2018    Vol. 143 No. 11
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Texas Nursing Jurisprudence and Ethics

This course meets the Texas requirement for 2 hours of education on Jurisprudence and Ethics.

Audience
This course is designed for all nurses licensed in Texas.

Course Objective
The purpose of this course is to provide basic knowledge of the laws and rules governing the practice of nursing in Texas in order to increase compliance and improve patient care. Texas nurses are legally obligated to be aware of standards that govern professional accountability. Information contained in this course is not intended to be used in lieu of lawful guidelines, but as a learning tool that increases the understanding of some regulations as they apply to nurses who are licensed within the state of Texas.

Learning Objectives
Upon completion of this course, you should be able to:
1. Outline the pertinent levels of nursing practice in Texas and the general scope of practice of each.
2. Identify specific laws and rules related to the practice of nursing in Texas.
3. Differentiate between ethical and legal practice.
4. Discuss the legal and ethical requirements related to professional boundaries and unprofessional conduct in nursing.

Faculty
Jane C. Norman, RN, MSN, CNE, PhD, received her undergraduate education at the University of Tennessee, Knoxville campus. There she completed a double major in Sociology and English. She completed an Associate of Science in Nursing at the University of Tennessee, Nashville campus and began her nursing career at Vanderbilt University Medical Center. Jane received her Masters in Medical-Surgical Nursing from Vanderbilt University. In 1978, she took her first faculty position and served as program director for an associate degree program. In 1982, she received her PhD in Higher Education Administration from Peabody College of Vanderbilt University. In 1998, Dr. Norman took a position at Tennessee State University. There she has achieved tenure and full professor status. She is a member of Sigma Theta Tau National Nursing Honors Society. In 2005, she began her current position as Director of the Masters of Science in Nursing Program.

Faculty Disclosure
Contributing faculty, Jane C. Norman, RN, MSN, CNE, PhD, has disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.
INTRODUCTION

What chapter of the Texas Occupations Code contains the Nursing Practice Act?

Nursing practice acts have a long history in the United States, with the first standards being enacted in the early 1900s [1]. In 1907, nineteen nurses from around the state formed the Texas Graduate Nurses’ Association in Fort Worth. These women had a collective interest in establishing standards for the delivery of nursing care and creating a nursing board [1]. Using recent Colorado legislation as a model, the Graduate Nurses’ Association advocated for nursing legislation in Texas. The Nurses Registration Act of 1909 (an early version of the Nursing Practice Act) passed the Texas Legislature, and thus the Board of Nurse Examiners, which became the Board of Nursing in 2007, was created [1].

The Texas Nursing Practice Act has undergone extensive revision and amendment since 1909 [1; 2]. Legislated to safeguard the public, its purpose is to ensure that minimum safety requirements are met by every nurse practicing in the state. The Nursing Practice Act (i.e., Chapter 301 of the Texas Occupations Code) includes laws and rules regulating nursing education, licensure, and practice [2]. Chapter 301 establishes the Texas Board of Nursing as an authority to adopt rules, develop standards for nursing programs, and discipline nurses who violate regulations [2]. Nurses who fall below the Board’s required minimum competency; who present a danger to patients, coworkers, or others; or who fail to comply with all Board of Nursing rules will be prohibited from working in the state.
In addition to Chapter 301 (the Nursing Practice Act), the Board of Nursing stipulates that Texas nurses are required to be familiar with Chapter 303 (Nursing Peer Review) and Chapter 304 (the Nurse Licensure Compact) [2]. Advanced practice registered nurses must also be familiar with Chapter 305 (the Advanced Practice Registered Nurse Compact). Several chapters of the Texas Administrative Code, which is a collection of all state agency rules, also pertain to nursing education, licensure, practice, and discipline. Together, these laws and rules form the basis for the legal practice of nursing and the regulation of nursing by the State of Texas. Although they are not technically laws, the Texas Board of Nursing Position Statements provide guidance regarding patient safety, scope of practice, and other important issues; the Board strongly encourages that nurses read all Position Statements, or at the very least, the Summary of Position Statements [3]. Texas nurses should also be familiar with the principles of nursing ethics and have a firm understanding of professional boundaries [3].

This course fulfills the continuing education requirement on jurisprudence and ethics related to the practice of nursing in Texas for all levels of nursing, including registered nurses (RNs), licensed vocational nurses (LVNs), registered nurse first assistants (RNFAs), and advanced practice registered nurses (APRNs) [3]. While this course will provide an overview of several pertinent sections of the laws and rules, all nurses are required to have up-to-date knowledge of them in their entirety in order to ensure compliance, retain licensure, and practice safely.

STANDARDS OF NURSING PRACTICE

The basic standards of competent practice directly impact how all nurses in Texas provide care. Not only must a nurse possess the knowledge of lawful and current care standards, but the knowledge must be demonstrated through consistent practice and intervention to prevent unauthorized, inappropriate, erroneous, illegal, contraindicated, or intentional nonperformance of care.

The Nursing Practice Act governs the practice of LVNs, RNs, APRNs, and RNFAs. LVNs are those persons licensed to practice vocational nursing, while RNs, APRNs, and RNFAs are all licensed to practice professional nursing, with various levels of specialization [3]. Both professional and vocational nurses are responsible and accountable for making decisions that are based upon their educational preparation and experience in nursing.

LICENSED VOCATIONAL NURSING

According to the Texas Nursing Practice Act, the practice of vocational nursing is defined as a “directed scope of nursing practice, including the performance of an act that requires specialized judgment and skill, the proper performance of which is based on knowledge and application of the principles of biologic, physical, and social science as acquired by a completed course in an approved school of vocational nursing. The term does not include acts of medical diagnosis or the prescription of therapeutic or corrective measures.” Vocational nursing involves [2]:

- Collecting data and performing focused nursing assessments of the health status of an individual
- Participating in the planning of the nursing care needs of an individual
- Participating in the development and modification of the nursing care plan
- Participating in health teaching and counseling to promote, attain, and maintain the optimum health level of an individual
- Assisting in the evaluation of an individual’s response to a nursing intervention and the identification of an individual’s needs
- Engaging in other acts that require education and training, as prescribed by Board rules and policies, commensurate with the nurse’s experience, continuing education, and demonstrated competency

Additionally, the Board of Nursing and the Nursing Practice Act state that an LVN requires appropriate supervision of an RN, APRN, physician assistant, physician, dentist, or podiatrist. The LVN is required to function within the parameters of the legal scope of practice and in accordance with the federal, state, and local laws, rules, regulations, policies, procedures, and guidelines of the employing healthcare institution or practice setting. LVNs are responsible for providing safe, compassionate, and focused nursing care to assigned patients with predictable healthcare needs [5].

PROFESSIONAL NURSING

The practice of professional nursing is defined as “the performance of an act that requires substantial specialized judgment and skill, the proper performance of which is based on knowledge and application of the principles of biologic, physical, and social science as acquired by a completed course in an approved school of professional nursing. The term does not include acts of medical diagnosis or the prescription of therapeutic or corrective measures.” Professional nursing involves [2]:

- Observation, assessment, intervention, evaluation, rehabilitation, care and counsel, or health teachings of a person who is ill, injured, infirm, or experiencing a change in normal health processes
• Administration of a medication or treatment as ordered by a physician, podiatrist, or dentist
• Maintenance of health or prevention of illness
• Performance of an act delegated by a physician
• The development of the nursing care plan
• Supervision or teaching of nursing
• Administration, supervision, and evaluation of nursing practices, policies, and procedures
• Requesting, receiving, signing for, and distribution of prescription drug samples to patients at practices at which an APRN is authorized to sign prescription drug orders

The Board of Nursing further defines the scope of practice of professional nursing [6]:

The RN takes responsibility and accepts accountability for practicing within the legal scope of practice and is prepared to work in all healthcare settings, and may engage in independent nursing practice without supervision by another healthcare provider. The RN, with a focus on patient safety, is required to function within the parameters of the legal scope of practice and in accordance with the federal, state, and local laws, rules and regulations; and policies, procedures and guidelines of the employing healthcare institution or practice setting. The RN is responsible for providing safe, compassionate, and comprehensive nursing care to patients and their families with complex healthcare needs.

Advanced Practice Registered Nursing

APRNs are registered nurses who have completed additional accredited advanced-practice education and internship as recognized by the Board of Nursing [4]. The Board of Nursing specifies that APRNs must practice within their individual scope in the advanced role, meaning the particular specialty and population focus that the nurse trained for in an advanced program [7]. The scope of practice may be defined by APRN organizations; however, in many instances, it can be up to the APRN's employer or supervisor to determine what duties he or she can perform and what types of patients can be treated [7]. This decision may be based on the nurse's clinical experience and his/her knowledge, skills, and competencies. APRNs may or may not practice the full scope of the professional role and specialty for which they trained, and an APRN is allowed to perform the full scope of duties of an RN. The Board suggests asking the following questions in order to help decide if an activity is within an individual APRN's scope of practice [7]:

• Is it consistent with the scope of one's recognized title or does it evolve into another advanced practice title recognized by the Board requiring additional formal education and legal recognition?
• Is it consistent with the Standards of Nursing Practice outlined in Board Rule 217.11?
• Are you willing to accept accountability and liability for the activity and outcomes?
• Is it consistent with one's education in the role and specialty?
• Is it consistent with one's professional scope of practice?
• Is it consistent with reasonable and prudent practice?
• Is it consistent with statutory or regulatory laws?
• Is it consistent with evidence-based care?

APRNs may delegate tasks to RNs and LVNs, but the task must be within the RN's/LVN's scope of practice [8]. The Texas Board of Nursing states (in Position Statement 15.18) that RNs are expected to carry out orders issued by APRNs if the orders are within the APRN's scope of practice for their specialty [9]. RNs are expected to question an order if it is believed to be non-efficacious or contraindicated.

TEXAS NURSING PRACTICE RULES

When should a nurse not accept an assignment or perform a task?

In addition to the Nursing Practice Act, there are several chapters of the Texas Administrative Code (i.e., Chapters 211–228) that contain rules pertinent to nursing. Texas Administrative Code Rule 217.11 (Standards of Nursing Practice) contains the minimum acceptable standards for all licensed nurses. It states that the Board of Nursing is responsible for regulating the practice of nursing within the State of Texas for LVNs, RNs, and APRNs, and that action against the nurse's license may result from a failure to meet the minimum acceptable level of practice, even if no patient injury results from a nurse's actions or inactions [10]. All nurses practicing in Texas must meet the minimum acceptable standards specified in Rule 217.11, which includes requirements to [10]:

• Know and conform to the Texas Nursing Practice Act and the Board's rules and regulations as well as all federal, state, or local laws, rules, or regulations affecting the nurse's current area of nursing practice
• Implement measures to promote a safe environment for clients and others
• Know the rationale for and the effects of medications and treatments and correctly administer the same
• Accurately and completely report and document: the client’s status, including signs and symptoms; nursing care rendered; physician, dentist, or podiatrist orders; administration of medications and treatments; client response(s); and contacts with other healthcare team members concerning significant events regarding client’s status
• Respect the client’s right to privacy by protecting confidential information unless required or allowed by law to disclose the information
• Promote and participate in education and counseling to a client(s) and, where applicable, the family/significant other(s) based on health needs
• Obtain instruction and supervision as necessary when implementing nursing procedures or practices
• Make a reasonable effort to obtain orientation/training for competency when encountering new equipment and technology or unfamiliar care situations
• Notify the appropriate supervisor when leaving a nursing assignment
• Know, recognize, and maintain professional boundaries of the nurse-client relationship
• Comply with mandatory reporting requirements of Texas Occupations Code Chapter 301 (Nursing Practice Act), Subchapter I, which include reporting a nurse who violates the Nursing Practice Act or a Board rule (except for minor incidents as stated in the Nursing Practice Act and Board rules) and contributed to the death or serious injury of a patient; whose conduct causes a person to suspect that the nurse’s practice is impaired by chemical dependency or drug or alcohol abuse; whose actions constitute abuse, exploitation, fraud, or a violation of professional boundaries; or whose actions indicate that the nurse lacks knowledge, skill, judgment, or conscientiousness to such an extent that the nurse’s continued practice of nursing could reasonably be expected to pose a risk of harm to a patient or another person, regardless of whether the conduct consists of a single incident or a pattern of behavior
• Provide, without discrimination, nursing services regardless of the age, disability, economic status, gender, national origin, race, religion, health problems, or sexual orientation of the client served
• Institute appropriate nursing interventions that might be required to stabilize a client’s condition and/or prevent complications
• Clarify any order or treatment regimen that the nurse has reason to believe is inaccurate, non-efficacious, or contraindicated by consulting with the appropriate licensed practitioner and notifying the ordering practitioner when the decision is made not to administer the medication or treatment
• Implement measures to prevent exposure to infectious pathogens and communicable conditions
• Collaborate with the client, members of the healthcare team and, when appropriate, the client’s significant other(s) in the interest of the client’s health care
• Consult with, utilize, and make referrals to appropriate community agencies and health care resources to provide continuity of care
• Be responsible for one’s own continuing competence in nursing practice and individual professional growth
• Make assignments to others that take into consideration client safety and that are commensurate with the educational preparation, experience, knowledge, and physical and emotional ability of the person to whom the assignments are made
• Accept only those nursing assignments that take into consideration client safety and that are commensurate with the nurse’s educational preparation, experience, knowledge, and physical and emotional ability
• Supervise nursing care provided by others for whom the nurse is professionally responsible
• Ensure the verification of current Texas licensure or other compact state licensure privilege and credentials of personnel for whom the nurse is administratively responsible, when acting in the role of nurse administrator.

As noted, nurses are required to be familiar with all Standards of Nursing Practice. Please refer to Chapter 217 of the Texas Administrative Code for Rule 217.11 in its entirety.
ETHICAL AND LEGAL ISSUES IN NURSING PRACTICE

What ethical concepts are central to nursing practice?

