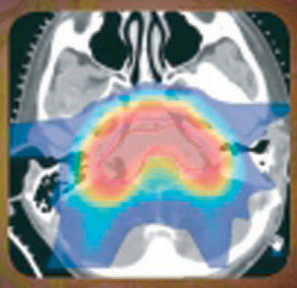
FIFTH EDITION

WASHINGTON AND LEAVER'S PRINCIPLES AND PRACTICE OF Radiation Therapy



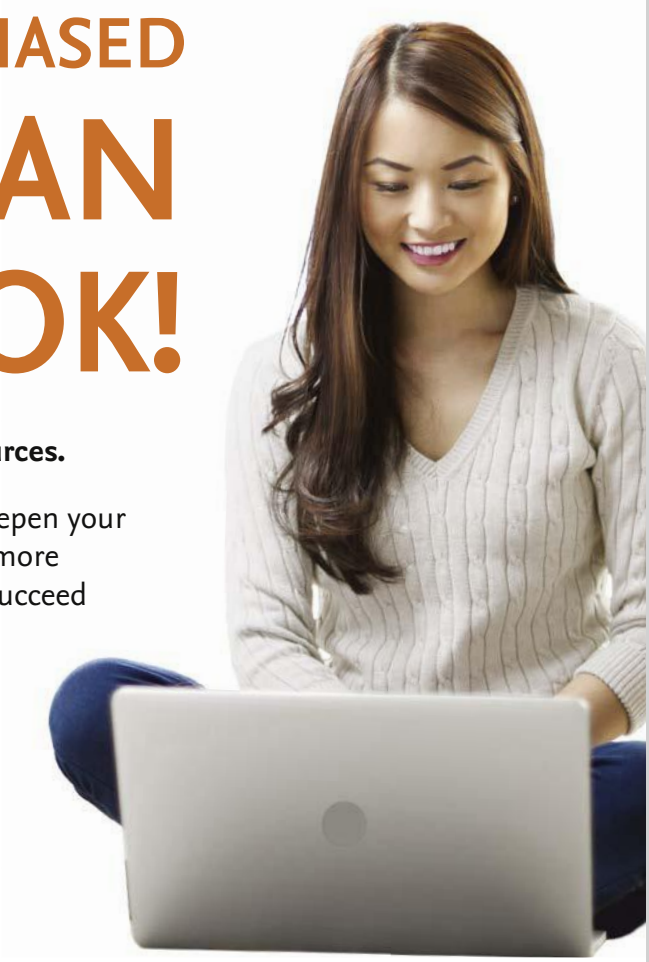
WASHINGTON
LEAVER
TRAD

ELSEVIER

Evolve® | Student Resources on Evolve
Access Code Inside

Evolve®

YOU'VE JUST PURCHASED MORE THAN A TEXTBOOK!



Enhance your learning with Evolve Student Resources.

These online study tools and exercises can help deepen your understanding of textbook content so you can be more prepared for class, perform better on exams, and succeed in your course.

Activate the complete learning experience that comes with each NEW textbook purchase by registering with your scratch-off access code at

http://evolve.elsevier.com/Washington/principles

If your school uses its own Learning Management System, your resources may be delivered on that platform. Consult with your instructor.

If you rented or purchased a used book and the scratch-off code at right has already been revealed, the code may have been used and cannot be re-used for registration. To purchase a new code to access these valuable study resources, simply follow the link above.

Place Sticker Here

REGISTER TODAY!

ELSEVIER

You can now purchase Elsevier products on Evolve!
Go to evolve.elsevier.com/shop to search and browse for products.

2019v1.0

WASHINGTON AND LEAVER'S PRINCIPLES AND PRACTICE OF Radiation Therapy

This page intentionally left blank

FIFTH EDITION

WASHINGTON AND LEAVER'S

PRINCIPLES AND PRACTICE OF

Radiation Therapy

Charles M. Washington,
EdD, MBA, RT(T), FASRT
Senior Director
Radiation Oncology
Memorial Sloan Kettering Cancer Center
New York, New York

Dennis Leaver,
MS, RT(R)(T), FASRT
Professor Emeritus
Department of Biology
Southern Maine Community College
South Portland, Maine

Megan Trad,
PhD, MSRS, RT(T)
Associate Professor
Radiation Therapy
Texas State University
San Marcos, Texas

ELSEVIER

Elsevier
3251 Riverport Lane
St. Louis, Missouri 63043

WASHINGTON AND LEAVER'S PRINCIPLES AND PRACTICE OF RADIATION THERAPY, FIFTH EDITION
ISBN: 978-0-323-59695-4

Library of Congress Control Number: 2019953768

Executive Content Strategist: Sonya Seigafuse
Senior Content Development Manager: Lisa P. Newton
Senior Content Development Specialist: Tina Kaemmerer
Publishing Services Manager: Deepthi Unni
Project Manager: Haritha Dharmarajan
Designer: Brian Salisbury

Printed in China

Last digit is the print number: 9 8 7 6 5 4 3 2 1

To those who have run and continue to run the race against cancer.
We sincerely hope those who read this work will grow in the knowledge
and understanding necessary to provide direction, care,
and compassion to their patients, family, and supportive friends.
Let us not grow tired in running our own race,
but instead encourage those around us.

This page intentionally left blank

CONTRIBUTORS

Robert D. Adams, EdD, MPH, FAAMD, FASRT
Assistant Professor
Radiation Oncology
University of North Carolina
Chapel Hill, North Carolina

Lisa Bartenhagen, MS, RT(R)(T) ARRT
Department Chair and Program Director
Medical Imaging and Therapeutic Sciences
University of Nebraska Medical Center
Omaha, Nebraska

E Richard Bawiec Jr., MS
Senior Medical Physicist, Varian Medical Systems. Barling, AR. Palo Alto, California

Lior Zvi Braunstein, MD
Assistant Attending
Radiation Oncology
Memorial Sloan Kettering Cancer Center
New York, New York

Leila Bussman Yeakel, MEd, RT(R)(T)
Program Director and Assistant Professor
Radiation Therapy Program
Mayo Clinic School of Health Sciences
Rochester, Minnesota

Jessica Church, MPH, RT(R)(T), CMD
Assistant Professor
School of Health Professions
The University of Texas MD Anderson Cancer Center
Houston, Texas

Gil'ad N. Cohen, MS
Senior Physicist
Medical Physics
Memorial Sloan Kettering Cancer Center
New York, New York

Annette M. Coleman, MA, RT(T)
Senior Project Manager
Portfolio Management, Oncology Informatics Elekta
Sunnyvale, California

Laura D'Alimonte, MRT(T), BSc, MHSc
Clinical Practice Manager
Radiation Therapy
Windsor Regional Hospital
Windsor, Ontario
Canada

Lawrence T. Dauer, PhD
Associate Attending Physicist
Department of Medical Physics, Department of Radiology
Memorial Sloan Kettering Cancer Center
New York, New York

Lisa DiProspero, MRT(T), BSc, MSc
Director, Practice-Based Research and Innovation
Director, Education Research Unit
Assistant Professor, Department of Radiation Oncology, University of Toronto
Sunnybrook Health Sciences Centre
Toronto, Ontario Canada

Erin Gillespie, MD
Radiation Oncologist
Radiation Oncology
Memorial Sloan Kettering Cancer Center
New York, New York

Amy Heath, MS, RT(T)
Program Manager, Radiation Therapy
Radiation Oncology
UW Health
Madison, Wisconsin
Adjunct Faculty
Radiation Therapy Program
University of Wisconsin – La Crosse
La Crosse, Wisconsin

Jana Koth, MPH
Clinical Education Coordinator
Radiation Therapy Program
University of Nebraska Medical Center
Omaha, Nebraska

Ronnie G. Lozano, BS, MSRS, PhD
Chair and Associate Professor
Radiation Therapy Program
Texas State University
San Marcos, Texas

Mazur Lukasz, PhD
Assistant Professor and Director of Division of Healthcare Engineering
Radiation Oncology, School of Medicine
University of North Carolina
Chapel Hill, North Carolina;
Assistant Professor
Carolina Health Informatics Program and School of Information and Library Science
University of North Carolina
Chapel Hill, North Carolina

Heather Mallett, MBA, RT(T)
Program Director
Radiation Oncology
Northwestern Memorial Hospital
Chicago, Illinois

James Mechalakos, PhD
Attending Physicist
Medical Physics
Memorial Sloan Kettering Cancer Center
New York, New York

Matthew Palmer, MBA, BA, CMD
President and Chief Operating Officer, Legion Healthcare Partners, Houston, Texas

Simon Powell, MD, PhD
Chair
Radiation Oncology
Memorial Sloan Kettering
New York, New York

Kameka Rideaux, MBA, BS(R)(T)
Senior Program Manager
Global Site Solutions VPT
Varian Medical Systems
Palo Alto, California

Narayan Sahoo, PhD
Professor
Radiation Physics
The University of Texas MD Anderson Cancer Center
Houston, Texas

Zachary Smith, MBA, RT(R)(T)
Director
Radiation Oncology/Respiratory Care
Baton Rouge General Pennington Cancer Center
Baton Rouge, Louisiana

Amanda Sorg, MLS, R(T), (CT)
Program Director
Radiation Therapy
Indiana University Northwest
Gary, Indiana

Maria Thompson, BS, RT(T)
Clinical Coordinator
OHSU Radiation Therapy Program
Oregon Health and Science University
Portland, Oregon

Kristi L. Tonning, BS, MS
Director
Radiation Therapy Program
Oregon Health and Science University
Portland, Oregon;
Assistant Professor
Department of Radiation Medicine
Oregon Health and Science University
Portland, Oregon

Nora Uricchio, MEd, RT(R)(T)
Program Director
Health Careers
Manchester Community College
Manchester, Connecticut

Melissa R. Weege, MS, RT(T), CMD
Radiation Therapy Program Director
Health Professions
University of Wisconsin – La Crosse
La Crosse, Wisconsin

Ana Weeks, MSc
Lead Product Owner
VisionRT
London, United Kingdom

Bettye Wilson, MA Ed. RT(R)(CT), RDMS, FASRT
Associate Professor Emerita
Critical and Diagnostic Care
University of Alabama at Birmingham
School of Health Professions
Birmingham, Alabama;
Adjunct Faculty
Radiography
Arizona Western College
Yuma, Arizona

REVIEWERS

Carol Chovanec, MS, RT(T)
Radiation Therapy Program Director
Bergen Community College
Paramus, New Jersey

Laura D'Alimonte, MRT(T), BSc, MHSc
Clinical Practice Manager
Radiation Therapy
Windsor Regional Hospital
Windsor, Ontario
Canada

Becky Dodge, PhD, RT(R)(T)
Assistant Professor/Coordinator
Master of Health Science Program
Washburn University
Topeka, Kansas

Anna Elizabeth Drew, RT(R)(CT)(T)
Radiation Therapist
Radiation Oncology
Northern Light Health
Cancer Center of Maine
Brewer, Maine

Janelle Duquette, BSc, MRT(T)
Faculty Service Officer
Radiation Therapy Program
University of Alberta
Edmonton, Alberta
Canada

Ruth M. Hackworth, MS, RT(R)(T)
Program Director, Radiation Therapy
The Ohio State University
James Cancer Hospital
Columbus, Ohio

Leia Levy, EdD, RT(T)
Program Director and Assistant Professor
University of St. Francis
Joliet, Illinois

Brian Liszewski, MRT(T), BSc
Radiation Therapist
Department of Radiation Oncology
University of Toronto
Toronto, Ontario
Canada

Don McCoy, RT(T)
Associate Professor
Community College of Denver-School of Health Sciences
Denver, Colorado

Amy Carson VonKadich, MEd, RT(T)
Department Chair
Diagnostic Medical Imaging
NHTI: Concord's Community College
Concord, New Hampshire

This page intentionally left blank

PREFACE

Since the first edition of this text was published in 1996, the field of radiation therapy has experienced tremendous growth. Improvements in conformal treatment planning, intensity-modulated radiation therapy, image-guided radiation therapy, particle therapies, adaptive therapies, brachytherapy, and patient immobilization have all allowed the radiation therapy team to enhance and improve clinical outcomes. More integrated electronic charting has allowed the entire radiation therapy team to improve treatment delivery documentation and quality assurance practices. Although the face of radiation therapy has evolved through these advances, this textbook remains committed to its original purpose. It is still designed to contribute to a comprehensive understanding of cancer management, improve clinical techniques involved in delivering a prescribed dose of radiation therapy, and apply knowledge and complex concepts associated with radiation therapy treatment planning and delivery. As the methods of delivering a prescribed dose of radiation therapy have expanded and improved, so has the effort to localize, plan, and deliver accurate daily treatment.

NEW TO THIS EDITION

Since the fourth edition, a new chapter has been added, and several chapters have been consolidated and additional information included. The infection control chapter has been divided into two to discuss infection as it relates to the person and infection's impact on the radiation oncology department. A new Advanced Procedures chapter has been developed to give further insight into the increasing complexity of radiation-based care delivery. Color images are now used throughout the text to better demonstrate key aspects that are not easily conveyed in grayscale.

LEARNING AIDS

Pedagogical features designed to enhance comprehension and critical thinking are incorporated into each chapter. Elements retained from the previous editions include the following:

- Chapter Outlines
- Key Terms lists
- Spotlight boxes that highlight key information and/or direct readers to more information on important topics
- Bulleted chapter summaries for easier reference
- An updated Glossary that includes significant terms from all chapters
- Review Questions
- Questions to Ponder

Of particular note are the Review Questions and Questions to Ponder at the end of each chapter. Review Questions reinforce the cognitive information presented in the chapter, helping the reader incorporate the information into the basic understanding of radiation therapy concepts. The Questions to Ponder are open-ended, divergent questions intended to stimulate critical thinking and analytic judgment. Answers to the Review Questions are found on the student Evolve website.

In addition, each chapter offers a reference list, giving the reader additional information sources. In each edition, the focus of every chapter has been to present the comprehensive needs of the radiation therapy management team. In fact, dozens of experts in the field have contributed to this new edition, including radiation therapists, medical dosimetrists, physicians, physicists, radiation oncologists, nurses, and radiation therapy students.

ANCILLARIES

For Instructors

A robust instructor ancillary suite is available online on the Evolve website, and includes the following:

- Test Bank of approximately 900 questions in ExamView format
- PowerPoint presentations for each chapter
- Image collection of all figures from the book

For Students

The student site contains the Answer Key to the Review Questions from the text.

Charles M. Washington
Dennis Leaver
Megan Trad

This page intentionally left blank

ACKNOWLEDGMENTS

We are grateful to the contributors of the chapters and for the reviewers who offered helpful feedback and suggestions. We also offer special thanks to the editorial staff at Elsevier for their patience and valuable contributions during the preparation and production of this work.

With this edition, we are pleased to introduce our third editor, Dr. Megan Trad, who is an associate professor at Texas State University. Megan serves on several national professional committees and continues to promote the field of radiation therapy. Her attention to detail and knowledge of radiation therapy principles augments the fifth edition of this work.

We would like to acknowledge and thank Dennis Leaver, one of the founding editors of the textbook, for his efforts in shaping radiation therapy education over the last 25 years. His pioneering spirit helped the educational field of radiation therapy transition from resources originally written for physicists and physicians, towards a focused effort of more than 5200 printed pages with over 200 separate contributors through five editions. A majority of that work was contributed by radiation therapists. His impact on the profession is undeniable.

Finally, it is our hope the expanded knowledge and progress in treatment planning, delivery, and patient care outlined in this work will ultimately enrich the patient's quality of life and reduce suffering from the effects of cancer.

Charles M. Washington
Dennis Leaver
Megan Trad

This page intentionally left blank

CONTENTS

This page intentionally left blank

1

Cancer: An Overview

Melissa R. Weege

OBJECTIVES

- Discuss how the changing theories of cancer affect treatment choices and outcome.
- Discuss how patient-focused care will provide an optimum treatment environment.
- Differentiate between benign and malignant tumors.
- Differentiate between stage and grade of a tumor.
- Explain what information physicians would need to know about a patient and his or her cancer to decide on an appropriate plan of treatment.
- Design a chart that details the strengths and weaknesses of the three major cancer treatments: radiation therapy, surgery, and chemotherapy.
- Discuss how each member of the radiation oncology team contributes to effective patient care and treatment.

OUTLINE

KEY TERMS

Adenocarcinoma
Adjuvant therapy
Anaplastic
Benign
Biopsy
Carcinomas
Cellular differentiation
Chemotherapeutic agents
Clinical staging
Epidemiology
Etiology
Exophytic
False negative
False positive
Grade
Immunotherapy
In situ
Interferon
Intrathecal
Malignant
Medical dosimetrist

Medical physicist
Metastasize
Natural history
Necrosis
NED (no evidence of disease)
Neoadjuvant therapy
Oncogenes
Palliation
Pathologic staging
Phase I studies
Phase II studies
Phase III studies
Phase IV studies
Port-a-cath
Posttherapy staging
Prognosis
Prospective study
Radiation oncologist
Radiation therapist
Radioprotectors
Radiosensitizers
Restaging
Retrospective studies
Sarcomas
Sensitive
Sentinel node
Simulation
Somatic cells
Systemic treatment
Targeted therapies
Therapeutic ratio
Tumor board
Tumor staging

Radiation therapy is the medical specialty that uses ionizing radiation to treat cancer and some benign diseases. The goal of radiation therapy is to deliver the maximum amount of radiation needed to kill the cancer while sparing normal surrounding tissue, also known as the **therapeutic ratio**.[1] To accomplish this goal, radiation therapy relies heavily on physics and biological sciences, including radiobiology and computer science. The technological and medical advances during the last 30 years have thrust radiation therapy into a new and exciting era in which the highest level of accuracy and the ability to greatly reduce dose to the normal structures is possible. However, it is important to remember that although the technology and equipment are advanced and exciting, the focus of radiation is on the person diagnosed with disease. The focus of the **radiation therapist** remains the patient, providing quality care, performing the daily radiation therapy treatments, educating, making referrals as needed, and making daily assessments. A meaningful, daily connection with the patient is as important as any other task the therapist accomplishes. Patients and their families should be seen as the most important focus of a radiation therapist's work.

PATIENT PERSPECTIVE

Although cancer is often a curable disease, the diagnosis is a life-changing event. In studying the various aspects of neoplasia, care providers can easily lose sight of the person behind the disease. The patient must be the focal point of all of the radiation therapist's actions. The highest level of quality care results from an in-depth knowledge of the disease process: psychosocial issues, patient care, and principles and practices of cancer management, including knowledge of radiation therapy as a treatment option. This knowledge provides the radiation therapist with the tools necessary for optimal treatment, care, and education of the cancer patient. Care that does not consider the whole person is unacceptable. Patient satisfaction has always been important in healthcare and continues to be a measured outcome in many cancer centers. Famiglietti et al[2] conducted a patient satisfaction survey where data were collected from 8069 patients receiving radiation treatments. Each question was rated on a 10-point Likert scale and analyzed for the patient's overall satisfaction. The results of this study align with other published findings that the most important determinant of patient satisfaction is the patient-provider relationship. In many healthcare settings, the provider is best defined as the physician. However, in this study, which focused on radiation oncology, the radiation therapist's relationship with patients was found to be the most significant contributor to overall patient satisfaction. The two variables with the greatest effect on patient satisfaction were the care provided by radiation therapists and pain management.[2] A significant connection with the patient each day is as important as any other task the therapist accomplishes during the delivery of a prescribed course of radiation therapy.

The Person Behind the Diagnosis

When providing treatment for a large number of people in whom cancer develops, care providers can easily forget that the patient has a life outside of treatment. The patient's concerns and worries continue, adding to the emotional, social, psychological, physical, and financial burdens that accompany a cancer diagnosis. In addition, other medical concerns unrelated to cancer may complicate treatment and further burden the patient. By the time a patient ends up in radiation therapy, they have seen numerous doctors and may have many other appointments scheduled.

Factors such as patient age, culture, religion, support systems, education, and family background play important roles in medical treatment compliance, attitudes toward treatment, and responses to treatment. Knowing as much as possible about the patient and factors that influence treatment outcome can help the radiation therapist provide quality patient care. An example would be the patient who requests a treatment time not convenient for the department schedule. For a radiation therapist who has many patients to accommodate and a very tight schedule, this request may seem unreasonable. It may turn out that a working relative is providing daily transportation to the clinic and does not have a flexible work schedule. An appointment time that interferes with the relative's work schedule may lead to the loss of employment. In this example, there are three possible outcomes. First, the radiation therapist gives the patient an appointment time that fits the treatment schedule and lets the patient work out the transportation issues. Second, the radiation therapist gives the patient the requested appointment time and changes other patient appointments, or third, the radiation therapist refers the patient and relative to community transportation resources and works with all parties to develop a plan for treatment. For reasons such as these, an in-depth knowledge of available patient resources is essential to ensure that all patients receive the care and help they need to deal with the disease and resulting life issues. The actual radiation treatment is only part of the radiation therapist's responsibility. A patient is not an organ with a cancer but a complete individual with a multitude of issues and needs that must be addressed. Because cancer affects the whole family, it is the responsibility of the radiation therapist to provide information and available resources to assist the patient and family in dealing with all the issues and challenges that a diagnosis of cancer brings. It is good to remember that sometimes the smallest act of compassion and connection with the patient and/or his or her family will transform the radiation treatment experience from frightening and overwhelming to comforting and trusting (Fig. 1.1).

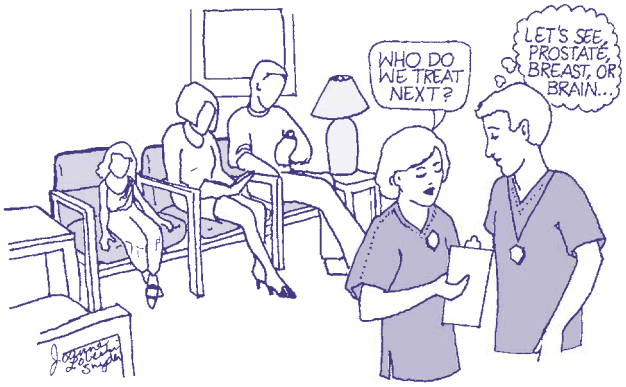


Fig. 1.1 Focus on the whole person, not the disease. (Courtesy Joanne Lobeski-Snyder.)

Cancer Patient Resources

In each medical facility, there is generally a myriad of cancer support services. These services can include general education, cancer site–specific education, support groups, financial aid, transportation to and from treatment, and activity programs. Social work departments are available to assist with the financial, emotional, and logistic issues that arise, and community services through churches and other organizations are available to support individuals and their families. National organizations such as the American Cancer Society have established programs and information hotlines that are available to all patients. Caring for a cancer patient is often a 24-hour-a-day job, and it is essential that resources are available at all hours. Community services are usually available for the caregivers because the caretaking toll can be physical, mental, emotional, and financial. Radiation therapists must become familiar with the services offered in their communities and nationally to better serve the patients and their family member caregivers. This is especially true for radiation therapists working at freestanding clinics not affiliated with a medical center. Educating patients and their families about available programs or services to address specific needs is an important component of quality care provided by the radiation therapist. Now that we have established that the patient is the focus for every member of the radiation therapy healthcare team, a historic look at cancer investigation is in order.

Two excellent national resources are:
American Cancer Society: https://www.cancer.org/
National Cancer Institute: https://www.cancer.gov/

Throughout recorded history, cancer has been a subject of investigation. Lacking current surgical techniques and diagnostic and laboratory equipment, early investigators relied on their senses to determine characteristics of the disease. Investigators were unable to thoroughly examine cells, so infections and other benign conditions were included in their category of cancer. Knowledge about these early observations, including examinations, diagnosis, and treatment, comes in part from Egyptian papyri dating back to 1600 BCE.[3] Initially, investigators believed that an excess of black bile caused cancer. This belief defined cancer as a systemic disease for which local treatment (such as surgery) only made the patient worse. In light of this, cancer was considered to be fatal with little possibility of a cure. When investigators could not prove the existence of black bile, the theory of cancer as an initially localized disease emerged. With this theory came the possibility of treatment with a potential for cure. However, because of the limited information available, few cures were accomplished.

In the fifth century BCE, Hippocrates began the classification of tumors by observation. Later, the discovery of the microscope enabled investigators to classify tumors on the basis of cellular characteristics.[3] Classification of tumors and their stages of growth continue as technology advances.

The cause of this deadly disease remained a mystery, and, for many decades, people even thought that cancer was contagious. This theory brought isolation and shame to cancer victims. Although this belief has long since vanished, less than 30 years ago, patients expressed concern about spreading the disease to loved ones. Unfortunately, today many cancer patients still suffer discrimination in the workplace and when trying to obtain health insurance coverage.

With the ability to examine the genetic makeup of a cancer cell, scientists can now determine many of the mutations that are responsible for a specific cancer initiation. This knowledge leads to earlier diagnosis in higher-risk individuals, improved screening examinations, and ultimately better treatment. It is now possible to develop specific chemotherapy, **immunotherapy**, and targeted therapy drugs for individual cancers and provide drugs that will be effective in blocking specific cancer initiation in high-risk individuals. This area is still in its infancy but has very exciting possibilities.

BIOLOGIC PERSPECTIVE

Building on the work of early investigators and aided by technologic advances, researchers are able to diagnose many tumors in extremely early stages. In addition, scientists are able to examine the deoxyribonucleic acid (DNA) of cells obtained through **biopsy** to determine mechanisms causing uncontrolled growth. Although it is true that technology and knowledge about cancer has increased during the past decades, there is still much to be learned.

