks.
- Time-outs.
- Peer review.
- Morning meetings.
- Checking source-to-skin distance (SSD).
- Reading the patient’s chart.
- Checklists.
- Barcodes.
- Pretreatment check system.
- Audits for competency verification.
- Communication.
- Training.
- Adequate staffing.

Redundancy of Checks

There is a greater chance that an error will be caught before it reaches the patient if multiple individuals check a specific component of the treatment. Asking the patient his or her name before treatment and checking the date of birth or the site of treatment decreases the chance that the wrong patient will be treated. Reading the treatment
parameters aloud to a colleague for verification prior to treatment is another example. This only works, however, if both radiation therapists fully understand that this action should not become routine recitation but should always encourage focus to help prevent errors.²⁰

**Time-outs**

A time-out stops the treatment process so that any questions can be answered to the satisfaction of the individual calling the time-out. Regardless of how it may affect the treatment schedule, all members of the team should respect a time-out and take it seriously.¹²

**Peer Review**

The process of peer review can be accomplished using multiple methods. A formal approach to conducting peer review would be to observe a colleague while he or she completes a specific procedure and assess the skills or end product according to a grading rubric. Or, it may involve simply bringing images to staff meetings to discuss image quality. The success of peer review requires therapists to view the procedure not as a punitive measure, but as a helpful tool that can improve skills and help determine if additional training is needed.

**Morning Meetings**

Treatment, simulation, dosimetry, physics, nursing, and physician representatives can attend morning meetings to review what is planned for the day. This gives therapists an opportunity to ask questions about a treatment plan that may be confusing. Physicians also can be alerted to events that will require their presence on the machine or in simulation.

Open meetings that everyone is invited to attend not only increase communication and a sense of community, but ultimately also promote an organizational culture of safety.¹⁹

**Checking Source-to-Skin Distance**

Checking the SSD is a simple method to verify information of a patient’s treatment plan and can help therapists catch multiple errors before they reach the patient. Checking the SSD may help expose shift errors, errors in the treatment plan contour, or measurements and incorrect isocenter placement.²¹

**Reading the Patient’s Chart**

Reviewing the patient’s chart is an excellent way to verify the correct area is being treated and that the lymph node status matches the treatment parameters. Mobility issues or the need for an interpreter also may be identified in the chart, which provides valuable information for the simulation therapist (see Table 2).

**Checklists**

Checklists are a valuable tool to ensure all steps have been completed prior to beam exposure. Checklists can be written or incorporated into the computer interface, requiring the therapist to respond to each item before the treatment can commence. Regardless of the type of system used, it must be used consistently and be valued by staff.¹²,¹⁷,²⁵

**Barcodes**

Barcodes have been used successfully to match a patient with the correct beam modifiers and accessories. They also have been used to verify the patient’s identity to ensure the correct patient is being treated.⁸

**Pretreatment Check System**

Prior to treatment, 2 therapists can confirm with each other all of the treatment parameters including but not limited to patient identification, treatment site, dose, field sizes, accessories, gantry, and collimator and table angles. This simple verification system alone can reduce errors.⁸,¹⁷

**Audits for Competency Verification**

Audits can be designed to identify gaps in knowledge about the equipment and its operation, especially in departments in which there has been a quick introduction of new equipment. Audits for image registration, for example, would ensure there is consistency among all members of the treatment team.

As with peer reviews, audits should be introduced in a positive light and as a continuing education opportunity rather than as a punitive event. Additional education and training can be provided to address any gaps in knowledge identified by the audits.¹²,¹⁷

**Communication**

An essential element in a culture of safety is clear communication between all team members. Taking the time
to clarify ambiguous information or provide additional information is important, especially with the complexity of the treatments delivered. Therapists must understand the treatment plan if they are to recognize errors in either the treatment plan or setup.

Being comfortable reporting errors is essential if the patient is to receive the best treatment possible. Communication flows best when each member of the team is respected and valued for their contribution.\textsuperscript{12,20}

Training

A variety of radiation therapy equipment exists, and it is highly unlikely that any 1 therapist has worked on every piece of equipment. New members of the team usually are trained using an informal process. The same holds true when new equipment arrives in the department. Even though there is some formal educational process for new equipment, not every member of the team is included unless the department shuts down for the training period. For this reason, additional training is an important component on the road to competence.

Audits, as mentioned previously, can be effective in identifying missing knowledge or competence. Providing an opportunity for therapists to become knowledgeable about all aspects of the equipment will go a long way toward error prevention. In addition, it is incumbent on the therapist to seek additional training and education in areas where he or she feels it is necessary.\textsuperscript{21}

Adequate Staffing

The role of the radiation therapist has changed with the increasing technology and complexity of treatment. Although this evolution has occurred rapidly, many of the same processes and procedures used in a less complex time still exist.

Therapists today tend to work at computers for longer periods. Supervisors who are accustomed to seeing therapists running in and out of the room may make the assumption that, because the therapists are “sitting around,” less are needed. A new staffing level recommendation is needed that will match the current demands of the profession.\textsuperscript{12,21}

Conclusion

A review of the literature regarding the role of radiation therapists in quality assurance and cultures of safety indicated a lack of research in this area. Although literature on this topic is scarce, the author’s visits to clinical sites and informal conversations with radiation therapists revealed that many therapists are active in exciting quality assurance programs established by their departments.

<table>
<thead>
<tr>
<th>Patient Chart Section</th>
<th>Information Gleaned</th>
<th>Information Usefulness</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>History and physical</td>
<td>Age</td>
<td>Simulation and treatment positioning and compliance</td>
<td>A review of the patient’s medical history and physical should occur prior to simulation and first treatment</td>
</tr>
<tr>
<td></td>
<td>Health status</td>
<td>Identification of educational barriers</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Comorbid disease status</td>
<td>Identification of social barriers</td>
<td></td>
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<tr>
<td></td>
<td>Mobility</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Living arrangements</td>
<td></td>
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<tr>
<td></td>
<td>Family support</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgical report</td>
<td>Tumor size</td>
<td>Match with area of interest to CT (simulation)</td>
<td>Each new chart should be checked by the therapist prior to simulation and first treatment</td>
</tr>
<tr>
<td></td>
<td>Tumor location</td>
<td>Match with dosimetry plan/prescription (treatment)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Local spread</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pathology report</td>
<td>Histology and grade</td>
<td>Match with area of interest to CT (simulation)</td>
<td>Each new chart should be checked by the therapist prior to simulation and first treatment</td>
</tr>
<tr>
<td></td>
<td>Lymph node status</td>
<td>Match with dosimetry plan/prescription (treatment)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Local and regional spread</td>
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and often take leadership roles. Information of this nature should be published and shared nationwide if therapists are to be equal partners with physicists and physicians in moving the profession forward. As Robert Adams, EdD, R.T.(T), CMD, said, “A technician will say doing these activities is for someone else; what would a therapist say?"  

Radiation therapists play an integral part in quality assurance and error reduction in the departments in which they work. A culture of safety is not possible unless all members of the team participate fully in making safety the most important priority. Many therapy departments are actively involved in nonpunitive error reporting systems, quality assurance committees, and research to identify error pathways and methods to either close the holes in the Swiss cheese or establish mitigating procedures to reduce the risk of error (see Box 4). Unfortunately, not all therapy departments take such active roles in error reduction.

In a national survey of radiation therapists conducted by Adams, 13% of respondents indicated they did not report errors because there was no reporting system in place at their facility. Sixteen percent of respondents indicated they had been reprimanded for reporting errors. An astounding 30% reported fear of reprimand was the greatest barrier to reporting errors, and the therapist’s personality was implicated as a barrier to error reporting in 3% of responses. The results of Adams’ study suggested that team members are not comfortable reporting errors. These results are extremely troubling when considering the consequences of not reporting errors. If departments are to establish a culture of safety successfully, all members of the treatment team must feel comfortable reporting errors. Regardless of personality traits, errors must be reported to decrease longevity and dosimetric effect of those errors. In a department where there is no error reporting system, radiation therapists have a responsibility to establish procedures for reporting errors, identifying error pathways, and developing safety measures. It will never be possible to prevent 100% of the errors in radiation therapy, but it is possible for all therapy team members to make error reduction and patient safety the main priority.

The study by Adams provides valuable information for radiation therapy educators in terms of communicating to their students both the necessity of error reporting and the importance of destroying error-reporting barriers to assure patient safety. In addition, educators should address methods for identifying errors, contributing and mitigating factors, error pathways, and possible solutions in their quality assurance curriculum.