In addition to their legal obligations, nurses have ethical obligations to their patients. The practice of nursing is primarily one of caring, and the ethical theories for nursing are often referred to as “the ethics of caring.” Nurses are expected to address both ethical and legal issues in their practice, which can be complex. As medical advancements and new technology progress, these must be incorporated into established ethical standards. The American Nurses Association has established the Code of Ethics for Nurses, which is intended to act as “a framework for nurses to use in ethical analysis and decision-making” [11]. The full text of this Code is available at http://nursingworld.org/DocumentVault/Ethics-1/Code-of-Ethics-for-Nurses.html.

Major ethical issues that may arise in the practice of nursing are related to the provision of patient-centered care, advocacy, delegation, self-care, and supporting colleagues and the profession [11]. Ethical concepts central to patient-centered care include advocacy, confidentiality, privacy, self-determination, and the dignity and worth of all persons. Ethical concepts central to nursing practice include accountability (i.e., accepting responsibility for one’s action or inaction), beneficence (i.e., the duty to do good), competence (i.e., only performing duties within one’s scope of practice, acquiring new skills and education), nonmaleficence (i.e., the duty to do no harm), veracity (i.e., truthfulness), and social reform (e.g., advocating for patients and groups). Additionally, as a nurse gains experience in his or her field and specialty, the ethic of teaching comes into play. This can simply involve helping an inexperienced nurse grow by passing along knowledge, or can involve more specific leadership, supervisory, or teaching roles.

Several ethical issues are addressed in the Texas Board of Nursing Position Statements [9]. These include the issue of initiation of cardiopulmonary resuscitation (CPR) in long-term care residents in the absence of a do not resuscitate (DNR) order (e.g., when initiation of CPR would appear futile and inappropriate given the nursing assessment of the resident, despite the premise that a DNR order may only be given by a physician). Other ethical issues discussed in the Position Statements include care of those with whom the nurse has a personal relationship and issues of patient confidentiality and privacy with regard to the use of social media. Reading, thought, and discussion about ethics and potential ethical dilemmas can help nurses respond appropriately and can help prevent unethical behaviors from occurring in the workplace.

There are also a variety of legal issues that affect the provision of nursing care and maintenance of a nursing license. It is important to note that, although possibly related, the laws governing nursing practice are different from the ethical framework(s) that nurses use to guide decision making. Laws pertaining to documentation, licensure, and standards of care have been established to ensure that nurses practice within a defined scope of practice and are aware of the boundaries of independent nursing action and responsibilities. These laws also act to hold nurses accountable for maintaining an acceptable standard of patient care. However, perhaps the greatest concern for nurses is the threat of negligence or malpractice claims.

According to tort law, four elements must be established for a ruling of malpractice [12]:

- Duty: The nurse owed a duty to meet a particular standard of care.
- Breach of duty: The nurse failed to perform the owed duty.
- Causation: There is a causal connection between the nurse’s failure and the patient’s injury.
- Damages: An injury occurred for which monetary compensation is adequate relief.

These elements must be shown by a “preponderance of the evidence,” defined as more than 50% probability, a lower standard than the “beyond a reasonable doubt” used in criminal law [13; 14]. Malpractice cases are decided on the basis of what a “jury is likely to think is fact” rather than actual fact [15].

PROFESSIONAL BOUNDARIES AND UNPROFESSIONAL CONDUCT

Which nursing actions constitute misconduct?

Another facet of ethical care and practice involves maintaining appropriate limits in the nurse/patient relationship. Based on the idea that there is an imbalance of power and potential for abuse in this relationship (due to the nurse’s power and the patient’s vulnerability), the State of Texas requires all nurses to be familiar with and abide by the laws and rules regarding the limits of the nurse/patient relationship [3; 16]. Nurses should strive to promote the patient’s best interests, dignity, and independence and refrain from inappropriate involvement in the patient’s personal relationships and/or the obtainment of personal gain at the patient’s expense. Violating professional boundaries of the nurse/patient relationship includes, but is not limited to, emotional, financial, physical, or sexual exploitation of the patient or the patient’s family [16]. These violations and other types of unprofessional conduct are grounds for disciplinary action by the Board.
The State of Texas defines unprofessional conduct, in Texas Administrative Code Rule 217.12, as "unprofessional or dishonorable behaviors of a nurse that the Board believes are likely to deceive, defraud, or injure clients or the public" [16]. These behaviors include but are not limited to [16]:

- Unsafe practice, including, but not limited to:
  - Carelessly failing, repeatedly failing, or exhibiting an inability to perform vocational, registered, or advanced practice nursing in conformity with the standards of minimum acceptable level of nursing practice set out in Rule 217.11
  - Carelessly or repeatedly failing to conform to generally accepted nursing standards in applicable practice settings
  - Improper management of client records
  - Delegating or assigning nursing functions or a prescribed health function when the delegation or assignment could reasonably be expected to result in unsafe or ineffective client care
  - Accepting the assignment of nursing functions or a prescribed health function when the acceptance of the assignment could be reasonably expected to result in unsafe or ineffective client care
  - Failing to supervise the performance of tasks by any individual working pursuant to the nurse's delegation or assignment
  - Failure of a clinical nursing instructor to adequately supervise or to assure adequate supervision of student experiences

- Failure of a chief administrative nurse to follow appropriate and recognized standards and guidelines in providing oversight of the nursing organization and nursing services for which the nurse is administratively responsible

- Failure to practice within a modified scope of practice or with the required accommodations, as specified by the Board in granting a coded license or any stipulated agreement with the Board

- Careless or repetitive conduct that may endanger a client's life, health, or safety (whether or not actual injury to a client is established)

- Inability to practice safely, as defined by demonstration of actual or potential inability to practice nursing with reasonable skill and safety to clients by reason of illness; use of alcohol, drugs, chemicals, or any other mood-altering substances; or as a result of any mental or physical condition

- Misconduct, including, but not limited to:
  - Falsifying reports, client documentation, agency records, or other documents
  - Failing to cooperate with a lawful investigation conducted by the Board
  - Causing or permitting physical, emotional, or verbal abuse or injury or neglect to the client or the public, or failing to report same to the employer, appropriate legal authority, and/or licensing board
  - Violating professional boundaries of the nurse/client relationship, including but not limited to physical, sexual, emotional, or financial exploitation of the client or the client's significant other(s)
  - Engaging in sexual conduct with a client, touching a client in a sexual manner, requesting or offering sexual favors, or language or behavior suggestive of the same
  - Threatening or violent behavior in the workplace
  - Misappropriating, in connection with the practice of nursing, anything of value or benefit, including, but not limited to, any property (real or personal) of the client, employer, or any other person or entity; or failing to take precautions to prevent such misappropriation
  - Providing information that was false, deceptive, or misleading in connection with the practice of nursing
  - Failing to answer specific questions or providing false or misleading answers that would have affected the decision to license, employ, certify, or otherwise utilize a nurse
  - Offering, giving, soliciting, or receiving or agreeing to receive (directly or indirectly) any fee or other consideration to or from a third party for the referral of a client in connection with the performance of professional services
  - Failure to repay a guaranteed student loan, as provided in the Texas Education Code §57.491, or to pay child support payments as required by the Texas Family Code §232.001
  - Diversion or attempts to divert drugs or controlled substances
  - Dismissal from a Board-approved peer assistance program for noncompliance and referral by that program to the Board
  - Other drug-related actions or conduct including, but not limited to:
    - Use of any controlled substance or any drug (prescribed or unprescribed), device, or alcoholic beverages while on duty or on call and to the extent that such use may impair the nurse's ability to safely conduct to the public the practice authorized by the nurse's license
THE USE OF SOCIAL MEDIA

The issue of exploitive or inappropriate use of patient information or images on social media is becoming increasingly significant. As discussed, the Board of Nursing Position Statement 15.29: Use of Social Media by Nurses offers clarification on the relevant ethical and legal issues regarding this topic, including the use of social media as a beneficial tool for nurses and patients alike. The statement emphasizes that confidentiality and privacy extend to online posts or conversations and, more specifically, that [9]:

- Patient-related images are not to be transmitted via electronic media, regardless of whether the patient is identified by name; taking photo or video of patients with personal devices, including cell phones, is prohibited. Images taken for legitimate purposes, using employer-provided devices, may be allowed based on employer policy.
- Use caution when having online social contact with patients or former patients. The fact that a patient may initiate contact with the nurse does not permit a personal relationship.
- Nurses should not make disparaging remarks about patients, co-workers, or employers on social media, even if persons are not identified.

For the full text of the Position Statement regarding the use of social media by nurses, and all other Position Statements, please visit https://www.bon.texas.gov/practice_bon_position_statements.asp.

CONCLUSION

It is the responsibility of the Texas Board of Nursing to enforce the rules regulating the practice of nursing as the rules are currently stated—not how individuals may wish them to be. As nurses are affected by these rules and regulations, they have the responsibility to keep informed of regulatory changes in order to maintain licensure. It should be remembered that practicing within the minimum standards, though a necessity, is not all that is expected of nurses. Fulfilling ethical obligations to patients, co-workers, employers, and society is also an important part of health care, and it is only when the regulatory and ethical aspects of practice are combined that a nurse can be fully effective.
Audience
This course is designed for nurses and allied health professionals involved in the care of older adults.

Course Objective
The purpose of this course is to provide the tools necessary for social workers, counselors, mental health professionals, and allied health professionals to successfully assess and care for older adults, an increasingly large portion of the U.S. population.

Learning Objectives
Upon completion of this course, you should be able to:

1. Review the demographic profile and associated myths of the elderly population in the United States.
2. Discuss age-related biologic and physiologic changes experienced by older adults.
3. Identify psychologic and social challenges and adjustments commonly encountered in the elderly population, with particular attention to elderly subpopulations, including custodial grandparents, racial/ethnic minority elders, gay and lesbian elders, and elderly women.
4. Outline the impact of long-term care on older adults and their care providers.
5. Describe assessments for depression, suicide, substance abuse, and elder abuse that specifically target older adults.
6. Discuss interventions that are sensitive to the biopsychosocial needs of the elderly and are appropriate ethically and legally.

Faculty
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Contributing faculty, Alice Yick Flanagan, PhD, MSW, has disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

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INTRODUCTION

Western society holds many myths about aging and the elderly. Americans tend to attribute more problems to advanced age than are actually reported, such as being dependent on others for financial support, transportation, and medical care. There is an image of the elderly as being highly dependent or living in nursing homes [50]. In the workforce, elderly workers are often believed to be untrainable [52]. Yet, simultaneously, these years are often viewed as the “golden years,” when one retires, travels, and has a certain amount of leisure time. It is difficult for the public, and healthcare professionals, to reconcile these seemingly opposing views of aging.

When 41 female nurses were asked about their fears of aging, and specifically of growing old as a woman, they used terms like: “dependency,” “ill health,” “loneliness,” “loss of dignity,” and “looking old” [1]. Cross-culturally, these myths are remarkably similar. For example, college students in Taiwan reported believing that older adults (e.g., older teachers) are resistant to change, not motivated to learn new things, and not willing to listen to new ideas [4]. Okoye and Obikeze conducted focus groups with 800 Nigerian youths, and the participants described the elderly as dependent, sickly, childlike, conservative, and suspicious [33]. In a study of adults in Columbia, individuals with negative stereotypes about the elderly were also more concerned about aging [53]. This gives some insight into societal perceptions about the elderly and aging. Qualms and fears toward aging often stem from negative cultural images and stereotypes of aging [1].

DEFINITION OF AGING

There is no one agreed upon definition of aging. One approach defines aging according to four key dimensions [86]:

- Aging is universal. All species experience the phenomenon of aging.
- Aging is intrinsic. External factors are not the primary cause of origin.
- Aging is progressive. It occurs progressively throughout the life cycle.
- Aging is deleterious. There will be negative physical ramifications.

It is important to distinguish chronologic aging from physiologic aging. All persons, without exception, grow old chronologically. However, physiologic aging is unique process and varies from person to person. It involves changes in how an individual responds to internal and external stressors as well as inalterable variables, such as genetic predisposition [7]. In addition, studies are now focusing on aging as a process and underscoring the concept of successful aging [89].
**AN OVERVIEW OF THE ELDERLY IN THE UNITED STATES**

**CURRENT TRENDS AND PROJECTIONS**

What age group is categorized as the oldest old?

The age at which one is considered “older” or “senior” is always evolving and is influenced by culture and societal life expectancy. In England in 1875, old age was defined as 50 years or older, as stated in the Friendly Societies Act [88]. Today, most developed countries in the world use the chronologic marker of 65 years as a definition of old age; in some cases, the age of 62 years is used as a chronologic marker because, in the United States, one could receive social security benefits starting at this age [87]. However, Mohanty notes that using the criterion of age at retirement or when one becomes eligible to receive retirement benefits is not universal, given the fact that there are so many in the world who live in areas in which there are no formal definitions of retirement [88]. Using these chronologic markers to define old age is arbitrary, but they can be useful when studying the group as a whole [2]. The elderly can be further divided into various segments: the young-old, defined as 65 to 74 years of age; middle-old, defined as 75 to 84 years of age; and the oldest-old, defined as those who are 85 years of age and older [3]. In 2010, there were 53,364 persons 100 years of age and older in the United States [94]. Worldwide, in 2015, there were more than 500,000 centenarians, and it is estimated by 2050, there will 3.7 million, with the greatest growth in China [90]. In the United States, it is projected that there will be 9.7 centenarians per 10,000 people by 2050 [90].