Theory of Cancer Initiation

Tumors are the result of abnormal cellular proliferation. This can occur because the process by which **cellular differentiation** takes place is abnormal or because a normally nondividing, mature cell begins to proliferate. Cellular differentiation occurs when a cell undergoes mitosis and divides into daughter cells. These cells continue to divide and differentiate until a mature cell with a specific function results. When this process is disrupted, the daughter cells may continue to divide with no resulting mature cell, thus causing abnormal cellular proliferation.

The cause of this cellular dysfunction has been the subject of research for many years. Researchers now know that cancer is a disease of the genes. Normal **somatic cells** (nonreproductive cells) contain genes that promote growth and genes that suppress growth, both of which are important to control the growth of a cell. In a tumor cell, this counterbalanced regulation is missing. Mutations occurring in genes that promote or suppress growth are implicated in the deregulation of cellular growth. Mutations in genes that promote growth force the proliferation of cells, whereas mutations to the genes that suppress growth allow unrestrained cellular growth. For many tumors, both mutations may be required for progression to full malignancy.[4–7]

The terms for the genes involved in the cancer process are *proto-oncogenes,* **oncogenes**, and *antioncogenes.* Proto-oncogenes are the normal genes that play a part in controlling normal growth and differentiation. These genes are the precursors of oncogenes (gene that regulates the development and growth of cancerous tissues), or cancer genes. The conversion of proto-oncogenes to oncogenes can occur through point mutations, translocations, and gene amplification, all of which are DNA mutations. Oncogenes are implicated in the abnormal

proliferation of cells. Antioncogenes are also called *tumor-suppressor genes*. These are the genes that tell cells to stop multiplying. Inactivation of antioncogenes allows the malignant process to flourish.[4–7]

DNA point mutations, amplification, or translocations transform a proto-oncogene into an oncogene, resulting in unrestricted cellular growth.

What causes these mutations to occur? For somatic cells, exposure to carcinogens such as certain viruses, sunlight, radiation, and cigarette smoke is implicated. In some situations, such as the familial form of retinoblastoma, gene mutations are passed down through generations. Random mutations that occur during normal cellular replication can also lead to unregulated cellular growth.

Researchers have identified several gene mutations, including the gene implicated in the familial form of breast cancer. With the use of gene mapping and advanced technology, study in this area will continue. To understand the principles of cancer treatment, a review of the cell cycle and an overview of tumor growth are necessary.

Review of the Cell Cycle

Mammalian cells proliferate through the process of mitosis, or cellular division. The outcome of this process is two daughter cells that have identical chromosomes as the parent. The cell cycle consists of the period of time and the activities that take place between cell divisions. The cell cycle consists of five phases called G0, G1, S, G2, and M (Fig. 1.2).

G0 is depicted outside of the cell cycle continuum because these cells are fully functioning but are not preparing for DNA replication. Most cells making up a tissue or organ are in the G0 phase. Given the proper stimulus, this reserve pool of cells can reenter the cell cycle and replicate.

G1, or the first growth phase, is characterized by rapid growth and active metabolism. The length of time that a cell remains in G1 is variable. Cells that are rapidly dividing spend little time in the first growth phase, whereas cells that are slow growing remain in G1 for a long period. The length of time spent in G1 varies from hours to years. During this time, the cell synthesizes the necessary ribonucleic acid (RNA) and proteins to carry out the function of the cell. Later in the first growth phase, the cell will commit to replication of DNA.

S phase, or synthesis, is the period in which DNA is replicated to ensure that the resulting daughter cells will have identical genetic material. G2, or the second growth phase, is the period in which the cell prepares for actual division. Enzymes and proteins are synthesized and the cell continues to grow and moves relatively quickly into the M, or mitotic, phase.

Cells are most sensitive to radiation during G2 and M phases of the cell cycle.

Tumor Growth

When all cells are operating normally, there is a balance between cells that are dying and the replication of cells. Although tumor growth is a result of an imbalance between replication and cell death, the rate of growth is influenced by many factors. Malignant cells possess damaged genetic material, resulting in increased cell death. In addition, while the tumor grows larger, the blood, oxygen, and nutrient supply is inadequate, creating areas of **necrosis**, or dead tissue.[8]

Initially, tumor growth is exponential, but although the tumor enlarges and outgrows the blood and nutrient supply, the rate of cell replication more closely equals the rate of cell death. This is demonstrated by the Gompertzian growth curve (Fig. 1.3). Tumors that are clinically detectable are generally in the higher portion of the curve. Treatment reduces the number of cells, thus moving the tumor back down the curve where the growth rate is higher. Tumor cells that were previously in the G0 phase are prompted to reenter the cell cycle. Cells that are rapidly dividing are more sensitive to the effects of radiation and chemotherapy.

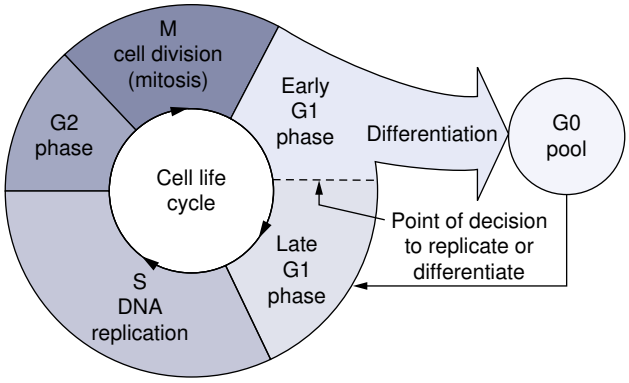


Fig. 1.2 Cell generation cycle. (From Otto SE. *Oncology Nursing*. 2nd ed. St. Louis, MO: Mosby; 1994.)

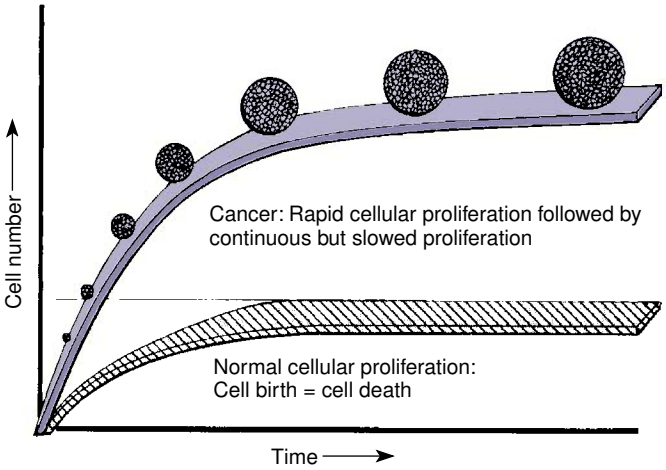


Fig. 1.3 Gompertz function as viewed by growth curve. (From Otto SE. *Oncology Nursing*. 2nd ed. St. Louis, MO: Mosby; 1994.)

Cancer cells do not die after a programmed number of cell divisions as do normal cells. Hence, cancer cells have the ability to proliferate indefinitely.

Tumor Classification

Tumors are classified by their anatomic site, cell of origin, and biologic behavior. Tumors can originate from any cell; this accounts for the large variety of tumors. Well-differentiated tumors (those that closely resemble the cell of origin) can be easily classified according to their histology. Undifferentiated cells, however, do not resemble normal cells, so classification is more difficult. These tumors are called undifferentiated, or **anaplastic**, which is a pathologic description of cells, describing a loss of differentiation and more primitive appearance.

Tumors are divided into two categories: benign or malignant (Table 1.1). **Benign** tumors are generally well differentiated and do not **metastasize** or invade surrounding normal tissue. Often, benign tumors are encapsulated and slow growing. Although most benign tumors do little harm to the host, some benign tumors of the brain (because of their location) are considered behaviorally malignant because of the adverse

TABLE 1.1 General Characteristics of Benign and Malignant Disease

Characteristics	Benign	Malignant
Local spread	Expanding, pushing	Infiltrative and invasive
Distant spread	Rare	Metastasize early or late by lymphatics, blood, or seeding
Differentiation	Well differentiated	Well differentiated to undifferentiated
Mitotic activity	Normal	Normal to increased mitotic rate
Morphology	Normal	Normal to pleomorphic
Effect on host	Little (depending on treatment and location of tumor)	Life-threatening
Doubling time	Normal	Normal to accelerated

effect on the host. Benign tumors may be noted by the suffix *-oma*, which is connected to the term indicating the cell of origin. For example, a *chondroma* is a benign tumor of the cartilage. Although this is a general rule, there are malignant tumors, such as melanoma, that end with the same suffix but are malignant.

Malignant tumors often invade and destroy normal surrounding tissue and, if left untreated, can cause the death of the host.

A well or moderately well-differentiated malignant tumor cell will resemble the cell from which it originated. A poorly differentiated cell will have very few of the characteristics of the originating cell, and an undifferentiated cell will have no characteristics of the original cell. They have the ability to metastasize, or spread to a site in the body distant from the primary site.

Malignant tumors often invade and destroy normal surrounding tissue and, if left untreated, can cause the death of the host.

Tumors arising from mesenchymal cells are known as **sarcomas**. These cells include connective tissue such as cartilage and bone. An example is a chondrosarcoma or a sarcoma of the cartilage. Although blood and lymphatics are mesenchymal tissues, they are classified separately as leukemias and lymphomas.

Carcinomas are tumors that originate from the epithelium. These include all the tissues that cover a surface or line a cavity. For example, the aerodigestive tract is lined with squamous cell epithelium. Tumors originating from the lining are called *squamous cell carcinoma* of the primary site. An example is squamous cell carcinoma of the lung. Epithelial cells that are glandular are called **adenocarcinoma**. An example is the tissue lining the stomach. A tumor originating in the cells of this lining is called *adenocarcinoma of the stomach*. Table 1.2 lists examples of nomenclature used in neoplastic classification. As in any classification system, some situations do not follow the rules. Examples include Hodgkin disease, Wilms tumor, and Ewing sarcoma. The system of classification continues to change while more knowledge of the origin and behavior of tumors become available. Table 1.3 lists histologies associated with common anatomic cancer sites.

Cancer Outlook

The American Cancer Society[6] estimates that approximately 1.7 million new cases of cancer will be diagnosed each year. Of those patients, approximately 607,000 will die of their disease.[9] Basal and squamous cell skin cancers and most **in situ** cancers (an early form of cancer defined by the absence of invasion) are not included in these numbers, except for bladder cancer. The cancer death rate has declined during the last 30 years and varies by age, gender, and race. Excluding carcinoma of the skin, the most common types of invasive cancers in the United States include prostate, lung, and colorectal cancer in men, and breast, lung, and colorectal cancer in women.[9] These statistics are not static and change with environmental, lifestyle, health, technologic, and other societal factors. According to a recent Surveillance, Epidemiology, and End Results Program (SEER) Cancer Statistics Review, the 5-year relative survival rate (from 2008 to 2014) for all primary cancer sites combined is nearly 70% (69.7%).[9] This is largely because of screening, better treatment techniques, and health education. Interestingly, obesity is now a significant risk factor in the development of many cancers.[9] Invasive carcinoma of the cervix has also decreased during the past 20 years as a result of cancer screening with the Papanicolaou (Pap) smear. Currently, more carcinoma in situ, or preinvasive, cancers of the cervix are found than invasive tumors. These in situ carcinomas, which carry a better prognosis, are not recorded in the American Cancer Society statistics.

Depending on the geographic location, the incidence of tumor sites also varies. For example, the incidence of stomach cancer is much greater in Japan than in the United States, and skin cancer is found more frequently in New Zealand than in Iceland. Diet and geographic environmental factors contribute to these tumor incidence differences.

TABLE 1.2 Classifications of Neoplasms

Tissue of Origin	Benign	Malignant
Glandular epithelium	Adenoma	Adenocarcinoma
Squamous epithelium	Papilloma	Squamous cell carcinoma
Connective tissue smooth muscle	Leiomyoma	Leiomyosarcoma
Hematopoietic	—	Leukemia
Lymphoreticular	—	Lymphoma
Neural	Neuroma	Blastoma

TABLE 1.3 Histologies Associated with Common Anatomic Cancer Sites

Site	Most Common Histology
Oral cavity	Squamous cell carcinoma
Pharynx	Squamous cell carcinoma
Lung	Squamous cell carcinoma
Breast	Infiltrating ductal carcinoma
Colon and rectum	Adenocarcinoma
Anus	Squamous cell carcinoma
Cervix	Squamous cell carcinoma
Endometrium	Adenocarcinoma
Prostate	Adenocarcinoma
Brain	Astrocytoma

ETIOLOGY AND EPIDEMIOLOGY

A tremendous amount of knowledge exists about factors that influence the development of cancer and the incidence at which it occurs.

Etiology and epidemiology are the two of these areas that have contributed to the growing knowledge in these areas.

Etiology

Etiology is the study of the cause of disease. Although the cause of cancer is unknown, many carcinogenic agents and environmental and genetic factors have been identified and are called risk factors. Experts use this information, as they have done with tobacco use, to establish prevention programs and identify high-risk individuals.

> Etiologic factors may include cigarette smoke, human papillomavirus, alcohol, sun exposure, diet, and obesity.[10]

Etiologic and epidemiologic information is helpful in determining screening tests for early detection, producing patient education programs, and identifying target populations. An example is a set of guidelines from the American Cancer Society for early detection of cancer.[11] These guidelines give recommendations for cancer screening exams for breast, colorectal, cervical, endometrial, lung, and prostate cancers.[11]

Epidemiology

Epidemiology is the study of disease incidence. National databases, such as SEER,[8] provide statistical information about patterns of cancer occurrence and death rates. With this information, researchers can determine the incidence of cancer occurrence in a population for factors such as age, gender, race, and geographic location. Researchers can also determine which specific type of cancer affects which specific group of people. An example is the higher incidence of prostate cancer in African-American males. Epidemiologic studies also help determine trends in disease such as the recent decrease of lung cancer in men, the decline of stomach cancer or the increase in malignant melanoma in the United States, and the increase in obesity-related cancers.[10]

DETECTION AND DIAGNOSIS

Early detection and diagnosis are keys to the successful treatment of cancer. Generally, the earlier a tumor is discovered, the lower the chance of metastasis or spread to other parts of the body and the better the chance for cure. For some tumors, such as carcinoma of the larynx, early symptoms, such as a very hoarse voice, cause the patient to seek medical care early in the course of the disease. As a result, the cure rate for early-stage larynx (glottic) (or true vocal cord) tumors is extremely high. Cancer of the ovary, however, is associated with vague symptoms such as bloating, upset stomach, or abdominal discomfort that could be the result of a number of medical problems. Consequently, a diagnosis is often made late in the course of the disease. Low cure rates for ovarian cancer reflect the results of late diagnosis.

Advances in medical diagnostic imaging, especially the use of computed tomography (CT), magnetic resonance imagining (MRI), and positron emission tomography (PET) imaging, allow physicians to see into the body and even visualize cellular activity. These increased capabilities have played a pivotal role in earlier detection and diagnosis of cancer. These advances have also provided the knowledge needed to reduce treatment volume to spare normal surrounding tissues in radiation therapy.

Screening Examinations

To identify cancer in its earliest stages (before symptoms appear and while the chance of cure is greatest), screening tests are performed. Examples include the Pap smear for cervical cancer, fecal occult blood testing or colonoscopy for colorectal cancer, low-dose CT scans for high-risk people, and mammograms for breast cancer.[11] Unfortunately, for many cancers, screening examinations are not readily available because of the inaccessibility of the tumor or the high cost in relation to the information yield associated with the tests.

To be useful, screening examinations must be **sensitive** (ability of a test to give a true-positive result) and specific (ability of the test to obtain a true-negative result) for the tumors they identify. If an examination is sensitive, it can identify a tumor in its extremely early stages. A sensitive test will not result in **false-negative** findings. A false-negative finding would be one where it appears that there is no cancer present when indeed there is cancer. For example, a Pap smear is sensitive because it can help detect carcinoma of the cervix before the disease becomes invasive. If a test is specific, it can identify a particular type of cancer. For example, a prostate-specific antigen (PSA) in the blood is used specifically for prostate cancer. Unfortunately, it results in a number of **false-positive** readings. Carcinoembryonic antigen may be elevated in a number of benign and malignant conditions. For this reason, the test is not specific, but it is the most sensitive test available for determining recurrences of colorectal cancer.

Screening tests may yield false-positive or false-negative readings. A false-positive reading indicates disease when in reality none is present. In these cases, patients may undergo additional unnecessary, morbid, and costly screening exams or treatments. A false-negative reading is the reverse; the test indicates no disease when in fact the disease is present. In these cases, a patient does not have needed treatment until later in the disease trajectory. The perfect scenario is to have a screening examination that is both very sensitive and specific. The cost of the screening examination often limits its use to all but extremely high-risk populations.

In 2002, the National Cancer Institute (NCI)[1] began a national lung screening trial for high-risk individuals that compared standard chest radiography with spiral CT as a screening tool. By April 2004, more than 53,000 individuals were enrolled in the study, and data were collected. In 2011, the NCI reported the finding of a 24% reduction in lung cancer mortality with low-dose CT screening when compared with conventional x-rays.[12] This program continues to be adopted nationwide to detect lung cancer in its early stages in the identified high-risk populations.

> A false-positive, sensitive but low-specificity screening examination results in the necessity of additional, often costly, diagnostic procedures to determine the diagnosis.

Workup Components

After a tumor is suspected, a workup, or series of diagnostic examinations, begins. The purpose of the workup is to determine the general health status of the patient and to collect as much information about the tumor as possible. To treat the patient effectively, the physician must know the type, location, and size of the tumor; the degree the tumor has invaded normal tissue; the amount of differentiation of the cells; the presence or absence of spread to distant sites; the lymph node involvement, if any; and amenability to specific treatment regimens. These questions are answered in the workup.

The workup depends on the type of cancer suspected and the symptoms experienced by the patient. The workup for a suspected lung tumor is different than that for a suspected prostate tumor. The same questions are answered, but because the two tumors are extremely different, the tests are based on the specific tumor characteristics. Additionally, the workup for an early-stage tumor will be different from later-stage disease. The incidence of bone metastasis in a stage I breast

cancer is extremely low, unlike stage IV disease. Therefore, the workup for stage I disease will not include a bone scan but would be ordered for stage IV disease.

For patients who have lifestyle habits that include carcinogens such as cigarette smoking, moderate to heavy alcohol use, chewing tobacco, and obesity, the workup will include diagnostic procedures to rule out the possibility of second primary cancers.

With advancing technology, more information is available to the physician than ever before. As new technologies emerge and prove useful in the information-gathering process, treatment becomes more effective. Before CT or MRI became available, small tumor extension into normal lung tissues was not visible on chest radiographs. The physician had to make an educated guess about the extent of the tumor invasion and to treat the patient based on the suspected condition. As a result, treatment fields had to be larger to encompass all the suspected disease. Much of the guesswork is eliminated with the use of ultrasound, CT, MRI, and PET, so treatment volumes can include only areas of known disease while limiting dose to the normal tissue, thereby producing a more effective treatment with fewer short-term and chronic treatment side effects.

Today, with the added imaging tool of PET and PET-CT, physicians can identify very small foci of disease that may be active near the primary tumor or located in other parts of the body undetectable to other forms of diagnostic imaging. PET has diagnostic value for tumors of the lung, head and neck, and breast, as well as for colorectal and esophageal tumors, lymphoma, and melanoma. The effectiveness of PET for other tumor types is under investigation. Determination of whether a suspicious posttreatment area is recurrent disease or an expected tissue change is another area in which PET excels.

Staging

Tumor staging is a means of defining the tumor size and extension at the time of diagnosis and is important for many reasons. Tumor staging provides a means of communication about tumors, helps in determining the best treatment, aids in predicting prognosis, and provides a means for continuing research. Staging systems have changed with advancing technologies and increased knowledge and will continue to progress while more information becomes known. For this reason, tumors that occur frequently have detailed staging classifications, whereas those that are rare have primitive or no working staging systems.

According to the American Joint Committee on Cancer (AJCC),[13] there are four types of staging that occur in cancer care. The first is **clinical staging**, which is based upon physical exam, pertinent imaging exams, and biopsies.[13] **Pathologic staging** refers to clinical staging with the addition of information from surgical removal of all or part of a tumor.[13] **Posttherapy staging** is determined after the first course of chemotherapy or hormone therapy and/or radiation therapy to see how treatment has impacted the cancer.[13] Lastly, **restaging** is performed in the cases of cancer recurrence after treatment.[13]

A common staging system adopted by the International Union Against Cancer and the AJCC is the TNM system. It should be noted that the TNM system for each cancer is different. Complete information on each cancer is available from the AJCC in the form of a Cancer Staging Manual.[13] The T category defines the size or extent of the primary tumor and is assigned numbers 1 through 4 or x. A T1 tumor is small and/or confined to a small area, whereas a T4 tumor is extremely large and/or extends into other tissues. The x indicates that there was an inability to obtain information necessary to make a determination. N designates the status of lymph nodes and the extent of lymph node involvement. A 0 through 4 or x designation exists depending on the extent of involvement, with N0 indicating that no positive nodes are present. N1 indicates positive nodes close to the site of the primary tumor, whereas N4 indicates positive nodes at more distant nodal sites. Nx indicates that the nodal status was not assessed. Not all cancers have the designation of N1 through N4. The **natural history** of a particular cancer and clinical treatment knowledge will affect the complexity of the staging system. M is the category that defines the presence and extent of metastasis. Again, the M category is generally categorized as 0, 1, or x, depending on the extent of metastatic disease. The designation M0 indicates no evidence of metastatic disease was found, whereas M1 indicates disease distant from the primary tumor. Mx indicates that the presence or absence of metastasis was not assessed. Specific tumors with a detailed staging criteria may have an expanded M designation (Fig. 1.4).

In TNM staging, additional subcategories are used for commonly occurring tumors. Notations are often used to determine whether the staging was accomplished through clinical, surgical, or pathologic methods. Although the TNM system is widely used, numerous staging systems exist that more accurately detail important tumor characteristics for prognostic and treatment information. For example, the International Federation of Gynecology and Obstetrics system is more commonly used in the staging of gynecologic tumors.

Surgical/Pathologic Staging

Surgical/pathologic staging offers the most accurate information about the tumor and the extent of disease spread. Although staging can be performed clinically, or without the use of invasive procedures, the status of the lymph nodes and micrometastatic spread would remain in question. During surgical staging, the physician has the opportunity to perform a biopsy of suspicious-looking tissue, obtain a sample of lymph nodes for microscopic examination, and observe the tumor and surrounding tissues and organs.

Ovarian disease may be staged surgically through the use of an intraoperative examination or surgical exploration of the abdomen because these tumors often spread by seeding into the abdomen. During the procedure, the primary tumor site is identified, the tumor is removed, suspicious areas are biopsied, and fluid is introduced into the abdominal cavity to be removed and examined for cancer cells. The amount of tumor left behind following the surgery provides important treatment and prognostic information. The greater the amount of information obtained about the tumor, the more accurate the staging is likely to be, which results in more effective treatment. Accurate staging is also able to limit aggressive treatment to only those patients who will benefit.

With the ability to look at a tumor's cellular DNA, a physician has even more information available to determine, within a tumor type, which tumor is more sensitive to a particular treatment and which tumor has a greater chance of recurrence. Tumor cell DNA examination is standard practice for a variety of cancers, and the staging has changed to include DNA characteristics, as well as clinical factors. For example, with breast cancer, overexpression of *HER2/neu* proto-oncogene or *BRCA1* or *BRCA2* will influence the overall treatment plan.[1]

Grade

The **grade** of a tumor provides information about its aggressiveness and is based on the degree of differentiation. Differentiation is divided into four categories: well differentiated, moderately well differentiated, poorly differentiated, and undifferentiated or anaplastic. Cancer cells that have the most characteristics of the original cell are well and moderately well differentiated. Cells in which the original cell is barely or not distinguishable are poorly differentiated or undifferentiated.

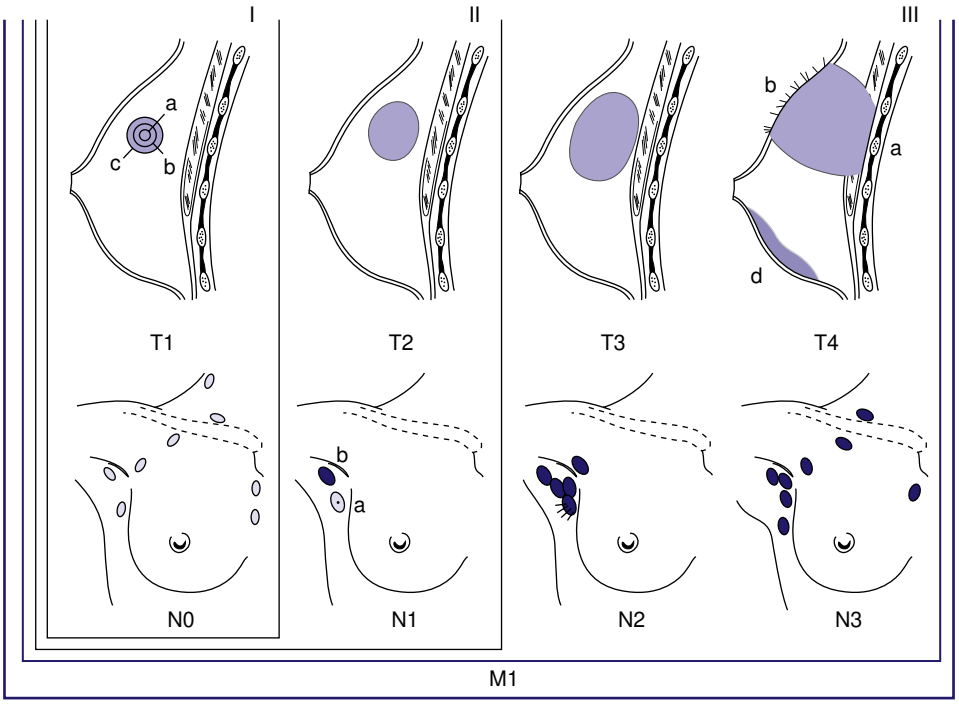


Fig. 1.4 A diagrammatic depiction of the breast cancer staging system. (From Rubin P. *Clinical Oncology*. 7th ed. Philadelphia, PA: WB Saunders; 1993.)