Radiation therapy has entered a new era of complexity, leaving many of the standard procedures and processes of the past behind. It is time for a widespread change and adoption of a culture of safety where informed radiation therapists are able to collect and analyze data about errors and potential errors. Radiation therapists have the opportunity to increase their involvement to reduce errors, including influencing the design of computer interfaces and workspaces to better enhance safety and usability.

The recommendations presented in the 2010 meeting “Safety in Radiation Therapy: A Call to Action” provide therapists with the opportunity to make the changes necessary to facilitate cultures of safety. In addition, therapists can increase the pool of knowledge by publishing and presenting information gleaned from their research, quality assurance studies, and experiences in their departments. A culture of safety depends upon every member of the team.

**Box 4**

**Recommendations for Radiation Therapist Participation in Error Reduction**

1. Participate in department quality assurance committees.
2. Participate in quality assurance studies.
3. Provide information to physicists and vendors regarding workplace design or computer interface.
4. Re-evaluate treatment and simulation schedules and rotation schedules with patient safety in mind.
5. Develop a system of reporting if one does not exist.
7. Become a clear communicator.
8. Work to establish friendly working conditions.
9. Evaluate skills and knowledge to ensure competency.
10. Volunteer to lead peer reviews or audits.
11. Conduct quality assurance studies and publish or present findings.
12. Adopt a commitment to safety respecting the contributions of all members of the team.
References


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Directed Reading Quiz

Error Prevention in Radiation Therapy

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Expiration Date: April 30, 2014*
Approved for 1.5 Cat. A CE credits and 2.0 MDCB credits

To earn continuing education credit for this Directed Reading, read the preceding article and circle the correct response to each statement. Transfer your responses to the answer sheet on Page 80, and then follow the directions for submitting the answer sheet. Members also may take quizzes online at www.asrt.org/drquiz. New and reinstated members are ineligible to take DRs from journals published prior to their most recent join date unless they have purchased access to the quiz from the ASRT. Note: Readers who are not ASRT members can receive credit by joining the ASRT. To join, call Member Services at 800-444-2778, or visit www.asrt.org/joinnow.

*Your answer sheet for this Directed Reading must be received by the ASRT on or before this date.

1. “Malfunction 54” was the result of a(n) ________ error.
   a. operator
   b. software
   c. hardware
   d. systems

2. Designing workspaces that reflect human characteristics follows a set of principles known as:
   a. single error approach.
   b. human factors engineering.
   c. anthropometry.
   d. occupational biomechanics.

3. Error terms found in the literature include all of the following except:
   a. near misses.
   b. reportable events.
   c. adverse events.
   d. mitigating factors.

4. Contributing factors are conditions that ________ errors.
   a. increase the risk of
   b. help identify
   c. directly cause
   d. prevent

5. Which of the following actions is not an example of a contributing factor to error?
   a. over-relying on a computer program
   b. complacently performing a procedure
   c. calling a time-out
   d. ineffectively communicating instructions

6. A complacent, status quo culture is likely to support a reporting system that focuses on:
   a. the big picture.
   b. quick fixes.
   c. long-term solutions.
   d. system analysis.

continued on next page
12. In the Swiss cheese model of system accidents, the solid portions in each slice of cheese represent:
   a. mitigating factors.
   b. contributing factors.
   c. failures in the system.
   d. opportunities for error.

13. An error that occurs in the treatment planning stages but is caught before it reaches the patient is known as a:
   a. contributing factor.
   b. direct cause.
   c. near miss.
   d. negligible error.

14. A heightened sense of awareness is difficult to maintain in radiation therapy because:
   a. adverse events that cause serious patient harm or injury do not commonly occur.
   b. radiation therapists operate more effectively in crisis management mode.
   c. radiation therapy departments do not invest in safety resources.
   d. clinically significant errors occur every day in radiation therapy departments.

15. An informed culture is one in which:
   a. there is a fear of reporting errors and near misses.
   b. team members inform each other of errors as they occur.
   c. data is collected to disprove errors.
   d. continuing education is practiced by all members of the team.

16. A ________ culture is defined as an organization that does not punish individuals for unintentional errors.
   a. condoning
   b. penal
   c. democratic
   d. just
17. Ostrom et al found _______ to be a common direct cause in all 7 error events they evaluated.
   a. inadequate training and experience
   b. hardware failures
   c. insufficient organizational policies and procedures
   d. a lack of supervision

18. A single event approach will help identify the direct cause of an error and prevent it from occurring again in every case.
   a. true
   b. false

19. Dosimetric impact refers to the _______ of an error in terms of the patient’s safety.
   a. severity
   b. frequency
   c. risk
   d. likelihood

20. Conducting a quality assurance study includes all of the following except:
   a. identifying the error.
   b. gathering error data.
   c. analyzing error data.
   d. disproving the error.

21. Which of the following methods is recommended to evaluate causes and contributing factors of a known error?
   a. A single error approach could be used to investigate the data.
   b. Staff members could retrace their steps up to the point when the error occurred.
   c. Data collected about the error could be presented at a staff meeting for discussion.
   d. The individual responsible for the error event could conduct an investigation.

22. Implementing peer review in the radiation therapy workplace could accomplish which of the following goals?
   1. improve radiation therapists’ skills
   2. help determine if additional training is needed
   3. provide opportunities to discuss image quality
   a. 1 and 2
   b. 1 and 3
   c. 2 and 3
   d. 1, 2, and 3

23. Checking source-to-skin distance prior to treatment delivery is considered a(n):
   a. mitigating factor.
   b. contributing factor.
   c. inefficient use of time.
   d. unnecessary procedure.

24. Reading the patient’s chart prior to simulation and treatment:
   1. serves as a second check of the area being treated.
   2. can provide useful information to the simulation therapist.
   3. is prohibited by the Health Insurance Portability and Accountability Act.
   a. 1 and 2
   b. 1 and 3
   c. 2 and 3
   d. 1, 2, and 3

25. In a study by Robert Adams, _______ % of respondents indicated they were fearful of reporting errors because of reprimand.
   a. 10
   b. 15
   c. 20
   d. 30
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Error Prevention in Radiation Therapy

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1. What is your primary area of practice?
   - Administration/Management
   - Education
   - Quality Management
   - RIS/HIS/Information Systems
   - Bone Densitometry
   - Magnetic Resonance
   - Radiation Therapy
   - RN
   - Cardiovascular-Interventional
   - Mammography
   - Radiography
   - Sonography
   - Computed Tomography
   - Nuclear Medicine
   - Research
   - Other

2. Which of the following best describes the highest educational level you have attained?
   - Student who has not yet taken Registry exam
   - Associate degree
   - Master's degree
   - Certificate
   - Bachelor's degree
   - Doctoral degree (e.g., Ph.D. or Ed.D.)

3. Why did you choose to complete this DR?
   - Interested in the topic
   - Topic pertained to my area of practice
   - Other
   - DR had the right number of CE credits
   - Needed CE credits immediately

4. How relevant is this DR to your practice?
   - Extremely relevant
   - Very relevant
   - Relevant
   - Somewhat relevant
   - Not relevant

5. How beneficial is this DR to your professional or personal development?
   - Extremely beneficial
   - Very beneficial
   - Beneficial
   - Somewhat beneficial
   - Not beneficial

6. How would you rate the level of difficulty of this DR?
   - Too difficult
   - Somewhat difficult
   - Just the right level
   - Somewhat easy
   - Too easy

7. How would you rate the length of this DR?
   - Too long
   - Somewhat long
   - Just the right length
   - Somewhat short
   - Too short

8. Did this DR meet your expectations?
   - Yes
   - No
   - Partially

9. Would you recommend this DR to a colleague?
   - Yes
   - No

10. Overall, how valuable are the Directed Readings to you?
    - Very valuable
    - Considerably valuable
    - Valuable
    - Slightly valuable
    - Not very valuable

If you have comments about this Directed Reading, please write them below or send them separately to Ellen Lipman, Director of Professional Development, ASRT, 15000 Central Ave SE, Albuquerque, NM 87123-3909 or elipman@asrt.org.
# Error Prevention in Radiation Therapy

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Note: For true/false questions, A=true, B=false.