According to the U.S. Census, there were 46.2 million Americans 65 years of age or older in 2014, which translates to 14.5% of the U.S. population [91; 103]. Florida led the country in older population, with 17.6% of the state’s population comprised of those 65 years of age or older [103]. By 2060, it is estimated that 98.2 million Americans will be 65 years of age or older [103]. This is due to the aging of the “baby boomer” generation (i.e., those born between 1946 and 1964).

The average life expectancy has continued to increase; it is estimated that by 2060, 19.7 million Americans will be 85 years of age or older [103]. In 2060, the youngest baby boomers will be 96 years of age [103]. The oldest old are one of the fastest growing population groups in the United States.

**COMMON MYTHS OF AGING**

As mentioned, society holds several myths about the elderly. Many of these myths may be easily disputed based on data from the U.S. Census and other studies.

- **Myth**: Most older adults do not have enough money and end up becoming destitute.
  
  **Fact**: As of 2014, 10% of Americans 65 years of age and older live in poverty [103]. This population is also more likely to have health insurance coverage than the general population. As of 2014, 93% were insured by Medicare [92].

- **Myth**: Most older adults live alone and are isolated.
  
  **Fact**: In 2015, 57.6% of persons 65 years and older were married [103]. An estimated 29% lived alone [105]. According to a survey conducted in 2009, 9 out of 10 individuals 65 years of age and older stated they talked to family and friends on a daily basis [93]. In 2008, an estimated 16% of the U.S. population lived in a household comprised of two adult generations or a grandparent or at least one other generation, compared with 12% in 1980 [93]. This multigenerational household trend has particularly affected those 65 years and older. Several factors have contributed to this trend, including the poor economy, an increase in immigrants, and adults getting married later [93].

- **Myth**: Many older Americans end up living in nursing homes.
  
  **Fact**: In 2014, only about 3.2% of adults 65 years of age and older lived in nursing homes [4]. Of those who reside in nursing homes, they tend to be the oldest-old (85 years of age and older) [105].

- **Myth**: Most older adults engage in very minimal productive activity.
  
  **Fact**: In 2015, 18.9% of persons 65 years and older were employed or actively looking for work, and this population represents 5.6% of the total labor force in the United States [110]. The elderly are more engaged in self-employed activities than younger persons. In 2010, 17.4% of those 65 years of age and older were self-employed, compared with 7% of those 16 years of age and older [5].
• Myth: Life satisfaction is low among the elderly.
   Fact: Field examined data from the Berkeley Older Generation Study and found that many elders are quite satisfied with their life [9]. More than one-third (36%) of persons older than 59 years of age and 15% of those older than 79 years of age stated they were currently experiencing the best time in their lives. A 2009 survey found that 60% of individuals 65 years of age and older stated they were very happy. Most of the factors that predict happiness for the young, such as good health and financial stability, also apply to the elderly.

• Myth: Old people feel old.
   Fact: According to a 2009 telephone survey, only 21% of individuals 65 to 74 years of age stated they felt old, and only 35% of those 75 years of age and older reported feeling old.

BIOLoGIC PRoCESSES AND PHYSICAL WELL-BEING IN oLDER ADuLTS

What conditions are more common among persons with sensory loss?

Biologic and physiologic changes are part of aging. Although it is not known why these changes occur, biologic theories of physiologic aging include [3; 7; 86; 95; 121; 140; 143]:

• Wear and tear: Aging is genetically determined, and as a result, the tissues and muscles eventually deteriorate.

• Cross-linkage: The body’s proteins attach to other structural substances, thus decreasing elasticity in the skin and causing other physical changes in the organs and slowing of physiologic processes.

• Autoimmune: As the body ages, it is unable to recognize the difference between healthy and diseased cells, causing it to react against itself.

• Cellular aging: The replication of cells slows as a result of aging.

• Apoptosis theory: Aging is due to inevitable pre-programmed cell death in our bodies. Apoptosis is a normal process in the body, but it is speculated that if dysregulated apoptosis could lead to Alzheimer disease, Parkinson disease, or cancer.

• Free radical: As free radical exposure increases in older organisms, the antioxidant system is not able to counteract the free radicals that have been generated and accumulated during the life of the cell, resulting in cellular death. Experimental findings have not conclusively supported this theory.

• Evolutionary: Humans’ developmental life cycles are affected by mutation and selection. In other words, all biologic dimensions are affected by mutation, and there will be variations among human beings. This will lead to a natural selection of those who are more fit to survive in an environment. Aging leads to vulnerability.

The losses in the physical arena for the elderly can be numerous, which may then compound and/or have implications in social and psychologic arenas. Studies have shown that brain tissues atrophy due to natural cell degeneration, with the volume of the brain decreasing by 15% or more between adolescence and old age [122]. Crews notes that the health status of older persons with vision and hearing loss is poorer compared with those without vision or hearing loss [10]. Rates of heart disease, hypertension, hip fractures, and stroke are higher among those with sensory loss [10]. In a study of more than 1,000 elders, 53.7% of those with impaired vision also had hypertension, compared with 43.1% of those without impaired vision. Of those with impaired hearing, 27.6% experienced heart disease, compared with 18.6% of those without a hearing loss [10]. Interestingly, the rates double when persons have both hearing and vision impairment. Almost one-fifth (19.9%) of persons with both impairments had experienced a stroke, while only 8% with no sensory loss had experienced a stroke [10].

Mobility is affected by muscle atrophy associated with advanced age. Muscle strength, for example, can decline 30% to 40% between 30 and 80 years of age [11]. This can lead to falls, which are common among the elderly. Thirty percent of those 65 years of age and older have fallen within the last 12 months, and 50% of persons older than 80 years of age have experienced a fall in the last 12 months [11]. The causes of these falls vary and include environmental factors, sensory losses, medical factors, and psychiatric conditions, such as depression or cognitive impairments [11; 12]. Most falls among the elderly occur in the morning. This is not surprising given that the majority of activity and movement occur during this time [146]. Loss of ambulatory mobility is also common after hospitalization among older adults. This phenomenon, known as hospital-associated disability, is present in previously independent and ambulatory adults who have impaired mobility upon hospital discharge. It occurs among 16% to 65% of adults 65 years and older [123]. Infrequent ambulation and bed rest are the most commonly cited causes [123].
With the increase in life expectancy, there is also an increase in the incidence of acute and chronic illnesses, such as cardiovascular diseases and hypertension. As a part of the aging process, the composition of vascular structures changes, affecting how peripheral arteries dilate and constrict [13]. The result is often hypertension, which affects 1 billion individuals worldwide [14]. Epidemiologic studies have noted that 12% to 14% of adults 65 years of age and older have hypertension [13]. However, it is important not to use age as the only criterion to determine the type of treatment for hypertension among the elderly. Frail elders should be assessed and treatment tailored for their specific needs [163].

Arthritis is also a leading cause of disability among older adults [5]. Arthritis may refer to rheumatoid arthritis or osteoarthritis. Rheumatoid arthritis is a systemic autoimmune disorder that attacks the joints, causing inflammation in the hands, feet, and other parts of the body [15]. Osteoarthritis breaks down the cartilage of joints, such as the shoulder, knee, hip, and ankle, causing pain and limitation of movement [15]. Osteoarthritis is one of the most common pain disorders in the United States and is the leading cause of disability among elders [124]. The knee is most commonly affected area, and experts predict that 3.5 million total knee replacements will be done annually by 2030 [124]. Because chronic arthritis pain and depressive symptoms are often comorbid, it is important for practitioners to assess these patients' mood and mental state. In a four-year longitudinal study with 299 elders living in a retirement community, strong social support and intact cognitive functioning were protective against chronic pain-related depression [164].

Sleep problems are also more common among the elderly, primarily stemming from changes in the sleep cycle that occur with age (e.g., decreased time spent in slow-wave sleep) [125]. Sleep difficulties, such as insomnia, are correlated with impaired physical and psychologic well-being and quality and length of life [96]. In a longitudinal study with elderly individuals in the United Kingdom, 44.7% complained of sleep dysfunction. Those who had greater restrictions of activities of daily living, greater numbers of reported physical illnesses, poor social support, higher levels of depression, and were widowed, divorced, or separated were more likely to report sleep complaints. One year later, of those who reported no sleep problems at baseline, an additional 21.4% reported increased impairment in obtaining adequate rest or sleep [96]. Depression was the strongest predictor of sleep problems. Ultimately, insomnia can increase the risk for other medical and psychologic complications in addition to adversely affecting a patient’s quality of life [125]. Practitioners might suggest increasing activities such as walking, running, resistance exercise, and tai chi, as some studies have shown that the sleep quality of older adults can improve when these activities are included in daily life [165].

HIV/AIDS

In industrialized countries, it is estimated that 10% to 15% of human immunodeficiency virus (HIV) infections occur in adults 50 years of age and older, and approximately one of every nine new HIV diagnoses in the United States occur in those 50 years of age or older [17; 18; 126]. This prevalence may be higher in developing countries [18]. In 2014, there were an estimated 7,391 HIV diagnoses among adults 50 years of age and older, accounting for 17% of total diagnoses in the United States [97]. Of these, 859 diagnoses occurred in persons 65 years of age and older [166]. This age group also accounts for 19% of all AIDS diagnoses, 29% of persons living with AIDS, and 35% of all AIDS-related deaths [97]. However, older adults are not generally considered an at-risk group. This has led to a lack of targeted education and screening among older adults. For example, only 32% of state departments of public health websites contained information about HIV/AIDS in elderly individuals [167].

Because the symptoms of HIV infection (i.e., fatigue, weight loss, memory loss) are similar to those of other age-related illnesses, such as dementia, and because many older adults harbor the misconception that they are not at risk, this population frequently goes untested for the virus [17]. When these individuals do seek medical help, symptoms are often attributed to other disorders, such as Alzheimer disease or a respiratory disorder [17]. It has been argued that women 50 years of age and older are more vulnerable to HIV infection during heterosexual encounters than men or younger women for several reasons [19]. Older women often do not insist on condom use because there is no longer the risk of pregnancy. Furthermore, male-to-female transmission of HIV is higher than female-to-male transmission [19]. Due to divorce or being widowed, increasing numbers of older people are becoming sexually active with multiple partners. This increase in sexual activity can also be partially attributed to older men more commonly using medication in order to maintain erections [20; 21]. Vaginal drying and thinning associated with menopause and aging can result in small tears or cuts during sexual activity, which also raises women's risk for infection with HIV [22]. Lusti-Narasimhan and Beard note that older women are generally more vulnerable to sexually transmitted infections because menopause affects the lining of the vagina, making it less protective to infection [127]. Furthermore, as one ages, the immune system also declines.
Ultimately, practitioners should be vigilant when working with older adults with HIV due to age-related comorbidities. Perhaps due in part to the misconception that the elderly are not sexual beings, practitioners often do not have conversations with their elderly clients about HIV/AIDS and other sexually transmitted infections [168]. In addition, polypharmacy is common in the older population, and drug interaction with HIV medications should be considered [128]. Generally, older adults metabolize antiretroviral medications slower, which could place them at risk for higher levels of toxicity. Older adults who are diagnosed with HIV/AIDS are also at greater risks for being diagnosed with cancers [126].

**CHALLENGES AND ADJUSTMENTS ASSOCIATED WITH AGING**

**PSYCHOLOGIC THEORETICAL FRAMEWORKS**

**Disengagement Theory**

Disengagement theory, originally proposed by Cumming and Henry, maintains that successful aging involves whole or partial disengagement [23]. In other words, as individuals age, they must accept a decline in status and forfeit some of their social and leadership roles. The goal is to help older individuals disengage so they can die more peacefully [169]. However, this theory is controversial, particularly in Western society, where work is central in defining one's identity. Furthermore, other theorists argue that it is not disengagement or alienation from society that defines successful aging; rather, some assert that new activities may be assumed for those roles that are given up [24]. According to this theory, for elders to successfully journey through the aging process they must remain active [24].

**Gerotranscendence Theory**

The gerotranscendence theory was developed by Lars Torns-tam in reaction to the tenets of disengagement theory. Torns-tam posited that older people do not retreat into themselves and withdraw socially. Instead, aging can be viewed from a positive perspective, as older adults become less occupied with themselves, material things, and achievement. They redefine themselves in terms of the world and their relationships with others [129]. This theory is not a revised version of disengagement theory, which focuses on pursuits of external things [169]. Instead, this theory emphasizes inner-development. For example, an older adult may appear to be disengaging and withdrawing by not participating as many social activities, and a practitioner might even speculate a diagnosis of depression. However, according to gerotranscendence theory, it is possible that the elder is simply becoming more deliberate and reflective [170]. In an interview study of 14 older adults between 80 and 96 years of age, themes that emerged were consistent with this theory [130]. The study participants discussed reconnecting with the past and past generations, focusing less on themselves, and worrying less about money and material possessions.

**Erikson’s Stages of Development**

**According to Erikson, what is the major task in late adulthood?**

Erik Erikson, a prominent developmental theorist, had a more optimistic view of aging, focusing on the positive ways of overcoming the various crises one encounters throughout life [25; 26]. Erikson postulated eight stages of psychosocial development. Each stage provides the individual with a choice of two alternatives to consider and accept; one is an opportunity for growth, while the other results in unhappiness. In late adulthood, individuals confront the challenge of integrity versus despair. During this stage, individuals reflect on their lives, and determine if they have lived a life of purpose. If so, the individual will feel contentment, having attained integrity [26].

Attainment of integrity is defined as the ability to examine all of one’s life experiences and find a sense of peace and accomplishment. However, despair will be experienced by those who have not lived a meaningful life. In these cases, death is either viewed as welcome, a means to end a miserable life, or is feared because one can no longer compensate for past failures [27]. This theory, as in other stage theories, recognizes that psychologic and social growth continue throughout an individual’s life [171].