Degree of differentiation is determined only by examination of cells obtained through biopsy under a microscope. For some tumors, such as high-grade astrocytoma, grade is the most important prognostic indicator. Grade is also more important than stage in bone and muscle tumors in determining treatment and prognosis.

Stage and grade offer an accurate picture of the tumor and its behavior. When physicians know the exact types of tumors with which they are dealing, treatment decisions can be made that effectively eradicate the tumors. (A detailed description of cancer detection and diagnosis is provided in Chapter 5.)

Grade can be determined only by examining tumor cells under a microscope.

TREATMENT OPTIONS

Cancer treatment demands a multidisciplinary approach. **Tumor boards** were established so that cancer specialists can work together to review information about newly diagnosed tumors and devise effective treatment plans. There are typically cancer-specific types of tumor boards, e.g., head and neck, breast, gastrointestinal, and brain. Participants of a tumor board can include surgeons, radiation oncologists, medical oncologists, radiologists, pathologists, social workers, plastic surgeons, and other medical personnel. All of these individuals play key roles in developing a treatment plan that effectively treats the tumor while helping the patient maintain a high quality of life (Fig. 1.5). Radiation therapists must be knowledgeable about the other modalities of treatment because their patients may have other treatments at the same time as radiation delivery, which will then change the side effects and the treatment plan. There is a difference in the radiation treatment plan when patients have surgery before or after the radiation is delivered or if chemotherapy is to be administered before or during radiation treatment. Radiation therapists, as part of the radiation therapy team, must interact intelligently with all members of the healthcare team.

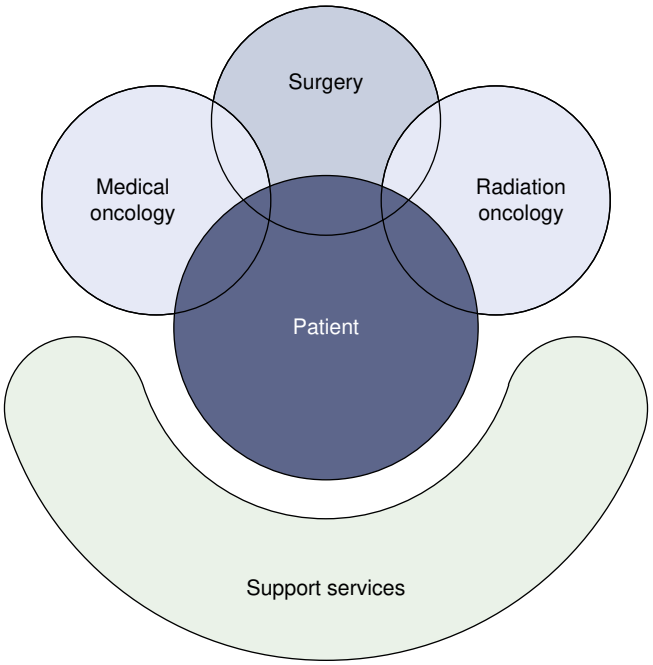


Fig. 1.5 The cancer patient receives treatment and support from multiple sources during disease management.

Surgery

As a local treatment modality, surgery plays a role in diagnosis, staging, primary treatment, **palliation** (noncurative treatment to relieve pain and suffering), and identification of treatment response. As a tool for diagnosis, surgery is used to perform a biopsy of a suspected mass to determine whether the mass is malignant and, if so, the cellular origin.

Biopsies are the only way to know for sure whether a lump or growth is cancerous. To provide the most effective treatment, the histology and cellular characteristics must be identified. The majority of biopsies that

are performed on patients do not end up finding cancer. Many biopsy methods exist, and the characteristics of the suspected mass determine the use of a particular method.

Common biopsy (surgical removal of a small tissue sample from a solid tumor to determine the pathology) methods include fine-needle aspiration, core needle, endoscopic, image guided, incisional, and excisional. The information obtained through a biopsy is essential for appropriate treatment management. A fine-needle aspiration biopsy would be used to determine the histology of a suspicious breast mass or other superficial lesion. During the biopsy, sample cells are collected in the needle from several areas of the suspected tumor (Fig. 1.6). The cells are then transferred to a microscopic slide for further examination. This method of biopsy is relatively quick and easy, with minimal patient discomfort and healing time. The disadvantage is that the collected cells are examined without the benefit of their neighboring cells to provide a glimpse of the tumor architecture. There is also the chance that malignant cells will be seeded along the needle track as the needle is withdrawn from the tumor.

A large-gauge needle (14 or 16 gauge) is used to perform a core-needle biopsy. As the needle is inserted into the suspected tumor, a core of tissue is collected. The tissue obtained can be sectioned and examined under a microscope. Using this method, the tumor architecture is preserved, allowing better identification of the tumor tissue of origin (Fig. 1.7).

During endoscopic procedures, such as a bronchoscopy or colonoscopy, suspicious tissue can be collected with the use of a flexible biopsy tool. The tool is passed through the scope, and tiny pincers are used to gather a small tissue sample. Tissue samples can then be frozen or embedded in paraffin, sectioned, stained, and examined under the microscope.

Image-guided biopsies are often used during needle biopsies to sample the tissue in the correct area. Often these areas are lungs, kidneys, liver, and lymph nodes, and are challenging to safely insert needles. Such imaging modalities that can be used for this include ultrasound, CT, interventional radiology, and MRI. A newer image-guided technique is MRI-guided biopsy of the prostate gland.[14]

A recent study indicates that MRI for prostate cancer can identify patients who are more likely to need a biopsy versus those who are not. The study included 651 men screened for prostate cancer with a PSA blood test and digital rectal exam. Each patient then underwent three procedures: an MRI scan, a biopsy guided by transrectal ultrasound (TRUS), and a biopsy guided by both a TRUS and MRI scan. Of the 651 men scanned, 289 were identified as having intermediate-stage prostate cancer, defined as a Gleason score of 7 or higher. The researchers found that using an MRI scan to determine the need for biopsy could have avoided 38% of biopsies and still identified 89% of clinically significant cancers.[15]

During an incisional biopsy, a sample of the tumor is removed with no attempt to remove the whole tumor. This method is often used with larger tumors or those that are locally advanced (Fig. 1.8). In excisional biopsies, on the other hand, an attempt is made to remove the entire tumor and any possible local spread, as in the case of malignant melanoma. When a nevus, or mole, becomes suspicious by changing colors or growing larger, an excisional biopsy is performed. The nevi and normal surrounding tissue (to include a safe margin of underlying tissue) are removed en bloc, or as one piece.

Surgery plays a major role in the treatment of cancer. With advances in knowledge, equipment, and techniques, procedures that are performed are now less radical and are apt to be part of a multidisciplinary treatment plan. The success of surgical intervention is dependent on the medical condition; wishes of the patient; and size, extent, and the location of the tumor.

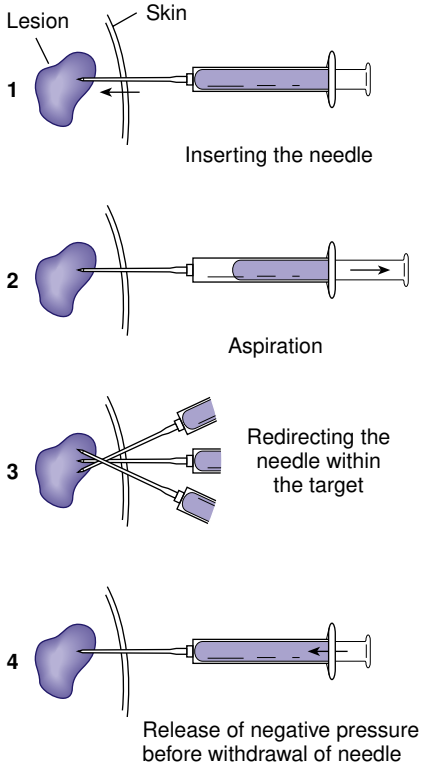


Fig. 1.6 The steps in aspiration of a palpable lesion. Step 3 indicates the way that the needle should be redirected in the target, and step 4 emphasizes the importance of releasing the negative pressure before withdrawing the needle. (From Koss LG. Needle aspiration cytology of tumors at various body sites. In: Silver CE, et al, eds. *Current Problems in Surgery*. Vol. 22. Chicago, IL: Year Book Medical Publishers; 1985.)

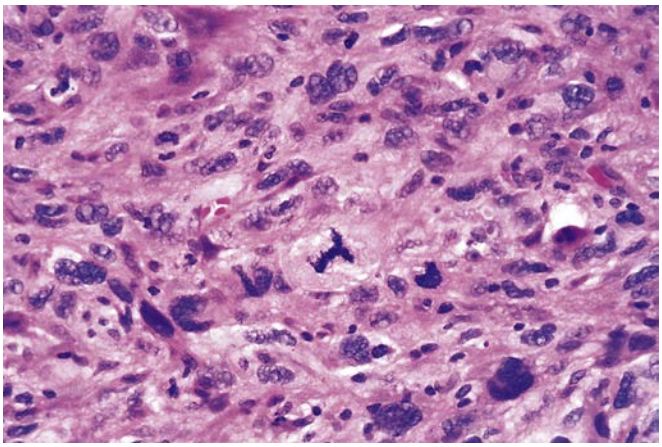


Fig. 1.7 An example of the tissue core obtained by needle biopsy of an anaplastic tumor shows cellular and nuclear variation in size and shape. The prominent cell in the center field has an abnormal appearance. (From Kumar V, Abbas A, Aster J. *Robbins Basic Pathology*. 9th ed. St. Louis, MO: Saunders; 2013.)

Not all patients are surgical candidates. Patients with preexisting medical conditions may have an unacceptable increase in surgical risk. For example, if the patient's pulmonary function is compromised, general anesthesia may be contraindicated, and surgical procedures are impossible. In addition, as with any treatment modality, the patient may decide not to have surgery, in favor of another type of treatment or no treatment at all.

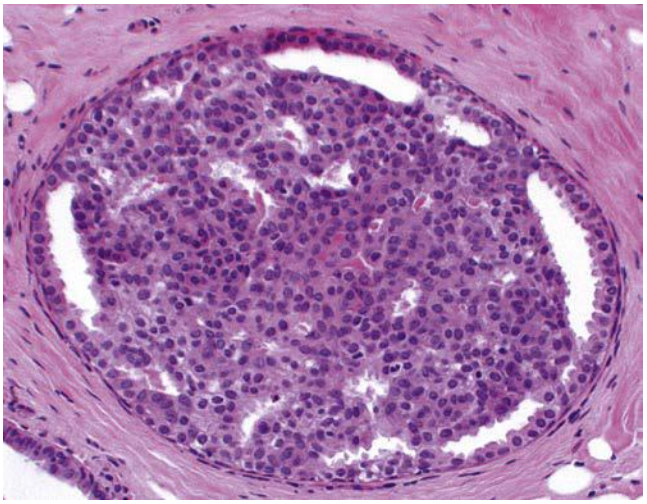


Fig. 1.8 Epithelial hyperplastic benign tumor in a breast biopsy specimen. The duct lumen is filled with a heterogeneous population of cells of differing morphology. Irregular slit-like fenestrations are prominent at the periphery. (From Kumar V, Abbas A, Aster J. *Robbins Basic Pathology*. 9th ed. St. Louis, MO: Saunders; 2013.)

Risks associated with surgery include adverse reactions to anesthesia, infection, and potential loss of function.

Because surgery is a localized treatment, it is most successful with small tumors that have not spread to neighboring tissues or organs. During surgery, the physician attempts to remove the entire tumor and any microscopic spread, requiring the removal of normal tissue. As the size and/or extent of the tumor increases, more normal tissue must be removed, thus increasing the risk of the procedure. Surgical intervention may be the only treatment necessary if the tumor can be completely removed. If, however, the surgical margins are positive for cancer cells, the tumor has a high recurrence rate, or gross tumor was left, further treatment is necessary.

Before surgery, radiation therapy or chemotherapy may be given to increase the likelihood of a complete resection. This is often referred to as **neoadjuvant therapy**. The goals of radiation or chemotherapy in this case are to destroy microscopic and subclinical disease and shrink the tumor. Lower doses of radiation and/or chemotherapy are used to prevent complications during and following surgery.

The location of the tumor is an important factor in the success of surgical treatment. If a tumor is located in an area that is inaccessible or close to critical structures or organs at risk (vital organs or normal tissue structures), surgery may not be possible. Damage to critical structures may be incompatible with life or may leave the patient in worse condition than before treatment. A cancer of the nasopharynx, for example, is located in an area in which accessibility is difficult because the cancer is close to the base of the brain and the cranial nerves. For these reasons, patients with cancers of the nasopharynx are not good candidates for surgical intervention. With improved technology and procedures, however, location of the tumor continues to become less of a barrier to successful treatment.

Surgical palliation is used to relieve symptoms the patient may be experiencing as a result of the disease. Removal of an obstruction of the bowel does not have a curative effect on the disease but provides the patient with symptom relief for an improved quality of life. Cutting nerves to reduce or eliminate pain caused by the tumor is another example of palliative surgery.

Radiation Therapy

Radiation therapy is a local treatment that can be used alone or with other treatment modalities. It can be used for a curative intent, as well as for tumor control, or for palliation. When it is used in conjunction with chemotherapy and/or surgery, it is referred to as **adjuvant therapy**, meaning "in addition to." Benefits of radiation therapy include preservation of function and better cosmetic results. An early-stage laryngeal tumor can be effectively treated by surgery or radiation. Surgery may require removal of the vocal cords, thus leaving the patient without a voice. Radiation therapy, however, can obtain the same results while preserving the patient's voice. In the past, surgery for patients with prostate cancer commonly left the patient impotent with a high chance for incontinence. Radiation therapy can preserve function in a majority of sexually active males while providing effective treatment.

Surgery and radiation therapy combined also obtain an optimal cosmetic result. In the past, breast cancer was usually treated with a radical mastectomy, leaving the patient disfigured. Currently, a common treatment for some types of breast cancer consists of a lumpectomy with sentinel node biopsy followed by adjuvant radiation therapy, and this leaves the patient with minimal disfigurement and an equal chance of cure. Examination of the **sentinel node**, or the primary drainage lymph node, decreases the extent of an axillary node dissection. As a result, the patient experiences fewer range-of-motion deficits, and the risk of lymphedema is lowered.

Radiation therapy plays a major role in palliation, as in the case of bone metastasis. If the condition is left untreated, the patient may experience a great deal of pain and is at risk for pathologic bone fractures. Radiation therapy to these sites usually eliminates the pain and prevents fractures. If a tumor is pressing on nerves, radiation therapy is given to reduce the size of the tumor, thus eliminating pressure on the nerves and providing pain relief.

Radiation therapy is limited to a local area of treatment. Patients with tumors that are diffuse throughout the body are not candidates for radiation therapy. Radiation therapy is further limited to areas in which a curative dose may be delivered without harming critical structures. Newer radiation therapy techniques of adaptive therapy, conformal therapy, image-guided radiation therapy, intensity-modulated radiation therapy, stereotactic radiosurgery, and proton treatments take advantage of the advances in diagnostic medical imaging and are able to almost "paint the tumor" with radiation, which greatly spares the normal tissues. Patients treated with these techniques experience fewer side effects than those treated with conventional radiation therapy techniques. All factors for a specific treatment plan must be examined to determine the most appropriate technique because one technique will not work for all types of treatments.

As with surgery, the patient's medical condition must be such that the patient can tolerate the treatment. If a patient is suffering from lung cancer and has little pulmonary function, radiation therapy may not be a suitable treatment option because it may further compromise the patient's ability to breathe. Numerous methods to deliver radiation exist. The two broad categories are external beam radiation therapy and brachytherapy.

Adverse long-term side effects of radiation are minimized by careful treatment planning and the use of appropriate fractionation schedules.

External Beam

Through the use of external beam x-rays, electrons, protons, or gamma rays can be delivered to the tumor. Linear accelerators are capable of producing x-rays within a specific energy range. Some treatment

machines can produce multiple x-ray, or photon, energies in addition to a range of electron energies and imaging capabilities. Cyclotrons or similar equipment are needed for proton treatment. Proton treatment is housed in larger cancer centers but is becoming more available even in smaller centers. External beam gamma rays are produced by cobalt 60 machines; although they were the primary treatment machine more than 40 years ago, their use is very limited today to MRI guided linear accelerators, such as ViewRay.[16]

The difference between x-rays and gamma rays is the mechanism of production. X-rays are produced by the interaction of electrons striking a target, whereas gamma rays are produced through radioactive decay.

High-energy x-rays are used to treat tumors that are deeper in the body, whereas electrons are effective at delivering energy to superficial tumors. For tumors such as pancreatic or breast cancer, electrons can be given at the time of surgery. Intraoperative radiation therapy is delivered directly to the tumor during surgery. This method allows a high dose to be delivered to the tumor while sparing the normal surrounding tissues. Not all tumors are amenable to this type of treatment because of their location, the extent of disease, or the patient's ability to withstand the rigors of surgery.

Treatment today is more precise and accurate than ever before. With the use of advanced treatment–planning computers, sophisticated treatment equipment, and much better imaging technology, a high dose of radiation can be safely delivered to the tumor with minimal damage to surrounding normal tissue. Conformal therapy, intensity-modulated radiation therapy, and adaptive radiation therapy are three examples of recent advances. Very simply explained, these techniques change the treatment field size and/or dose to vary with the shape of the tumor as the treatment machine is positioned or rotates around the body. These more advanced treatment techniques are covered in depth in Chapters 15 and 16.

Brachytherapy

Brachytherapy, or "short-distance therapy," uses radioactive materials such as cesium-137 (^{137}Cs), iridium-192 (^{192}Ir), palladium-103 (^{103}Pd), cesium-131 (^{131}Cs), or iodine-125 (^{125}I). Through the use of brachytherapy, the radioactive sources can be placed next to or directly into the tumor. Because the energy of the radioactive sources is low, a high energy is delivered to the tumor, with the nearby normal tissues receiving a very small dose. Brachytherapy is accomplished by using a multitude of techniques, including interstitial, intracavitary, and oral applications.

During an interstitial (in-tissue) implant, radioactive sources are placed directly into the tumor. The sources may remain in place permanently, or they may be removed once the prescribed dose has been delivered. Treatment of prostate cancer is a good example for both of these methods. For a permanent implant, tiny seeds of ^{103}Pd, ^{131}Cs, or ^{125}I are placed in the prostate. These seeds remain in the prostate, with their radioactivity decreasing with time. Because of the low energy of the radioactive material, the patient poses no threat to his family and friends. Determination of the type of implant offered depends on the skill and preference of the radiation oncologist, the available resources, and the patient's wishes. Cancers of the head and neck and breast are suitable for interstitial implants.

High-dose afterloading equipment is available in many departments, eliminating the need for extended hospitalization. For example, during the lumpectomy for breast cancer, a special balloon or catheter is placed in the tumor bed. The balloon is attached to a catheter that extends outside of the patient's body. Later, when the patient has been discharged from the hospital with the balloon in place, they will go for radiation therapy treatment. Treatment is delivered in a specially designed suite. Once all of the quality assurance tests have been completed to ensure a safe and accurate treatment, the catheter will be connected to the high-dose afterloading machine. The treatment begins when a radioactive source enters the catheter and travels into the balloon. The source will pause at predetermined spots, delivering the dose prescribed to the tumor bed. This technique is referred to as high dose-rate brachytherapy. Recently, this technique has also been used for prostate cancer treatment as well.[17]

Intracavitary implants are performed by placing the radioactive material in a body cavity, as in the case of treatment for cervical or endometrial cancers. Applicators are placed in the body cavity, often at the time of surgery, and later the radioactive sources are inserted and remain until the prescribed dose has been delivered. The prescribed dose can be delivered during several days as an inpatient procedure (low-dose brachytherapy) or, more commonly, in one or more fractions, as an outpatient procedure (high-dose brachytherapy).

Interluminal brachytherapy is used when the radioactive material is placed within a body tube such as the esophagus or bronchial tree. The radioactive material is positioned in the lumen at the tumor site and removed once the prescribed dose is delivered.

Brachytherapy can also be used to treat choroid melanomas of the eye.[18] In this procedure, tiny pellets of radiation are placed on a small carrier called a plaque, which is sewn to the back of the eye.[18] This is very effective treatment and often eliminates the need to have an enucleation or eye removal.[18]

Radioactive drugs called radiopharmaceuticals can be delivered by mouth or by vein. For cancers of the thyroid, bone, or prostate, this can be a very effective treatment method. This can also be known as systemic radiation. Common radioactive sources used in these procedures include radioactive iodine, strontium, and samarium.[19]

Brachytherapy provides a high dose to a small area, which spares normal surrounding tissue.

The tremendous arsenal of treatment delivery methods and the successful outcomes achieved make radiation therapy a major weapon in the fight against cancer. While the ability to detect and image a tumor improves, the precision of the treatment delivery methods will continue to advance. Treatments that are commonly used today were only dreams 20 years ago.

Chemotherapy

Unlike surgery and radiation therapy, chemotherapy is a **systemic treatment** (killing cells of the primary tumor and those that may be circulating through the body). With the use of cytotoxic drugs (drugs with the ability to kill cancer cells) and hormones, chemotherapy aims at killing cells of the primary tumor and those that may be circulating through the body. Chemotherapy may be administered as a primary treatment or as part of a multidisciplinary treatment plan as an adjuvant treatment modality. Similar to other major cancer treatments, chemotherapy is most successful when the tumor burden is small. Many chemotherapy agents affect the cell during a specific phase of the cell cycle. Tumors that rapidly divide provide more opportunities for the cytotoxic effects to take place because more cells are in the cell cycle. Today, biologic drugs are developed that are specific to individual treatment. A sample of a tumor is grown and analyzed with the drugs developed to attack the specific cancer mutations or weaknesses.[20]

Administration of **chemotherapeutic agents** is accomplished through a variety of methods, depending on the drugs prescribed. The route of administration depends on the drugs used, the type of cancer, and patient-related factors. Oral administration is the easiest method, but it requires full patient compliance in taking the drugs and in taking the drugs at the correct times. Injections can be self-administered by the patient or administered by the oncology nurse. Intraarterial administration requires an infusion pump connected to a catheter that has been placed in an artery near the tumor. Heparin, a blood thinner, is added to the cytotoxic agent to prevent clotting at the catheter site. Bladder cancer is often treated with an intracavitary administration, whereby the chemotherapy drugs are instilled directly into the bladder. Cytotoxic drugs are introduced into the abdomen using an intraperitoneal administration through a catheter or implanted port. **Intrathecal** injection requires drugs to be instilled into the space containing cerebrospinal fluid, as is often the case with leukemia treatment. Although most chemotherapy drugs can be administered by the patient or a nurse, intrathecal administration is done only by a physician. One of the more common methods of drug installation is the intravenous (IV) route. Drugs may be administered by using a syringe entering the vein directly or piggybacked with other fluids. Typically, a patient has a central line called a **port-a-cath** for access to the venous system.[21] This helps to preserve the veins that can become damaged from repeated injections. Blood can be drawn, injections can be given, and drugs can be administered via the central line (Fig. 1.9).

Chemotherapy agents are very toxic, and safety precautions must be taken during preparation and administration, such as the wearing of gloves, gowns, and face shields. Certain drugs have vesicant or blistering potential and, if spilled on the skin or outside of the vein, will cause ulceration and tissue damage, so extra precautions must be taken. For these reasons, patients coming to radiation therapy with IV lines for chemotherapy must be treated with extra care to preserve the patency of the IV line. Often these individuals have small, weak veins, so finding a site for the IV line is difficult at best. If a problem occurs with an IV line, the therapist should immediately call the nurse charged with the care of that patient to prevent total failure of the site. Precautions must also be taken when treating patients with central lines or port-a-cath to prevent accidental dislodgment of the device.

Chemotherapy administration methods depend on the types of drugs prescribed.

Chemotherapeutic Agents

Chemotherapeutic agents are classified by their action on the cell or their source and include alkylating agents, antimetabolites, antibiotics, hormonal agents, nitrosoureas, vinca alkaloids, targeted cancer drugs, and miscellaneous agents[5,20,22] (Table 1.4).

Alkylating agents were the first drugs identified to have anticancer activity. This class of drugs is related structurally to mustard gas; they are not cell cycle specific, but rather work throughout the cycle. The mechanism of action is to bond with nucleic acids, thereby interfering with their action. Side effects include bone marrow depression, amenorrhea in women and azoospermia in men, and carcinogenesis. Administration of alkylating agents is associated with an increased risk of acute myelogenous leukemia and is related to the total drug dose. Examples of alkylating agents include cyclophosphamide and chlorambucil.

Antimetabolites act by interfering with the synthesis of new nucleic acids. They are cell cycle specific and are much more toxic to proliferating cells but are not associated with delayed bone marrow suppression or carcinogenesis. Side effects include gastrointestinal toxicity and acute bone marrow suppression. Examples of antimetabolites include methotrexate, often used with intrathecal administration, gemcitabine, and 5-fluorouracil.