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Expires: April 30, 2014
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No Photocopies Accepted
Most radiation treatments occur without incident and contribute to the comfort or cure of cancer patients, yet complex technology offering more promising and accurate techniques for targeting malignancies requires extensive training, continuing education, and attention from the radiation therapists who deliver the radiation. The consequences of a single error are enormous, as outlined by feature articles in The New York Times beginning in 2010. These and other reports, such as the ECRI Institute (formerly Emergency Care Research Institute) naming of radiation therapy errors as the No. 1 hazard in health care, have focused public, professional, and regulatory attention on radiation oncology processes, equipment, and delivery of care.

Several professional organizations responded immediately to the articles in The New York Times, including the American Society of Radiologic Technologists. In a letter to the newspaper’s editor and testimony before a U.S. House of Representatives subcommittee, ASRT Board of Directors members emphasized that although radiation therapy errors are tragic, they are rare, and establishing national education and certification standards for technical personnel who perform radiation therapy procedures is the best way to ensure quality and safety of the procedures. Other organizations, such as the American Association of Physicists in Medicine (AAPM), the American Society for Radiation Oncology (ASTRO), and the Medical Imaging and Technology Alliance (MITA) have made statements, published white papers, or developed initiatives to address safety in radiation therapy.

The ASRT Education and Research Foundation’s Health Care Industry Advisory Council (HCIA) includes representatives of important companies in the radiology and radiation oncology industries who work together in a noncompetitive environment to advance patient care. Members meet annually, and they occasionally form subcommittees to discuss significant issues in the radiologic sciences. The HCIA Subcommittee on Patient Safety and Quality in Radiation Therapy met November 14, 2011, in Albuquerque, New Mexico.

A committee of concerned radiation therapists, managers, and representatives of radiation therapy equipment vendors (see Box) discussed the issue of safety in radiation therapy in detail and considered cooperative and workable solutions focusing primarily on the areas they represent: the role of the radiation therapist and the support provided to therapists and other radiation oncology staff from equipment vendors. The committee’s evaluation and recommendations are categorized according to workplace staffing, workplace culture, skills assessment, and applications training.

**Workplace Staffing**

Ensuring consistent, accurate, and effective radiation treatment requires cooperation of a team of radiation oncology specialists. As of February 2012, 15 states did not regulate radiation therapists. Still, radiation therapists must maintain high degrees of accuracy when delivering treatment, think critically, and at times use independent, professional, and ethical judgment.
The Critical Role of the Radiation Therapist

in every aspect of their work. Supervised by radiation oncologists, therapists review protocols, operate increasingly sophisticated equipment, monitor and assess patients, and initiate treatments that can extend for several weeks. In effect, there are no requirements regarding education and expertise for radiation therapists in states that have no licensing regulations.

Accreditation programs address radiation therapist certification and staffing, recommending a minimum of 2 therapists per active linear accelerator regardless of patient volume, and more therapists based on the annual number of new patients at a facility and ratio of procedures performed. Intensity-modulated radiation therapy (IMRT) is an example of the radiation oncology team’s ability to conform isodose distributions more precisely to targets’ shapes, which reduces dose to adjacent structures. The planning and delivery of radiation under this newer technology is more complex, however, than with conventional linear accelerator procedures.

Radiation therapists always have had to review all approved treatment plans, instructions, prescriptions, and images to ensure that the information is consistent and valid before delivering any treatment. The evolution of radiation treatments to more complex planning and targeting, including but not limited to IMRT, requires an ever vigilant approach to quality assurance.

In a 2010 survey of the radiation therapist and dosimetrist workforce, the ASRT found that most radiation therapists reported that exactly 2 therapists per linear accelerator routinely were scheduled at their facilities, and as many as 41% of facilities reported routinely scheduling 1 therapist per linear accelerator between 1 and 8 hours a day. Most of these instances were for 1-hour periods, but 10% of facilities responded that only 1 therapist staffed a treatment machine for 8 hours each day. One therapist always should be attentive to the patient, and another to the treatment console. Cost often is cited for maintaining minimum staffing levels, but the costs to patients — and in real settlements and potential litigation resulting from errors — are much higher.

**Best Practices:**
- All radiation therapy is delivered only by ARRT-registered radiation therapists.
- All sites providing radiation therapy staff at the level of 2 therapists per machine at all times.

**Recommendations:**
- ASRT will continue to support the Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy bill and other efforts to ensure registered radiation therapists deliver care.
- Sites should evaluate workflow and staffing levels to determine whether (and when) fewer than 2 therapists staff each machine and correct as soon as possible.

**Workplace Culture**

The radiation therapist is the ultimate gatekeeper in the delivery of curative doses of radiation. As such,
all members of the treatment team must recognize the therapist’s critical role in safeguarding the patient. Doing so requires that radiation therapists and others on the radiation oncology and health care teams view therapists as professionals and embrace a culture that strongly supports safety.

In a report on IMRT safety considerations, Moran et al suggested several considerations to support a culture of safety, including trust among department members, event tracking, review and follow-up, hiring and ongoing training of personnel, use of standard operating procedures, defining each team member’s roles and responsibilities, and effective communication among team members.9

Administrators set the tone for safety and professionalism in radiation oncology facilities by openly supporting error prevention and reporting.14 A survey conducted by Robert Adams, EdD, MPH, R.T.(R)(T), of the University of North Carolina, questioned 250 radiation therapists throughout the United States regarding errors. Although most radiation therapists reported good communication with dosimetrists, department administrators, and radiation oncologists in particular, only 78% strongly agreed that they are encouraged to report clinical errors. In addition, 16% of radiation therapists surveyed reported that they have been reprimanded by their supervisors for reporting clinical errors. Fear of reprimand is the greatest barrier to error reporting.16

A culture shift begins, however, with radiation therapists, who must continually promote and practice within the profession’s standards and ethics. Radiation therapists must take the time to perform time-outs and double-checks — and trust one another as well as all team members. A culture of professionalism and patient safety requires radiation therapists to be able to inherently say or believe, “I trust you and your work, but I am double-checking it; I expect you to do the same for me.”

Promoting safety and professionalism also means minimizing distractions while delivering treatments. In the ASRT workplace survey, the reported primary distraction in the clinical setting for radiation therapists (28.4%) was interruptions from other people such as nurses, physicians, or fellow therapists.15 Radiation therapists and other team members should work together to develop policies, procedures, communication standards, and — if necessary — physical barriers or reminders to minimize distractions while radiation therapists are treating patients and the beam is on.

Further, the radiation oncology team must recognize and practice within the scope of existing standards and ethics in their professions. The American Registry of Radiologic Technologists Rules of Ethics include possible sanctions for any radiation therapist who fails “to immediately report to his or her supervisor information concerning an error made in connection with imaging, treating, or caring for a patient.”17

The ASRT Practice Standards for Medical Imaging and Radiation Therapy also clearly outline that radiation therapists determine, because of safety concerns, “when to withhold treatment until a licensed independent practitioner is contacted.” When documenting treatment data, the therapist also is expected to document exceptions from the established criteria or procedures.11

Radiation therapists also should be encouraged to document all attempts to correct deviations from standards of care or planned treatments. Therapists should work within their scope of practice and follow their practice standards and rules of ethics by reporting appropriate events. They also should continue to enhance the perception of their professionalism by participating in lifelong learning, research, and publishing opportunities.

As administrators establish cultures that encourage safety, it is imperative that radiation therapists feel they can report errors and near-misses — according to the standards and ethics that guide their profession — without fear of negative repercussions. Any reporting system is only as strong as its accurate and consistent participation. Error reporting should not be tied to performance evaluation.

Best Practices:
- Administrators, radiation oncologists, radiation therapists, and all oncology staff members embrace a culture that supports radiation therapist professionalism.
- Radiation therapists and other radiation oncology professionals adhere to professional ethics and standards of practice established by their professions.
- Reporting of errors is expected and encouraged.
Special Report
The Critical Role of the Radiation Therapist

**Recommendations:**
- ASRT and its members continue to support efforts to develop consistent and mandatory error reporting.
- Radiation therapy site managers should implement changes to encourage reporting of errors and near-misses and investigate a systematic approach to error reporting, tracking, and correction.
- Radiation therapists should embrace a comprehensive approach to professionalism that includes lifelong learning, error reporting, and process improvement.

**Skills Assessment**
Medical care improves because of dedicated providers and advances in technology. Radiation therapy is no exception to this rule. Radiation therapists must be prepared with the basic knowledge required to work on a new modality before the equipment vendors arrive to install the equipment and train staff on its proper operation. For example, additional training specific to IMRT is critical before beginning work with the modality. If radiation therapists do not understand the basics of the technology and modality before the equipment arrives, applications trainers can’t focus on the tasks at hand: specific function and safe, effective operation of the newly installed system.