**Peck’s Developmental Tasks of Aging**

Peck’s Developmental Tasks of Aging is another theoretical framework to understanding aging, maintaining that older adults must complete three development tasks to achieve happiness [28]. First, shifting from a work-role preoccupation to self-differentiation is necessary. As many older persons retire, a new identity and social role must be created. New interests should be explored, and ultimately, individuals should realize that their identities are worthwhile regardless of their occupation [28].

The second task involves shifting from body preoccupation to body transcendence [28]. Those who transcend preoccupations with health issues, physical changes, and youth-based beauty ideals will be more satisfied with life.

Finally, the third task is the shift from self-preoccupation to self-transcendence. As death becomes more of a reality, persons may become depressed. However, others accept it with a healthy and positive attitude; this improves the quality of life [28].
Activity Theory
Activity theory asserts that older adults must remain embedded in social activities and relationships in order to accomplish their goals [169]. Starting from middle age and progressing into the later developmental years, being intrinsically linked with others, activities, and tasks that are viewed as meaningful are believed to produce physically, psychologically, and emotionally good health [98]. In other words, sedentariness does not promote wellness for elders [169].

Socioemotional Selectivity Theory
Socioemotional selectivity theory focuses on elders’ changed mentality and worldviews. As individuals age, their goals may change from being knowledge-oriented to being more emotion-related [171]. According to this theory, the elderly become more purposeful with whom they interact, looking for emotionally rewarding relationships. Conflicts tend to be avoided, knowing that their remaining time is short [171].

Age Stratification Theory
The historical context of an elder’s life forms the basis for the age stratification theory. Individuals and their generational cohort may respond, behave, and adhere to certain worldviews due to the historical, social, and cultural events that occurred during their lifetimes. These experiences then shape how individuals view social roles, cope with stressors, and respond to various events [98].

DEPRESSION AND SUICIDE
Depression can affect the elderly and is more prevalent among those who have experienced the loss of friends and family members [29]. The death of a spouse is a stressful event that may precipitate depression and may predict the onset of illness and earlier death [3]. Older women tend to experience greater depression and, once depressed, tend to stay depressed for longer periods of time compared with their male counterparts [131]. Older women with long, stable marriages were more likely to experience depression compared with women who had been married for a short period of time or whose marital quality was not as good [131].

Depression is a concern among older adults because it can place them at greater risk for developing medical illnesses. The converse is also true; those who have medical illnesses or disability are also at risk for depression [30]. For example, older adults with high blood pressure and depression are three times more likely to experience a stroke compared with older hypertensive individuals who are not depressed [29]. It is interesting to note that older persons with rheumatoid arthritis or osteoarthritis experience higher levels of depressive symptoms [30]. As individuals age, it is more likely they will experience some form of chronic pain. Adults between 45 and 64 years of age are more likely to report that they experience physical suffering lasting more than 24 hours [172].

The highest rates of depression in the elderly occur in those who have had strokes, coronary artery disease, cancer, Parkinson disease, and Alzheimer disease [84]. Recurrence rates are also very high. Although it is a misconception that the elderly are more depressed than the general public, they may still be at risk. It is important to assess each person individually.

Suicide is also a concern, as suicide is the seventeenth leading cause of death among the elderly, and individuals 65 years of age and older account for 20% of all suicides in the United States [31; 32; 173]. It is important to note that the rate of suicide is higher among older persons who are divorced or widowed [32]. White men 85 years of age and older are the most vulnerable, with a rate of 49.8 deaths per 100,000 persons [99]. Practitioners should be mindful that older adults are less likely to express emotional pain compared with their younger counterparts and are also less likely to endorse suicidal ideations [132]. It is important to account for risk factors more common in an older population, such as chronic illness, pain, loneliness, and social isolation, some of which may not be part of suicide risk assessments [132].

The Institute for Clinical Systems Improvement asserts that clinicians should routinely screen all adults for depression using a standardized instrument. (https://www.guideline.govsummaries/summary/50406. Last accessed May 10, 2017.)

Strength of Recommendation/Level of Evidence:
Strong recommendation/low quality evidence
(The work group feels that the evidence consistently indicates the benefit of this action outweighs the harms. This recommendation might change when higher quality evidence becomes available.)

GRIEF, MOURNING, AND BEREAVEMENT
Although the terms “grief,” “mourning,” and “bereavement” are often used interchangeably, they have specific and unique meanings. Grief is a normal reaction to a loss, while mourning is the expression of grief and the process by which individuals adjust to the loss. Bereavement is the period of time during which grief and mourning occur [35; 133]. Psychosocial support is essential for individuals who have lost loved ones and can help to decrease the risks of morbidity, substance abuse, and mortality commonly found among widows/widowers and other persons who have lost a loved one [36].
Grief
Grief comprises a range of feelings, thoughts, and behaviors in the realm of the physical, emotional, and social domains [35]. Individuals may have trouble sleeping, changes in appetite, or other physical symptoms or illness. Studies have shown that widowers may be at risk of poor nutrition and inadequate caloric intake, and widows who were financially dependent on their spouse are vulnerable to falling into a state of poverty [174]. Emotions can include sadness, anxiety, guilt, and anger. A return to work, activities with friends, and taking care of family are beneficial behaviors in the social domain. The issue of grief becomes more prevalent among older adults as they inevitably face the death of family members and friends. In a qualitative study with older adults 62 to 88 years of age, the participants described experiences that were laced with emotional distress [134]. They also talked about how their grief was unique and did not meet traditional expectations in terms of intensity and severity.

In cases of terminal illness, grief counseling should begin before death occurs, with a focus on life meaning and contributions [37]. Awareness and understanding of the mediators of grief responses can assist in recognizing individuals who may be at increased risk for adapting poorly to the loss. These mediators are [38]:

- Nature of attachment (how close and/or dependent the individual was with regard to the deceased)
- Mode of death (the suddenness of the death)
- Historical antecedents (how the individual has handled loss in the past)
- Personality variables (factors related to age, gender, ability to express feelings)
- Social factors (availability of social support; involvement in ethnic and religious groups)
- Changes and concurrent stressors (number of other stressors in the individual’s life, as well as coping styles)

Mourning
Satisfactory adaptation to loss is dependent on tasks of mourning [38]. In the past, “stages” of mourning were discussed; however, the stages were not clear-cut and were not always followed in the same order. The tasks associated with mourning include [38]:

- Accepting the reality of the loss
- Experiencing the pain of the loss
- Adjusting to the environment in which the deceased is missing (external, internal, and spiritual adjustments)
- Finding a way to remember the deceased while moving forward with life

After an individual’s death, the family should be encouraged to talk about the deceased, as this promotes acceptance of the death. A wide range of emotions is normal during the mourning process. Explaining the process can help family members understand that experiencing these emotions is a necessary aspect of grieving. Frequent contact with family members after the loved one’s death can ensure that the family is adjusting to the loss. Referrals for psychosocial and spiritual interventions should be made as early as possible to optimize their efficacy.

Older adults who lose a spouse will not only mourn the loss but also be confronted with their own mortality. They also have to cope with assuming new roles and potentially learning new tasks. Those who had been married a long time may feel they have lost a part of themselves [133].

Bereavement
Bereavement can trigger a host of physical and psychologic issues because of its highly stressful nature [100]. In one study of persons 50 years of age and older who lost a parent, there was a 83% likelihood of body mass index (BMI) loss compared with counterparts who did not lose a parent [175]. Loss of a spouse resulted in a 37% increased risk of BMI loss compared with those who had not lost a spouse.

How bereavement services are provided vary. Programs usually involve contacting the family at regular intervals to provide resources on grieving, coping strategies, professional services, and support groups [36; 37; 39]. Notes or cards are especially beneficial at the time of the first holidays without the deceased, significant days for the family (deceased’s birthday, spouse’s birthday), and the anniversary of the death. Bereavement services should extend for at least one year, but a longer period may be necessary [36; 39].

ALCOHOL AND SUBSTANCE ABUSE
Alcohol and substance abuse/dependence in the elderly are generally hidden problems. However, between 2002 and 2006, substance use rates have almost doubled among those 50 to 54 years of age. It is estimated that slightly more than 10% of the elderly abuse prescription drugs, with up to 5 million elderly individuals projected to have drug use disorders and 4.4 million requiring substance abuse treatment by 2030 [101; 135; 176]. It is estimated that more than 80% of patients 57 to 85 years of age are taking at least one prescription medication daily. In addition, more than 50% are taking more than five medications daily [177]. Several factors contribute to the invisibility of these disorders. First, many elderly individuals do not disclose alcohol or substance abuse because they are ashamed. This is compounded by healthcare professionals’ reluctance to ask older adults about substance abuse, mostly due to the prevalent images of young
people misusing substances [40]. Additionally, the symptoms of alcohol and substance abuse can mimic or resemble conditions associated with aging, thereby masking an underlying drinking or substance disorder [40]. Finally, some older adults may be isolated, with minimal social contacts or networks to intervene in cases in which alcohol or substance use has become a problem.

The prevalence of alcoholism in the older population is estimated to be 10% to 18% and is the second most frequent reason for admitting elders to inpatient psychiatric facilities [41]. It is estimated that 3 million persons older than 65 years of age abuse alcohol; only 15% receive any treatment [42]. Studies indicate that 6% to 11% of elderly patients who are admitted to hospitals exhibit symptoms of alcoholism; furthermore, 20% of elderly patients in psychiatric wards and 14% of elderly patients in emergency departments have symptoms of alcohol abuse [43]. Among nursing home residents, it is estimated that as many as one-half have problems related to alcohol [44].

Late-onset alcoholism is common in the elderly, and several risk factors may contribute to the development of alcohol use disorders in older age. Some may use alcohol to self-medicate to mitigate physical symptoms, such as difficulty sleeping or chronic pain. Mourning a loved one, loss of social supports, and loneliness can also instigate alcoholism later in life [102]. In general, late-onset alcoholism is more common among older women than older adult men [136]. It is also more prevalent among older adults in higher socioeconomic brackets. Compared with early-onset alcoholism, individuals with late-onset alcoholism tend to experience less psychosocial and legal consequences as a result of the substance abuse [136].

Rigler argues that the Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria for alcohol use disorder may be difficult to apply to older adults [45]. For example, age-related physiologic changes may change the individual’s response to alcohol, increasing their sensitivity and levels of tolerance. Because of this, they may not spend a lot of time or expend a great amount of energy in activities related to alcohol or substance consumption [46]. Thus, these persons would not meet the DSM criteria for alcohol use disorder as they require smaller amounts of alcohol to become intoxicated. In addition, the DSM criterion of giving up activities or responsibilities as a result of substance use may not be appropriate for older adults because they may have fewer regular activities resulting from diminished vocational or social responsibilities [46]. Unfortunately, there are few evidence-based substance abuse treatment approaches that are targeted for older adults. Practitioners tend to simply adapt treatments created for younger populations for older adults [135].

ELDER ABUSE

The 2015 White House Conference on Aging identified elder abuse as a top priority in public health [178]. Elder abuse refers to “any knowing, intentional, or negligent act by a caregiver or any other person that causes harm or a serious risk of harm to a vulnerable adult” [47]. There are three general categories of elder abuse, which appeared for the first time in the 1987 Amendments to the Older Americans Act [48]. These three categories of elder abuse are: domestic elder abuse, institutional abuse, and self-neglect or self-abuse [48].

Definitions of elder abuse vary based upon state statutes. However, the National Center on Elder Abuse has identified seven types of behavior associated with elder abuse [49]:

- Physical abuse: Use of physical force that results in injury, pain, and impairment, such as slapping, punching, kicking, or restraining
- Sexual abuse: Nonconsensual contact of any form
- Emotional abuse: Infliction of distress, anguish, and/or pain through verbal or nonverbal acts
- Financial/material exploitation: Illegal or improper use of an elder’s resources, property, funds, and/or assets without the consent of the elder
- Neglect: Refusal or failure to provide goods or services to an older adult, including denying food or medical-related services
- Abandonment: Desertion of an elderly person by the individual who has physical custody or who is the primary caretaker
- Self-neglect: Behaviors of elderly persons that jeopardize their own safety and/or physical health

Epidemiologic studies of the prevalence of elder abuse indicate a prevalence of between 2% and 10% [137]. In a survey study with 3,005 adults between 57 and 85 years of age, 0.2% disclosed to physical abuse in the last year, 9% reported verbal abuse, and 3.5% indicated financial abuse [138]. These prevalence rates may be lower than the actual rate given the amount of under-reporting due to fear of reprisals, embarrassment/shame, and hopelessness [179]. A study of 441 elderly Michigan individuals living in nursing homes found that 21% of family members reported some type of elder neglect in the last year [139]. The factor most predictive of neglect was limited ability to engage in activities of daily living. Cognitive impairment also appears to be predictive of elder abuse [179].
The U.S. Preventive Services Task Force concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening all elderly adults for abuse and neglect. (https://www.guideline.gov/summaries/summary/39425. Last accessed May 10, 2017.)

Strength of Recommendation: I (Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.)

SPECIAL POPULATIONS

GRANDPARENTS PARENTING

Typically, older adults do not think about parenting at their particular life stage; however, there has been an increase in grandparents parenting in the last decade. In 2015, it was estimated that 5.8 million children younger than 18 years of age in the United States resided with a grandparent; 2.6 million grandparents were responsible for the basic needs of one or more grandchildren younger than 18 years of age [8]. Out of custodial grandparents, 1.6 million are grandmothers and 1 million are grandfathers [8]. Between 2006 and 2015, there was an 8.3% increase in custodial grandparents. The reasons for grandparents taking over parenting responsibilities of their grandchildren are numerous, ranging from parents’ substance abuse, divorce, health and mental health concerns, reported child abuse, and death of a parental figure [180]. Many grandparents assume these roles so their grandchildren do not enter the foster care system.