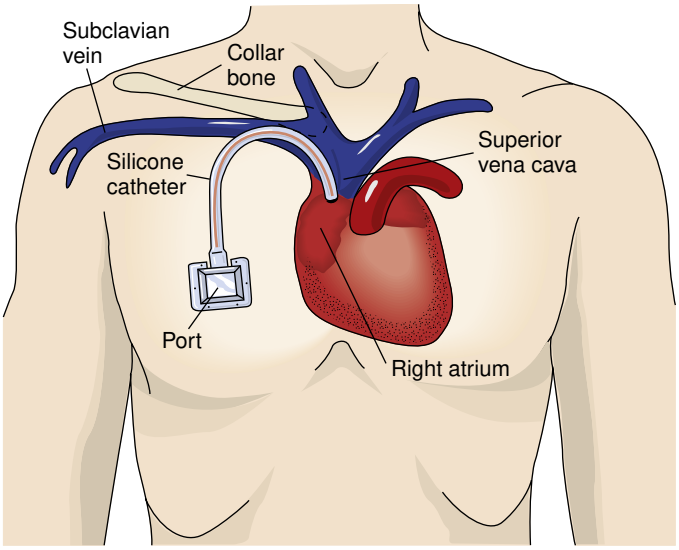


Fig. 1.9 Port-a-cath central line. Commonly used in chemotherapy treatment for access to the venous system. (From Perry AG, Potter PA, Ostendorf WR. *Nursing Interventions and Clinical Skills*. 7th ed. St Louis, MO: Elsevier; 2020.)

Antitumor antibiotics are derived from microbial fermentation. Antibiotics act on the DNA to disrupt DNA and RNA transcription. Although they are not cell cycle specific, the effects of the antibiotics are more pronounced in the S or G2 phase. Examples of anticancer antibiotics include doxorubicin (Adriamycin), bleomycin, epirubicin, mitomycin C, and actinomycin D. Side effects include cardiac toxicity, skin ulceration with extravasation, pulmonary toxicities, bone marrow suppression, and increased effects of radiation therapy.

Hormonal agents act to eliminate or displace natural hormones. Lupron is an injectable hormone therapy used to treat prostate cancer. Lupron is injected under the skin or into a muscle and can help to slow down cancer growth. Steroid hormones are used to clinically manipulate cells by binding to specific intracellular receptors and interacting with DNA to change cellular function. The most common use is in the treatment of breast cancer when the tumor is positive for estrogen and progesterone receptors. Examples of hormonal agents include tamoxifen, raloxifene (Evista), fulvestrant (Faslodex), anastrozole (Arimidex), and letrozole (Femara).[22] Side effects include hot flashes, depression, loss of libido, deep vein thrombosis, and an increase in endometrial cancers.

Nitrosoureas are not cell cycle specific, but they are lipid soluble and able to cross the blood-brain barrier. Their action is similar to that of alkylating agents in that they interfere with DNA synthesis. Examples include carmustine (bis-chloroethylnitrosourea) and streptozocin. Side effects include delayed myelosuppression, gastrointestinal toxicity, and delayed nephrotoxicity.

Vinca alkaloids are derived from the periwinkle plant. By binding to a substance that is needed for mitosis and solute transport, the vinca alkaloids stop cell replication in metaphase. Neurotoxicity, severe ulceration of the skin (if extravasation occurs), and myelosuppression are the dose-limiting side effects. Examples include vincristine, vinblastine, and etoposide (VP-16). Such drugs are used in the treatment of lymphoma, leukemia, and testicular cancers.

Miscellaneous agents are a class of drugs that have varied action and are from a number of different sources. The platinum

TABLE 1.4 Chemotherapeutic Drug Classifications with Side Effects

Drugs	Major Side Effects
Alkylating Agents	
Carboplatin	Nausea and vomiting, bone marrow suppression, ototoxicity, neurotoxicity, and hyperuricemia
Cisplatin	Neurotoxicity, myelosuppression, nephrotoxicity, nausea and vomiting, hypokalemia, and hypomagnesemia
Cyclophosphamide	Myelosuppression, anorexia, stomatitis, alopecia, gonadal suppression, nail hyperpigmentation, nausea and vomiting, diarrhea, and hemorrhagic cystitis
Dacarbazine	Nausea and vomiting, anorexia, vein irritation, alopecia, myelosuppression, facial flushing, and radiation recall
Melphalan	Hypersensitivity, nausea, myelosuppression, amenorrhea, pulmonary infiltrates, and sterility
Antimetabolites	
Capecitabine	Diarrhea, nausea, vomiting, neurotoxicity, myelosuppression, and sores in mouth
Cytarabine	Myelosuppression, diarrhea, nausea and vomiting, alopecia, rash, fever, conjunctivitis, neurotoxicity, hepatotoxicity, pulmonary edema, and skin desquamation of the palms and soles of the feet
Gemcitabine	Nausea, vomiting, rash, hair loss, bruising, bleeding, and myelosuppression
Methotrexate	Nausea and vomiting, oral ulcers
5-Fluorouracil (5-FU)	Oral and gastrointestinal ulcers, nausea and vomiting, diarrhea, alopecia, vein hyperpigmentation, and radiation recall
Antitumor Antibiotics	
Bleomycin	Anaphylaxis, pneumonitis, pulmonary fibrosis, alopecia, stomatitis, anorexia, radiation recall, skin hyperpigmentation, fever, chills, and nausea and vomiting
Dactinomycin (actinomycin D)	Nausea and vomiting, stomatitis, vesication, alopecia, radiation recall, myelosuppression, and diarrhea
Doxorubicin	Myelosuppression, vesication, cardiotoxicity, stomatitis, alopecia, nausea and vomiting, radiation recall, and diarrhea
Epirubicin	Hair loss, flushing, itching, or rash, sores in mouth, diarrhea, nausea, vomiting
Mitomycin	Myelosuppression, vesication, nausea and vomiting, alopecia, pulmonary fibrosis, hepatotoxicity, stomatitis, and hyperuricemia
Hormonal Agents	
Corticosteroids Dexamethasone Hydrocortisone Prednisone	Nausea, suppression of immune function, weight gain, hyperglycemia, increased appetite, cataracts, impaired wound healing, menstrual irregularity, and interruption in sleep and rest patterns
Antiandrogen Flutamide	Impotence and gynecomastia
Antiestrogen Tamoxifen Goserelin acetate (Zoladex)	Nausea and vomiting, hot flashes, fluid retention, changes in menstrual pattern, increase in bone pain, and hypercalcemia
Gonadotropin-releasing hormone Leuprolide	Impotence, decreased libido, increase in bone and tumor pain, genital atrophy, and gynecomastia
Nitrosoureas	
Carmustine	Nausea and vomiting, vein irritation, myelosuppression, stomatitis, nephrotoxicity, and pulmonary fibrosis
Streptozocin	Nausea and vomiting, fever, chills, nephrotoxicity, diarrhea, myelosuppression, and hypoglycemia
Plant Alkaloid	
Etoposide	Nausea and vomiting, diarrhea, stomatitis, parotitis, anaphylaxis, hypotension, myelosuppression, radiation recall, hepatotoxicity, and alopecia
Paclitaxel (Taxol)	Anaphylaxis, hypotension, nausea and vomiting, cardiotoxicity, myelosuppression, neurotoxicity, alopecia, stomatitis, and diarrhea
Vinblastine	Neurotoxicity, anorexia, myelosuppression, stomatitis, alopecia, gonadal suppression, peripheral neuropathy, and vesication
Vincristine	Neurotoxicity, constipation, myelosuppression, alopecia, vesication, peripheral neuropathy, and paralytic ileus
Miscellaneous Agents	
Asparaginase	Anaphylaxis, nausea and vomiting, fever, chills, myelosuppression, hyperglycemia, abdominal pain, diarrhea, pancreatitis, and anorexia
Hydroxyurea	Nausea and vomiting, alopecia, myelosuppression, allergic reactions, radiation recall, rash, azotemia, and dysuria
Pentostatin	Nausea and vomiting, rash, myelosuppression, vein irritation, nephrotoxicity, and hyperuricemia
Procarbazine	Nausea and vomiting; stomatitis; peripheral neuropathy; and severe gastrointestinal and central nervous system effects if taken with foods containing tyramine, alcohol, or monoamine oxidase inhibitor
Topotecan	Diarrhea, nausea and vomiting, myelosuppression, anorexia, and influenza-like symptoms

compounds such as cisplatin and carboplatin are included in this category, along with the taxanes such as paclitaxel and docetaxel. Cisplatin and carboplatin act similar to the alkylating agents, with nephrotoxicity and myelosuppression as the dose-limiting side effects. The action of the taxanes is opposite of that of the vinca alkaloids and results in a disrupted mitosis, along with other cellular processes. Toxicities include neutropenia, cardiac toxicity, mucositis, alopecia, and neuropathy.

It is important for the radiation therapist to be familiar with the various chemotherapy drugs and how they interact with radiation therapy. For example, the treatment for a breast cancer patient who has taken Adriamycin or bleomycin will be modified to consider the synergistic effects of these drugs. Adriamycin is toxic to the heart and in combination with radiation therapy has a much greater toxic effect. The same is true for bleomycin and radiation therapy treatment to the lungs. Radiation therapy methods to minimize the toxic effects would include shielding or lowering the total dose.

Some chemotherapy drugs can enhance the effects of radiation by increasing cellular sensitivity.

Chemotherapy Principles

Chemotherapy is used as a primary treatment and in combination with surgery and radiation therapy. Surgery is performed in an attempt to remove as much of the tumor as possible, decreasing the number of tumor cells. Chemotherapy drugs are then administered to eliminate the residual tumor cells at the primary site and those that are circulating throughout the body. In combination with radiation therapy, chemotherapeutic agents, such as doxorubicin, often act as **radiosensitizers** (chemicals and drugs that help enhance the lethal effects of radiation) and increase the effects of treatment. **Radioprotector** (certain chemicals and drugs that diminish the response of cells to radiation) chemotherapeutic agents such as amifostine limit the effect of the radiation on the normal cells, decreasing treatment side effects.

Although single-agent chemotherapy is used occasionally, a combination of drugs is more often administered. Each of the drugs selected for a particular treatment will have a known effect on the specific tumor treated. With combination chemotherapy, the physician can select drugs that act on the cell during different phases of the cell cycle, increasing the cell-killing potential. In addition, drugs with different known toxicities are used for maximum effectiveness, resulting in fewer side effects.[23]

Targeted Cancer Therapies

Targeted cancer therapies are drugs or other substances that interfere with specific target molecules in the cancer cell that are responsible for abnormal growth and spread.[24] These drugs work by either blocking the cellular instructions to proliferate or by providing instructions to the cell to die. These drugs focus on specific targets within the cell that have a major role in cellular proliferation. Targeted therapies approved for use in cancer treatment include angiogenesis inhibitors, apoptosis inducers, cancer vaccines and gene therapy, gene expression modulators, hormone therapies, immunotherapies, monoclonal antibodies, and signal transduction inhibitors.[24] Some examples are imatinib mesylate (Gleevec), bevacizumab (Avastin), trastuzumab (Herceptin), rituximab (Rituxan), G-CSF (Neupogen), and erlotinib (Tarceva), pembrolizumab (Keytruda), and nivolumab (Opdivo)[24] (Table 1.5).

PROGNOSIS

A **prognosis** is an estimation of the life expectancy of a cancer patient based on all the information obtained about the tumor and from clinical trials. A prognosis is, however, only an estimate. The duration of a person's life is a mystery, and thousands of cancer patients have outlived or underlived their estimated life expectancy. A patient's mental attitude plays an important role in the prognosis but is not a factor usually considered.

Prognostic determination does not consider the patient's mental attitude, which has an enormous impact on disease survivability.

Prognosis plays a role in the treatment plan. If a patient has a prognosis of 2 months, treatment is given in a manner such that the patient has the maximum time allowable to spend with family and friends. In this situation, a treatment lasting 7 weeks would likely be more

TABLE 1.5 Targeted Therapies

Drug	Cancer Treatment	Action
Imatinib mesylate (Gleevec)	Specific types of leukemia and GI cancers	Targets tyrosine kinase enzymes or proteins that lead to uncontrolled growth
Trastuzumab (Herceptin)	Breast cancer and gastroesophageal adenocarcinoma tumors with overexpression of HER2/neu protein	Prevents *HER-2* from sending growth-promoting signals
Rituximab (Rituxan)	B-cell non-Hodgkin lymphoma, chronic myelogenous leukemia (CLL)	Antibody against CD20 antigens on tumor cells causing cell death
Nivolumab (Opdivo)	Colorectal, head and neck, kidney, lymphoma, liver, lung, skin	Induces antitumor immune response when it binds to PD-1 cell receptor
Erlotinib (Tarceva)	Non-small cell lung cancer and pancreatic cancer	Targets tyrosine kinase enzymes associated with epidermal growth factor receptors and inhibits cell growth
Bevacizumab (Avastin)	Breast, cervical, colorectal, kidney, lung, ovarian cancer	Blocks growth of blood vessels to tumors, which reduces tumor growth and spread
Pembrolizumab (Keytruda)	Bladder, cervical, head and neck, lymphoma, skin, and stomach cancer	Induces antitumor immune response when it binds to PD-1 cell receptor
Growth-colony stimulating factor (Neupogen)	Hematopoietic cells, cells of bone marrow	Regulates and stimulates production of neutrophils
Cetuximab (Erbitux)	Squamous cell carcinoma of the head and neck Colorectal cancer	Binds to epidermal growth factor receptor and prevents activation from growth signals

GI, Gastrointestinal; *HER2,* Human epidermal growth factor (Also called HER2/neu); *CD20,* An antigen found on B-Cells; *PD-1,* A protein found on T-Cells.

intrusive than helpful. The goal of treatment is to eradicate the tumor or provide palliation while preserving quality of life for the patient. The prognosis provides the information to ensure that this goal is accomplished. When a patient is labeled terminal, it can also affect friends and caregivers. Friends may suddenly disappear because of the belief that they don't know what to say to the patient, and caregivers may provide care that is more distant. Remember that a person is alive until they die and should be treated with the same compassion, empathy, and care as any other friend or patient.

For patients and their families, this information provides a timeline to accomplish tasks or goals in preparation for impending death. This may include making a will, taking a long-awaited trip, and gathering family members from across the country. Factors specific to each tumor determine the prognosis. The natural history (the normal progression of a tumor without treatment) provides information about the tumor behavior. For example, some tumors grow slowly and cause the host few problems until late in the disease process, whereas other tumors grow rapidly and spread to distant sites at an early stage of tumor development. Generally, slow-growing tumors are associated with better prognoses than are tumors that have already metastasized at the time of presentation. Natural history information is also valuable in determining the most effective treatment for the patient, thus affecting the prognosis. The method of treatment also determines the prognosis based on information obtained through clinical trials. As more effective treatment is delivered, the prognosis improves. As stated earlier, cancer demands a multidisciplinary approach to treatment. Finding the most effective combination of treatments has a profound effect on the prognosis.

Patterns of Spread

Growth characteristics and spread patterns of a tumor have important prognostic implications. Tumors that tend to remain localized are more easily treated and thus generally have a better prognosis than do those that are diffuse or spread to distant sites early in the development of the malignancy.

Tumors that are **exophytic**, or grow outward, have better prognoses than those that invade and ulcerate underlying tissues. When a tumor is exophytic, it does not communicate with blood vessels and lymphatic vessels until later in the disease process. Blood vessels and lymphatic vessels are the highways of cancer cell transport to distant sites. Multicentric tumors, or tumors that have more than one focus of disease, can be more difficult to treat because the volume of tissue required for treatment is larger to encompass the entire organ or region. In addition, detecting all the tumor foci that may be at different stages in the development process is difficult.

Tumor dissemination, or spread, can be accomplished through the blood, lymphatics, and seeding, or extension into surrounding tissues. Tumor cells invading blood or lymph vessels can be transported to distant sites in the body. The mechanisms responsible for these cells taking root and growing in one area and not another are not clear. However, many tumors have a propensity to spread to specific sites.

Prostate cancer commonly metastasizes to the bones. For this reason, a bone scan is included in the workup if evidence exists that metastasis has already occurred at the time of diagnosis. In addition, when the primary tumor is unknown and the patient presents with metastatic disease, the sites of the metastasis give a clue about the primary tumor's location. Table 1.6 lists metastatic sites associated with common primary sites.

Tumor cells may also disseminate through seeding. Cells break off from the primary tumor and spread to new sites, where they grow. Ovarian cancer cells often spread by way of the peritoneal fluid to the abdominal cavity by this method; thus, the staging intraoperative examination is an important diagnostic and staging tool. Cells from a medulloblastoma of the brain often seed into the spinal canal by means of the cerebrospinal fluid, thus necessitating the treatment of the entire spinal cord and brain.

Tumor cells may also extend past the origin or original organ. This is known as extension or regional spread. It can include invasion through the organ wall into nearby organs or tissues.[25] This can also include tumors extending into the walls of nearby lymphatics. For example, a tumor in the head and neck region can extend into the cervical lymph nodes, known as extracapsular extension.[25] This is generally considered a poor prognosis.

Prognostic Factors

For each tumor, specific prognostic factors are based on the cellular and behavioral characteristics, tumor site, and patient-related factors. Determination of prognostic factors is made through clinical trials in which factors related to the disease and patient are statistically analyzed for a group of patients. With this method, factors that have the greatest influence on prognosis are determined.

Tumor-related factors that are often of prognostic significance include grade, stage, tumor size, status of lymph nodes, depth of invasion, and histology (including molecular information related to genes and cell receptors present). Patient-related prognostic factors include age, gender, race, and medical condition. Each factor displays a different level of importance in specific tumors. For example, the main prognostic indicator for breast cancer is the status of the axillary lymph nodes and molecular receptor status, whereas for a soft tissue sarcoma, it is histologic grade.

CLINICAL TRIALS

Much of the progress made in the management of cancer is the result of carefully planned clinical trials. This type of research can be conducted at a single clinical site or in collaboration with many institutions. The advantage of collaboration is that a greater number of patients can participate in the study, thus increasing the significance of the results. Because cancer management is multidisciplinary, clinical trials are often a collaborative effort among disciplines. Research methodology for clinical trials can be accomplished through retrospective or prospective studies that examine randomized or nonrandomized samples of the population to be studied.

Clinical trials provide research-based evidence about specific treatment effectiveness. It is through these trials that the most effective treatment with the fewest long-term side effects can be achieved.

TABLE 1.6 Common Metastatic Sites of Primary Tumors

Primary Site	Common Metastatic Sites
Lung	Liver, adrenal glands, bone, and brain
Breast	Lungs, bone, and brain
Stomach	Liver
Anus	Liver and lungs
Bladder	Lungs, bone, and liver
Prostate	Bone, liver, and lungs
Uterine cervix	Lungs, bone, and liver

Retrospective Studies

Studies that review information from a group of patients treated in the past are retrospective. The treatment has already been delivered, and the information is collected (often on a national basis) and analyzed. **Retrospective studies** have an advantage in that the information can be obtained rather quickly; the investigator does not have to wait years to see the results of a particular treatment. However, a number of drawbacks are apparent with retrospective studies and can lead to errors. Complete information about a treatment is not always easy to obtain and is often incomplete. Outside factors that may have influenced the treatment and results are not controlled and may not be accurately documented.

Prospective Studies

A clinical trial that is planned before treatment, with eligibility criteria for patient selection, is a **prospective study**. Investigators have the advantage of knowing the information that is essential to the study, thus leading to more complete and accurate documentation. In addition, better control of external factors that might influence the results of the study is possible. A disadvantage of prospective studies is the length of time needed to observe the results of a particular treatment. Depending on the length of the follow-up necessary to accurately assess the results, prospective trials can last 5 years or longer. The lung cancer screening study mentioned at the start of the chapter is an example of a prospective study.

Studies that examine the effectiveness of treatment are classified by the study objectives. **Phase I studies** are used to determine the maximum tolerance dose for a specific treatment. The end point can be either acute or long-term toxicity. **Phase II studies** are used to determine whether the Phase I treatment is significantly effective—given the acute and/or long-term side effects—to continue further study. **Phase III studies** are used to compare the experimental treatment with standard treatment with a randomized sample. **Phase IV studies** are conducted once treatments are approved by the US Food and Drug Administration. The study entails watching over a longer period of time the effects of the treatment in terms of survival and long-term side effects.[26]

Randomized Studies

Clinical studies often include several methods of treatment to determine which method results in the best outcome. After meeting all eligibility requirements for the study, patients are randomly selected for one of the treatment arms. The purpose of randomization is to eliminate any unintentional "stacking of the deck" and increase the accuracy of results and conclusions. Although patients may have the same type, grade, stage, and extent of cancer, each person responds individually to the disease and treatment. Care providers cannot control these factors, but randomization helps minimize their effects on the end result. With randomization, each arm of the study has approximately equal numbers of individuals with varying reactions.

Survival Reporting

In the planning stages of a clinical trial, an end point or objective must be established; otherwise, the study can continue indefinitely with no data analysis. Rates of survival at a set end point are one type of information used to determine the benefit of one treatment over another. Survival reporting, however, can be accomplished with many methods. With absolute survival reporting, patients alive at the end point and those who have died are counted. Patients lost to follow-up are included, but the fact that patients may have died from other causes is not considered. Adjusted survival reporting includes patients who died from other causes and had **no evidence of disease** (NED) at the times of their deaths. Relative survival reporting involves the normal mortality rate of a similar group of people based on factors such as age, gender, and race.

In addition, survival reporting at the end point includes information about the status of the disease. At the end point, the patient may be alive with NED, disease free, or alive with disease. Of equal importance is the information about treatment failures. Treatment failures are classified as local, locoregional, or distant and are based on tumor recurrences at the primary or nearby lymph node sites or metastatic disease. This information is valuable for ongoing clinical trials and for determining types of treatment techniques to prevent future failures.

THE RADIATION ONCOLOGY TEAM

The effectiveness of patient care and treatment is dependent on the teamwork of individuals in the entire radiation therapy department, the patient, and related medical professionals. From the receptionist to the physician, each individual has an important role in the goal of treating the person with cancer (Fig. 1.10). The **radiation oncologist** has the overall responsibility for the patient's care and treatment. The patient is an important member of the team and works in collaboration by complying with treatment requirements and letting team members

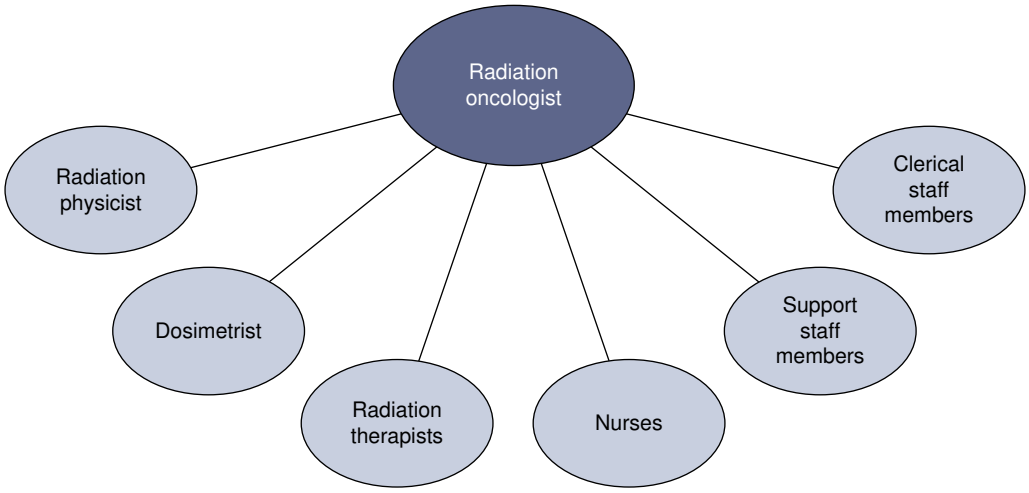


Fig. 1.10 The radiation oncology team.

know the individual effects of treatment. The patient also brings into the treatment their family and support system, who also influence the treatment outcome. Community and national cancer support resources play a role in providing information and possible financial or emotional support following the cancer diagnosis. The support that is provided by these sources is important in the overall emotional and psychosocial wellness of the patient.

Each member of the radiation therapy team, under the direction of the radiation oncologist, is essential in providing the most effective patient care and treatment. Team members work together collaboratively to share their expertise and contribute their abilities to the treatment process. Every day in every department, each of the radiation therapy team members has the opportunity to improve the quality of life for the cancer patient and his or her family. It may be answering a question, referring the patient to a support group, or giving a family member a hug. Each of these small actions has the potential to have a huge positive effect on the patient and his or her family.

When a patient enters the radiation therapy department, the first person he or she interacts with is the administrative assistant. Before the patient's arrival, this individual is involved in obtaining the patient's medical records and diagnostic images. The administrative assistant obtains insurance and the appropriate personal information and informs the other members of the radiation therapy team that the patient has arrived. The patient is taken to the consult/examination room to talk with the radiation oncologist (the physician who reviews the medical findings with the patient and discusses treatment options and the benefits of radiation therapy as well as the possible side effects). By the time the patient is in the examination room, the physician has become very familiar with the patient's medical history by talking with the patient's primary physician and reviewing all of the medical records. The physician reviews the medical findings with the patient and discusses treatment options that are available. The physician and patient will discuss the benefits of radiation therapy and the possible side effects. By the end of the consult and examination, the physician will have a treatment plan in mind, and the patient will be sent on for treatment planning and/or **simulation**. A **medical dosimetrist** (radiation therapy practitioner responsible for production of the patient's treatment plan and any associated quality assurance components) is responsible for designing the patient's treatment to accomplish the physician's prescription by using the most effective techniques possible. A medical dosimetrist is often a radiation therapist who has had additional education but may also be an individual with a physics or medical physics background. The medical dosimetrist will work collaboratively with a medical physicist. The **medical physicist** is responsible for quality assurance of all radiation therapy equipment from acceptance testing and commissioning of new equipment to regularly scheduled calibration and testing of equipment already in the department. The medical physicist oversees all treatment planning and radiation safety programs and is involved with clinical physics procedures. Before treatment, the patient will undergo a simulation or a procedure designed to delineate the treatment fields and construct any necessary immobilization or treatment devices. During a simulation, the radiation therapist (medical practitioner on the radiation oncology team who sees the patient daily and is responsible for treatment delivery and daily assessment of patient tolerance to treatment) is able to explain the simulation and treatment procedures and answer any questions the patient may have. Simulation provides an excellent time to assess the patient's medical condition and educational and support needs. Once the physician has approved of the simulation and treatment plan, the patient goes to the treatment machine. Depending on the purpose of treatment, the patient may be scheduled for 1 to 7 weeks of treatment. During treatment, the radiation oncologist generally sees the patient once a week to ensure that the treatment is progressing as expected. The radiation therapist sees the patient every day and is responsible for assessing the patient's reaction to treatment and the general medical condition. Radiation therapists and department nursing staff educate the patient about skin care, nutrition, and support services and provide appropriate referrals as necessary. Once the radiation therapy prescription has been completed, the patient will be scheduled for a follow-up appointment. The radiation oncologist may see the patient in follow-up for many years, or the primary physician may follow the patient.