The skills of recently hired and temporary staff also can vary in radiation oncology facilities and should be a primary concern for administrators as part of the safety and quality culture. Competency checklists for new and temporary staff help ensure that all radiation therapists are prepared to perform procedures specific to a site; they also help ensure that staff members are ready for applications training from vendors.

Organizations such as ACR and AAPM have begun facilitating peer-to-peer review to share best practices. This sort of peer assessment could help minimize problems associated with communication and fear of reprisal among staff. Peer-to-peer review is meant to be an ongoing program that is part of continuous improvement.

As part of workplace culture shifts, administrators, radiation therapists, and the entire radiation oncology team should view training and continuing education as an ongoing process. Post-training assessments and competency assessments, along with periodic reassessments, should be viewed as opportunities to learn and help staff grow, not as disciplinary situations. The ARRT is implementing a new approach to maintenance of registration that applies to radiation therapists certified beginning January 1, 2011.

**Best Practices:**
- Employers conduct preassessments of radiation therapist skills before beginning applications training and postcompetency assessments following training.
- Radiation oncology providers conduct ongoing peer-to-peer assessment.

**Recommendations:**
- All radiation oncology sites installing new equipment or upgrades should work with applications trainers to develop and implement checklists for preassessment and postassessment of radiation therapists’ skills.
- Therapists should use the assessments as a method for identifying gaps in skills and knowledge and seek opportunities for continued professional development in these areas.

**Applications Training and Support**
Radiation oncology sites and team members must adjust processes, policies, procedures, and learning according to newer complex planning and procedures. There are also several challenges for sites and trainers in providing applications training. Among these are time constraints vs increased time requirements to cover complex modalities, along with inconsistent commitment to training on the part of staff and management. The goal of applications training is to provide the highest quality care for radiation oncology patients, and to ensure that staff members are competent and comfortable with new technologies in their departments to safely operate the equipment. This requires having radiation therapists who are thoroughly and completely trained on clinical equipment. Too often, however, applications training is viewed as an “event,” an interruption to schedules, and a drain on productivity and revenue.

In creating a culture that focuses on safety and professionalism, all radiation oncology sites installing and
updating equipment should consider applications training a requirement for staff rather than an option. In the ASRT’s survey of the radiation therapy workplace, more than 90% of managers reported that they have the latitude to facilitate time for training activities. Currently, however, busy staff in revenue-strapped radiation oncology departments seldom find — or make — time to attend entire applications training sessions. Problems often occur that pull staff away from important sessions, affecting training continuity and effectiveness.

Radiation oncology sites and radiation therapists are accountable to attend and be engaged in applications training as a critical part of their missions to provide safe, quality patient care. Vendors and their applications trainers are accountable to provide effective and thorough training programs.

In a culture that emphasizes quality and patient safety, time spent on applications training is viewed as “safety time.” Radiation therapists always work to minimize frequent interruptions to treatments. Yet a potential outcome of poorly planned and attended or executed applications training could be these types of interruptions, resulting from help needed should problems arise because staff attended training intermittently, or assessments did not adequately ensure staff understood how to handle unusual situations. Organization, planning, and preparation help ensure that application installs and training run smoothly, which can save time.

Many facilities have installations from more than 1 vendor or an equipment upgrade that affects the operation of another piece of equipment made by the same vendor or another vendor. Radiation oncology team members can be faced with making multiple calls or attending multiple trainings relevant to equipment, and they can be subjected to mixed messages or confusion when trying to resolve equipment performance problems related to cross-vendor systems. Providers and vendors would benefit from improved cooperation among vendors when testing, training, and supporting radiation therapy systems. Multivendor training events would be more desirable than separate events, although multivendor events can be difficult to coordinate.

Best Practices:
- Radiation therapy managers, radiation therapists, and vendor representatives work together to help ensure successful implementation and training for sites purchasing new radiation therapy equipment.
- Vendors cooperate to improve multivendor implementation, training, and support for radiation therapy sites.

Recommendations:
- HCIAC Subcommittee on Patient Safety and Quality in Radiation Therapy will spearhead efforts to provide guidelines for successful radiation therapy equipment installation and training, including preparedness and competency checklist suggestions.
- All HCIAC member companies should conduct additional multivendor prerelease and testing and explore possible multivendor training, along with cross-vendor support systems for help desks and online support groups.
- Sites installing equipment cooperate with vendors to support successful and complete installation and appropriate, uninterrupted training of all radiation therapy staff to ensure safe, quality patient care.

For more information about the HCIAC Subcommittee on Patient Safety and Quality in Radiation Therapy meeting and recommendations, access the full white paper at www.asrtfoundation.org/safetyintherapywhitepaper.

References
Special Report

The Critical Role of the Radiation Therapist


16. Adams R. National study to determine the comfort levels of radiation therapists to report errors. Study presented at: 35th ASRT Radiation Therapy Conference; October 2-4, 2011; Miami, FL.


Transitional to Electronic Medical Records

Many radiation therapy centers and departments are considering the transition from paper treatment records to electronic medical records (EMRs), also called electronic health records. EMR systems have several advantages, including patient safety, efficiency, cost-effectiveness, and security, but they also present challenges. Transitioning from paper-based medical records to an electronic system can require significant time and resources, and the process may feel overwhelming. Many questions arise when a radiation therapy department considers making the transition:

- Will EMRs benefit the department?
- Who should be involved in the project?
- What support and resources are required?
- What are the hardware and software needs?
- How do providers select a software vendor?
- How do providers establish electronic processes and create electronic documents?
- What are the options for implementation?
- What training and staff support is required?

This article answers some of these questions to help radiation therapy centers and departments transition to a paperless system.

Focus on Electronic Medical Records

There is considerable focus on EMRs in the United States, Canada, and abroad. President Barack Obama has proposed to make all health records in the United States electronic by 2014. Congress approved more than $20 billion toward EMR subsidies, and in 2009 Medicare began awarding a 2% bonus to physicians who use EMRs. In fact, the Centers for Medicare and Medicaid Services (CMS) will begin imposing penalties on Medicare providers who do not use EMR in 2015.

In 2001, Canada’s prime minister initiated the Commission on the Future of Health Care in Canada. The commission’s mandate was to provide recommendations to ensure the long-term sustainability of a health care system for all Canadians that would be universally accessible, high quality, and publicly administered. Encouraging the development of a national EMR system was a key recommendation. Canada Health Infoway is an independent nonprofit organization funded by the Canadian federal government tasked with accelerating the development of EMR systems in Canada. In 2009 the Canadian government increased EMR system spending by $500 million, bringing their total investment toward EMR to $2.1 billion.

The United Kingdom initiated a national database for EMRs and aims to have an EMR system for 50 million patients by 2014. Many other European countries also have established EMR initiatives. Nine countries implemented or were planning to implement nationwide EMR systems as of 2010.

The literature suggests that patient safety, efficiency, and reduced cost are the primary factors driving the need for EMRs in health care. Use of EMRs can improve communication between health care providers from separate facilities, which in turn can result in more coordinated care. EMRs can help flag dangerous
medication interactions and allergies, minimize the unsafe use of abbreviations, eliminate illegible handwriting, and reduce ordering of duplicate tests. EMRs also could make it possible for patients to access their records, appointments, and lab results electronically, and may enable them to refer to follow-up instructions and communicate with their health care providers through a computerized system. The Commission on the Future of Health Care in Canada reported:

> Paper records are increasingly becoming obsolete and inadequate. They limit the flow of information, insufficiently document patient care, impede the integration of health care delivery, create barriers to research, and limit the information available for administration and decision-making.

Despite the advantages of EMRs and the governmental push to implement them, most health care providers in North America still use paper records. Canada Health Infoway’s goal was for 50% of Canadian medical records to be available electronically by the end of 2010. By 2009, however, the country was only about one-third of the way there. In the United States, it was estimated that fewer than 18% of physicians used EMRs in 2007. In 2011, the National Center for Health Sciences found that 57% of office-based physicians were using electronic health records. EMR use across the United States ranged from 40% to 84%.

Advantages of Electronic Medical Records

Whether or not making the transition to EMRs seems inevitable for health care facilities, it’s important to understand the potential benefits and challenges associated with being paperless before initiating such a large project. According to Shelman, “It is a common misconception that being paperless is a goal. Being paperless is a method of achieving a goal.”