Often, grandparents are placed in these new roles without much preparation, making the task more difficult. Some older adults may feel uncomfortable addressing issues such as drugs, sexually transmitted infections, gangs, and school violence [54]. Some studies indicate that these new parenting roles, particularly if the grandchildren have physical or mental health problems, trigger anxiety and negative well-being for grandparents [55]. In one study, Ross studied 50 African American grandparents raising grandchildren, and a majority (94%) reported increased stress [56]. Those grandparents who were involved in counseling and special school programs reported less stress. In a separate study of African American custodial grandparents, sleep disorders were common, with most linking the lack of sleep or poor sleep quality on the stresses of parenting their grandchildren [16].

Stress also results from the financial constraints associated with raising grandchildren. In the United States, more than one-half of all grandparents raising grandchildren have incomes below the federal poverty level [57]. The unanticipated costs of raising children in retirement years may severely impact financial independence, as these individuals may already be living on a tight budget. With additional medical costs and, at times, costs associated with other therapies, many grandparents may experience caregiving burden [57]. Custodial grandparents who are unable to work may have difficulty applying for Temporary Assistance for Needy Families (TANF) [34]. The TANF family grant offers financial support based on the income of the entire family, but it also has a work requirement for the grandparent [34].

The additional stress in assuming primary care of grandchildren may also be a contributing factor to the poorer physical health of custodial grandparents. Grandparents who are caring for their grandchildren report worse self-reported health symptoms, such as more body pain and general health perception, compared with their counterparts not providing care to their grandchildren [51]. Although there are negative effects, there are also positive outcomes for custodial grandparents. Some view it as a second chance to rectify mistakes they feel they made as parents [141]. In a study of custodial grandmothers, some reported enjoying parenting the second time because they felt they had more experience, had learned from past mistakes, and could now offer wisdom. In many respects, this created a sense of freedom, relaxation, and confidence [142]. Some grandmothers felt they had more time and attention to give to their grandchildren compared with raising their own children, when they had additional demands such as work [142].

ELDERLY ETHNIC MINORITIES

The elderly population in the United States is far from homogeneous in terms of race and ethnicity. Minority populations have increased from 5.7 million in 2000 (16.3% of the elderly population) to 8.1 million in 2010 (20% of the elderly) and are projected to increase to 13.1 million in 2020 (24% of the elderly). In 2013, 21.2% of persons 65 years of age and older were from a racial/ethnic minority groups [181]. By 2050, it is projected that almost 30% of those 85 years of age and older will be from a racial/ethnic minority groups [182]. Of this, the largest groups were African American (8.3%), Hispanic (7%), Asian American and Pacific Islanders (3.4%), and Native Americans and Alaskans (less than 1%). African American adults constitute 11% of the older population [144]. Finally, by 2050, it is projected that there will be 918,000 Native Americans elders, about 1% of the population [145].
Given the discrimination and oppression that racial and ethnic minority elders may have experienced over the years, they may be reluctant to seek mainstream health and mental health services. In addition, some may be limited in English proficiency, which is often another barrier to help-seeking and compliance with health and mental health services. Practitioners should be aware of the dynamics that stem from the result of cultural differences in values, belief systems, health beliefs, attributions of causation to illness and problems, and communication styles [104]. Not understanding cultural differences can lead practitioners to take on a deficit or pathology perspective when viewing their clients.

ELDERLY WOMEN

In examining historical trends, there are gender differences in longevity rates; women tend to live longer than men [5]. For example, women who reach 65 years of age are expected to have a life expectancy of an additional 20.5 years; men who reach 65 years of age have an average life expectancy of 17.9 years [181]. As such, there are significantly more older women (25.1 million) than men (19.6 million) [181]. This longer lifespan has social and economic ramifications. In general, elderly women are more likely to be widowed, living alone, and experience greater poverty than their male counterparts. According to the U.S. Census, 39.9% of women 65 years of age and older are widowed compared with 12.7% of men in this same age-group [5]. Almost half of women 75 years of age and older live alone [181]. Elderly women are twice as likely to live by themselves compared with elderly men. Despite some of these negative social trends, a qualitative study of 15 urban elderly women related stories of survival, strength, and resilience [106]. The themes that emerged in these narratives were that of being able to rebound from adversity and tapping into social network systems that stemmed from their churches, community, and family.

GAY AND LESBIAN ELDERLY

There are an estimated 2.4 million lesbian, gay, bisexual, and transgender (LGBT) individuals 50 years of age and older, a number that is expected to double by 2030 [183]. The overall predominant attitude about sexuality is that it is a private matter, and the general myth is that elderly individuals are sexless [107]. Therefore, the unique needs of gay, lesbian, and transgendered/transsexual elderly are often ignored or unacknowledged. Furthermore, in a heteronormative society, older adults may have experienced (and continue to experience) discrimination [184]. Elderly homosexuals experience intersecting oppression stemming from ageism as well as homophobia. Older gay men, for example, are stereotyped as “dirty,” “lecherous,” and “oversexed” [108]. These stereotypes lead to discrimination, marginalization, and oppression and affect health, mental health, and social services. One of the major fears associated with aging in the gay community is decline in health status and not being able to access services that accommodate to gays’ and lesbians’ needs and concerns [107]. Lesbians tend to express concern about lack of recognition of same-sex partners and lack of services that are sensitive and relative to gays and lesbians. Gay men tend to fear being alone in later life. It has been hypothesized that, due to the discriminatory policies affecting gay and lesbian individuals’ access to different types of services, older gay and lesbian women are more vulnerable to needing long-term care than their same-age heterosexual counterparts [147]. After controlling for race, age, and education, researchers found that women living with female partners were more likely to need help with bathing or dressing compared with women living with or married to male partners. Similarly, men living with male partners were more likely than men living with or married to female partners to need help with errands.

It is important to use the lifespan perspective to understand the experiences of older gay and lesbian adults [148]. Their reality is shaped by a culture that has historically criminalized, medicalized, and pathologized same-sex relationships. Therefore, they have historically been socially isolated and ostracized by their families and friends [109]. In addition, access to care and social services have been adversely impacted, which then has led to health disparities [148].

LONG-TERM CARE

Which factors are predictive of an elder entering a nursing home?

In the United States, there were 1.4 million adults residing in nursing homes at the end of 2014 [149]. Approximately 2.6% of individuals 65 years of age or older and 9.5% of those 85 years of age or older are residents of nursing homes. Women are highly represented among nursing home residents, comprising 65.6% of this population. In addition, the majority (77.9%) are non-Hispanic white [149]. In terms of residents’ level of impairment, 21% are able to carry out no activities of daily living, but 38.7% are characterized as having only mild cognitive impairment [149].

Institutions providing long-term care to older individuals often provide a variety of services, including personal, social, and medical services. Key factors that predict elders entering a nursing home include [111]:

- Non-Hispanic white race
- Lower income bracket
- Restricted activities of daily living
- Cognitive impairments or a history of falls
- Chronic diseases (e.g., diabetes, cardiac conditions, stroke)
- Limited social supports (e.g., widowed, divorced, few or no children)
Although nursing homes remain an integral factor in long-term care, there have been concerted efforts to move away from institutionalized care and to home- or community-based options [80]. This may be in part due to most individuals' wishes to remain in their own homes for as long as possible, receiving more patient-centered and responsive care. It is important to note that family members provide the majority of care to older individuals. In 2009, 42 million people in the United States provided unpaid care to an adult [81].

Providing long-term care is complicated, as integrated psychosocial and medical care is often required. Specialized assessment tools, including the Resident Assessment Instrument, are available in order to assist in the development of care plans for residents in long-term care facilities [82].

Ten ethical issues have been identified as having significance in geriatrics and long-term care [79]:

- **Beneficence**: The main concern should be for the well-being of the client or patient.
- **Non-maleficence**: Harm should be avoided.
- **Futility of treatment**: Interventions should be consistent with the individual's goals.
- **Confidentiality**: All laws should be conformed to in regards to confidentiality.
- **Autonomy and informed consent**: All patients have the right to self-determination, including the right to refuse treatment. Persons should also be encouraged to complete a healthcare directive and to name a proxy in the event that they are incapacitated.
- **Clinician-patient relationship**: All clinicians should strive to create a therapeutic alliance with the patient.
- **Truth telling**: Communication should be honest and thorough, and medical terminology should not be used to obscure the truth.
- **Justice**: An objective decision-making process should be used.
- **Non-abandonment**: Clinicians have the responsibility of ensuring that patients are provided with adequate therapy. If a therapeutic relationship must be terminated, it may not end until time has been given for the patient or his or her proxy to make other arrangements.
- **Limited resources**: Make decisions and allocate limited healthcare resources in a nondiscriminatory and objective manner.

For elders and their family members who believe their rights have been violated or who have complaints about their long-term care services, all states have an Ombudsman Program under the Title VII Older Americans Act that is overseen by the Administration on Aging [112]. Volunteers from this program work with elders and families to advocate on their behalf to provide information about long-term care, to investigate complaints, and to promote changes in institutions in order to improve the quality of life for long-term care residents.

**ASSESSMENT TOOLS FOR OLDER ADULTS**

This section will touch on key assessment tools in the areas of depression, suicidality, substance and alcohol abuse, and elder abuse. Elderly patients should be routinely screened for these conditions, in spite of some practitioners' discomfort with asking questions about sensitive topics. These population-appropriate assessments may be included in other health screening tools [58].

**SCREENING TOOLS FOR DEPRESSIoN**

Structured instruments like the Center for Epidemiologic Studies Depression scale (CES-D) and the Beck Depression Inventory are brief self-reports that measure signs and symptoms of depression [59; 60]. These practical tools are easily accessed and administered by practitioners. However, they are self-reports and can be unreliable, particularly for those with impaired memory. The CES-D is a 20-item instrument consisting of closed-ended questions; the Beck Depression Inventory is a 21-item rating inventory.

In addition to these tools, a specific assessment measure for older adults, the Geriatric Depression Scale (GDS), has been developed [85]. Available in both a short and long form, this scale consists of 15 to 30 closed-ended questions. The GDS is recommended when screening older adults for depressive symptoms [84].

If a practitioner finds that an older individual scores positively for depression, the patient should be further evaluated in a clinical interview to determine whether the symptoms are of sufficient intensity, number, and duration to meet the criteria for major depression or dysthymia.
SCREENING TOOLS FOR COGNITIVE IMPAIRMENT

Older adults are more likely to experience cognitive decline, and presence of the early signs of impairment should prompt immediate intervention [83]. Patients who display symptoms of changes in psychologic status may be evaluated for dementia or cognitive impairment using the Mini Mental State Examination (MMSE). The MMSE consists of 11 items that assess five areas of cognitive function: orientation, registration, attention and calculation, recall, and language. A maximum score is 30, and any score less than 24 indicates cognitive impairment [83]. Because the MMSE takes little time to administer, it may be integrated into practice relatively easily.

The Mini-Cog is also another quick screening tool used to assess for cognitive impairment. It involves a three-item recall and a clock drawing test and takes about three to five minutes to administer. The patient is given three unrelated words to remember, then is asked to draw the face of a clock, with the time of 10 minutes after 11 o’clock. After drawing the clock, the patient is asked to repeat the original three words. He or she receives one point for each recalled word [150]. A score of 0 indicates likelihood of cognitive impairment, and a score of 3 indicates no concern of cognitive impairment. If the score is 1 or 2, the results of the clock drawing test are taken into account; an abnormal drawing is suggestive of cognitive impairment. This test has a sensitivity rate of 99% and classified a group of subjects correctly 96% of the time [150]. In a study of elderly veterans, researchers found that the majority of participants with no documented diagnoses of dementia failed the Mini-Cog [151]. The authors concluded that this simple screening tool can easily be incorporated into standard assessments.

In addition, the Alzheimer’s Association has published a cognitive assessment toolkit intended to allow practitioners to detect cognitive impairment quickly and efficiently during the Medicare annual wellness visits. The toolkit is available online at https://www.alz.org/documents_custom/141209-CognitiveAssessmentToo-kit-final.pdf.

ASSESSMENT TOOLS FOR SUICIDALITY

Asking questions about thoughts and/or intent to harm oneself is often uncomfortable for practitioners [61]. However, it can be done in a non-confrontational manner that conveys caring and respect. It is also recommended that cultural sensitivity be at the forefront of practitioners’ minds when assessing for risk of suicide. Individuals from certain cultural backgrounds may view suicide as sinful [61; 152]. Taking this into consideration, questions include: With this much stress, have you thought of hurting yourself? Do you think life is worth living? Have you ever thought of killing yourself? How would you do it? Do you have the tools to carry out your plan? What would stop you or what has stopped you from carrying out your plan?

When suicidal ideation is known or suspected, a more direct approach, using forced choice questioning, may be helpful [62]. Shea recommends inquiring about specific symptoms with an emphasis on overestimation in order to prevent individuals from underestimating the symptoms [62]. For example, a clinician might ask: “Do you think about hurting yourself 20 hours a day?”

The Depression and Suicide Screen (DSS) may also be useful. It consists of five items, is simple to administer, and can be used in health and mental health settings. The DSS requires patients to answer yes or no to following questions [113]:

- Is your life pretty full? If no, score 1 point.
- Do you still enjoy doing the things you used to do? If no, score 1 point.
- Do you think it is too much trouble to do the things you used to do? If yes, score 1 point.
- Do you feel that you are a useful person who is needed by others? If no, score 1 point.
- Do you feel tired without any specific reason? If yes, score 1 point.

A score of 2 or greater is considered sensitive for depression and/or suicidality.

SCREENING TOOLS FOR ALCOHOL ABUSE

How does the Michigan Alcohol Screening Test-Geriatric (MAST-G) vary from the standard MAST test?