Depending on the size of the department, the team may be very small or very large. In a small outpatient facility, the team may consist of a physician, radiation therapist, administrative assistant, and part-time physicist (see Fig. 1.10). The role of the team members in this scenario is vastly different from that of the members in a large department with multiple physicians, treatment and simulation radiation therapists, medical dosimetrists, physicists, nurses, and clerical and support staff. Generally, as the department grows larger, the job descriptions of the team members become more specific. In a large department, a radiation therapist's role may be limited to the actual treatment, and another radiation therapist is responsible for simulations. The role of the radiation therapist in dosimetry might be limited to treatment planning, calculations, and quality assurance procedures. In a large department, the role of the physician may also be limited to one area of expertise. For example, one physician might treat only those patients with head and neck tumors. In a small department, however, the radiation therapist's role will include treatment, simulation, treatment planning, patient care, and quality assurance. For the radiation therapist, there are opportunities for working in a number of different clinical sites, from freestanding comprehensive cancer centers to university medical centers. Each center offers different opportunities and challenges for the radiation therapist who is willing to continue to learn and grow.

For an individual who is interested in joining the radiation therapy team, it is important to learn and understand as much as possible about all aspects of radiation therapy. It is not enough to "study for the exam," because the important examinations do not happen in the classroom but rather in the clinic, with real patients.

SUMMARY

- Remember that the patient has a life outside of the cancer diagnosis. His or her past, cultural mores, religious beliefs, and other factors will influence all aspects of the treatment trajectory.
- Patient support resources are available at local, regional, state, and national levels. Radiation therapists should be aware of these resources to better meet the needs of their patients.
- Cancer has been studied for centuries, and there is still much to learn.
- Cancer occurs when normal cellular proliferation mechanisms break down.
- Cells that are rapidly dividing are more responsive to the effects of radiation and chemotherapy.
- Tumors are classified by their anatomic site, cell of origin, and biologic behavior.
- Benign tumors are generally well differentiated and do not harm the patient.
- Malignant tumors may be well differentiated to undifferentiated, may grow rapidly or very slowly, often metastasize, and invade surrounding tissues.
- Tumors are generally named for the tissue in which they arise.
- The stage of cancer defines the extent of the disease and is determined by the type of tumor.

- The grade of a tumor is determined following examination under a microscope and determines how aggressive a tumor will be.
- A multidisciplinary approach to cancer treatment is essential. Working together, physicians from all disciplines develop treatment plans that best treat the cancer and preserve the quality of life for the patient.
- Clinical trials are important in gaining information regarding the effectiveness of treatment modalities and methods. This research furthers the knowledge base in the treatment of cancer.
- The radiation team encompasses those in the radiotherapy department and those associated with the patient and other healthcare providers. Communication and teamwork are essential in providing the patient the best treatment and treatment experience possible.
- The radiation therapist has the ability to have a monumental and positive impact on each of the patients treated. This opportunity comes through accurate treatment, positive and engaging attitude, and genuine caring for patients.
- The care given by the radiation therapists had the greatest influence on overall patient satisfaction.

REVIEW QUESTIONS

The answers to the Review Questions can be found by logging on to our website at: http://evolve.elsevier.com/Washington+Leaver/principles

1. How would a theory of cancer as an initially diffuse disease affect the treatment and outcome?
2. What are the characteristics of benign and malignant cells?
3. What would a primary tumor of the bone be called?
4. What would a tumor arising from cells lining the oral cavity be called?
5. What are the roles surgery plays in the overall management and treatment of cancer?
6. What is the role of radiation therapy in the treatment of cancer?
7. What is the role of chemotherapy in the treatment of cancer?
8. What is the difference between etiology and epidemiology?
9. What roles does the radiation therapist play in patient care and treatment?

QUESTIONS TO PONDER

1. An 8-year-old child comes to your department for treatment. What factors need to be considered when scheduling an appointment?
2. What cancer patient resources are available in the hospital in which you work? What resources are available in your community?
3. Mr. Jones has a T2 tumor of the larynx, and Mrs. Smith has a T4 tumor of the larynx. What differences would you expect to see in the tumors and in the treatment plans for each of these patients?
4. How are etiology and epidemiology related to cancer screening?
5. Is prostate-specific antigen a specific and sensitive screening exam?
6. Analyze a clinical trial taking place in the hospital in which you work. What type of research is being done?

REFERENCES

1. Beasley M, Driver D, Dobbs HJ. Complications of radiotherapy: improving the therapeutic index. *Cancer Imaging*. 2005;5(1):78–84.
2. Famiglietti FM, Neal EC, Edwards TJ. Determinants of patient satisfaction during receipt of radiation therapy. *Int J Radiat Oncol Biol Phys*. 2013;87:148–152.
3. Sudhakar A. History of cancer, ancient and modern treatment methods. *J Cancer Sci Ther*. 2009;1(2):1–4.
4. Baumann M, Cordes N, Naase M, et al. Molecular cancer and radiation biology. In: Halperin EC, Brady LW, Perez CA, et al, eds. *Perez and Brady's Principles and Practice of Radiation Oncology*. 7th ed. Philadelphia, PA: Lippincott, Williams, and Wilkins; 2019.
5. Solomon E, Borrow J, Goddard AD. Chromosome aberrations and cancer. *Science*. 1991;254(5305):1153–1159.
6. Weinberg RA. Tumor suppressor genes. *Science*. 1991;254(5305):1138–1145.
7. Yunis JJ. The chromosomal basis of human neoplasia. *Science*. 1983;221(4607):227–235.
8. SEER program. National Cancer Institute website. https://seer.cancer.gov/. 2018. Accessed January 23, 2019.
9. Noone AM, Howlader N, Krapcho M, et al, eds. SEER Cancer Statistics Review, 1975–2015. https://seer.cancer.gov/csr/1975_2015/. Accessed February 4, 2019.
10. ACS cancer prevention blueprint targets controllable risk factors. American Cancer Society website. https://www.cancer.org/latest-news/acs-cancer-prevention-blueprint-targets-controllable-risk-factors.html. 2019. Accessed January 23, 2019.
11. American Cancer Society facts and figures 2019. American Cancer Society website. https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2019.html. 2019. Accessed January 23, 2019.
12. Aberle DR, Adams AM, Berg CD, et al. Reduced lung-cancer mortality with low-dose computed tomographic screening. *N Engl J Med*. 2011;365(5):395–409.
13. Cancer staging system: what is cancer staging? American Joint Committee on Cancer website. https://cancerstaging.org/references-tools/pages/what-is-cancer-staging.aspx. 2019. Accessed January 23, 2019.
14. Moore CM, Robertson NL, Arsanious N, et al. Image-guided prostate biopsy using magnetic resonance imaging-derived targets: a systematic review. *Eur Urol*. 2013;63(1):125–140.
15. MRI may reduce unnecessary prostate biopsies. Harvard Men's Health Watch website. https://www.health.harvard.edu/mens-health/mri-may-reduce-unnecessary-prostate-biopsies. 2018. Accessed February 4, 2019.
16. ViewRay website. https://viewray.com/. Accessed January 25, 2019.
17. Yamada Y, Rogers L, Demanes DJ, et al. American Brachytherapy Society consensus guidelines for high-dose rate prostate brachytherapy. *Brachytherapy*. 2012;11(1):20–32.
18. Radiation therapy for eye cancer. American Cancer Society website. https://www.cancer.org/cancer/eye-cancer/treating/radiation-therapy.html. 2014. Accessed January 23, 2019.
19. Systemic radiation therapy. American Cancer Society website. https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/radiation/systemic-radiation-therapy.html. 2017. Accessed January 24, 2019.

20. American Joint Committee on Cancer. *Cancer Staging Manual*. 8th ed. New York, NY: Springer; 2018.
21. NCI dictionary of cancer terms. National Cancer Institute website. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/port-a-cath. Accessed January 25, 2019.
22. Skeel RT. *Handbook of Cancer Chemotherapy*. 9th ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2016.
23. How chemotherapy drugs work. American Cancer Society website. https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/chemotherapy/how-chemotherapy-drugs-work.html. 2016. Accessed January 23, 2019.
24. Targeted cancer therapies. National Cancer Institute website. https://www.cancer.gov/about-cancer/treatment/types/targeted-therapies/targeted-therapies-fact-sheet. 2019. Accessed January 25, 2019.
25. SEER training modules: cancer registration and surveillance modules. National Cancer Institute website. https://training.seer.cancer.gov/staging/systems/summary/regionalized.html. 2018. Accessed January 24, 2019.
26. What are the phases of clinical trials? American Cancer Society website. https://www.cancer.org/treatment/treatments-and-side-effects/clinical-trials/what-you-need-to-know/phases-of-clinical-trials.html. 2016. Accessed January 25, 2019.
27. Jain RK, Kozak KR. Molecular pathophysiology of tumors. In: Halperin EC, Brady LW, Perez CA, et al, eds. *Perez and Brady's Principles and Practice of Radiation Oncology*. 7th ed. Philadelphia, PA: Lippincott, Williams, and Wilkins; 2019.

2

The Ethics and Legal Considerations of Cancer Management

Bettye Wilson

OBJECTIVES

- List and define the terminology associated with the ethics and legal consideration of cancer management.
- Discuss the traditional ethical theories and models.
- Define patient autonomy and informed consent.
- Discuss advance directives.
- Differentiate between the types of living wills.
- Evaluate the patient care partnership to determine the scope of patient rights included therein.
- Explain how informed consent and patient autonomy are related.
- Recognize the role of the healthcare team in patient confidentiality.
- Apply Health Insurance Portability and Accountability Act (HIPAA) compliance standards in the clinical setting.
- Identify the stages of grief.
- Support dying patients and their families.
- Quote the legal doctrines applicable to patient care.
- Examine the role of risk management.
- Discuss medical records, their content, confidentiality of, and electronic record vulnerability.
- Determine the role of the Standards of Ethics and Practice Standards on the practice of radiation therapy.

OUTLINE

KEY TERMS

Advance directives
Analytical model
Assault
Autonomy
Battery
Beneficence
Civil law
Code of ethics
Collegial model
Confidentiality
Consequentialism
Contractual model
Covenant model
Deontology
Doctrine of foreseeability
Doctrine of personal liability
Doctrine of res ipsa loquitur
Doctrine of respondeat superior
Durable power of attorney for healthcare
Emotional intelligence
Engineering model
Ethics
False imprisonment
Incident
Informed consent
Invasion of privacy
Justice
Laws
Legal concepts
Legal ethics
Libel
Living will
Medical record
Moral ethics
Negligence
Nonconsequentialism
Nonmaleficence
Practice standards
Priestly model
Risk management
Role fidelity
Scope of practice
Slander
Teleology
Tort law
Values
Veracity
Virtue ethics

A diagnosis of cancer is one of the most, if not the most, feared diagnoses any patient can receive. Although numerous advancements have been made in the treatment of these diseases and there are many survivors, it is general knowledge that a cancer diagnosis is a life-altering event. Whether surgery, medical oncology, radiation oncology, or any combination of the three is used to treat the disease, patients often feel that they have little real control over the outcome. They are also acutely aware of the potential morbidity associated with treatment measures. One cancer patient may have summed up the experience of being diagnosed with cancer in a newspaper column she wrote about the event: "We cancer patients tend to recall our diagnosis day with the kind of clarity that comes with any catastrophic event. 'I'm sorry, but …,' the oncologist begins. Your heart races… or maybe it seems to stop. Your hands sweat. The noise of blood coursing through your veins deafens you to everything but the doctor's voice: 'You have cancer.' Just as many Americans can tell you where they were when the twin towers fell, so can we recall, in often minute detail, that moment when our world stood still."[1]

Each year in the United States, more than 1.5 million people will receive a cancer diagnosis. More than one-third of those who are diagnosed will succumb to their illness.[2] A diagnosis of cancer changes a person's life in ways many can only imagine. Although the diagnosis does not mean that the disease is terminal, it is certainly bad news and a negative event. Dr. Elisabeth Kübler-Ross is perhaps the best known authority on the subject of dealing with those experiencing forms of grief. In her studies on people with terminal illnesses, she found that the emotional cycle experienced by those with terminal illnesses was not unique to them but is also found in individuals experiencing circumstances they perceive as having a negative effect on their lives.[3] A diagnosis of cancer certainly fits the bill. The quest to beat the disease begins with personal courage and fortitude and with extensive involvement of dedicated healthcare professionals. Those who care for and treat cancer patients must understand their obligations as professionals. Not only must they care for and treat the patients, they must also deal with the emotions of the patients' families and other healthcare professionals. There are also legal issues that must be addressed and sometimes avoided, as will be discussed in the chapter.

THE CASE FOR ETHICS IN RADIATION THERAPY

Every aspect of the world of healthcare is fast paced and ever changing, and radiation therapy is no exception. To provide quality patient care in this fast-paced dynamic world, all healthcare providers must keep abreast of the latest treatment developments and technological advancements. In addition, all must be well versed in the ethical and legal considerations of cancer management. Radiation therapists and radiation therapy students deal with patients who have specific needs related to their attempts to control catastrophic diseases that are taking over their lives and the lives of those close to them. Defining the roles and responsibilities of the radiation therapy student, the practicing radiation therapist, and other members of the radiation oncology team as they care for their patients is extremely important. In addition to developing the technical skills necessary to practice in the profession, members of the radiation oncology team must develop an understanding of the basic theories regarding ethics, patients' rights, and the scope of practice and code of ethics for radiation therapy. The medical-legal aspects of informed consent, record keeping, and confidentiality are also important.

Radiation therapists and medical imaging technologists are credentialed by the American Registry of Radiologic Technologists (ARRT). The ARRT uses the terms Registered Technologists (RTs) and Registered Radiologist Assistants (RRAs) to describe those certified under its umbrella. Upon certification, individuals may use the initials RT followed by the initial(s) designating their area(s) of certification. In radiation therapy, these initials would be RT(T) ARRT. The primary professional membership organization for those credentialed by the ARRT is the American Society of Radiologic Technologists (ASRT). The ASRT developed a code of ethics to guide radiation therapy students on elements of the field while they develop their knowledge and skills, and to guide practicing radiation therapists in their professional conduct (Box 2.1). However, the Code of Ethics for Radiation Therapists does not list all principles and rules by which radiation therapists are governed. The ARRT developed a mission-based, more comprehensive document called the "Standards of Ethics."[4] This document is published and enforced by the ARRT. The Standards of Ethics are applicable to individuals who are certified through the ARRT and are either currently registered or were previously. The Standards of Ethics also apply to applicants for ARRT examinations and certifications, as well as students enrolled in radiation therapy educational programs. The document is composed of a preamble and three parts or sections: Section A outlines the Code of Ethics, Section B contains the Rules of Ethics, and Section C describes the administrative procedures followed by the ARRT when an individual is accused of violating the Code as related to the established rules.

BOX 2.1 Code of Ethics for Radiation Therapists

- The radiation therapist advances the principal objective of the profession to provide services to humanity with full respect for the dignity of mankind.
- The radiation therapist delivers patient care and service unrestricted by concerns of personal attributes or the nature of the disease or illness and nondiscriminatory with respect to race, color, creed, sex, age, disability, or national origin.
- The radiation therapist assesses situations; exercises care, discretion, and judgment; assumes responsibility for professional decisions; and acts in the best interest of the patient.
- The radiation therapist adheres to the tenets and domains of the scope of practice for radiation therapists.
- The radiation therapist actively engages in lifelong learning to maintain, improve, and enhance professional competence and knowledge.

From the American Society of Radiologic Technologists, 2018.

The ARRT Code of Ethics contains 10 guiding principles (Box 2.2). As stated at the beginning of the code, "The Code of Ethics shall serve as a guide by which Registered Technologists and Candidates may evaluate their professional conduct as it relates to patients, health care consumers, employers, colleagues, and other members of the health care team."[5] This is quite a powerful and comprehensive statement. It is so inclusive that it seems be a guide to how RTs and candidates should behave around everyone. Isn't everyone a potential consumer? Does this statement mean that professional behaviors extend into off-the-job activities? The answer to both of these questions is yes. But it must be remembered that the Code of Ethics is aspirational, which simply means that the principles of the code are those to which the ARRT hopes RTs and candidates will aspire or will seek to achieve. On the other hand, mandatory rules do exist in the second part or section of the Standards of Ethics. Appropriately, these rules are titled the "Rules of Ethics." The ARRT Board of Trustees recommends modification of the Standards of Ethics when necessary. In 2009 the ARRT Board recommended revision of some of the rules. Rule 2 was expanded to better address examination subversion. Rule 18 was incorporated into Rule 6, and a new Rule 18 was added to better address subversion of the ethical standards for continuing education (CE). In addition, a new

BOX 2.2 Code of Ethics

The **Code of Ethics** forms the first part of the "Standards of Ethics." The Code of Ethics shall serve as a guide by which certificate holders and candidates may evaluate their professional conduct as it relates to patients, healthcare consumers, employers, colleagues, and other members of the healthcare team. The Code of Ethics is intended to assist certificate holders and candidates in maintaining a high level of ethical conduct and in providing for the protection, safety, and comfort of patients. The Code of Ethics is aspirational.

1. The radiologic technologist acts in a professional manner, responds to patient needs, and supports colleagues and associates in providing quality patient care.
2. The radiologic technologist acts to advance the principal objective of the profession to provide services to humanity with full respect for the dignity of mankind.
3. The radiologic technologist delivers patient care and service unrestricted by the concerns of personal attributes or the nature of the disease or illness, and without discrimination on the basis of sex, race, creed, religion, or socioeconomic status.
4. The radiologic technologist practices technology founded upon theoretical knowledge and concepts, uses equipment and accessories consistent with the purposes for which they were designed, and uses procedures and techniques appropriately.
5. The radiologic technologist assesses situations; exercises care, discretion, and judgment; assumes responsibility for professional decisions; and acts in the best interest of the patient.
6. The radiologic technologist acts as an agent through observation and communication to obtain pertinent information for the physician to aid in the diagnosis and treatment of the patient and recognizes that interpretation and diagnosis are outside the scope of practice for the profession.
7. The radiologic technologist uses equipment and accessories, uses techniques and procedures, performs services in accordance with an accepted standard of practice, and demonstrates expertise in minimizing radiation exposure to the patient, self, and other members of the healthcare team.
8. The radiologic technologist practices ethical conduct appropriate to the profession and protects the patient's right to quality radiologic technology care.
9. The radiologic technologist respects confidences entrusted in the course of professional practice, respects the patient's right to privacy, and reveals confidential information only as required by law or to protect the welfare of the individual or the community.
10. The radiologic technologist continually strives to improve knowledge and skills by participating in continuing education and professional activities, sharing knowledge with colleagues, and investigating new aspects of professional practice.

From the American Registry of Radiologic Technologists, 2017.

administrative procedure was incorporated to link ethics infractions to violation of both federal and state laws. After a period of public comment on the changes, they went into effect in August 2009. There are currently 22 Rules of Ethics (Box 2.3). These are rules that truly govern the professional behaviors of RTs, RRAs, and candidates for ARRT certification. The Rules of Ethics are not aspirational; they are enforceable. Those individuals found in violation of the ARRT Rules of Ethics are subject to sanctions ranging from private reprimand to the most dreaded sanction of all—permanent revocation of certification. The rules not only govern activities in which an RT, an RRA, or a candidate might personally engage; they also include instances in which individuals, although not directly involved, are aware of activities that violate ethical standards but permit the activities to occur. A thorough examination and understanding of the ARRT Standards of Ethics must be an integral part of education in radiation therapy and imaging sciences. Students, especially those with questionable criminal activity in their background, unless the matter was adjudicated in juvenile court, should be encouraged to submit a preapplication for ARRT certification at least 6 months before graduation from their educational program. By doing so, their past criminal activity may be examined by the ARRT Ethics staff and/or the ARRT Ethics Committee in the determination of whether the individual has violated the Rules of Ethics and whether he or she is eligible or ineligible for ARRT certification. The names of individuals sanctioned by the ARRT are published in the "Annual Report to Technologists" and may also be found on the ARRT website.

Any professional code of ethics serves two major functions: education and regulation. It educates persons in the profession who do not reflect on ethical implications of their actions unless something concrete is before them. It also educates other professionals and the general public regarding the ethical standards expected of a given profession.[6] Professional codes of conduct should accomplish several objectives: (1) describe the values held by the profession, (2) impose obligations on practitioners to accept the values and practices included within the code, and (3) hold professionals liable for adherence to those obligations with possible penalties for nonconformance.[7] It is an obligation to society of any profession to assist in the development of social attitudes and policies that govern not only the operation of the profession but also the expectations of the public.[7] Understanding ethical concepts and legal issues and developing interpersonal skills, through the study of the material in this chapter, should enable students and practicing radiation therapists to care for their patients humanely and compassionately while adhering to the professional code of ethics. After all, it is not just the cancer that is being cared for and treated—it is the patient.

ETHICAL ASPECTS OF CANCER MANAGEMENT

Definitions and Terminology

Webster's New Collegiate Dictionary[8] defines **ethics** as "(1) the discipline dealing with what is good and bad, moral duty, and obligation; (2) a set of moral principles or values; (3) a theory or system of moral values; and (4) the principles of conduct governing an individual or a group." Ethics for an individual derive from the person's values.[9] There are four main sources of **values**: culture, experience, religion, and science.[6] Individuals gather an understanding of right and wrong from the cumulative experiences of life and develop patterns of approaching situations in which the complexities of right and wrong must be addressed.[10]

Cancer patients experience a variety of emotions, and although radiation therapy students and practitioners are cognitively and intellectually prepared to treat their cancer, they must also be able to treat the emotions they experience. This requires that students, therapists, and other members of the patient care team develop an understanding of their personal level of emotional intelligence (EI).