Much of the literature refers to important advantages associated with patient safety and efficiency that drive the need for EMRs in health care, although they might be less relevant to radiation therapy. However, a number of advantages apply to radiation therapy specifically. EMR systems provide immediate access to patient information for staff members within a radiation therapy department and at other centers that share the same database. Thus, staff resources and expertise can be shared between centers or departments if required, and patients can be transferred as needed between providers. The benefits of an EMR system, however, extend beyond multicenter radiation therapy facilities.

**Time Saving**

Because all members of the radiation therapy team have immediate access to electronic records, no time is spent searching for or retrieving treatment records from various areas in the department, such as the treatment units, patient assessment clinics, or treatment planning areas. Electronic records also expedite the process when patients return for subsequent treatment courses that require past treatment information. Previous records are immediately accessible without having to order or transport charts. For example, if a nurse or physician receives telephone inquiries from patients who completed treatments, he or she can immediately access information about past treatments and care received. More than 1 health care worker can access the patient record at the same time, as well. For example, a radiation oncologist could complete documentation related to a patient assessment while a radiation therapist accesses the treatment set-up notes to prepare the room.

**Security**

There also is a security advantage to EMRs; the electronic records can be accessed only by staff members who have been given access rights. Because EMRs are kept within a secured private network and are password protected, there is no need to lock them up at the end of each day. Paper records also require physical storage space, which can be an issue in some centers and departments.

**Legibility**

Yet another advantage of EMRs in radiation therapy is the legibility of electronic documentation. Improved legibility plays a major role in error reduction. According to a July 2006 report from the Institute of Medicine, poor handwriting by medical practitioners results in more than 7000 deaths annually in the United States. Illegible notes also can lead to inefficiencies because staff must take time to decipher them or confirm the communication with the person who wrote the notes.
**Consistency**

Electronic documents can promote a more consistent and thorough approach to documentation. Paper documents permit the user to write items anywhere on the paper, in any format. Electronic document templates have form fields (e.g., check boxes, drop-down menus, and free text fields) that prompt users to enter the appropriate information in a particular format. This standardization minimizes the time spent deciphering unclear or incomplete documentation and helps ensure safe patient care.

**Cost Efficiency**

Radiation therapy is a dynamic field, and documents require revisions to reflect the latest changes to processes and procedures. EMRs offer cost savings related to efficiency and reduced use of paper and printing. Because electronic documents can be edited easily and made available immediately, there are no redesign or reprinting costs and associated delays, and no paper is wasted when versions become outdated.

**Reporting and Analysis**

Software for paperless systems offers the opportunity to gather data and statistics because the electronic information can be exported to reports. The reporting capability does not apply to documents scanned into the system (as opposed to those created in the system) but would require manual work. Reporting can provide useful information about the radiation therapy process, such as length of time required to complete a complicated treatment plan.

**Challenges**

The paperless radiation therapy center or department, despite its many advantages, is not without challenges. But processes usually can be adapted or modified to overcome most issues associated with EMRs.

As with any electronic system, there is a small risk of losing documentation. Back-up systems need to be in place for those rare occasions when computer networks are not functioning and electronic documents cannot be accessed. Further, some processes might require a number of staff members to make entries in the same documents. Computer skills vary among users, and a user might inadvertently delete entries within a document if that document is not locked down. Rigorous training is needed to ensure that data entry mistakes are minimized or eliminated, and some documents may need to be locked down only after treatment is completed.

Finally, it is important to note that certain restrictions and anomalies can occur with software that only can be rectified by upgrading software versions.

**Overview of an Electronic System**

For the purpose of this discussion, software applications from Varian Medical Systems (Palo Alto, California) are described. Differences between some paper and electronic processes are outlined in the Table.

The commercial software houses the electronic treatment record as a communication tool and enables recording and verifying of the patient’s treatment details. This record is located in a central server that is accessible to multiple users from computers with appropriate software installed. Only individuals who have been granted rights can access the system via their usernames and passwords.

The potential to compromise patient confidentiality is one of the main criticisms of electronic records, and remote access options need to be considered in EMR design. Radiation oncologists can connect to EMRs remotely using a virtual private network (VPN) when they are off-site. VPNS provide a secure connection to the EMR applications via the Internet. As an alternative, a virtual desktop or cloud computing product can allow access to Varian applications from any location using a secured 128-bit encrypted network.
Management Toolbox

Transitioning to Electronic Medical Records

Table

<table>
<thead>
<tr>
<th>Examples of Paper vs Electronic Processes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prostate Radiation Treatment for a Typical Patient with Prostate Cancer</td>
</tr>
<tr>
<td>Pre-electronic (Paper)</td>
</tr>
<tr>
<td>The radiation oncologist completes the radiation therapy paper requisition.</td>
</tr>
<tr>
<td>Simulation gathers treatment package from clerks. Simulation checks the patient scheduling system for upcoming appointments for the day. Radiation therapists initiate documentation and paperwork.</td>
</tr>
<tr>
<td>Clerk calls simulation to inform them of the patient’s arrival.</td>
</tr>
<tr>
<td>Radiation therapist conducts patient education and documents it on paper.</td>
</tr>
<tr>
<td>Simulation brings patient treatment package to dosimetry and places in the radiation oncologist’s in-box.</td>
</tr>
<tr>
<td>Radiation oncologist indicates that contours are complete in treatment planning database. Radiation oncologist documents pertinent planning details on the planning worksheet.</td>
</tr>
<tr>
<td>Planning is complete. The treatment planning database is updated to indicate the plan is ready for radiation oncologist review. Frequently, a phone call to the radiation oncologist is required.</td>
</tr>
<tr>
<td>Physicist completes plan check.</td>
</tr>
<tr>
<td>Patient checks in with clerk and patient is brought to the linear accelerator waiting area for first treatment.</td>
</tr>
<tr>
<td>Patient data is brought up on linear accelerator console for treatment. Patient identity is confirmed with paper photo.</td>
</tr>
<tr>
<td>At completion of radiation treatment, the treatment package is brought to review clinic. Patient is seen and documentation is added to treatment record.</td>
</tr>
</tbody>
</table>

as application virtualization; no data is transferred to the remote workstation and all data remains on the central server. It is important to discuss remote access options with the EMR vendor to ensure compatibility with the software used by the center or department.

Using commercial EMR software, all members of the radiation oncology team can communicate with one another and create, assign, and send electronic tasks. These tasks generally are associated with the patient’s information in the system, but other tasks also can be shared. The user can add pertinent information in the notes section of the task dialogue box and can select the care path of the patient at any time. This view displays all tasks assigned to the patient, and instantly alerts the user to the current progression of the patient’s planning or treatment stage. Most clinical areas of the department are operated by a team of individuals, so electronic task lists are intended for a specific clinical area rather than individuals. However, the radiation oncologists have specific task lists because their work
A number of other representatives should be involved in specific phases of the project, including information technology (IT), health information services (HIS), and quality and risk management personnel. IT support is required for installation and configuration of software and licenses. HIS staff must participate because radiation therapy electronic records are a part of the patient’s permanent health record. Because identification of potential risks is essential, early discussions about the project should include quality and risk management staff members. These representatives also should conduct periodic risk reviews to ensure the team can develop response strategies as the project progresses.

**Planning**

In the planning phase, the team must develop an initial plan for the paperless initiative. Priorities should be identified and roles and responsibilities of team members defined. The team also should establish a tentative project timeline and develop a responsibility plan.
matrix to ensure someone is accountable for each project activity. It is important to establish realistic deadlines consistent with the project’s goals and available resources. The implementation time varies from 1 site to the next, but it may take weeks or months, depending on the size of the center or department.

The team must determine the frequency, duration, required attendees, and priorities of team meetings, and should select 1 or 2 members responsible for setting the agenda, coordinating the meetings, and keeping the group focused. Meeting participants should document discussions and actions for future reference. In particular, team members should document the team’s rationales for process decisions so they can be referenced later.

Identifying Technical Requirements

It is essential to consider hardware and software requirements early in the planning phase. Once determined, a vendor contract should be negotiated and the software system installed, configured, and tested. These steps can take considerable time and should include configuring and testing user rights.

Software vendors can offer suggestions and assistance, and the team should consult several potential vendors before selecting one. It also is recommended to make a site visit to a paperless facility of similar size using the same software being considered. A majority of project time is spent mapping current processes and discussing potential changes to current processes. Because other paperless centers have had similar discussions already, they may provide helpful suggestions. The vendor likely will be able to supply contact information for these sites.