There are several screening tools available for assessing older adults with problem drinking. The Drug Abuse Screening Test (DAST) is a 28-item questionnaire consisting of yes or no responses. The Short Michigan Alcohol Screening Test (SMAST) is a 13-item questionnaire with a similar response format. These instruments are commonly used but may not be appropriate for the elderly population. However, a longer version of the SMAST, the Michigan Alcohol Screening Test-Geriatric (MAST-G) was specifically developed in order to accurately assess alcohol abuse and dependence in older adults [46]. The MAST-G consists of 24 items, which may limit its incorporation into regular screening procedures. As opposed to the standard MAST, this version focuses more on drinking in response to grief and changes in drinking patterns over time.
The CAGE Questionnaire for Alcohol Abuse is a brief, easy-to-administer screening device that is easily incorporated into a medical or psychosocial assessment; it is the most widely used instrument in clinical practice (Table 1) [63]. The CAGE Questionnaire consists of four closed-ended items that assess an individual's perception of their drinking habits. Affirmative responses to any one item indicate a potential problem with alcohol abuse [64]. However, this tool does not identify those who may be in the early stages of alcohol abuse [63].

In general, patients will be willing to answer questions if they perceive that the practitioner is caring and nonthreatening. Responses to the screening questions will be most accurate when patients believe their responses will be kept confidential and will help with their health diagnosis [136].

SCREENING FOR ELDER ABUSE

There is no one single tool that is considered the criterion standard to assess and measure elder abuse [179]. One tool, the Indicators of Abuse form, is available for practitioners to use when observing and interviewing the client and family members for elder abuse [65]. This tool is not dependent upon self-reporting but is based on observation and assessment. Researchers have been able to isolate caregiver characteristics that are strongly related to elder abuse [65]. These characteristics include the caregiver's personal and emotional problems, financial dependence of a caregiver on the elder, and the caregiver's general lack of knowledge about the elder's health and psychologic concerns. Furthermore, elder abuse was also correlated with family conflict, the elder's lack of social support, and history of past abuse (though not by the caregiver) [65]. Using these findings, the Indicators of Abuse form was developed. Based on observations and lengthy interviews with both the elder and family members, it asks practitioners to estimate how large the problem is in two areas: dimensions related to the caregiver (e.g., behavior problems, financial status, alcohol/substance problem, or marital/family conflict) and dimensions related to the elder (e.g., social isolation, unrealistic expectations, suspicious falls/injuries, or behavior problems) [65].

Another good assessment instrument is the Elder Abuse Suspicrion Index (EASI). It is a five-item tool that provides practitioners a very quick sense whether there is suspicion about the potential presence of elder abuse [114]. It was originally developed for physicians, but it may be used by practitioners in diverse disciplines. The screening questions are:

- Have you relied on people for any of the following: bathing, dressing, shopping, banking, or meals?
- Has anyone prevented you from having food, clothes, medication, glasses, hearing aids, or medical care, or from being with people you wanted to be with?
- Have you been upset because someone talked to you in a way that made you feel shamed or threatened?
- Has anyone tried to force you to sign papers or use your money against your will?
- Has anyone made you afraid, touched you in ways that you did not want, or hurt you physically?

The Brief Abuse Screen for the Elderly (BASE) is another instrument, consisting of only five questions, that takes less than one minute to complete [153]. This tool is designed for the practitioner to complete to determine level of suspicion—the patient is not questioned directly. It is ideally suited for practitioners to use in conjunction with a patient screening tool [153].

Assessing for elder abuse does not only involve asking questions to the elderly client. It is also about asking oneself difficult self-evaluative questions, such as: “Do I hold ageist attitudes? How are these attitudes translated when I conduct an assessment? Do I believe that older adults can be abused, even sexually abused?” Pervasive ageist attitudes held by practitioners can result in a failure to acknowledge that elder abuse (particularly sexual abuse) can occur [154]. This can impact whether certain assessment questions are even asked.
GENERAL GUIDELINES FOR INTERVENTIONS

Wellness and purpose have become important emphases when working with older adults [66]. In the past, aging was associated with disability, loss, decline, and a separation from occupational productivity. Although client growth and positive change and development are values that practitioners embrace, the unconscious acceptance of societal myths and stereotypes of aging may prevent practitioners from promoting these values in elderly individuals [115]. In a study of 200 older adults residing in assisted living facilities, participants scored low on levels of depression and high for successful aging, despite having a variety of chronic health conditions [155]. Researchers also found few differences between the young-old and the old-old subgroups in terms of their ratings of successful aging. More than half of the residents exercised regularly, which had both physiologic and social benefits. It is important not to assume that older adults will automatically decline, and it is important to give these patients a sense of purpose and activities that promote successful aging. In a qualitative study conducted by Griffith, Caron, Desrosiers, and Thibeault, older adults defined meaningful occupational roles in a variety of ways [67]. For some, meaningful occupations involved using a skill they are good at; for others, meaningful occupations help to express an identity they value. According to Penick, there is no empirical evidence that older adults do not desire purposeful activities and goals, although their goals may be different from those in other stages of the developmental life cycle [68]. A study conducted by Greenfield and Marks found that elders who were not engaged in activities that promoted a sense of identity were more likely to experience negative psychologic well-being and less sense of a purpose in life [69]. However, those who were engaged in meaningful activities, like formal volunteering, were more likely to experience positive psychologic well-being. Consequently, caring for older adults necessitates a focus on wellness, goals, and purpose, which requires practitioners to shed stereotypical views of aging. Environments that provide older adults with opportunities to explore and formulate new goals are vital [68]. In assessments of older individuals, practitioners should encourage older adults to talk about what gives meaning to their lives and to identify goals based on their social interests [68]. Furthermore, Koenig and Spano argue that the concept of hope may have to be redefined given the context of the lives of elders [115]. For example, if hope is defined as achievement and control, this may be problematic for elders. However, if hope is reconceptualized to mean strengthening existing coping skills and capabilities to transcend challenges, then elders can be empowered to focus on their strengths versus their deficits.

Reminiscence interventions may also be beneficial for older adults. As a therapeutic intervention, reminiscing allows older adults to recall and relive past events in order to integrate their experiences [156]. However, this approach consists of more than simply recalling past memories; these interventions emphasize the importance of the reflective process in assisting individuals to define and redefine themselves [185]. Some counselors use photographs, videos, autobiographies, or other materials to help trigger memories. These concepts are reflected in nursing homes and other long-term care facilities that encourage residents to display family photos or create memory books [186]. This type of intervention can improve self-esteem, mood, cognition, and behavioral functioning. In reminiscence groups with caregivers participation, caregivers reported learning more about the patients and appreciating their lives and experiences [156].

One study evaluated a spiritual reminiscence group consisting of patients with mild-to-moderate dementia in Taiwan over six weeks [185]. Those who participated in the intervention showed increases in hope, life satisfaction, and spiritual well-being compared with the control group.

ENGAGEMENT

Coping with loneliness can involve increasing the number of social contacts or intensifying certain specified relationships and lowering individuals' expectations about relationships [157]. Increasing or intensifying social networks can involve various approaches. Cattan and White identified three key aspects of interventions for older adults that support active engagement: group activities that provide support (e.g., support for bereavement), interventions targeted to a specific subgroup (e.g., widowers), and activities or interventions emphasizing elders' control [70]. Several interventions for older adults that focus on decreasing social isolation have been identified and may be classified into four general categories [71]. The first type of intervention to address isolation is one-on-one telephone support services, whereby a counselor checks in with elders periodically. Second, teleconferencing, whereby a group of elders are brought together via a phone conference, has been found to be a cost-effective and useful intervention. Third, face-to-face support groups were found to be beneficial in reducing social isolation, particular groups that last for at least five months [71]. Lastly, with increasing Internet accessibility, e-mails and Internet support groups can also be beneficial for older individuals. A study exploring the use of videoconferencing with frail elders in Australia found that the patients preferred videoconferencing with a pain specialist over a face-to-face consultation [116]. A 2016 systematic review found that social connectedness and support were increased in elders who used Internet technologies, although the effects were short term [187]. As discussed, loneliness is often intertwined with other variables, such as shyness or limited resources. Therefore, interventions
should not simply focus on providing venues for older adults to meet; interventions and programs that focus on people's expectations about friendships and relationships are equally important [157].

**AUTONOMY AND EMPOWERMENT**

Autonomy is a quality valued by all, but it may be even more important for persons whose movements are restricted by physical limitations, which is often the case with older individuals. Autonomy refers to the freedom and ability to act on one's own behalf [72]. It is described as having two attributes: independence and control. Independence entails the physical ability to act as one wishes; control is defined as perception of one's ability to exert power [72]. Control also refers to self-determination, or the ability to choose for oneself or formulating and executing a plan for oneself [117]. When older adults perceive they are losing their sense of autonomy, they are more vulnerable to becoming apathetic, depressed, powerless, and indecisive [158]. Family members become more involved as well [188]. For those living in nursing home facilities, it is crucial to provide them with choices and to empower them to make those choices, even simple decisions such as which foods to eat, activities to engage in, and clothes to wear [158].

Autonomy is central in promoting a sense of empowerment. Empowerment is the process by which individuals or groups perceive they can make positive changes or impact within their own lives related to interpersonal relationships and an array of social, political, and economic arenas [73]. In one small study of older adult women, the participants expressed the importance of relationships in the feeling of empowerment, including the significance of mutuality, problem solving based on collectivism, and mutual support and action [73]. Cox and Parsons recommend small group interventions, particularly for older women, that emphasize self- and mutual-help, meaningful relationships, and problem-solving skills [73].

With these overall themes in mind, Silverstone offers several practice guidelines when caring for older individuals [74]:

- Assessment and diagnosis of an older adult's needs should take place within the context of the individual, family, and environment.
- Differential features of practice with older adults should be listed. These features may include health, mental health, loss, control, spirituality, and adaptive behaviors. Listing these different areas should help practitioners consider the array of domains to be covered in psychosocial assessments. It also assists practitioners to identify areas in which they may need to seek additional education and/or information.
- Collaboration with members from multidisciplinary teams is vital in order to address areas of importance to older adults.
- Practitioners should seek evidence-based literature to inform their practice.

**ETHICAL PRACTICE WITH ELDERS**

General societal misconceptions regarding the elderly can influence practitioners' ethical decision-making capabilities when working with older adults [75]. The first misconception is that older adults are helpless victims and must be rescued [75]. Another misconception is that older adults cannot change at this stage in their lives. Some may also believe that because this life stage is characterized by decline, older individuals are not able to better themselves or heal [75]. If practitioners are influenced, consciously or unconsciously, by this bias, it can then affect or motivate their decision-making processes.

**PROMOTING AUTONOMY AND SELF-DETERMINATION**

The ethical principle of beneficence mandates the duty of practitioners to do good and avoid harm [76]. The balance of good and harm is continuously evaluated. All persons have the right to self-determination, and it should be assumed that all adults (with some exceptions) have the capability to make decisions. Practitioners are responsible for encouraging the client to be autonomous [77]. A four-step process to assist practitioners to promote beneficence and client autonomy has been developed [76]:

- Discuss each client's values and preferences.
- Evaluate care plans related to physical safety, independence, and each client's values and preferences.
- Protect the client's autonomy by considering the client's values and preferences and weighing them with potential negative consequences of implementing any care regimen.
- Support each client's values and preferences, even if they conflict with the practitioner's own value system.
The violation of clients’ autonomy and self-determination can be very subtle. Practitioners should consider the role of power dynamics between the two parties and how the practitioner’s expert status inadvertently reinforces a hierarchical relationship [118]. In a study of 21 older adults receiving in-home nursing care, one of the main themes that emerged was the elders’ need to be treated as people—as unique individuals and not cases [159]. The participants reported wanting to be treated with respect and dignity and wanting to make decisions about their care. Furthermore, older adults with chronic conditions eventually learn to live with and have established competencies and routines to manage it. They are still active in their decision making and want to continue to be [160].

Informed consent is the direct expression of the principle of autonomy. The three criteria for informed consent are competence, voluntariness, and being informed [189].

CAPACITY

What options should be considered when obtaining informed consent for an elder with a significant cognitive impairment?

Decision-making capacity refers to an individual’s ability to understand, appreciate, reason, and ultimately express choices. There are different categories of decision-making capacity, such as personal, medical, and financial [119]. It is important for practitioners not to assume that elders cannot make their own decisions, as this would be based on the ageist assumption that with age comes a lack of mental capacity. However, practitioners should remember that some losses may be associated with the normal process of aging. Loss of hearing, for example, can lead to miscommunication and a sense of isolation, anxiety, or paranoia. Therefore, effective communication, regardless of client disabilities, is key in helping elders make informed choices [78]. It is also important to remember that assessing an older adult’s level of capacity should be continuous [161].

The issues of an elder’s mental capacity and self-determination come into play with informed consent, particularly if cognitive impairments are present. Informed consent involves three dimensions: the communication of the information, the opportunity to ask questions, and the process of making a decision [162]. As stated, an elder’s self-determination should be promoted. It must involve not only the communication of the information but also giving older adults the opportunity to ask questions about their care, the intervention, and/or services provided to them and empowering them to make the decision. However, there may be times when an elder cannot give informed consent. One way to assess if the elder understands the intervention is to have him/her reiterate what the intervention entails [6]. However, there are a few options when an elder’s capacity is compromised. First, a surrogate caregiver could provide consent. Second, double informed consent could occur, whereby the surrogate caregiver gives informed consent and the elder client gives assent. Finally, it is possible to obtain early informed consent from the elder via legally binding documentation of wishes prior to any cognitive impairment [6].

Several tools are available to assess capacity, including [161]:
- Aid to Capacity Evaluation
- MacArthur Competency Assessment Test for Clinical Treatment
- The Assessment of Capacity for Everyday Decision-Making
- Semi-Structured Clinical Interview for Financial Capacity

These tools evaluate different dimensions of capacity, highlighting the lack of consensus on the criteria to determine capacity.