Although addressed by many individuals in the field of psychology throughout the years, the concept of EI was popularized by Daniel Goleman in his 1995 text *Emotional Intelligence: Why It Can Matter More Than IQ*. Goleman describes **EI** as the ability to perceive, evaluate, understand, and control emotions in ourselves and others.[11] In earlier work, Peter Salovey and John Mayer described the same ability as "the subset of social intelligence that involves the ability to monitor one's own and others' feelings and emotions, to discriminate among them and to use this information to guide one's thinking and actions."[12] Salovey and Mayer also described four factors that influence EI: perceiving emotions, reasoning with emotions, understanding emotions, and managing emotions.[12] To assess personal EI, individuals need to first determine their own emotional perceptions and how they reason

BOX 2.3 Rules of Ethics

The Rules of Ethics form the second part of the *Standards of Ethics.* They are mandatory standards of minimally acceptable professional conduct for all certificate holders and candidates. Certification and registration are methods of assuring the medical community and the public that an individual is qualified to practice within the profession. Because the public relies on certificates and registrations issued by the American Registry of Radiologic Technologists (ARRT), it is essential that certificate holders and candidates act consistently with these Rules of Ethics. These Rules of Ethics are intended to promote the protection, safety, and comfort of patients. The Rules of Ethics are enforceable. Certificate holders and candidates engaging in any of the following conduct or activities, or who permit the occurrence of the following conduct or activities with respect to them, have violated the Rules of Ethics and are subject to sanctions as described hereunder:

1. Using fraud or deceit in procuring or attempting to procure, maintain, renew, or obtain or reinstate certification or registration as issued by ARRT; employment in radiologic technology; or a state permit, license, or registration certificate to practice radiologic technology. This includes altering in any respect any document issued by the ARRT or any state or federal agency, or by indicating in writing certification or registration with the ARRT when that is not the case.
2. Subverting or attempting to subvert ARRT's examination process, and/or the structured self-assessments that are part of the Continuing Qualifications Requirements (CQR) process. Conduct that subverts or attempts to subvert ARRT's examination and/or CQR assessment process includes, but is not limited to:
   - (i) disclosing examination and/or CQR assessment information by using language that is substantially similar to that used in questions and/or answers from ARRT examinations and/or CQR assessments when such information is gained as a direct result of having been an examinee or a participant in a CQR assessment or having communicated with an examinee or a CQR participant; this includes, but is not limited to, disclosures to students in educational programs, graduates of educational programs, educators, anyone else involved in the preparation of candidates to sit for the examinations, or CQR participants; and/or
   - (ii) receiving examination and/or CQR assessment information that uses language that is substantially similar to that used in questions and/or answers on ARRT examinations or CQR assessments from an examinee, or a CQR participant, whether requested or not; and/or
   - (iii) copying, publishing, reconstructing (whether by memory or otherwise), reproducing, or transmitting any portion of examination and/or CQR assessment materials by any means, verbal or written, electronic or mechanical, without the prior expressed written permission of ARRT or by using professional, paid, or repeat examination takers and/or CQR assessment participants, or any other individual for the purpose of reconstructing any portion of examination and/or CQR assessment materials; and/or
   - (iv) using or purporting to use any portion of examination and/or CQR assessment materials that were obtained improperly or without authorization for the purpose of instructing or preparing any candidate for examination or participant for CQR assessment; and/or
   - (v) selling or offering to sell, buying or offering to buy, or distributing or offering to distribute any portion of examination and/or CQR assessment materials without authorization; and/or
   - (vi) removing or attempting to remove examination and/or CQR assessment materials from an examination or assessment room, or having unauthorized possession of any portion of or information concerning a future, current, or previously administered examination or CQR assessment of ARRT; and/or
   - (vii) disclosing what purports to be, or what you claim to be, or under all circumstances is likely to be understood by the recipient as, any portion of "inside" information concerning any portion of a future, current, or previously administered examination or CQR assessment of ARRT; and/or
   - (viii) communicating with another individual during administration of the examination or CQR assessment for the purpose of giving or receiving help in answering examination or CQR assessment questions, copying another candidate's, or CQR participants answers, permitting another candidate or a CQR participant to copy one's answers, or possessing unauthorized materials including, but not limited to, notes; and/or
   - (ix) impersonating a candidate, or a CQR participant, or permitting an impersonator to take or attempt to take the examination or CQR assessment on one's own behalf; and/or
   - (x) use of any other means that potentially alters the results of the examination or CQR assessment such that the results may not accurately represent the professional knowledge base of a candidate, or a CQR participant.
3. Convictions, criminal proceedings, or military court-martials as described below:
   - (i) conviction of a crime, including a felony, a gross misdemeanor, or a misdemeanor, with the sole exception of speeding and parking violations. All alcohol and/or drug related violations must be reported; and/or
   - (ii) criminal proceeding where a finding or verdict of guilt is made or returned but the adjudication of guilt is either withheld, deferred, or not entered, or the sentence is suspended or stayed; or a criminal proceeding in which the individual enters a plea of guilty or nolo contendere (no contest); or in which the individual enters into a pretrial diversion activity; or
   - (iii) military court-martials related to any offense identified in these Rules of Ethics.
4. Violating a rule adopted by a state or federal regulatory authority or certification board resulting in the individual's professional license, permit, registration or certification being denied, revoked, suspended, placed on probation or a consent agreement or order, voluntarily surrendered, subjected to any conditions, or failing to report to ARRT any of the violations or actions identified in this Rule.
5. Performing procedures which the individual is not competent to perform through appropriate training and/or education or experience unless assisted or personally supervised by someone who is competent (through training and/or education or experience).
6. Engaging in unprofessional conduct, including, but not limited to:
   - (i) a departure from or failure to conform to applicable federal, state, or local governmental rules regarding radiologic technology practice or scope of practice; or, if no such rule exists, to the minimal standards of acceptable and prevailing radiologic technology practice;
   - (ii) any radiologic technology practice that may create unnecessary danger to a patient's life, health, or safety.

   Actual injury to a patient or the public need not be established under this clause.
1. Delegating or accepting the delegation of a radiologic technology function or any other prescribed healthcare function when the delegation or acceptance could reasonably be expected to create an unnecessary danger to a patient's life, health, or safety. Actual injury to a patient need not be established under this clause.
2. Actual or potential inability to practice radiologic technology with reasonable skill and safety to patients by reason of illness; use of alcohol, drugs, chemicals, or any other material; or as a result of any mental or physical condition.

BOX 2.3 Rules of Ethics—cont'd

3. Adjudication as mentally incompetent, mentally ill, chemically dependent, or dangerous to the public, by a court of competent jurisdiction.
4. Engaging in any unethical conduct, including, but not limited to, conduct likely to deceive, defraud, or harm the public; or demonstrating a willful or careless disregard for the health, welfare, or safety of a patient. Actual injury need not be established under this clause.
5. Engaging in conduct with a patient that is sexual or may reasonably be interpreted by the patient as sexual, or in any verbal behavior that is seductive or sexually demeaning to a patient; or engaging in sexual exploitation of a patient or former patient. This also applies to any unwanted sexual behavior, verbal or otherwise.
6. Revealing a privileged communication from or relating to a former or current patient, except when otherwise required or permitted by law, or viewing, using, or releasing confidential patient information in violation of HIPAA.
7. Knowingly engaging or assisting any person to engage in, or otherwise participating in, abusive or fraudulent billing practices, including violations of federal Medicare and Medicaid laws or state medical assistance laws.
8. Improper management of patient records, including failure to maintain adequate patient records or to furnish a patient record or report required by law; or making, causing, or permitting anyone to make false, deceptive, or misleading entry in any patient record.
9. Knowingly assisting, advising, or allowing a person without a current and appropriate state permit, license, registration, or an ARRT registered certificate to engage in the practice of radiologic technology, in a jurisdiction that mandates such requirements.
10. Violating a state or federal narcotics or controlled substance law.
11. Knowingly providing false or misleading information that is directly related to the care of a former or current patient.
12. Subverting, attempting to subvert, or aiding others to subvert or attempt to subvert *ARRT's Continuing Education (CE) Requirements for Renewal of Registration,* and/or ARRT's CQR. Conduct that subverts or attempts to subvert ARRT's CE or CQR Requirements includes, but is not limited to:
    (i) providing false, inaccurate, altered, or deceptive information related to CE or CQR activities to ARRT or an ARRT recognized recordkeeper; and/or
    (ii) assisting others to provide false, inaccurate, altered, or deceptive information related to CE or CQR activities to ARRT or an ARRT recognized recordkeeper; and/or
    (iii) conduct that results or could result in a false or deceptive report of CE or CQR completion; and/or
    (iv) conduct that in any way compromises the integrity of the CE or CQR requirements such as sharing answers to the posttests or self-learning activities, providing or using false certificates of participation, or verifying credits that were not earned.
13. Subverting or attempting to subvert the ARRT certification or registration process by:
    (i) making a false statement or knowingly providing false information to ARRT; or
    (ii) failing to cooperate with any investigation by the ARRT.
14. Engaging in false, fraudulent, deceptive, or misleading communications to any person regarding the individual's education, training, credentials, experience, or qualifications, or the status of the individual's state permit, license, or registration certificate in radiologic technology or certificate of registration with ARRT.
15. Knowing of a violation or a probable violation of any Rule of Ethics by any certificate holder or candidate and failing to promptly report in writing the same to the ARRT.
16. Failing to immediately report to his or her supervisor information concerning an error made in connection with imaging, treating, or caring for a patient. For purposes of this rule, errors include any departure from the standard of care that reasonably may be considered to be potentially harmful, unethical, or improper (commission). Errors also include behavior that is negligent or should have occurred in connection with a patient's care, but did not (omission). The duty to report under this rule exists whether or not the patient suffered any injury.

From the American Registry of Radiologic Technologists, 2018.

with them. They may ask themselves what evokes certain feelings within themselves and why they feel certain emotions. Then they must ask themselves how they deal with those feelings. Personal examination of EI will assist in understanding what emotions a patient may be feeling and how those emotions are manifested in the clinical setting. With that understanding, the student or therapist will be better able to empathize and modify, if necessary, patient interaction and treatment.

Ethics are based on values.

In the study of ethics, a person must distinguish between **moral** and **legal ethics**. Morality has to do with conscience. It is a person's concept of right or wrong as it relates to conscience, God, a higher being, or a person's logical rationalization. *Morality* can be defined as fidelity to conscience. **Legal concepts** are defined as the sum of rules and regulations by which society is governed in any formal and legally binding manner. The law mandates certain acts and forbids other acts under penalties of criminal sanction. **Laws**, the foundation of which is ethics, are primarily concerned with the good of a society as a functioning unit.[13,14]

The foundation of law is ethics.

In dealing with ethical issues in cancer treatment, healthcare professionals should consider bioethics. *Miller-Keane Encyclopedia & Dictionary of Medicine, Nursing, & Allied Health, Seventh Edition*[15] defines *bioethics* as the application of ethics to the bioethical sciences, medicine, nursing, and healthcare. The text further states that the practical ethical questions raised in everyday healthcare are generally in the realm of bioethics. There are seven written principles associated with bioethics. Referred to as the *Principles of Biomedical Ethics,* the seven are inclusive of autonomy, beneficence, confidentiality, justice, nonmaleficence, role fidelity, and veracity.[5] It is generally desirable for those who practice in the healthcare setting to innately prescribe to the aforementioned principles. **Autonomy** emphasizes the right of patients to make decisions for themselves, free of interference by others. It also recognizes that patients are to be respected for their independence and freedom to control their own actions and decision-making capacity. Theoretically, each person should be recognized and respected for his or her social uniqueness and moral worth. In healthcare, this theory means that individuals should and must be respected for their abilities to make their own choices and develop their own plans for their lives.[16] **Beneficence** is defined as doing good and calls on healthcare professionals to act in the best interest of patients, even when it might be inconvenient or sacrifices must be made. Palliative treatment may be considered a form of beneficence in radiation oncology because it helps relieve pain and suffering, thereby "doing good," but this can be viewed as a problem in some cases. When

a patient has expressed no desire for prolongation of her or his life by any means, palliative treatment may not be viewed as a beneficent act. **Confidentiality** is the principle that relates to the knowledge that information revealed by a patient to a healthcare provider, or information that is learned in the course of a healthcare provider performing her or his duties, is private and should be held in confidence. To hold something in confidence in essence means to keep it secret. A secret is information that a person has a right or an obligation to conceal. In healthcare, confidentiality is based on obligatory secrets, of which there are three types: natural, promised, and professional.[17,18] Natural secrets are those that involve information that is naturally harmful if it were to be revealed. Promised secrets are those that involve information that an individual has promised someone that they will not reveal. The professional secret is the type of secret that is of most importance in healthcare. Professional secrets are knowledge and information learned in the course of professional healthcare practice that, if revealed, would harm the patient while also harming the profession and the society that depends on the profession for important care and services.[16] The obligation of healthcare providers to keep professional secrets is not only recognized within the frame of bioethics but also is seen as a patient right and is protected within the frame of law as well. In 1973, the American Hospital Association (AHA) constructed and adopted what became known as "A Patient's Bill of Rights." This document was further refined, revised, and copyrighted in 1992 and 1998. More recently, the document has again been revised and renamed the "Patient Care Partnership." The document, a patient brochure, is intended to provide patients with an explanation of what to expect during their stay in the hospital, and to explain their rights and responsibilities. The brochure is currently available in eight languages. The translation into multiple languages reflects the patient diversity within the healthcare population of the United States. The brochure contains the tenets of "A Patient's Bill of Rights," with information included on the following patient rights and responsibilities:

- High-quality patient care
- A clean and safe environment
- Patient's involvement in his or her care
- Protection of the patient's privacy
- Help when the patient leaves the hospital
- Help with the patient's billing claim

As noted in the list of brochure topics above, protection of a patient's privacy is considered a patient right. The "Patient Care Partnership" is also related to other topics in ethics and will be discussed further in a later section of this chapter.

In 1996, the federal government became more involved in the regulation of healthcare with the passage of the Health Insurance Portability and Accountability Act (HIPAA), Public Law 104-191. Under this provision of healthcare law, overseen primarily by the U.S. Department of Health and Human Services, healthcare facilities, providers, and employees are mandated under penalty of law to publish rules to ensure (1) standardization of electronic patient administrative, financial, and health data; (2) creation of unique health identifiers for employees, healthcare providers, and health plans; and (3) security standards that protect the confidentiality and integrity of "individually identifiable health information," past, present, and future.[19]

All employees working in healthcare and students in healthcare educational programs are required to be trained in HIPAA regulatory requirements and compliance. At the heart of HIPAA regulations is confidentiality of health information. Confidentiality is the ethical principle that relates to all of the others.

Confidentiality is the ethical principle that binds all the seven bioethical principles.

Justice is the ethical principle that relates to fairness and equal treatment for all. Essentially, the application of the bioethical principle of justice asks persons to ensure that fairness and equity are maintained among individuals.[20] Treatment of all patients as equals regardless of the nature of their illness, age, gender, sexual preference, socioeconomic status, religious preference, national origin, and similar factors is considered a form of justice. The Patient Protection and Affordable Care Act of 2010 (HR 39620) (Public Law 111-148) is yet another step in ensuring equal treatment of all individuals seeking medical help. Also called "Obama Care," among other things, the Act contains the following provisions:

- Prohibits health insurers from denying a patient coverage because of their medical histories
- Prevents health insurers from charging different premiums based on medical histories and gender
- Provides a subsidy to low- and middle-income Americans to help purchase insurance
- Expands Medicaid to include more low-income Americans

The Act has come under major scrutiny by the current administration, and attempts have been made to rescind the Act, with nothing in line to replace it. Although the Act has flaws, it attempts to bring "Justice" into the realm of American healthcare.[21]

Nonmaleficence directs healthcare professionals to avoid harmful actions to patients. Professionals must avoid mishandling or mistreating patients in any manner that may be construed as harmful. Indeed, most healthcare professionals can recite what has been expressed as the first part of the original Hippocratic Oath: "First, do no harm." **Role fidelity** is the principle that reminds healthcare professionals that they must be faithful to their role in the healthcare environment. Healthcare professions have defined standards of practice, which will be discussed later in this chapter. The last of the seven principles of biomedical ethics is veracity. **Veracity** is truthfulness within the realm of healthcare practice. Under certain conditions, it is acceptable for confidentiality to be breached and veracity to be disregarded. These situations include, but are not exclusive to, civil cases, criminal cases, suspected child and elder abuse, and matters of public health and safety.[7] Even under the aforementioned conditions, healthcare professionals should safeguard as much patient information as they can by answering only the questions asked of them and disclosing only subpoenaed information.

Ethical Theories and Models

Ethics is the systematic study of morals (e.g., the rightness or wrongness of human conduct and character as known by natural reason), although many people believe that ethics simply means using common sense. A respectable value system and appropriate ethical behaviors are desirable traits for those serving in any healthcare profession. Ethical problem-solving begins with an awareness of ethical issues in healthcare and is the sum of ethical knowledge, common sense, personal and professional values, practical wisdom, and learned skills.[18] Although an individual's personal system of decision-making may be developed from values and experiences, it generally involves some understanding and application of basic principles common to formal ethical theories.[5]

Ethical theories may be divided into the following three broad groups:

1. Teleology (consequentialism)
2. Deontology (nonconsequentialism)
3. Virtue ethics

Teleological ethical theories assert that the consequences of an act or action should be the major focus when deciding how to solve an ethical problem. Because of this, **teleology** is also called **consequentialism**. It has often been stated that teleologists believe that the ends justify the means. Two forms of consequentialism exist: egoism and

utilitarianism. In egoism, the best long-term interests of an individual are promoted. Egoists believe that in evaluating an act or action for its moral value, the act or action must produce a greater ratio of good over bad for the individual, for the long term, than any of the possible alternatives. There are essentially two types of egoism: impersonal and personal. Impersonal egoists generally believe that everyone should behave in a fashion that promotes her or his best long-term interests, whereas personal egoists pursue their own best long-term interests and perform in a manner that benefits only themselves. They usually make no attempt to advocate or control what others should do. Because the role of healthcare professionals is to serve others, the practice of egoism in any form is incompatible and undesirable. The ethical theory of utilitarianism holds that people should act to produce the greatest ratio of good to evil for everyone. Attributed to the work of Jeremy Bentham and his student John Mill, this theory is considered most applicable to ethical decision-making in healthcare.[22] Bentham and Mill surmised that behaviors are right if they promote happiness and pleasure for everyone, and wrong to the extent that they do not produce pleasure, only pain. There are two categories or forms of utilitarianism: act and rule. Those who practice act utilitarianism believe that ethical behaviors should be geared toward performing acts that produce the greatest ratio of good to bad. The act itself, and its positive consequences, is their only genuine consideration. Rule utilitarianists believe that individuals should base their ethical choices on the consequences of a rule or rules under which an act or action falls without primary consideration of the consequences. The so-called rules may be those derived from religious belief, such as the Ten Commandments; those offered by professional codes of conduct or ethics, such as the Code of Ethics for Radiation Therapists; those developed by professional organizations in the interest of their clients, such as the AHA's Patient Care Partnership; or those that may be considered an arbitrary set of an individual's personal beliefs.[7]

Deontology, or **nonconsequentialism**, uses formal rules of right and wrong for reasoning and problem-solving. Developed by Immanuel Kant in its purest form, the ethical theory of deontology seeks to exclude the consideration of consequences when performing ethical acts or making ethical decisions. Kant surmised that morality is based on reason and that the principles derived from reason are universal and should be designated as universal truths. Because there was no definition or explanation of these truths, Kant created what is known as the "categorical imperative." The categorical imperative states that "… we should act in such a way as to will the maxim of our actions to become universal law."[14] A maxim is a statement of general truth, fundamental principle, or rule of conduct.[23] Although there are several maxims attributed to Kant, the one that is most relevant to the healthcare professions is "We must always treat others as ends and not as means only."[14] Application of this maxim to healthcare professionals simply means that those adhering to this principle would never view their positions as just jobs for which they receive financial remuneration, but instead would consider each patient as an individual (autonomy) to whom a professional duty is owed (beneficence, confidentiality, justice, nonmaleficence, role fidelity, and veracity) and to which these principles of biomedical ethics should be applied.

Virtue ethics is the use of practical wisdom for emotional and intellectual problem-solving. Practical reasoning, consideration of consequences, rules established by society, and the effects that actions have on others play important parts in applying the theory of virtue ethics. This approach to problem-solving serves the healthcare professional by integrating intellect, practical reasoning, and individual good.[18] Application of this theory to healthcare may be problematic, because instead of focusing on the acts or actions of individuals, this theory focuses on the individual performing the act or action.[23] Healthcare professionals work together as a team to provide patients with high-quality care. Promotion or consideration of self, like egoism, has no place in the healthcare professions.

Regardless of which values a person holds and to which ethical theory he or she subscribes, the person will face ethical problems that must be solved. Healthcare professionals, radiation therapists included, will face these types of problems almost daily. Many ethicists have described and identified numerous types of ethical problems. Four categories consistently traditionally emerged from the numerous types identified: ethical dilemmas, ethical dilemmas of justice, ethical distress, and locus of authority issues.[7] *Ethical dilemmas* arise when an individual is faced with an ethical situation to which there is more than one seemingly correct solution. The only problem is that all solutions cannot be applied, and choosing one precludes choosing the other(s). In ethical dilemmas, a choice must be made and implemented. Ethical problems associated with the distribution of benefits and burdens on a societal basis are called *ethical dilemmas of justice*. The most obvious manifestation of ethical dilemmas of justice in healthcare is that of allocation of scarce resources. *Ethical distress* occurs when there is a problem that has an obviously correct solution, but there are institutional constraints prohibiting its application. *Locus of authority* issues occur when there is a problem and there is a question as to whose authority the problem falls under. In other words: Whose job is it to clean up this mess or rectify this situation? No one wants to take the responsibility. In recent years, the past 15 to 20 or so, a new category of ethical problem has surfaced in healthcare—conflict of interest.[13] Conflicts of interest arise when an individual engages in an activity from which he or she could profit in several ways, such as when a conflict exists between a person's obligations to the public and his or her own self-interest. Consider the following example:

Dr. Jones is a radiation oncologist at Intercollegial Medical Center. He also is part owner of a freestanding medical imaging center that has a positron emission tomography-computed tomography scanner (PET/CT). Dr. Jones refers all of his oncology patients to the freestanding center for frequent PET/CT scans. Could this possibly be a conflict of interest? It could be viewed as such, because by sending these patients to the freestanding center, Dr. Jones is increasing the income of the center, thereby increasing the profit margin of the owners, of which he is one. Joint venture and self-referrals are just two of the areas that have been identified as presenting the potential for conflicts of interest.[19]

In addition, oral presentations given at state, regional, and national conferences that provide CE credits for attendees should communicate a conflict of interest statement by the presenter at the beginning of the talk. If the presenter has a conflict of interest, it can compromise the presentation and at times distort the interpretation of clinical research. Disclosure of conflicts of interest is an important step for a speaker, as it usually addresses the issue of potential bias.

Models for ethical decision-making involve different methods of interaction with the patient. The engineering or **analytical model** identifies the caregiver as a scientist dealing only in facts and does not consider the human aspect of the patient. The **engineering model** is a dehumanizing approach and is usually ineffective.[18] For example, with the engineering model, the radiation therapist considers the patient only as a lung or brain rather than as an individual who has thoughts, feelings, and emotions. This type of approach in the care of cancer patients is cold, unfeeling, and extremely inappropriate.

The **priestly model** provides the caregiver with a godlike, paternalist attitude that makes decisions *for* and not *with* the patient. This approach enhances the patient's feeling of loss of control by giving the caregiver not only medical expertise but also authority about moral issues.[24] An example of this model is the therapist or student forcing

a patient to comply with planning or treatment procedures regardless of the patient's pain or discomfort because the physician ordered it or because the disease is known to respond to treatment. Patients must be allowed to make their own decisions regarding their treatment (autonomy).

The **collegial model** presents a more cooperative method of pursuing healthcare for both provider and patient. It involves sharing, trust, and consideration of common goals. The collegial model gives more control to the patient while producing confidence and preserving dignity and respect.[18] For example, the therapist takes the extra time required to get acquainted with patients and listen to their needs. This knowledge enables the therapist to help patients cooperate with the demands of positioning for planning and treatment. Although the collegial model takes time, its application is crucial to the humane treatment of cancer patients.

The **contractual model** maintains a business relationship between the provider and patient. A contractual arrangement serves as the guideline for decision making and meeting obligations for services. With a contractual arrangement, information and responsibility are shared. This model requires compliance from the patient; however, the patient is in control of the decision making.[18] The contractual model is best represented by the process of **informed consent**. When provided with comprehensive and thorough information, competent patients will be able make decisions in an informed manner.

The **covenant model** recognizes areas of healthcare not always covered by a contract. A covenant relationship deals with an understanding between the patient and healthcare provider that is often based on traditional values and goals.[18] The covenant model is demonstrated by a patient trusting the caregiver to do what is right. This trust is often based on previous experience with healthcare, particularly cancer care procedures and treatment.

The role of the radiation therapist in regard to ethical decision-making involves the application of professionalism, the selection of a personal theory of ethics, and the choice of a model for interaction with the patient. The difficulties encountered are the result of constant changes in healthcare, patient awareness, and evolving growth of radiation therapy in a highly technical and extremely impersonal world of healthcare.[24] Additional difficulties may arise when some healthcare professionals realize that they have never selected or examined which ethical theory that they subscribe to or their level of EI. To subscribe to an ethical theory, individuals must first examine their personal values. As mentioned earlier in this chapter, ethics are based on values and are derived from four main sources:

- Culture
- Experience
- Religion
- Science

Although individuals vary in how many and what values they derive from each source, studies show that culture and religion are at the forefront of values development. Many scholars agree that religion, or even the lack of religious beliefs, is a part of culture.[25] Seeking to understand the cultural and religious belief of patients is essential to the understanding of their underlying values.

Values are core beliefs concerning what is desirable and help assess the worth of intangibles.[7] They provide the foundation for decisions individuals make in their personal and professional lives.

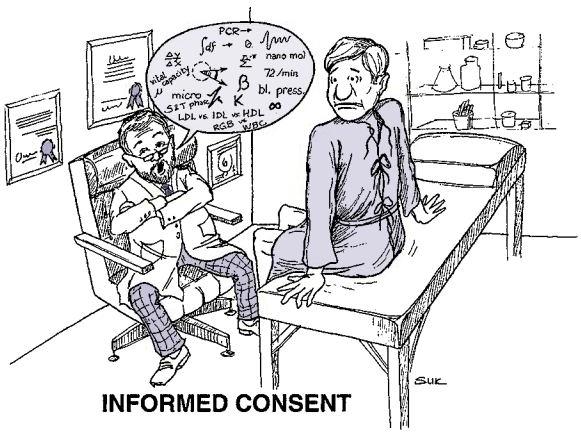
It is not especially easy for people to examine and clarify their values. For that reason, several individuals have sought to develop a useful means of doing just that. One of those individuals was the ethicist Louis Rath.[9] In the mid-1960s, Rath developed what he termed *values clarification*. Rath formulated a values clarification exercise to assist individuals in discovering, analyzing, and prioritizing their personal values. The exercise contains questions that prompt individuals to make choices based on their particular feelings about specific topics and examine the feelings that were associated with their choices. By completing the exercise, Rath hoped that individuals would discover and be able to describe their values. He also sought to encourage these individuals to exhibit their discovered values daily. Discovering personal values will assist in the development of professional values. This will serve radiation therapists well as they provide quality patient care and treatment.