After conferring with possible vendors, the project team must select the most appropriate vendor system. Choosing the right vendor depends on several factors:

- Cost.
- Compatibility with current equipment.
- Staff experience with the software or similar software.
- Ease of use and reliability.
- Customization and configuration options.13,23

It is also helpful to view product demonstrations conducted by the vendor sales representatives.

Some vendors may provide temporary licenses so the project team can explore and learn about the software. Some applications have “floating” licenses, meaning they are not tied to particular computers but can be accessed by any user on any computer within the network. Once the maximum number of licenses is in use, an additional user cannot access the application until a license is freed when a user closes the application. It is important to ensure that an adequate number of licenses is secured and any anticipated future software needs are considered.

Software compatibility used in the electronic process is imperative. The paperless process also can require additional hardware such as new or upgraded personal computers (PCs), monitors, keyboards, and mice. A setup example is 2 dedicated paperless PCs for each treatment unit. A large monitor with a wireless keyboard and mouse can be used inside the treatment room to view and record setup information. The size of the monitor depends on its distance from the treatment couch and how well radiation therapists can see the screen. Any PCs stationed in the treatment room should be out of the way of the primary beam to prevent damage to the PC. Treatment planning therapists, clerks, radiation oncologists, and physicists should have dual monitors in their workspaces for simultaneous viewing of more than 1 application. An additional PC with dual monitors can be placed outside the room to view and record patient care and treatment information. The outside PC also can be used to communicate to other radiation therapy team members as needed.

Patient assessment areas can contain a dedicated computer for each staff member. Staff members must document patient assessments and monitor their electronic task pads for incoming assignments.

Developing Electronic Processes

EMR processes should model current paper practices.24 Mapping current paper processes is an excellent way to account for all steps before establishing electronic processes. Electronic documents that resemble existing paper documents will require fewer changes for staff. Mapping paper processes also facilitates process improvement. When initiating conversion to electronic records, the staff can identify potential improvements to workflow, safety, and quality. Adequate time should be scheduled in the project timeline for any electronic document revisions and for stakeholders to give feedback on draft documents.
Once mapping is complete, the team must draft electronic processes to replace the paper practices and create electronic templates to replace the paper documents. Each step of the radiation therapy process must be considered. For example, if occasional paper radiation therapy orders are filled out in new patient clinics and hand-delivered to a scheduling clerk in radiation oncology, the team can establish a standard way for the clerk to receive the documents electronically and create a template for the electronic version of these orders.

**Implementation**

**Testing and Modifying Processes**

During the implementation phase, pilot processes and documents along the care continuum should be tested. This helps the team identify potential oversights or problems before going live with the new EMR system. The pilot can be conducted using test patient information.

The team might choose to test the electronic radiation therapy order (requisition) before implementing other processes and documents. The requisition can be initiated by the radiation oncologist and transferred to a clerk for appointment scheduling. After appointments are booked, the radiation therapists who perform simulations can proceed. Testing the requisition can help the team assess how the electronic process will affect procedures and disciplines involved in radiation oncology. Some centers continue parallel paper requisitions along with the electronic records while assessing the new system. Testing is key to assessing system functionality, along with system security and scalability, or the ability to add users and patients to the system.13,25

**Training**

Nearly one-half of information system projects fail because they are not accepted by users.26 Communication is essential to gain staff support for the project. Introductory training sessions can communicate the project scope, objectives, and software terminology. The sessions also can provide the opportunity to explain the roll-out process, such as introducing an electronic radiation therapy order that might be piloted before transitioning to a completely electronic system.

Training objectives should be established to ensure all staff members are trained consistently. Objectives could include in-depth training on software functionality, specific electronic documents, and an overview of the electronic process.

Depending on the number of staff members being trained and the amount of preparation required, the team might consider identifying staff “champions.” These champions could be radiation therapists representing the treatment units, CT simulation, or treatment planning who are trained as experts in the processes, software, and electronic documents. The champions can train other staff members, provide valuable expertise when modifying processes and creating electronic templates, and offer assistance once the EMR system is in operation.

After completing introductory sessions, the site should schedule small group sessions of 2 or 3 people for hands-on training. Training details can be adjusted according to the comfort of individual staff members and their familiarity with computers. It might be more effective to focus on the essentials when training and provide more detailed training at a later date as staff members grow more comfortable with the software.

**Preparing To Go Live**

Radiation therapy departments have numerous options for going live with an EMR system, and all have advantages and disadvantages. The team initially may choose to implement 1 or 2 electronic documents to give staff time to learn the process. Or, the team might decide to implement the entire process at once to expedite the transition period. Some radiation therapy centers or departments might choose to briefly continue the paper process in tandem with the electronic EMR to minimize risks associated with flawed processes or documents. The decision depends on a number of factors, including the number of patients in the system, staff size, the amount of training required, the experience and skill set of the staff, leadership preferences, and external pressures or deadlines.

Another option is to begin the electronic process with new patients referred for CT simulation as of a specified date. This allows the staff to become comfortable with the paperless process gradually. Extra time and staff resources often are scheduled for these patients to allow for the staff learning curve. One challenge of this approach is that the department operates a paper process for some patients and an electronic process for others. As the weeks progress, however, more
and more patient EMRs will be created. After approximately 6 to 7 weeks, the entire department may be ready to operate in a completely paperless environment. Even with this gradual approach to implementation, the process can be overwhelming. Providing extra staff members and time increases the likelihood of success.\textsuperscript{13}

Close-out

In the close-out phase, the team should ensure a process is in place to sustain the project. Staff should not be given the opportunity to revert back to paper documents. Instead, the team should provide all staff with the resources, time, and support required to successfully work with the new electronic system.

There are limited reports in the literature specific to benchmarking the effects of electronic records in a radiation therapy environment. Ideally, however, the team will establish metrics to determine the impact of the EMR system and its effect on workflow processes, clinical outcomes, staff perceptions, and costs. Baseline measurements should be established early on while the department still is working with paper processes for comparison.

All staff members can ask team members for help regarding urgent issues or questions related to the paperless transition. Team members can encourage the staff to document nonurgent feedback, suggestions for improvement, or problems with the software, processes, or documents. The team can collect this feedback regularly and make process changes and modifications as needed.

Conclusion

Making a smooth paperless transition requires detailed planning and preparation from all stakeholders. The initiation phase involves identifying these stakeholders, creating a team, and developing a project plan. The planning phase includes mapping paper practices, developing electronic processes, and securing, configuring, and testing the hardware and software. During the implementation phase, the team should decide on training objectives, deliver training, and prepare to go live with the EMR system. Finally, the close-out phase requires continual monitoring of the project and modification of processes as needed. With enough planning, support, and leadership, transitioning to an EMR system is an obtainable goal, and one that should be celebrated.

References


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As part of their preclinical preparation, radiation therapy students complete a range of patient care activities that includes medical equipment identification, patient positioning, taking vital signs, and performing clinical procedures. Aside from patient physical indicators, basic patient care also includes identifying the 5 stages of grief, a model introduced by psychiatrist Elizabeth Kübler-Ross, MD, in her 1969 book *On Death and Dying.*

To the professional radiation therapist, patient care also encompasses the psychosocial effects of treatment that extend beyond the stages of grief, including emotional, behavioral, mental, environmental, spiritual, and interactional. Although radiation therapists are trained to focus on the physiological aspects of administering radiation therapy, they often overlook the cancer patient’s psychosocial needs because they are insufficiently prepared to identify, understand, and intercede in this area of patient care.

Prediction, identification, and intervention to address patient psychosocial stress indicators prior to and during radiation treatment can improve the patient’s quality of life; however, patient care training lacks information that helps radiation therapists identify these indicators. Patient stress is experienced by most, if not all, cancer patients. It shows at the beginning of treatment and continues throughout, eventually requiring support and intervention. By identifying these concerns and sources of distress, radiation therapists can better support patients physiologically and psychologically, and can become stronger patient advocates as part of the radiation oncology health care team. Ultimately, this could reduce unnecessary patient stress and anxiety.

### Adjusting and Coping

Crisis adjustment, or psychosocial adaptation, to cancer is an ongoing process where the patient attempts to manage emotional distress, solve specific cancer-related problems, and gain some degree of control over cancer-related life events. Critical phases of crisis adjustment appear throughout the lifecycle of the cancer patient: diagnosis, treatment (ie, surgery, radiation therapy, and chemotherapy), post-treatment, remission, recurrence, palliative care, and survivorship.