CONFIDENTIALITY

The ethical principle of confidentiality is defined as the preservation of client privacy. When older individuals are at risk of harming themselves or being harmed by others, as in the case of elder abuse, the issue of confidentiality becomes a challenge. The ethical intervention is dependent upon state and national laws. Therefore, practitioners should be well-versed in their state’s laws regarding elder abuse, advance directives, and other relevant issues. In addition, practitioners should clearly present the limitations of confidentiality to the client.

CONCLUSION

Age-sensitive practice is crucial and will continue to grow more important as the nation’s demographic shifts and life expectancy increases. The older segment of the population is extremely diverse in terms of the span of developmental, social, and psychologic needs. Resilience and potentiality rather than decline and deficits should be emphasized throughout all assessments and interventions. Practitioners must explore their beliefs and values to determine if any normative ageist assumptions about the elderly are present. Instead of viewing the elderly as a group with many problems, diseases, and pathologies, a strength perspective that emphasizes their rich and diverse life experiences should be infused into clinical practice. In order to facilitate the best care for older adults, the promotion of knowledge and skills in these areas is vital.
**Responsible and Effective Opioid Prescribing**

Includes 3 Pharmacotherapeutic/Pharmacology Hours

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**Audience**

This course is designed for nurses and healthcare professionals who may alter prescribing practices or intervene to prevent drug diversion and inappropriate opioid use.

**Course Objective**

The purpose of this course is to provide clinicians who prescribe or distribute opioids with an appreciation for the complexities of opioid prescribing and the dual risks of litigation due to inadequate pain control and drug diversion or misuse in order to provide the best possible patient care and to prevent a growing social problem.

**Learning Objectives**

Upon completion of this course, you should be able to:

1. Apply epidemiologic trends in opioid use and misuse to current practice so at-risk patient populations can be more easily identified, assessed, and treated.
2. Create comprehensive treatment plans for patients with pain that address patient needs as well as drug diversion prevention.
3. Evaluate behaviors that may indicate drug seeking or diverting as well as approaches for patients suspected of misusing opioids.
4. Identify state and federal laws governing the proper prescription and monitoring of controlled substances.

**Faculty**

Mark Rose, BS, MA, is a licensed psychologist and researcher in the field of alcoholism and drug addiction based in Minnesota. He has written or contributed to the authorship of numerous papers on addiction and other medical disorders and has written books on prescription opioids and alcoholism published by the Hazelden Foundation. He also serves as an Expert Advisor and Expert Witness to various law firms on matters related to substance abuse, is on the Board of Directors of the Minneapolis-based International Institute of Anti-Aging Medicine, and is a member of several professional organizations.

**Faculty Disclosure**

Contributing faculty, Mark Rose, BS, MA, has disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

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**Division Planner Disclosure**

The division planner has disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

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INTRODUCTION

Pain is the leading reason for seeking medical care, and pain management is a large part of many healthcare professionals’ practice. Opioid analgesics are approved by the U.S. Food and Drug Administration (FDA) for moderate and severe pain and are broadly accepted in acute pain, cancer pain, and end-of-life care, but are controversial in chronic noncancer pain. In response to the long-standing neglect of severe pain, indications for opioid analgesic prescribing were expanded in the 1990s, followed by inappropriate prescribing and increasing abuse, addiction, diversion, and overdose through the 2000s. In tandem with the continued under-treatment of pain, these practice patterns led to needless suffering from uncontrolled pain, opioid analgesic addiction, and overdose. Opioid analgesic prescribing and associated overdose peaked in 2011 with both now in multi-year decline.

Patients show substantial opioid response variations in analgesia and tolerability and may exhibit a range of psychologic, emotional, and behavioral responses that reflect inadequate pain control, an emerging opioid use problem, or both. Clinician delivery of best possible care to patients with pain requires appreciation of the complexities of opioid prescribing and the dual risks of inadequate pain control and inappropriate use, drug diversion, or overdose. A foundation for appropriate opioid prescribing is the understanding of factual data that clarify the prevalence, causality, and prevention of serious safety concerns with opioid prescribing.

SCOPE OF THE PROBLEM

How is inappropriate opioid analgesic prescribing defined?

Inappropriate opioid analgesic prescribing for pain is defined as the non-prescribing, inadequate prescribing, excessive prescribing, or continued prescribing despite evidence of ineffectiveness of opioids [1]. Appropriate opioid prescribing is essential to achieve pain control; to minimize patient risk of abuse, addiction, and fatal toxicity; and to minimize societal harms from diversion. The foundation of appropriate opioid prescribing is thorough patient assessment, treatment planning, and follow-up and monitoring. Essential for proper patient assessment and treatment planning is comprehension of the clinical concepts of opioid abuse and addiction, their behavioral manifestations in pain patients, and how these potentially problematic behavioral responses to opioids both resemble and differ from physical dependence and pseudo-dependence. Prescriber knowledge deficit has been identified as a key obstacle to appropriate opioid prescribing and, along with gaps in policy, treatment, attitudes, and research, contributes to widespread inadequate treatment of pain [2].
The current extent of opioid analgesic use in the United States is unprecedented in the country’s history and unparalleled anywhere in the world. Before 1990, physicians in the United States were skeptical of prescribing opioids for chronic noncancer pain. But as of 2017, 1 of 25 adults is prescribed an opioid such as oxycodone and hydrocodone for chronic pain, and sales of opioid analgesics now total more than $9 billion each year [3].

Worldwide consumption of opioid analgesics has increased dramatically in the past few decades, with the United States driving a substantial proportion of this increase. For example, the 1990 global consumption of hydrocodone was 4 tons (3,628 kg), compared with the 2009 consumption of 39 tons (35,380 kg); 99% of this was consumed in the United States. Similarly, 3 tons (2,722 kg) of oxycodone were consumed globally in 1990, versus 77 tons (69,853 kg) in 2009, of which 62 tons (56,245 kg or 81%) were consumed in the United States [3]. With only 4.5% of the world’s population, the United States annually consumes more than 80% of all opioid supplies, including [4]:

- 99% of all hydrocodone
- 80% of all oxycodone
- 58% of all methadone
- 54% of all hydromorphone
- 49% of all fentanyl
- 43% of all meperidine

This disproportionate rate of opioid consumption reflects sociocultural and economic factors and standards of clinical medicine.

Between 1992 and 2003, the U.S. population increased 14%, while persons abusing opioid analgesics increased 94% and first-time non-medical opioid analgesic users 12 to 17 years of age increased 542% [4]. It is interesting to note that while opioid prescribing has increased precipitously among adults in the United States, the rate remained low and steady for children between 1996 and 2012 [5]. To assist in monitoring the public health problem associated with prescribed opioids, numerous governmental, non-profit, and private sector agencies and organizations are involved in collecting, reporting, and analyzing data on the abuse, addiction, fatal overdose, and treatment admissions related to opioid analgesics.

Before it was halted in 2011, the Drug Abuse Warning Network (DAWN) provided estimates of the health consequences of nonmedical use of individual drugs, including opioid medications [6]. DAWN indicates that opioid abuse is a growing problem in the United States. In 2005 and 2011, hydrocodone and its combinations accounted for 51,225 and 97,183 emergency department visits, respectively. Oxycodone and its combinations resulted in 42,810 visits to the emergency department in 2005; this number increased to 175,229 visits in 2011 [7; 8]. Visits for nonmedical use of all opioids increased from 217,594 to 420,040 during the six-year period.

**PAIN MANAGEMENT APPROACHES**

Healthcare professionals should know the best clinical practices in opioid prescribing, including the associated risks of opioids, approaches to the assessment of pain and function, and pain management modalities. Pharmacologic and nonpharmacologic approaches should be used on the basis of current knowledge in the evidence base or best clinical practices. Patients with moderate-to-severe chronic pain who have been assessed and treated, over a period of time, with non-opioid therapy or nonpharmacologic pain therapy without adequate pain relief, are considered to be candidates for a trial of opioid therapy [9; 10]. Initial treatment should always be considered individually determined and as a trial of therapy, not a definitive course of treatment [11].

**ACUTE PAIN**

Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids in a quantity no greater than that needed for the expected duration of severe pain. In most cases, three days or less will be sufficient; more than seven days will rarely be needed [10]. However, it is important to note that this guideline is based on emergency department prescribing guidelines for non-traumatic non-surgical pain [12]. It may be necessary to prescribe for longer periods in patients with acute severe pain.

With postoperative, acute, or intermittent pain, analgesia often requires frequent titration, and the two- to four-hour analgesic duration with short-acting hydrocodone, morphine, and oxycodone is more effective than extended-release formulations. Short-acting opioids are also recommended in patients who are medically unstable or with highly variable pain intensity [13; 14; 15].
CHRONIC PAIN
Nonpharmacologic therapy and non-opioid pharmacologic therapy are the preferred first-line therapies for chronic pain. If opioid are used, they should be combined with nonpharmacologic therapy and non-opioid pharmacologic therapy, as appropriate. Clinicians should consider opioid therapy only if expected benefits for pain and function are anticipated to outweigh risks to the patient [10].

Opioid therapy for chronic pain should be presented as a trial for a pre-defined period (e.g., ≤30 days). The goals of treatment should be established with all patients prior to the initiation of opioid therapy, including reasonable improvements in pain, function, depression, anxiety, and avoidance of unnecessary or excessive medication use [1; 10]. The treatment plan should describe therapy selection, measures of progress, and other diagnostic evaluations, consultations, referrals, and therapies.

In opioid-naïve patients, start at the lowest possible dose and titrate to effect. Dosages for opioid-tolerant patients should always be individualized and titrated by efficacy and tolerability [1; 10]. When starting opioid therapy for chronic pain, clinicians should prescribe short-acting instead of extended-release/long-acting opioid formulations [10].

The need for frequent progress and benefit/risk assessments during the trial should be included in patient education. Patients should also have full knowledge of the warning signs and symptoms of respiratory depression. Prescribers should carefully reassess evidence of benefits and risks when increasing the dosage to ≥50 mg morphine equivalent dose (MED) per day. Decisions to titrate dose to ≥90 mg MED/day should be avoided or carefully justified [10].

Prescribers should be knowledgeable of federal and state opioid prescribing regulations. Issues of equianalgesic dosing, close patient monitoring during all dose changes, and cross-tolerance with opioid conversion should be considered. If necessary, treatment may be augmented, with preference for nonopioid and immediate-release opioids over long-acting/extended-release opioids. Taper opioid dose when no longer needed [16].

PALLIATIVE CARE AND PAIN AT THE END OF LIFE
Unrelieved pain is the greatest fear among people with a life-limiting disease, and the need for an increased understanding of effective pain management is well-documented [27]. Although experts have noted that 75% to 90% of end-of-life pain can be managed effectively, rates of pain are high, even among people receiving palliative care [27; 28; 29; 30; 31; 32; 33; 34; 35; 36].

The inadequate management of pain is the result of several factors related to both patients and clinicians. In a survey of oncologists, patient reluctance to take opioids or to report pain were two of the most important barriers to effective pain relief [37]. This reluctance is related to a variety of attitudes and beliefs [27; 37]:

- Fear of addiction to opioids
- Worry that if pain is treated early, there will be no options for treatment of future pain
- Anxiety about unpleasant side effects from pain medications
- Fear that increasing pain means that the disease is getting worse
- Desire to be a “good” patient
- Concern about the high cost of medications

Education and open communication are the keys to overcoming these barriers. Every member of the healthcare team should reinforce accurate information about pain management with patients and families. The clinician should initiate conversations about pain management, especially regarding the use of opioids, as few patients will raise the issue themselves or even express their concerns unless they are specifically asked [38]. It is important to acknowledge patients’ fears individually and provide information to help them differentiate fact from fiction. For example, when discussing opioids with a patient who fears addiction, the clinician should explain that the risk of addiction is low [27]. It is also helpful to note the difference between addiction and physical dependence.

There are several other ways clinicians can allay patients’ fears about pain medication:

- Assure patients that the availability of pain relievers cannot be exhausted; there will always be medications if pain becomes more severe.
- Acknowledge that side effects may occur but emphasize that they can be managed promptly and safely and that some side effects will abate over time.
- Explain that pain and severity of disease are not necessarily related.

Encouraging patients to be honest about pain and other symptoms is also vital. Clinicians should ensure that patients understand that pain is multidimensional and emphasize the importance of talking to a member of the healthcare team about possible causes of pain, such as emotional or spiritual distress. The healthcare team and patient should explore psychosocial and cultural factors that may affect self-reporting of pain, such as concern about the cost of medication.
Clinicians’ attitudes, beliefs, and experiences also influence pain management, with addiction, tolerance, side effects, and regulations being the most important concerns [27; 34; 37; 39; 40; 41]. A lack of appropriate education and training in the assessment and management of pain has been noted to be a substantial contributor to ineffective pain management [37; 39; 41; 42]. As a result, many clinicians, especially primary care physicians, do not feel confident about their ability to manage pain in their patients [37; 39].

Clinicians require a clear understanding of available medications to relieve pain, including appropriate dosing, safety profiles, and side effects. If necessary, clinicians should consult with pain specialists to develop an effective approach.

Strong opioids are used for severe pain at the end of life [30; 34; 43; 44]. Morphine, buprenorphine, oxycodone, hydrocodone, fentanyl, and methadone are the most widely used in the United States [45]. Unlike nonopioids, opioids do not have a ceiling effect, and the dose can be titrated until pain is relieved or side effects become unmanageable. For an opioid-naïve patient or a patient who has been receiving low doses of a weak opioid, the initial dose should be low, and, if pain persists, the dose may be titrated up daily until pain is controlled.