Patients should actively participate in their own care. Patients' awareness of their rights, their needs, and the availability of the many treatment options provides both opportunities and complications. As mentioned earlier, the AHA has published the "Patient Care Partnership: Understanding Expectations, Rights, and Responsibilities" (Box 2.4), and every medical institution has the responsibility to make this document available to its patients. Each patient's responsibility for the treatment process grows with the knowledge provided by patient education.[18]

PATIENT AUTONOMY AND INFORMED CONSENT

Cancer remains one of the most dreaded diseases and often evokes images of death, disfigurement, intolerable pain, and suffering. In the late 1980s, the central ethical issue in caring for the cancer patient was whether to tell the patient that the diagnosis was cancer. Today, advancements in treatment, surgery, chemotherapy, and radiation therapy have resulted in longer periods of remission, improved survival, and even cures. These advances have generated more complex ethical issues.[26] More than half of all cancer patients ultimately need radiation therapy. The physician and patient must weigh the benefits of therapy against possible complications.[2]

The healthcare professional's ability to listen to patients sensitively, grasp the patient's truth, and honor that truth is indispensable, even across religious, social, cultural, and age barriers. To be effective and supportive, physicians and caregivers must, in a sense, be masters of each patient's personal language. This ability to listen and communicate is an extremely important clinical skill that must be learned. There are at least three courses or areas within a radiation therapy program curriculum where these skills can be taught: patient care, ethics, and clinical education. Mastery of listening and communicating should be highly valued.[24]



Truth telling, which is required for informed consent, is an extremely curious principle. Many people have been taught from

BOX 2.4 The Patient Care Partnership: Understanding Expectations, Rights, and Responsibilities

When you need hospital care, your doctor and the nurses and other professionals at our hospital are committed to working with you and your family to meet your healthcare needs. Our dedicated doctors and staff serve the community in all its ethnic, religious, and economic diversity. Our goal is for you and your family to have the same care and attention we would want for our families and ourselves. The sections in this brochure explain some of the basics about how you can expect to be treated during your hospital stay. They also cover what we will need from you to care for you better. If you have questions at any time, please ask. Unasked or unanswered questions can add to the stress of being in the hospital. Your comfort and confidence in your care are very important to us.

What to expect during your hospital stay:

- **High-quality hospital care.** Our first priority is to provide you the care you need, when you need it, with skill, compassion, and respect. Tell your caregivers if you have concerns about your care or if you have pain. You have the right to know the identity of doctors, nurses, and others involved in your care, in addition to students, residents, or other trainees.
- **A clean and safe environment.** Our hospital works hard to keep you safe. We use special policies and procedures to avoid mistakes in your care and keep you free from abuse or neglect. If anything unexpected and significant happens during your hospital stay, you will be told what happened, and any resulting changes in your care will be discussed with you.
- **Involvement in your care.** You and your doctor often make decisions about your care before you go to the hospital. Other times, especially in emergencies, those decisions are made during your hospital stay. When decision-making takes place, it should include:
- Discussion of your medical condition and information about medically appropriate treatment choices. To make informed decisions with your doctor, you need to understand:
  a. The benefits and risks of each treatment.
  b. Whether your treatment is experimental or part of a research study.
  c. What you can reasonably expect from your treatment and any long-term effects it might have on your quality of life.
  d. What you and your family will need to do after you leave the hospital.
  e. The financial consequences of using uncovered services or out-of-network providers.

Please tell your caregivers if you need more information about treatment choices.

1. *Discussing your treatment plan.* When you enter the hospital, you sign a general consent to treatment. In some cases, such as surgery or experimental treatment, you may be asked to confirm in writing that you understand what is planned and agree to it. This process protects your right to consent to or refuse a treatment. Your doctor will explain the medical consequences of refusing recommended treatment. It also protects your right to decide if you want to participate in a research study.
2. *Getting information from you.* Your caregivers need complete and correct information about your health and coverage so that they can make good decisions about your care. That includes:
   - Past illnesses, surgeries, or hospital stays.
   - Past allergic reactions.
   - Any medicines or dietary supplements (such as vitamins and herbs) that you are taking.
   - Any network or admission requirements under your health plan.
3. *Understanding your healthcare goals and values.* You may have healthcare goals and values or spiritual beliefs that are important to your well-being. They will be taken into account as much as possible throughout your hospital stay. Make sure your doctor, your family, and your healthcare team know your wishes.
4. *Understanding who should make decisions when you cannot.* If you have signed a healthcare power of attorney stating who should speak for you if you become unable to make healthcare decisions for yourself, or a "living will" or "advance directive" that states your wishes about end-of-life care, give copies to your doctor, your family, and your care team. If you or your family need help making difficult decisions, counselors, chaplains, and others are available to help.
5. *Protection of your privacy.* We respect the confidentiality of your relationship with your doctor and other caregivers, and the sensitive information about your health and healthcare that are part of that relationship. State and federal laws and hospital operating policies protect the privacy of your medical information. You will receive a Notice of Privacy Practices that describes the ways that we use, disclose, and safeguard patient information and that explains how you can obtain a copy of information from our records about your care.
6. *Help preparing you and your family for when you leave the hospital.* Your doctor works with hospital staff and professionals in your community. You and your family also play an important role in your care. The success of your treatment often depends on your efforts to follow medication, diet, and therapy plans. Your family may need to help care for you at home. You can expect us to help you identify sources of follow-up care and to let you know if our hospital has a financial interest in any referrals. As long as you agree that we can share information about your care with them, we will coordinate our activities with your caregivers outside the hospital. You can also expect to receive information and, where possible, training about the self-care you will need when you go home.
7. *Help with your bill and filing insurance claims.* Our staff will file claims for you with healthcare insurers or other programs such as Medicare and Medicaid. They will also help your doctor with needed documentation. Hospital bills and insurance coverage are often confusing. If you have questions about your bill, contact our business office. If you need help understanding your insurance coverage or health plan, start with your insurance company or health benefits manager. If you do not have health coverage, we will try to help you and your family find financial help or make other arrangements. We need your help with collecting needed information and other requirements to obtain coverage or assistance.

While you are here, you will receive more detailed notices about some of the rights you have as a hospital patient and how to exercise them. We are always interested in improving. If you have questions, comments, or concerns, please contact _____.

Courtesy, American Hospital Association, 2018.

early childhood to tell the truth, but doing so is often extremely difficult and sometimes even seems wrong. Not long ago, lying to a patient about the cancer diagnosis was the norm. Caregivers believed that telling the truth would be destructive and that patients preferred ignorance of their conditions. Studies over the years, however, have conclusively documented that cancer patients want to know their diagnoses and do not suffer psychological injury as a result of the truth.[26]

As discussed earlier, the claim that each person is free to make life-directing decisions is known as the bioethical *principle of autonomy*. The concept of autonomy, understood in this sense, is crucial to ethics. Without some sense of autonomy, no sense of responsibility exists, and, without responsibility, ethics is not possible.[27] In conventional cancer therapy, patient autonomy is protected further by the practice of consent. The American Medical Association's principles of medical ethics imply the following about informed consent: a

BOX 2.5 Informed Consent

To give informed consent, the patient must be informed of the following:

1. The nature of the procedure, treatment, or disease.
2. The expectations of the recommended treatment and the likelihood of success.
3. Reasonable alternatives available and the probable outcome in the absence of treatment.
4. The particular known risks that are material to the informed decision about whether to accept or reject medical recommendations.

From Gurley LT, Callaway WJ. *Introduction to Radiologic Technology*. 7th ed. St. Louis, MO: Mosby; 2011.

physician shall be dedicated to providing competent medical service with compassion and respect for human dignity, shall deal honestly with patients and colleagues, and shall make relevant information available to patients. Patients should be informed and educated about their conditions, should understand and approve their treatments, and should participate responsibly in their own care.[28] The basic element of informed consent is the patients' right to understand and participate in their own healthcare. Informed consent is a doctrine that has evolved sociologically and legally with the changing times. Every patient is entitled to receive information about a procedure or treatment before it is performed[17] (Box 2.5). Consent contains three important aspects: communication, ethics, and law.[7] The communication aspect of consent involves physicians or their agent telling the patient what he or she needs to know so that they may make a decision as to what course of action is best for him or her. The aspect of ethics in consent may involve conflict between the beneficent approach of the healthcare professional (doing good by providing the best level of care that they can) and patient autonomy (the patient's right to make his or her own decisions, even those that may be considered bad decisions), regarding his or her care. The law aspect is simply the fact that patients have legal rights that have been established through guidelines and the court system in the consent process. Although there are several types of consent, informed consent is the most critical. Informed consent must be secured in writing for all procedures, treatments, and research considered invasive and/or that pose significant risk(s).

Informed consent must be secured in writing.

Informed consent is considered a procedure in which patients may agree to or refuse treatment based on information provided to them by their physician or designee(s). The patient must be fully informed concerning the nature of the procedure or treatment—the associated risks, including complications; side effects and potential mortality; desired outcome; and possible alternative procedures or treatments. To give consent, a person must have the legal capacity to do so. The capacity is ensured if a person is a competent adult; the legal guardian or representative of an incompetent adult; an emancipated, married, or mature minor; the parent or legal guardian of a child; or an individual obligated by court order.[7]

Competency refers to the minimal mental, cognitive, or behavioral ability or trait required to assume responsibility. In general, the law recognizes only decisions or consents made by competent individuals. Persons older than the age of 18 years are presumed to be competent; however, this may be disputed with evidence of mental illness or deficiency. If the individual's condition prevents the satisfaction of criteria for competency, the person may be deemed incompetent for the purpose of informed consent. Mental illness does not automatically render a person incompetent in all areas of functioning. Respect for autonomy demands that individuals, even if they are seriously mentally impaired, be allowed to make decisions of which they are capable. Minors are not generally considered legally competent and therefore require the consent of parents or designated guardians.[28] As noted earlier, there are exceptions to this rule. When a minor legally marries, he or she is considered an autonomous adult. The same applies to minors who petition the court and are granted emancipated or mature minor status. These minors generally do not live with their parents nor are they dependent on them for support. In addition, minors serving in the uniformed services are also given autonomous adult status.[23]

A person's competency status may be altered if he or she is under the influence of certain medications, especially those used for pain control. The rule directing that a patient may not sign a document or give informed consent for a procedure after being medicated was established to protect the person going to surgery. Persons who have been premedicated for procedures are considered incompetent. However, persons experiencing intractable pain may be incapable of exercising autonomy until after they are medicated and pain free or experiencing pain control.[20]

The responsibility for obtaining informed consent from a patient clearly remains with the physician and cannot be delegated. However, it is known that many times, other healthcare professionals secure informed consent for certain procedures. The legality of this can be challenged if the facility does not have appropriate written policies and procedures regarding the securing of informed consent by a nonphysician. The courts believe that a physician is in the best position to decide which information should be provided for a patient to make an informed choice. The scope of disclosure in any situation is a physician's responsibility. Some states, however, also have legislative standards or state statutes that define the information that the physician must tell a patient.[6]

Informed consent must be secured by a physician, unless otherwise specified by facility policy and procedure, or state law.

Often, a third person (a healthcare provider) is present during the informed consent session because patients are reluctant to question their physicians but will likely question the witness. The witness can then inform the physician about the patient's lack of understanding. The third-party signature is merely an attestation that the informed consent session took place and that the signature on the document is that of the patient.[28] The patient must be able to understand the information as presented, and no attempt must be made to influence the decision. In the United States today, obtaining true informed consent can present a real challenge because of language barriers (linguistic diversity). Medical interpreters and other services are seeing increased use as those seeking healthcare services in the United States continue to become more diverse. General agreement exists that informed consent is an active, shared decision-making process between the healthcare provider and patient. To give informed consent, patients must understand the information that is provided to them. Communication is key to the process, and, when a patient and his or her healthcare providers cannot communicate because of language barriers, quality healthcare may be compromised. To deliver quality healthcare to everyone, all providers of healthcare must continuously seek better forms and more venues of communication. Medical interpreters and consent forms in a patient's language are

two of the current attempts to communicate essential information to patients, establish their understanding, and ensure that they truly are informed before they give consent.

Confidentiality

A struggle exists in medical practice between confidentiality and truthfulness. According to Garrett et al,[16] truthfulness is summarized in two commands: "Do not lie," and "You must communicate with those who have a right to the truth." Truthfulness must not be the only consideration in discussing patients' rights and caregivers' obligations to patients. One of the major restrictions a healthcare profession imposes is strict confidentiality of medical and personal information about a patient. This information cannot be revealed without consent of the patient.

Breach of confidence is one of the major problems encountered in providing patient care and can result in legal problems. Information should not be discussed with other department personnel, except in the direct line of duty if it is requested from one ancillary department to another or with the nursing service to meet specific medical needs. In the radiation therapy setting, staff members must be especially careful not to discuss patients in hallways or around the treatment area unless the discussion is directly related to the treatment. Unless a patient expressly and explicitly forbids such, healthcare professionals have the right to consult other healthcare providers in the effort to help the patient.[16] Staff members should never discuss information with their own families or friends, even in the most general terms, because doing so is a violation of confidentiality and HIPAA. The patient's treatment chart should be kept in a secure area, inaccessible to anyone not involved in the treatment. Electronic patient records should only be accessed by those with a specific need to know the contents of the record, or by those required to document care within the record. Confidentiality issues must be stressed in every educational program at every opportunity.[10] Implementation of HIPAA regulations has provided more strict regulations regarding the confidentiality of patient information contained within standard or electronic forms. All healthcare professionals and others who may be exposed to confidential information while working in the healthcare setting are required to receive HIPAA training. Noncompliance with HIPAA regulations is dealt with harshly. Violation of HIPAA policies can result in institutional sanctions and monetary fines, and individuals may be terminated for their violations. To help ensure HIPAA compliance, all healthcare employees and students undergo mandatory HIPAA training.

> All healthcare employees and students must receive mandatory HIPAA training.

There are some exceptions to confidentiality. These exceptions are generally grouped under four general headings: those commanded by state law, those arising from legal precedent, those resulting from a peculiar patient-provider relationship, and in cases of proportionate reason.[19] Exceptions may include particular types of wounds (e.g., gunshot and knife), certain communicable diseases (e.g., human immunodeficiency virus, hepatitis, and syphilis), acute poisonings (ingestion of caustic substances), automobile accidents, and abuse (especially child, elder, and spousal).[18] Subject to state law, confidentiality may also be overridden when the life or safety of the patient is endangered, such as when knowledgeable intervention can prevent threatened suicide or self-injury. In addition, the moral obligation to prevent substantial and foreseeable harm to an innocent third party usually is greater than the moral obligation to protect confidentiality.[29]

Roles of Other Healthcare Team Members

Patients and families dealing with cancer may be suddenly thrust into a new and potentially threatening world of blood tests, diagnostic procedures, therapeutic procedures, and specialists. A family physician or internist who is familiar with the patient's history and has established a trusting relationship with the patient can be a key member of the cancer management team. This physician can help the patient and his or her family, make appropriate treatment decisions, and can act as a liaison between the patient and others involved in the evaluation and treatment. If a patient does not have a physician to act as an advocate at the time of the cancer diagnosis, a physician should quickly be chosen to serve in this capacity throughout the course of the illness.[24]

In most situations, other healthcare professionals are available to help patients cope with the emotional effects of cancer. Nurses who spend much time at a patient's bedside can provide important information to the patient and physician. Social workers are invaluable in assessing the level of a family's psychological distress and their capacity to cope with the illness.[28] Community resources such as veteran patient programs (e.g., Reach to Recovery) that involve people who have coped with cancer in their own lives can provide valuable information and help reassure patients and their families. The local clergy may be able to provide spiritual guidance based on their knowledge of a particular patient's and family's needs.[25] Ultimately, most cancer patients will be treated by a radiation therapist. The therapists must not only treat the patient's body; they must also help provide emotional support, all within the scope of practice for the profession. The responsibilities and scope of practice of radiation therapists are included in Box 2.6.

DYING PATIENTS AND THEIR FAMILIES

Care for the dying patient and family has changed dramatically over the years with improvements in technology. The evolution of terminal care changed curing to caring, beginning with the publication of Dr. Elisabeth Kübler-Ross's book *On Death and Dying*.[3] Because radiation therapists and their students deal daily with terminally ill patients, they must explore questions concerning patients' rights, refusal of treatment, and quality of life, and must understand the emotional state of cancer patients. A basic fear of dying is present in all humans. Patients fear the diagnosis, the treatment, the disease, and the death associated with it.[20] Dr. Kübler-Ross identified a grief cycle experienced by individuals with terminal illnesses and other catastrophic events that negatively affect their lives.[3] The grief cycle may include the following stages:

1. Shock: The initial reaction to hearing news of the bad event
2. Denial: Pretending that what is, isn't
3. Anger: Outward demonstration of pent-up emotion and frustration
4. Bargaining: Trying to find a way out of the situation
5. Depression: Realization of the facts
6. Testing: Searching for realistic resolutions to the problem
7. Acceptance: Coping with the situation and finding a way forward

Those in the grief cycle obviously experience highs and lows. It is a part of the radiation therapist's job to identify the cycles and to provide whatever type of emotional support is necessary to get the patient through the cycles. As mentioned earlier in the chapter, discovering one's own EI helps to identify and cope with the emotional needs of patients, although a listening ear is often all that patients require.

Although the final stage of a terminal illness is obvious, its beginning is less well-defined. At some point during the treatment of patients who have metastatic cancer, the focus of management shifts

BOX 2.6 Practice Standards for Medical Imaging and Radiation Therapy (Radiation Therapy Practice Standards)

Preface to Practice Standards

A profession's practice standards serve as a guide for appropriate practice. The **practice standards** define the practice and establish general criteria to determine compliance. Practice standards are authoritative statements established by the profession to judge the quality of practice, service, and education provided by individuals who practice in medical imaging and radiation therapy.

Practice standards can be used by individual facilities to develop job descriptions and practice parameters. Individuals outside the imaging, therapeutic, and radiation science community can use the standards as an overview of the role and responsibilities of the individual as defined by the profession.

The individual must be educationally prepared and clinically competent as a prerequisite to professional practice. Federal and state laws, accreditation standards necessary to participate in government programs, and lawful institutional policies and procedures supersede these standards.

Format

The practice standards are divided into six sections: introduction, scope of practice, clinical performance, quality performance, professional performance, and advisory opinion statements.

Introduction. The introduction provides definitions for the practice and the education and certification for individuals in addition to an overview of the specific practice.

Scope of Practice. The scope of practice delineates the parameters of the specific practice.

Clinical Performance Standards. The clinical performance standards define the activities of the individual in the care of patients and delivery of diagnostic or therapeutic procedures. The section incorporates patient assessment and management with procedural analysis, performance, and evaluation.

Quality Performance Standards. The quality performance standards define the activities of the individual in the technical areas of performance, including equipment and material assessment, safety standards, and total quality management.

Professional Performance Standards. The professional performance standards define the activities of the individual in the areas of education, interpersonal relationships, self-assessment, and ethical behavior.

Advisory Opinion Statements. The advisory opinions are interpretations of the standards intended for clarification and guidance for specific practice issues.

Each performance standards section is subdivided into individual standards. The standards are numbered and followed by a term or set of terms that identify the standards, such as "assessment" or "analysis/determination." The next statement is the expected performance of the individual when performing the procedure or treatment. A rationale statement follows and explains why an individual should adhere to the particular standard of performance.

Criteria. Criteria are used in evaluating an individual's performance. Each set is divided into two parts: the general criteria and the specific criteria. Both criteria should be used when evaluating performance.

General Criteria. General criteria are written in a style that applies to imaging and radiation science individuals. These criteria are the same in all of the practice standards, with the exception of limited x-ray machine operators, and should be used for the appropriate area of practice.

Specific Criteria. Specific criteria meet the needs of the individuals in the various areas of professional performance. Although many areas of performance within imaging and radiation sciences are similar, others are not. The specific criteria are drafted with these differences in mind.

Introduction to Radiation Therapy Practice Standards

Definition

The practice of radiation therapy is performed by healthcare professionals responsible for the administration of ionizing radiation for the purpose of treating diseases, primarily cancer.

The complex nature of cancer frequently requires the use of multiple treatment specialties. Radiation therapy is one such specialty. It requires an interdisciplinary team of radiation oncologists, radiation therapists, medical radiation physicists, medical dosimetrists, and nurses. Typically, the radiation therapist administers the radiation to the patient throughout the course of treatment. Radiation therapy integrates scientific knowledge, technical competency, and patient interaction skills to deliver safe and accurate treatment with compassion.

Radiation therapists must demonstrate an understanding of anatomy, physiology, pathology, and medical terminology. In addition, comprehension of oncology, radiobiology, radiation physics, radiation oncology techniques, radiation safety, and the psychosocial aspects of cancer are required.

Radiation therapists must maintain a high degree of accuracy in positioning and treatment techniques. They must possess, use, and maintain knowledge about radiation protection and safety. Radiation therapists assist the radiation oncologist in localizing the treatment area, participating in treatment planning, and delivering high doses of ionizing radiation as prescribed by the radiation oncologist.

Radiation therapists are the primary liaison between patients and other members of the radiation oncology team. They also provide a link to other healthcare providers, such as social workers and dietitians. Radiation therapists must remain sensitive to the physical and emotional needs of the patient through good communication, patient assessment, patient monitoring, and patient care skills. Radiation therapy often involves daily treatments extending over a period of several weeks utilizing highly sophisticated equipment. It requires a great deal of initial planning, as well as constant patient care and monitoring. As members of the healthcare team, radiation therapists participate in quality improvement processes and continually assess their professional performance.

Radiation therapists think critically and use independent, professional, and ethical judgment in all aspects of their work. They engage in continuing education to include their area of practice and to enhance patient care, radiation safety, public education, knowledge, and technical competence.

Education and Certification

Radiation therapists prepare for their role on the interdisciplinary team by successfully completing an accredited educational program in radiation therapy and attaining appropriate primary certification by American Registry of Radiologic Technologists (ARRT). Those who have passed the radiation therapy examination use the credential R.T.(T).

To maintain ARRT certification, radiation therapists must complete appropriate continuing education requirements to sustain a level of expertise and awareness of changes and advances in practice.

Overview

An interdisciplinary team of radiation oncologists, radiation therapists, dosimetrists, medical physicists, and other support staff plays a critical role in the delivery of health services as new modalities emerge and the need for radiation therapy treatment procedures evolve. A comprehensive procedure list for the radiation therapist is impractical because clinical activities vary by practice needs and expertise of the radiation therapist. Although radiation therapists gain more experience, knowledge, and clinical competence, the clinical activities for the radiation therapist may evolve.

BOX 2.6 Practice Standards for Medical Imaging and Radiation Therapy (Radiation Therapy Practice Standards)—cont'd

State statute, regulation, or lawful community custom may dictate practice parameters. Wherever there is a conflict between these standards and state or local statutes or regulations, the state or local statutes or regulations supersede these standards. A radiation therapist should, within the boundaries of all applicable legal requirements and restrictions, exercise individual thought, judgment, and discretion in the performance of the procedure.

Radiation Therapist Scope of Practice

The scope of practice of the medical imaging and radiation therapy professional includes:

- Providing optimal patient care.
- Receiving, relaying, and documenting verbal, written, and electronic orders in the patient's medical record.
- Corroborating patient's clinical history with procedure, ensuring information is documented and available for use by a licensed independent practitioner.
- Verifying informed consent.
- Assuming responsibility for patient needs during procedures.
- Preparing patients for procedures.
- Applying principles of ALARA (as low as reasonably achievable) to minimize exposure to patient, self, and others.
- Performing venipuncture as prescribed by a licensed independent practitioner.
- Starting and maintaining intravenous access as prescribed by a licensed independent practitioner.
- Identifying, preparing, and/or administering medications as prescribed by a licensed independent practitioner.
- Evaluating images for technical quality, ensuring proper identification is recorded.
- Identifying and managing emergency situations.
- Providing education.
- Educating and monitoring students and other healthcare providers.
- Performing ongoing quality assurance activities.
- Applying the principles of patient safety during all aspects of patient care.

The scope of practice of the radiation therapist also includes:

1. Delivering radiation therapy treatments as prescribed by a radiation oncologist.
2. Performing simulation, treatment planning procedures, and dosimetric calculations as prescribed by a radiation oncologist.
3. Utilizing imaging technologies for the explicit purpose of simulation, treatment planning, and treatment delivery as prescribed by a radiation oncologist.
4. Detecting and reporting significant changes in patients' conditions and determining when to withhold treatment until the physician is consulted.
5. Monitoring doses to normal tissues within the irradiated volume to ensure tolerance levels are not exceeded.
6. Constructing/preparing immobilization, beam directional, and beam modification devices.
7. Participating in brachytherapy procedures.

Radiation Therapy Clinical Performance Standards

Standard One—Assessment
The radiation therapist collects pertinent data about the patient and the procedure.

Standard Two—Analysis/Determination
The radiation therapist analyzes the information obtained during the assessment phase and develops an action plan to complete the procedure.

Standard Three—Patient Education
The radiation therapist provides information about the procedure and related health issues according to protocol.

Standard Four—Performance
The radiation therapist performs the action plan.

Standard Five—Evaluation
The radiation therapist determines whether the goals of the action plan have been achieved.

Standard Six—Implementation
The radiation therapist implements the revised action plan.

Standard Seven—Outcomes Measurement
The radiation therapist reviews and evaluates the outcome of the procedure.

Standard Eight—Documentation
The radiation therapist documents information about patient care, the procedure, and the final outcome.

Radiation Therapy Quality Performance Standards

Standard One—Assessment
The radiation therapist collects pertinent information regarding equipment, procedures, and the work environment.

Standard Two—Analysis/Determination
The radiation therapist analyzes information collected during the assessment phase to determine the need for changes to equipment, procedures, or the work environment.

Standard Three—Education
The radiation therapist informs the patient, public, and other healthcare providers about procedures, equipment, and facilities.

Standard Four—Performance
The radiation therapist performs quality assurance activities.

Standard Five—Evaluation
The radiation therapist evaluates quality assurance results and establishes an appropriate action plan.

Standard Six—Implementation
The radiation therapist implements the quality assurance action plan for equipment, materials, and processes.

Standard Seven—Outcomes Measurement
The radiation therapist assesses the outcome of the quality management action plan for equipment, materials, and processes.

Standard Eight—Documentation
The radiation therapist documents quality assurance activities and results.

Radiation Therapy Professional Performance Standards

Standard One—Quality
The radiation therapist strives to provide optimal patient care.

Standard Two—Self-Assessment
The radiation therapist evaluates personal performance.

Standard Three —Education
The radiation therapist acquires and maintains current knowledge in practice.