The patient’s coping method has a direct bearing on the efficacy of treatment. In general, patients who adjust successfully remain focused on the physical treatment of cancer once the psychological stressors are minimized. On the other hand, cancer patients who do not adjust well can become detached and withdrawn from society and tend to focus on the psychological aspect of well-being rather than the physical.

Few cancer patients exhibit healthy psychological adjustment to their diagnosis, and for many cancer patients, poor adjustment can lead to psychosocial disorders ranging from stress to depression. The relatively small proportion of cancer patients showing successful adjustment to cancer-associated psychosocial indicators are able to minimize disruptions in their lives, regulate emotional distress, and remain actively...
involved in aspects of life that continue to hold meaning and importance.8

Training
By definition, therapy means to treat. Regardless of specialization, the therapist is bound by occupational ethics and standards that focus on treatment of the patient. As an agent between the cancer patient and oncologist, the radiation therapist has a duty not only to address the physical aspects of patient care, but also to gain insight into the psychosocial aspects. Radiation therapists must be able to integrate their understanding of cancer patients’ basic psychosocial needs into their role as cancer care managers. Unfortunately, little radiation therapist training is provided concerning patient psychosocial issues, despite the critical responsibilities of the position.

In 2007, the Department of Psychiatry and Behavioral Sciences at Memorial Sloan-Kettering Cancer Center introduced a new standard of patient care that mandated psychosocial aspects be integrated into routine cancer care. The standard requires patients to be screened during their initial visit to assess their psychosocial needs and includes a treatment plan to address increased anxiety, post-traumatic stress, and depression.9

Psychosocial Disorders
Between 35% and 45% of all cancer patients experience significant emotional distress.10 The term “psychosocial” has a more expansive meaning than the terms “emotional” or “psychological.” The root phrase psycho relates to the mind, and social reflects the relationships people have with family and society.11

Anxiety, a leading psychosocial stressor, can be identified throughout cancer treatment and can fluctuate depending on severity of diagnosis and treatment. In a sample of 320 adult cancer patients, researchers found that 44% reported some anxiety and 23% reported significant anxiety.12 Possible causes of anxiety range from insufficient pain medication to substance withdrawal (eg, alcohol, opioids, or sedatives).

Psychological distress can vary by type of cancer, amount of pain, prognosis, and other factors. Studies have documented the presence of symptoms meeting the criteria for post-traumatic stress disorder (PTSD) and post-traumatic stress symptoms (PTSS) in adults and children with cancer, as well as in the parents of children diagnosed with cancer.13 Left undiagnosed, PTSD and PTSS can contribute to other psychosocial stressors that affect family, work, and other societal roles. PTSD and PTSS also could affect adherence to medical treatment and medical advice, leading to adverse medical outcomes.14

Cancer patients with advanced disease (typically inpatient) can exhibit symptoms of cognitive disorders and delirium, causing distress not only for the patient but also for the care providers and family members. Delirium is a global cerebral dysfunction characterized by disordered awareness, attention, and cognition.14 Occurrence rates of cognitive disorders and delirium can range from 28% to 48% in patients with advanced cancer.14 Delirium can be recognized in many advanced cancer patients and can be reversed with proper identification and treatment.

Identifying Priorities of Psychosocial Need
Because radiation therapists spend a majority of time with the patient, it is crucial they identify and investigate suspected psychosocial issues and communicate findings to the health care team for corrective action.

In a 1989 survey of Canadian radiation therapy professionals, Taenzer and Fisher asked the therapists to respond to a list of open-ended questions concerning perceived patient psychosocial issues. Fear of dying, fear of disfigurement, and financial concerns were the top 3 issues listed. Respondents then were asked to list and rank perceived patient psychosocial issues in the following categories: personal-emotional concerns, family-social-financial concerns, concerns related to health care system interactions, and concerns related to radiation therapy treatment. The most common issues listed in regards to frequency and patient distress were fear of side effects, fear of the unknown, fear of dying, and not knowing what to expect when undergoing radiation therapy.7 Survey respondents also were asked to rank the psychosocial issues they were able to help patients with most. Respondents felt they were least able to help with patients’ fear of dying, fear of a painful death, and fear of an unknown future. They felt most helpful with patients’ embarrassment related to washing restrictions, fears related to the treatment room and machinery, and adapting lifestyle to treatment demands.7

The radiation therapists surveyed expressed the need for additional skills in listening, providing emotional support, communicating, and understanding the services
available. The survey results demonstrated that patients' most difficult concerns are also the hardest for radiation therapists to address. Understanding patients' daily issues provides valuable insight to the health care team. Thus, the skills needed to understand patient perception could help initiate patient care training programs in the radiation therapy profession.

**Psychosocial Indicators and Radiation Therapy**

Psychosocial stressors specific to radiation therapy include but are not limited to physical efficiency, anxiety, and fatigue. Psychosocial disorders presented by radiation therapy patients can vary by diagnosis, stage of disease, patient age, and treatment modality. One study showed that women with breast cancer diagnoses demonstrated the highest stress before and during treatment. Younger patients displayed a decrease in anxiety throughout treatment, whereas elderly patients demonstrated an increase in anxiety throughout the course of radiation therapy. Head-and-neck cancer patients present with depression and anxiety before beginning radiation therapy, which can increase significantly throughout treatment because of the extent and variety of side effects they experience. In a study of 40 radiation therapy patients with nonmetastatic head-and-neck cancer (50% receiving chemotherapy), approximately 50% presented with mild to severe depression. Depression also can intensify side effects associated with radiation therapy, such as fatigue and weight loss, and may cause sleep deprivation.

Fatigue is the most common and ongoing symptom of radiation therapy affecting patient quality of life. A prospective study from March 2004 to September 2005 showed that 90 patients with cancer who were receiving radiation therapy, 87% showed signs of fatigue that increased gradually over the course of treatment and peaked during the final week of treatment. Unlike normal feelings of fatigue, radiation-induced fatigue can be debilitating by reaching levels that affect physical and social activities, even discontinuities or termination of treatment.

**Conclusion**

Despite the radiation therapist's critical role in identifying patient psychosocial needs, therapists receive little training and information to support this responsibility. The radiation therapist must be able to identify the diversity of psychosocial variables that inflict cancer patients so he or she can facilitate total patient care. Understanding a cancer patient's physical and emotional needs is a crucial part of this care. By better identifying and understanding patient psychosocial issues and needs, the radiation therapist can treat beyond the physical implications of cancer and help patients achieve a better quality of life throughout their treatment.

**References**

My Perspective

Mitchell, Lozano


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Extrapulmonary small cell carcinoma (EPSCC) is a rare form of cancer that arises in sites such as the stomach, small bowel, salivary glands, esophagus, kidney, and breast. Like its pulmonary counterpart, EPSCC can be aggressive in growth rate, has a tendency to metastasize, and is difficult to cure. Treatment of EPSCC can vary by location, extent of disease, and patient preference, and the ideal treatment paradigm has yet to be universally defined or accepted. Although there is little comparative data regarding the management of this rare cancer, literature describing institutional trends and outcomes regarding EPSCC treatment is available.

**Background**

In 1930, Duguid and Kennedy described EPSCC, and the cancer has been discovered in nearly every organ system since that time, although it is most commonly found in the gastrointestinal tract and the genitourinary system. EPSCC has an overall incidence of 0.1% to 0.4% and makes up only 2.5% to 5% of small cell cancers. Patients with EPSCC tend to be men. The disease presents during the sixth or seventh decade of life, and a correlation exists between EPSCC and a history of smoking and alcohol consumption. Brennan et al found that 32% of EPSCC patients in their study were past smokers and 19% were current smokers. In addition, 56% of EPSCC patients in a study by Haider et al had a history of smoking.

EPSCC is a poorly differentiated neuroendocrine tumor which arises from multipotential stem cells. Studies have found that histological criteria similar to pulmonary small cell carcinoma may be applied to EPSCC biopsy samples. The presence of round or spindle-shaped small cells with dense nuclei and sparse cytoplasm are indicative of small cell carcinoma.

Patient evaluation and workup should include a history and physician examination, computed tomography (CT) scan, bronchoscopic examination, sputum cytology analysis, and positron emission tomography (PET) or magnetic resonance (MR) imaging. The National Comprehensive Cancer Network recommends an abdominal and chest CT scan for proper staging workup and suggests considering a brain MR or CT scan and a pelvic CT scan. Studies describe the staging of EPSCC to be similar to staging of pulmonary small cell carcinoma.