Standard Four—Collaboration and Collegiality
The radiation therapist promotes a positive and collaborative practice atmosphere with other members of the healthcare team.

Standard Five—Ethics
The radiation therapist adheres to the profession's accepted ethical standards.

Standard Six—Research and Innovation
The radiation therapist participates in the acquisition and dissemination of knowledge and the advancement of the profession.

Radiation Therapy Advisory Opinion Statements

Injecting medication in peripherally inserted central catheter lines or ports with a power injector is within the scope of practice where federal or state law and/or institutional policy permits.

From the American Society of Radiologic Technologists. *The Practice Standards for Medical Imaging and Radiation Therapy: Radiation Therapy Practice Standards*. Albuquerque, NM: American Society of Radiologic Technologists; 2018.

from aggressive therapy to palliative care, from efforts to suppress tumor growth to attempts to control symptoms. Signals that the goals of treatment must be changed include the recognition of the tumor's progression, the failure of therapy to control the disease, the patient's deteriorating strength, and the patient's loss of interest in pursuing previously important objectives and pleasures. Rarely is this decision difficult; rather, it reflects the natural acceptance of the inevitability of patients' deaths on the part of families, caregivers, and patients themselves.[28] Indeed, Dr. Kübler-Ross identifies this acceptance as the last stage in the grief cycle.

During the past decade, people in many countries have come to accept the notion that aggressive life support (i.e., prolonging life to the bitter end) is often not the right action to take. The ethics of allowing terminally ill patients to die with dignity has evolved. In recent years, the concept of the individual's right of self-determination has been central in the resuscitation issue. The medical and legal communities have recognized that self-determination is no more than an extension of the patient's right to informed consent. In the past, some physicians may have been placed in the extremely uncomfortable position of wanting to comply with a patient's wish to die in peace and dignity but fearing a malpractice suit by family members for failing to do all that should, could, or might have been done to prolong the life of the dying patient. The response to this dilemma, the living will, also called an Advance Directive, was created. The purpose of the **living will** is to allow the competent adult to provide direction to healthcare providers concerning his or her choice of treatment under certain conditions, should the individual no longer be competent by reason of illness or other infirmity, to make those decisions. The living will also provides the patients' family with knowledge of what a person would or would not want done. The concept of the living will assumes that the individual executing the directive:

1. Demonstrates competency at the time.
2. Directs that no artificial or heroic measures be undertaken to preserve his or her life.
3. Requests that medication be provided to relieve pain.
4. Intends to relieve the hospital and physician of legal responsibility for complying with the directives in the living will.
5. Has the signature witnessed by two disinterested individuals who are not related, are not mentioned in the last will, and have no claim on the estate.[28]

In practice, actions to carry out a living will may involve withholding or discontinuing interventions such as ventilator support, chemotherapy, surgery, radiation therapy, and even assisted nutrition and hydration.[24] The decision to withhold curative therapy is based on the conclusion that the course of the patient's disease is irreversible and extraordinary measures to sustain life are not in the patient's best interest. To nullify the routinely mandatory order for cardiopulmonary resuscitation in the event of a cardiac arrest, many hospitals require the physician in charge of a terminally ill patient to issue a specific do-not-resuscitate (DNR) order. The Joint Commission requires that every hospital have a no-code DNR policy.[16] Plans for the patient's death, including issuance of the DNR order, should be made soon after the issue has been discussed with the patient and family. In most situations, patients and their families are relieved to know that every effort will be made to maintain the patient's comfort and that death will be peaceful.[26] The only problem with this is that often those treating the patient are not aware of the DNR order, and many times a patient may be resuscitated in the diagnostic imaging or radiation therapy department. To comply with a DNR, everyone involved in the patient's care must be made aware of its existence. All hospitals must have written policies and procedures describing the way that patients' rights are protected at their institutions. The living will is not the only document that can be used by individuals to guide the direction of their medical treatment should they become unable to do so.

POLST, which stands for Physician Orders for Life-Sustaining Treatment, is a national movement that promotes the rights of seriously ill or frail patients to make informed decisions about medical treatments and to have those preferences honored by healthcare professionals. More information is available at: http://polst.org/professionals-page/?pro=1.

The durable power of attorney for healthcare is another such document. The **durable power of attorney for healthcare** is a legal document that allows an individual to designate any willing individual, 18 years of age or older, to be his or her surrogate and make decisions in matters of healthcare. The designee can be a family member, friend, or another trusted individual. The durable power can be used to accept or refuse treatment; however, the treatments that are desired or not desired must be specified in the document. Both the living will and the durable power of attorney for healthcare are considered **advance directives**. Both documents are useful in that they clearly describe the wishes of the patient when he or she was considered competent. These documents may also contain instructions for disposal of the body upon death, especially when an individual chooses to donate his or her body to medical science for research. This helps avoid treatment and other conflicts among families and surrogates.[16]

Before treating a patient, always check the healthcare record for do-not-resuscitate orders and advance directives.

Hospice Care

During the Middle Ages, a hospice was a way station for travelers. Today a hospice represents an intermediate station for patients with terminal illnesses. The hospice movement began with programs to provide palliative and supportive care for terminally ill patients and their families, and still provides those services today. Hospice services also include home, respite, and inpatient hospital care and support during bereavement. In addition to providing 24-hour care of the patient, the goal of hospice care is to help the dying patient live a full life and to offer hope, comfort, and a suitable setting for a peaceful, dignified death. The hospice team assists family members in caring for the patient by providing physical, emotional, psychological, and spiritual support. Several types of hospices are available, including free-standing facilities, institutionally based units, and community-based programs.[13]

Patients may enter the hospice on their own or may be referred by family members, physicians, hospital-affiliated continuing care coordinators and social workers, visiting nurses, friends, or clergy. Although admission criteria vary, they usually include the following: a terminal illness with an estimated life expectancy of 6 months or less; residence in a defined geographic area; access to a caregiver from immediate family members, relatives, friends, or neighbors; and the desire for the patient to remain at home during the last stage of the illness. On the initial assessment visit, a member of the hospice team obtains the patient's medical history and emotional and psychosocial histories of the patient and family and discusses nursing concerns. After the program begins, team members meet regularly to review the care plan for each patient and put into effect and supervise services for the patient and family.[26]

Most families prefer home care for dying relatives if they can rely on the supportive environment offered by a hospice. Institutionalization

is perceived as impersonal and impractical, and acute care hospitals are not designed for the long-term care of terminal patients. A private home can be transformed to accommodate the level of care required, and nurses can instruct family members in physical care techniques, symptom management, nutrition, and medications. After the patient and family are made to feel confident and capable of managing the physical care, they can begin to address the emotional and spiritual issues surrounding death. During a patient's terminal illness, many problems arise, some of which test the hospice team's ingenuity and endurance. In general, however, simple remedies, common sense, good nursing care, preventive medicine, and the generous use of analgesia should be used to help reduce patient suffering.[20]

MEDICAL-LEGAL ASPECTS OF CANCER MANAGEMENT

Definitions and Terminology

Radiation therapists need to perform their duties with confidence, especially in today's litigious society. They must be aware that consumers are more aware of the standard of care that they should receive and more cognizant about seeking legal compensation. Healthcare professionals must become more knowledgeable about legal definitions concerning the standard of care. Legally, the term "standard of care" means exercising that degree of care, education, knowledge, and skills that is possessed by others in the same profession.[29]

The type of law that governs noncriminal activities is known as **civil law**. One type of civil law is commonly called "tort law." The word *tort* is an Old French word meaning "wrong."[23] In today's terms, a tort is considered a wrongful act committed against a person or a person's property, the one exception being breach of contract. **Tort law** is personal injury law. The act may be malicious and intentional or the result of negligence and disregard for the rights of others. Torts include conditions for which the law allows compensation to be paid to an individual damaged or injured by another. This type of law was created to preserve peace among individuals by providing a venue for assessing fault for wrongdoing (culpability), deter those who wrong others, and provide compensation for those injured.[28] Two types of torts exist: unintentional and intentional.[17] Unintentional torts are considered those acts that are not intentionally harmful but still result in damage to property or injury to person. Examples of unintentional torts in the healthcare setting include failure of the healthcare provider to properly provide for the safety of a patient or failure to properly educate a patient, resulting in harm. Intentional torts are defined as willful acts committed against person or property. Healthcare providers incur duties incidental to their professional roles. The law does not consider the professional and patient to be on equal terms; greater legal burdens or duties are imposed on the healthcare provider.[28]

Tort law is a type of civil law.

Several situations exist in which a tort action can be taken against the healthcare professional because of deliberate action. Intentional torts include assault, battery, false imprisonment, libel, slander, invasion of privacy, and intentional infliction of emotional distress.

Assault is defined as the threat of touching in an injurious way. If patients feel threatened and believe they will be touched in a harmful manner, justification may exist for a charge of assault. To avoid this, professionals must always explain what is going to happen during a procedure and reassure the patient in any situation involving the threat of harm.[17] Radiation therapists must always seek permission to touch and treat a patient.

Battery consists of the actual act of harmful, unconsented, or unwarranted contact with an individual. Again, a clear explanation of what is to be done is essential. If the patient refuses to be touched, that wish must be respected. Battery implies that the touch is a willful act to harm or provoke, but even the most well-intentioned touch may fall into this category if the patient has expressly forbidden it. This should not prevent the therapist from placing a reassuring hand on the patient's shoulder, as long as the patient has not forbidden it and the therapist does not intend to harm or invade the patient's privacy. However, any procedure performed against a patient's will may be construed as battery.[6]

False imprisonment is the intentional confinement without authorization by a person who physically constricts another with force, threat of force, or confining clothing or structures. This becomes an issue if a patient wishes to leave and is not allowed to do so. Inappropriate use of physical restraints may also constitute false imprisonment. The confinement must be intentional and without legal justification. Freedom from unlawful restraint is a right protected by law. If the patient is improperly restrained, the law allows redress in the form of damages. Proof of all elements of false imprisonment must be established to support the claim that an illegal act was performed. False imprisonment requires proof that the alleged victim was really confined, that the confinement was intended by the perpetrator, and that consent was not obtained. If they are dangerous to themselves or others, patients may be restrained. An example of false imprisonment is a therapist using restraints on a patient without the patient's consent or without informing and obtaining consent from the family of a child.[24]

Libel is written defamation of character. Oral defamation is termed **slander**. These torts affect the reputation and good name of a person. The basic element of the tort of defamation is that the oral or written communication is made to a person other than the one defamed. The law recognizes certain relationships that require an individual to be allowed to speak without fear of being sued for defamation of character. For example, radiation oncology department supervisors who must evaluate employees or give references regarding an employee's work have a qualified privilege. Radiation therapists can protect themselves from this civil tort by using caution while conversing within the hearing of patients and their families.[28]

Invasion of privacy charges may result if confidentiality of information has not been maintained or the patient's body has been improperly and unnecessarily exposed or touched. Protection of the patient's modesty is vital during simulation, planning, and treatment procedures.[24] Healthcare providers must make sure that the patient is covered to the extent that treatment allows. Maintaining privacy is also extremely important in regard to video monitors in treatment areas. No one should ever be in the viewing area except authorized and necessary staff members.

Negligence refers to neglect or omission of reasonable care or caution. An unintentional injury to a patient may be negligence. The standard of reasonable care is based on the doctrine of the reasonably prudent person. This standard requires that a person perform as would any reasonable individual of ordinary prudence with comparable education and skill and under similar circumstances. In the relationship between a professional person and a patient, an implied contract exists to provide reasonable care. An act of negligence in the context of such a relationship is called *malpractice*. Negligence, as used in malpractice law, is not necessarily the same as carelessness. A person's conduct can be considered negligent in the legal sense even if the individual acts

carefully. For example, if a therapist without prior education and training on a specific procedure attempts the procedure and does it carefully, the conduct can be deemed negligent if harm results to the patient.[13]

LEGAL DOCTRINES

Doctrine of Personal Liability

Radiation therapists should be concerned about the risk of being named as defendants in medical malpractice suits. Things can go wrong, and mistakes can be made. The legal responsibility of the radiation therapist is to give safe care to the patient.

The fundamental rule of law is that persons are liable for their own negligent conduct. This is known as the **doctrine of personal liability** and means that the law does not permit wrongdoers to avoid liability for their own actions, even though someone else may also be held legally liable for the wrongful conduct in question under another rule of law. Although they cannot be held liable for actions of hospitals or physicians, therapists can be held responsible and liable for their own negligent actions.[5]

Doctrine of Respondeat Superior

The **doctrine of respondeat superior** ("let the master answer") is a legal doctrine that states that an employer is liable for negligent acts of employees that occur while they are carrying out the orders or serving the interests of the employer. As early as 1698, courts declared that a master must respond to injuries and losses of persons caused by the master's servants. Nineteenth-century courts adopted the phrase *respondeat superior*, which is founded on the principle of social duty that all persons, whether by themselves or by their agents or servants, shall conduct their affairs in a manner not to injure others.[6] This principle is based on the concept that profit from the work of others, and the duty to select and supervise employees, are joined in liability.[7]

Doctrine of Res Ipsa Loquitur

In a malpractice action for negligence, the plaintiff has the burden of proving that a standard of care exists for the treatment of the medical problem, the healthcare provider failed to abide by the standard, this failure was the direct cause of the patient's injury, and damage was incurred. The legal community describes the aforementioned circumstances as the steps in a medical malpractice lawsuit, such as duty, breach of duty, and causation and damages. If the alleged negligence involves matters outside of general knowledge, an acceptable medical expert must establish these criteria. A long-accepted substitute for the medical expert has been the **doctrine of res ipsa loquitur**,[10] which means "the thing speaks for itself." Courts have decided to resolve the problem of expert unavailability in certain circumstances by applying res ipsa loquitur, which requires the defendant to explain the events and convince the court that no negligence was involved.[28] The Standards of Practice for Radiation Therapists may be used by either the defense or the prosecution to support or refute negligent behavior, as can expert witnesses. These standards are readily accessible to everyone via the ASRT website.

Doctrine of Foreseeability

The **doctrine of foreseeability** is a principle of law that holds an individual liable for all natural and proximate consequences of negligent acts to another individual to whom a duty is owed. The negligent acts could or should have been reasonably foreseen under the circumstances. A simpler definition is persons reasonably foreseeing that certain actions or inactions on their part could result in injury to others. In addition, the injury suffered must be related to the foreseeable injury. Routine radiation therapy equipment checks are important in overcoming this doctrine.[6]

RISK MANAGEMENT

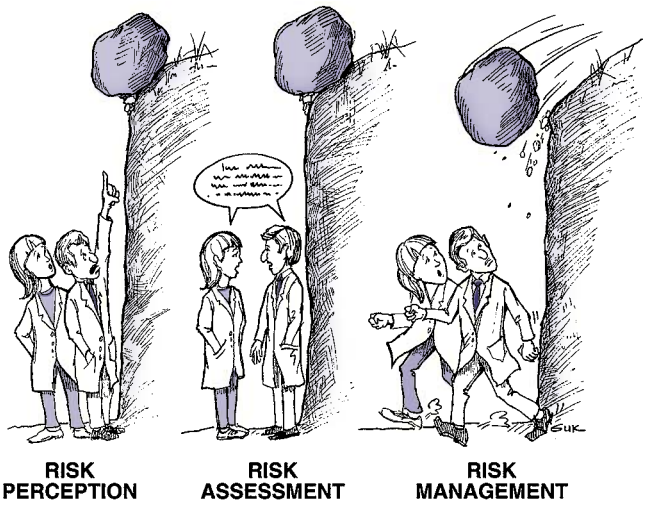
Conceived little more than a decade ago, the concept of risk control, or risk management, was believed to be the key element in loss prevention from adverse medical incidents. **Risk management** links every quality improvement program with measurable outcomes necessary to determine overall effectiveness. Effectiveness here means success in reducing patient injury. An acute care hospital or medical center has the duty to exercise such reasonable care in looking after and protecting the patient. The legal responsibility of any healthcare practitioner is safe care. Risk management, which is a matter of patient safety, is the process of avoiding or controlling the risk of financial loss to staff members and the hospital or medical center. Poor-quality care creates a risk of injury to patients and leads to increased financial liability. Risk management protects financial assets by managing insurance for potential liability by reducing liability through surveillance. The job of risk management is to identify actual and potential causes of accidents or incidents involving patients and employees and to implement programs to eliminate or reduce such occurrences.[6] The number one reason for medical liability (malpractice) claims in medical imaging and radiation therapy is patient falls.

Hospital liability and malpractice insurance, also known as *patient liability insurance,* is intended to cover all claims against the hospital that arise from the alleged negligence of physician staff members and employees. Many have discussed whether radiation therapists should carry malpractice insurance. In making that decision, persons must determine the extent of provisions for malpractice coverage in their institutions. According to the doctrine of respondeat superior, the employer is liable for employees' negligent acts during work. The authority and responsibility of a physician supervising and controlling the activities of the employee supersede those of the employer, according to the doctrine of the borrowed servant. Regardless of how these legal doctrines may be applied, the fundamental rule of law that every therapist should clearly know and understand is the doctrine of personal liability. Persons are liable for their own negligent conduct, although most healthcare employees are covered under their employers' liability insurance. A wrongdoer may not be able to escape

responsibility even though someone else may be sued and held legally responsible. In some situations, hospital insurers who have paid malpractice claims have successfully recovered damages from negligent employees by filing separate lawsuits against them.[6]

Hospital employees are instructed to report any patient injury to administration through the department manager. An incident report is routinely used to document unusual events in the hospital. An **incident** is defined as any happening that is not consistent with the routine operation of the hospital or the routine care of a particular patient. It may be an accident or a situation that could result in an accident.[23] Hospitals use incident reports in their accident-prevention programs to advise insurers of potential suits and prepare defenses against suits that might arise from documented incidents. Incident reports should be prepared according to the institution's published policies and procedures. An incident report is no place for opinion, accusation, or conjecture; it should contain only facts concerning the incident reported.[30] Incident reports should never be placed in the patient's written or electronic chart. There are usually written hospital and departmental procedures for completing and submitting incident reports. These reports ultimately end up in the office of risk management.

Incident reports should not be placed in patients' written or electronic healthcare records.



MEDICAL RECORDS

The radiation oncology **medical record** is used to chronologically document the care and treatment rendered to the patient. All components of the patient's evaluation and cancer must be documented in the radiation oncology record. The format usually includes the following: a general information sheet listing the names of pertinent relatives, follow-up contacts, family physicians, and persons to notify in an emergency; an initial history and findings from the physical examination; reports of the pathology examinations, laboratory tests, diagnostic imaging procedures, and pertinent surgical procedures; photographs and anatomic drawings; medications currently used; correspondence with physicians and reimbursement organizations; treatment setup instructions; daily treatment logs; physics, treatment planning, and dosimetry data; progress notes during treatments; summaries of treatment; and reports of follow-up examinations. Patients' radiation oncology records must be maintained and secured in the department separate from hospital and clinic records to ensure ready access at any time.[30] Radiation oncology medical records are commonly maintained in both paper and electronic formats. Medical record entries should be made in clear and concise language that can be understood by all professional staff members attending to the patient. Handwritten entries must be legible. An illegible record is worse than no record because it documents a failure by staff members to maintain a proper record and may severely weaken a hospital's or physician's defense in a negligence action. Entries into the paper record should be made in ink, and persons making entries should identify themselves clearly by placing their signatures after each entry. The hospital and physician should be able to determine who participates in each episode of patient care.[28] Entries should be made daily by the therapist operating the treatment machine. Any other therapist involved in the treatment of a patient that day should also check the daily entry for accuracy and initial the record.

Medical records are sometimes used by staff members to convey remarks inappropriate for a patient's chart. The following are examples of entries that should never be made:

- This is the third time therapist X has been negligent.
- Dr. A has mistreated this patient again.
- This patient is a chronic complainer and a nuisance.
- This patient smells; nursing staff should see that she gets a bath.

Such editorial comments are inevitably used against the physician and hospital in any negligence action filed by the patient. In addition, although the trend moves toward access by patients to their own medical records, patients are more likely to read and react with hostility to such comments.[28]

The general rule is to avoid the need for making corrections, but because humans are not perfect, corrections must be made from time to time. In the paper record, a staff member should simply draw a line through an incorrect entry because doing so allows others to identify what was initially written and corrected. The staff member should initial the correction, enter the time and date, and insert the correct information. Mistakes in the chart should not be erased, blacked out, or covered with a "white-out" product because doing so may create suspicion concerning the original entry.[30] Proper charting and documentation protocols should be taught in healthcare professional educational programs, as well as in the clinical setting. There are proper charting procedures.[7] The following lists contain information on charting information in the medical record in the "always" and "never" categories.

Always

1. Write so that others can read what is written (legibly, in paper records).
2. Make electronic entries so that others understand what is being communicated.
3. Use ink (in paper records).
4. Use correct spelling and approved standard medical abbreviations.
5. Enter accurate information: correct and precise.
6. Chart concisely.
7. Provide entries that are thorough.
8. Begin each new entry with the date and time (military notations) of the entry.
9. Chart information as it occurs.
10. Keep the information confidential.
11. Sign each entry with your name and title (electronic identification information or electronic signatures are acceptable).

Never

1. Chart with a pencil (in paper records).
2. Black-out, white-out, or erase entries.
3. Include unnecessary details.
4. Include critical comments about anyone (e.g., the patient, his or her family, or other healthcare professionals).
5. Leave blank spaces.
6. Use unapproved or improper abbreviations.
7. Record information for others.
8. Divulge patient information.
9. Use initials in place of your signature.
10. Chart for anyone else.
11. Leave a patient's electronic healthcare chart open.

Charting and other forms of documentation are written communication tools used to provide comprehensive healthcare data on an individual patient basis. Charting is the recording of patient information and observation regarding a specific patient in his or her long-term written or electronic record, such as the patient's chart. Documentation, on the other hand, is also the recording of any information relevant to patient care and treatment, but that information does not have to be entered into the patient chart.[7] There are forms used in a variety of healthcare departments that are specific to the services offered by that department. These documents are generally stored in the department only, for reference and use by that department only. What needs to be remembered most is that the patient's medical record is a legal document and as such is admissible in a court of law. It provides evidence concerning the care and treatment provided to the patient and the standards under which the care and treatment were administered.[27]

Radiation therapists under the direct supervision of the radiation oncologist and medical physicist carry out daily treatments. All treatment applications must be described in detail (orders) and signed by the responsible physician. Similarly, any changes in the planned treatment by the physician may require adjustment in immobilization, new calculations, and even a new treatment plan. Therefore, the therapist, physicist, and dosimetrist must all be notified of the changes.[27]

SUMMARY

- The ethical and legal considerations in cancer management are numerous and varied. The development of professional ethical characteristics begins with the discovery of an individual's personal values.
- Ethics are based on values, and knowing one's own values serves to enhance a person's concept of right versus wrong. Professional ethics is an extension of personal ethics. Healthcare professionals innately subscribe to the Principles of Biomedical Ethics.
- Professional standards guide the practice of medical imaging and radiation therapy. The Standards of Ethics, including the Code of Ethics and the Rules of Ethics, along with the Practice Standards for Medical Imaging and Radiation Therapy, are the prevailing structured professional guides and rules under which medical imaging technologists, radiologist assistants, radiation therapists, and aspiring students perform their healthcare duties.
- In healthcare, failure to perform according to ethical and other professional standards subjects practitioners to penalties under the law.
- In addition to the development of technical knowledge and skills, the foundation of radiation oncology includes standards of conduct and ideals essential to meeting the emotional and physical needs of patients.
- Radiation therapists must first view their profession as more than just a job. Student therapists should not pursue a simple goal to just pass a series of examinations and eventually the registry or earn a degree. Student therapists should set goals that establish them as professionals.
- An ideal professional has superior technical knowledge and works in harmony and cooperation with peers, physicians, and other healthcare personnel. With the appropriate educational background and determination to excel, a person can practice professionalism and achieve technical excellence.
- By delivering excellent patient care within professional standards, quality patient care can be provided by a healthcare team that is focused on the needs of the patients, both emotionally and physically, while recognizing and respecting patient rights.

Case I: Quality Care for All

As a student therapist, Susan observes many clinical situations. She is assigned to a treatment area that has an extremely high volume of patients. Susan observes that a staff member has treated a patient without an important treatment device in place. When she approaches the staff member about the situation, he mumbles something about the patient being palliative. Obviously, the treatment error must be corrected. How does Susan ethically and professionally handle this issue that her conscience dictates be addressed? Is this an ethical or a legal issue?

Case II: You Really Need This Treatment

Sam is a staff radiation therapist in a large center. He has a patient on his treatment schedule who is uncooperative and verbally abusive to the staff members. It is time for the patient's treatment, but once in the treatment room, he refuses to cooperate by not getting into the position required and holding still. Sam knows the patient is uncomfortable and needs the treatment to relieve symptomatic disease. Should Sam restrain the patient and force him to have the treatment? What legal and ethical considerations are involved in Sam's final decision?

Case III: To Tell or Not to Tell

Mrs. Smith is a 50-year-old woman with three adult children. She has been admitted to the hospital for tests to rule out cancer. While the tests are being processed, her husband and children meet with the doctor and ask him not to tell Mrs. Smith whether the results are malignant. They tell the doctor that she is afraid of cancer and that if she is given the diagnosis, she will become severely depressed and give up all desire to live. The physician is not comfortable with this request, but the family insists. The physician reluctantly agrees. What ethical and legal concepts are implicated in the family's request and physician's decision to comply with it?

Case IV: Maintaining a Standard of Care

Currently employed in a small radiation oncology center, Sandra has the task of orienting a new employee to the department and the treatment machine to which she is assigned. The new radiation therapist, Jane, although older than Sandra, is newly graduated from an educational program and has recently taken the American Registry of Radiologic Technologists Examination for Radiation Therapy. She