Although there is no standard staging system for EPSCC, studies typically use a 2-stage system introduced by the Veterans’ Administration Lung Study Group. This system groups patients into 1 of 2 categories: limited or extensive disease. Limited-stage disease is defined as being confined to the primary site, with or without lymph node involvement, and is safely encompassed within 1 radiation therapy treatment portal. Extensive-stage disease is defined as having spread beyond locoregional boundaries and is not safely encompassed in 1 treatment portal. It has been suggested that using
patients received a single-modality treatment regimen. Only 18% of patients received 3 forms of treatment including surgery, concurrent chemotherapy and radiation therapy, and radiation therapy alone experienced 18-month and 28 months, while those treated with either surgery or radiation therapy alone experienced 18-month and 11-month median survival, respectively. Brenn et al investigated treatment patterns for patients with limited-stage EPSCC and found that 30% of patients received concurrent chemotherapy and radiation therapy, and 34.5% received 3 forms of treatment including surgery, chemotherapy, and radiation therapy. Only 18% of patients received a single-modality treatment regimen. EPSCC can be surgically resected depending on the size and location of the lesion. Typically this is reserved for patients with limited-stage disease. Haider et al reported 55% of patients with limited-stage disease and 26% of patients with extensive-stage disease had surgery. When patients have limited-stage disease confined to a single organ, surgery can be curative. There is evidence that surgical resection can result in longer disease-free survival, although it is primarily for locoregional control. Surgery often is performed in combination with chemotherapy because patients treated with surgery alone tend to have systemic recurrence.

Chemotherapy has become a mainstay for treating EPSCC. The literature described platinum- and doxorubicin-based chemotherapy regimens as effective for limited- and extensive-stage EPSCC. Primary regimens include cisplatin or carboplatin coupled with etoposide or irinotecan, similar to pulmonary small cell carcinoma programs. The National Comprehensive Cancer Network chemotherapy regimens consist of the drugs cisplatin, etoposide, and carboplatin for patients with limited-stage disease. The chemotherapy treatment regimen for patients with extensive-stage EPSCC is similar to that of limited-stage patients, but it should include more cycles of chemotherapy and irinotecan. In a study of patients with limited- and extensive-stage EPSCC, 3 to 4 cycles of chemotherapy treatment were administered using cisplatin and etoposide or carboplatin and etoposide. The limited-stage patient group received an average of 4 cycles; the extensive-stage patient group received 3 cycles. The researchers found a positive correlation between the number of chemotherapy cycles and overall survival. Concurrent chemotherapy is recommended for limited-stage EPSCC, and chemotherapy alone often is used for managing extensive-stage EPSCC.

Radiation therapy has been described as an adjuvant treatment, which tends to improve local control. Radiation therapy doses range from 4000 centigrays (cGy) to 6400 cGy. However, in some studies the most common dose was 5000 cGy given in 25 fractions. Brenn et al found that patients with limited-stage disease who received adjuvant radiation therapy treatment experienced a 1-year recurrence-free survival rate of 42.3% and were less likely to experience loco-regional failure compared to those treated with chemotherapy alone.

Treatment for limited- and extensive-stage pulmonary small cell carcinoma in patients showing no evidence of brain metastasis includes consideration for prophylactic cranial irradiation (PCI). PCI also has relatively few side effects, making it a reasonable treatment option. The same PCI regimens for pulmonary small cell carcinoma are typically used for patients with EPSCC.

Studies comparing results of PCI for patients with pulmonary small cell carcinoma have found that patients had a significantly lower failure rate in the brain and an overall survival advantage compared to those who did not receive PCI. Reported data suggests that the acute and long-term neurocognitive effects of PCI were less than expected and that the benefits of PCI far outweigh its drawbacks. Rubenstein et al found that 17% of patients receiving PCI experienced acute side effects such as nausea and fatigue, while 7% experienced late complications as a result of PCI. One study administered PCI to 7 patients with EPSCC, 6 of whom were diagnosed with limited-stage
Case Summary

Radiation Oncology Management of Extrapulmonary Small Cell Cancer

disease. None of the patients had experienced brain metastasis at the time of their follow-up analysis.1 Including patients with both limited- and extensive-stage EPSCC, Cicin et al reported an overall survival of 32 months, and Hueser et al reported between 9.2 and 14 months.3-6 Brennan et al

Box
Case Study

In June 2010, a 71-year-old man started to experience pain in the lower pelvis and perineum. The patient eventually developed blood in his urine and some clot passage, which progressed to urinary obstruction. He presented to the emergency room in September 2010. His medical history was significant for prostate cancer and basal cell carcinoma of the skin. The patient underwent a prostatectomy in 2001 and experienced undetectable prostate-specific antigen levels ever since. He also underwent Mohs surgery for basal cell carcinoma. In addition, the patient had a 20 pack-year smoking history but had quit smoking 35 years earlier.

Initial workup included a cystoscopic examination of the bladder mucosa, which was normal, but the patient had a large anterior rectal wall mass approximately 4.7 cm in size. A biopsy was performed and pathology described a highly cellular sample with hyperchromatic chromatin, a high nuclear-to-cellular ratio, and nuclear molding. Frequent mitotic figures and apoptotic cells were present. An immunohistochemical panel found the tumor cells positive for CAM 5.2 and AE1/AE3 — stains used for identifying cells of epithelial origin — and strongly positive for CD56, a marker for neuroendocrine differentiation. The cells also were negative for prostate-specific antigens and synaptophysin P63, cytokeratin 5/6, and CDX2 — stains specific to other cancers. This combination of features was thought to be consistent with a poorly differentiated neuroendocrine carcinoma, also known as small cell carcinoma.

The patient underwent a staging PET-CT examination and MR head scan in September 2010. The PET-CT images revealed a soft tissue, fluorodeoxyglucose (FDG) avid mass located in the right and posterior pelvis. The mass extended inferiorly toward the floor of the pelvis along the sidewall toward the posterior region of the penile bulb. There was also an FDG-avid focus located in the inferior right ischium consistent with local bony metastasis. The MR head scan showed no evidence of disease. The CT scan of the lungs showed a lesion in the right middle lung, which was negative for FDG activity and considered benign. Based on these findings, the patient was diagnosed with a small cell carcinoma in the pelvis, classified as limited-stage based on the ability to safely cover the disease in a single radiation portal.

Because of the location and extent of the patient’s disease, he was not eligible for surgical resection. The patient was offered chemotherapy combined with radiation therapy. He received 2 cycles of cisplatin and etoposide. A second PET-CT examination evaluated his treatment response, and he was found to have had an excellent initial response to chemotherapy. He received 2 more cycles of chemotherapy followed by 2 final cycles of chemotherapy concurrent with radiation therapy treatment.

The patient underwent a CT scan for radiation therapy treatment planning. To minimize dose to the small bowel, a prone positioning belly board with a prone head pillow was used. A foam cushion was placed under his ankles for comfort.

A 3-D conformal treatment plan was created using a 4-field technique (anteroposterior, posterolateral, and left-lateral) and 15-megavolt (MV) photons. To minimize bowel dose, 30° wedges were used on the left and right laterals. The planning target volume and draining regional lymph nodes were prescribed a dose of 4600 cGy in 23 fractions delivered once daily, Monday through Friday, over 30 days. After completion of the first course of radiation treatment, the planning target volume was increased to 1400 cGy in 7 fractions using the same position, 4-field technique, 30° wedges, and 15-MV photons. Total dose was 6000 cGy in 30 fractions over 41 days.

The patient then elected to have PCI. His treatment setup included a clear, plastic angled head rest and a thermoplastic mask. Whole-brain radiation treatment was delivered in 10 fractions of 250 cGy using 6-MV photons. Custom blocked fields were created to minimize dose to orbits and oral cavity.

The patient tolerated radiation therapy well with only slight fatigue and some diarrhea that was controlled with loperamide. He was hospitalized once with neutropenic fever during his course of therapy. The patient showed no evidence of disease at his 6-month follow-up.
reported a 5-year survival rate of 25.4% for patients with limited-stage disease and 0% for patients with extensive-stage disease.\(^1\) Similarly, Haider et al reported a 5-year survival rate of 31% in patients with limited-stage disease, while patients with extensive-stage disease had a 2% 5-year survival rate.\(^6\)

**Conclusion**

EPSCC is an aggressive disease, and there is no consensus on the best treatment to cure or control it. Because of its rarity, very few multi-institutional studies have been conducted and very little collective data has been released. As more becomes known through further research about EPSCC, a standard of care can be established to treat this deadly disease more effectively.

**References**


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