More than one route of opioid administration will be needed by many patients during end-of-life care, but in general, opioids should be given orally, as this route is the most convenient and least expensive. The transdermal route is preferred to the parenteral route, although dosing with a transdermal patch is less flexible and so may not be appropriate for patients with unstable pain [34]. Intramuscular injections should be avoided because injections are painful, drug absorption is unreliable, and the time to peak concentration is long [34].

**CREATING A TREATMENT PLAN AND ASSESSMENT OF ADDICTION RISK**

Information obtained by patient history, physical examination, and interview, from family members, a spouse, or state prescription drug monitoring program (PDMP), and from the use of screening and assessment tools can help the clinician to stratify the patient according to level of risk for developing problematic opioid behavioral responses (Table 1). Low-risk patients receive the standard level of monitoring, vigilance, and care. Moderate-risk patients should be considered for an additional level of monitoring and provider contact, and high-risk patients are likely to require intensive and structured monitoring and follow-up contact, additional consultation with psychiatric and addiction medicine specialists, and limited supplies of short-acting opioid formulations [10; 26].

Despite limited evidence for reliability and accuracy, screening for opioid use is recommended by the American Society of Interventional Pain Physicians, as it will identify opioid abusers and reduce opioid abuse. (https://www.guideline.gov/summaries/summary/38257. Last accessed April 17, 2017.)

**Level of Evidence:** Limited (Evidence is insufficient to assess effects on health outcomes because of limited number or power of studies, large and unexplained inconsistency between higher-quality trials, important flaws in trial design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.)

Before deciding to prescribe an opioid analgesic, clinicians should perform and document a detailed patient assessment that includes [1]:

- **Pain indications for opioid therapy**
- **Nature and intensity of pain**
- **Past and current pain treatments and patient response**
- **Comorbid conditions**
- **Pain impact on physical and psychologic function**
- **Social support, housing, and employment**
- **Home environment (i.e., stressful or supportive)**
- **Pain impact on sleep, mood, work, relationships, leisure, and substance use**
- **Patient history of physical, emotional, or sexual abuse**

If substance abuse is active, in remission, or in the patient’s history, consult an addiction specialist before starting opioids [1]. In active substance abuse, do not prescribe opioids until the patient is engaged in treatment/recovery program or other arrangement made, such as addiction professional co-management and additional monitoring. When considering an opioid analgesic (particularly those that are extended-release or long-acting), one must always weigh the benefits against the risks of overdose, abuse, addiction, physical dependence and tolerance, adverse drug interactions, and accidental exposure by children [10; 16].

Screening and assessment tools can help guide patient stratification according to risk level and inform the appropriate degree of structure and monitoring in the treatment plan. It should be noted that despite widespread endorsement of screening tool use to help determine patient risk level, most tools have not been extensively evaluated, validated, or compared to each other, and evidence of their reliability is poor [17].
### RISK STRATIFICATION FOR PATIENTS PRESCRIBED OPIOIDS

<table>
<thead>
<tr>
<th>Level</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Low Risk</strong></td>
<td>Definable physical pathology with objective signs and reliable symptoms. Clinical correlation with diagnostic testing, including MRI, physical examination, and interventional diagnostic techniques. With or without mild psychologic comorbidity. With or without minor medical comorbidity. No or well-defined and controlled personal or family history of alcoholism or substance abuse. Age 45 years or older. High levels of pain acceptance and active coping strategies. High motivation and willingness to participate in multimodal therapy and attempting to function at normal levels.</td>
</tr>
<tr>
<td><strong>Medium Risk</strong></td>
<td>Significant pain problems with objective signs and symptoms confirmed by radiologic evaluation, physical examination, or diagnostic interventions. Moderate psychologic problems, well controlled by therapy. Moderate coexisting medical disorders that are well controlled by medical therapy and are not affected by chronic opioid therapy (e.g., central sleep apnea). Develops mild tolerance but not hyperalgesia without physical dependence or addiction. Past history of personal or family history of alcoholism or substance abuse. Pain involving more than three regions of the body. Defined pathology with moderate levels of pain acceptance and coping strategies. Willing to participate in multimodal therapy, attempting to function in normal daily life.</td>
</tr>
<tr>
<td><strong>High Risk</strong></td>
<td>Widespread pain without objective signs and symptoms. Pain involving more than three regions of the body. Aberrant drug-related behavior. History of alcoholism or drug misuse, abuse, addiction, diversion, dependency, tolerance, or hyperalgesia. Major psychologic disorders. Age younger than 45 years. HIV-related pain. High levels of pain exacerbation and low levels of coping strategies. Unwilling to participate in multimodal therapy, not functioning close to a near normal lifestyle.</td>
</tr>
</tbody>
</table>

Source: [17] Table 1

### RISK ASSESSMENT TOOLS

**Opioid Risk Tool (ORT)**  
The Opioid Risk Tool (ORT) is a five-item assessment to help predict aberrant drug-related behavior. The ORT is also used to establish patient risk level through categorization into low, medium, or high levels of risk for aberrant drug-related behaviors based on responses to questions of previous alcohol/drug abuse, psychologic disorders, and other risk factors [18].

**Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R)**  
The Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R) is a patient-administered, 24-item screen with questions addressing history of alcohol/substance use, psychologic status, mood, cravings, and stress. Like the ORT, the SOAPP-R helps assess risk level of aberrant drug-related behaviors and the appropriate extent of monitoring [19].

**CAGE and CAGE-AID**  
The original CAGE (Cut down, Annoyed, Guilty, and Eye-opener) Questionnaire consisted of four questions designed to help clinicians determine the likelihood that a patient was misusing or abusing alcohol. These same four questions were modified to create the CAGE-AID (adapted to include drugs), revised to assess the likelihood of current substance abuse [20].

**Diagnosis, Intractability, Risk, and Efficacy (DIRE) Tool**  
The Diagnosis, Intractability, Risk, and Efficacy (DIRE) risk assessment tool is a clinician-rated questionnaire that is used to predict patient compliance with long-term opioid therapy [21]. Patients scoring lower on the DIRE tool are poor candidates for long-term opioid analgesia.
Mental Health Screening Tool
The Mental Health Screening Tool is a five-item screen that asks about a patient’s feelings of happiness, calmness, peacefulness, nervousness, and depression in the past month [22]. A lower score on this tool is an indicator that the patient should be referred to a specialist for pain management.

Informed Consent and Treatment Agreements
The initial opioid prescription is preceded by a written informed consent or “treatment agreement” [1]. This agreement should address potential side effects, tolerance and/or physical dependence, drug interactions, motor skill impairment, limited evidence of long-term benefit, misuse, dependence, addiction, and overdose. Informed consent documents should include information regarding the risk/benefit profile for the drug(s) being prescribed. The prescribing policies should be clearly delineated, including the number/frequency of refills, early refills, and procedures for lost or stolen medications.

The treatment agreement also outlines joint physician and patient responsibilities. The patient agrees to using medications safely, refraining from “doctor shopping,” and consenting to routine urine drug testing (UDT). The prescriber’s responsibility is to address unforeseen problems and prescribe scheduled refills. Reasons for opioid therapy change or discontinuation should be listed. Agreements can also include sections related to follow-up visits, monitoring, and safe storage and disposal of unused drugs.

PERIODIC REVIEW AND MONITORING
What are the 5 A’s of monitoring chronic opioid response?
When implementing a chronic pain treatment plan that involves the use of opioids, the patient should be frequently reassessed for changes in pain origin, health, and function [1]. This can include input from family members and/or the state PDMP. During the initiation phase and during any changes to the dosage or agent used, patient contact should be increased. At every visit, chronic opioid response may be monitored according to the “5 As” [1; 23]:

- Analgesia
- Activities of daily living
- Adverse or side effects
- Aberrant drug-related behaviors
- Affect (i.e., patient mood)

Signs and symptoms that, if present, may suggest a problematic response to the opioid and interference with the goal of functional improvement include [24]:

- Excessive sleeping or days and nights turned around
- Diminished appetite
- Short attention span or inability to concentrate
- Mood volatility, especially irritability
- Lack of involvement with others
- Impaired functioning due to drug effects
- Use of the opioid to regress instead of re-engaging in life
- Lack of attention to hygiene and appearance

The decision to continue, change, or terminate opioid therapy is based on progress toward treatment objectives and absence of adverse effects and risks of overdose or diversion [1]. Satisfactory therapy is indicated by improvements in pain, function, and quality of life. Brief assessment tools to assess pain and function may be useful, as may UDTs. Treatment plans may include periodic pill counts to confirm adherence and minimize diversion.

Involvement of Family
Family members of the patient can provide the clinician with valuable information that better informs decision making regarding continuing opioid therapy. Family members can observe whether a patient is losing control of his or her life or becoming less functional or more depressed during the course of opioid therapy. They can also provide input regarding positive or negative changes in patient function, attitude, and level of comfort. The following questions can be asked of family members or a spouse to help clarify whether the patient’s response to opioid therapy is favorable or unfavorable [24]:

- Is the person’s day centered around taking the opioid medication? Response can help clarify long-term risks and benefits of the medication and identify other treatment options.
- Does the person take pain medication only on occasion, perhaps three or four times per week? If yes, the likelihood of addiction is low.
- Have there been any other substance (alcohol or drug) abuse problems in the person’s life? An affirmative response should be taken into consideration when prescribing.
- Does the person in pain spend most of the day resting, avoiding activity, or feeling depressed? If so, this suggests the pain medication is failing to promote rehabilitation. Daily activity is essential, and the patient may be considered for enrollment in a graduated exercise program.
- Is the person in pain able to function (e.g., work, do household chores, play) with pain medication in a way that is clearly better than without? If yes, this suggests the pain medication is contributing to wellness.
Assessment Tools

**VIGIL**

VIGIL is the acronym for a five-step risk management strategy designed to empower clinicians to appropriately prescribe opioids for pain by reducing regulatory concerns and to give pharmacists a framework for resolving ambiguous opioid analgesic prescriptions in a manner that preserves legitimate patient need while potentially deterring diverters. The components of VIGIL are:

- Verification: Is this a responsible opioid user?
- Identification: Is the identity of this patient verifiable?
- Generalization: Do we agree on mutual responsibilities and expectations?
- Interpretation: Do I feel comfortable allowing this person to have controlled substances?
- Legalization: Am I acting legally and responsibly?

The foundation of VIGIL is a collaborative physician/pharmacist relationship [25].

**Current Opioid Misuse Measure (COMM)**

The Current Opioid Misuse Measure (COMM) is a 17-item patient self-report assessment designed to help clinicians identify misuse or abuse in chronic pain patients. Unlike the ORT and the SOAPP-R, the COMM identifies aberrant behaviors associated with opioid misuse in patients already receiving long-term opioid therapy [26]. Sample questions include: In the past 30 days, how often have you had to take more of your medication than prescribed? In the past 30 days, how much of your time was spent thinking about opioid medications (e.g., having enough, taking them, dosing schedule)?

**Pain Assessment and Documentation Tool (PADT)**

Guidelines by the CDC, the Federation of State Medical Boards (FSMB), and the Joint Commission stress the importance of documentation from both a healthcare quality and medicolegal perspective. Research has found widespread deficits in chart notes and progress documentation with chronic pain patients receiving opioid therapy, and the Pain Assessment and Documentation Tool (PADT) was designed to address these shortcomings [46]. The PADT is a clinician-directed interview, with most sections (e.g., analgesia, activities of daily living, adverse events) consisting of questions asked of the patient. However, the potential aberrant drug-related behavior section must be completed by the physician based on his or her observations of the patient.

**The Brief Intervention Tool**

The Brief Intervention Tool is a 26-item, “yes-no,” patient-administered questionnaire used to identify early signs of opioid abuse or addiction. The items assess the extent of problems related to drug use in several areas, including drug use-related functional impairment [22].

**Urine Drug Tests**

UDTs may be used to monitor adherence to the prescribed treatment plan and to detect unsanctioned drug use. They should be used more often in patients receiving addiction therapy, but clinical judgment is the ultimate guide to testing frequency (Table 2) [47]. The CDC recommends clinicians should use UDT before starting opioid therapy and consider UDT at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs [10]. However, this recommendation was based on low-quality evidence that indicates little confidence in the effect estimate.

Initially, testing involves the use of class-specific immunoassay drug panels [1]. If necessary, this may be followed with gas chromatography/mass spectrometry for specific drug or metabolite detection. It is important that testing identifies the specific drug rather than the drug class, and the prescribed opioid should be included in the screen. Any abnormalities should be confirmed with a laboratory toxicologist or clinical pathologist. Immunoassay may be used point-of-care for “on-the-spot” therapy changes, but the high error rate prevents its use in major clinical decisions except with liquid chromatography coupled to tandem mass spectrometry confirmation.

Urine test results suggesting opioid misuse should be discussed with the patient using a positive, supportive approach. The test results and the patient discussion should be documented.

<table>
<thead>
<tr>
<th>Monitoring Tool</th>
<th>Patient Risk Level</th>
<th>Low</th>
<th>Medium</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urine drug test</td>
<td>Every 1 to 2 years</td>
<td>Every 6 to 12 months</td>
<td>Every 3 to 6 months</td>
<td></td>
</tr>
<tr>
<td>State prescription drug</td>
<td>Twice per year</td>
<td>Three times per year</td>
<td>Four times per year</td>
<td></td>
</tr>
</tbody>
</table>

Source: [47] Table 2
CONSULTATION AND REFERRAL

It is important to seek consultation or patient referral when input or care from a pain, psychiatry, addiction, or mental health specialist is necessary. Clinicians who prescribe opioids should become familiar with opioid addiction treatment options (including licensed opioid treatment programs for methadone and office-based opioid treatment for buprenorphine) if referral is needed [1].

 Ideally, providers should be able to refer patients with active substance abuse who require pain treatment to an addiction professional or specialized program. In reality, these specialized resources are scarce or non-existent in many areas [1]. Therefore, each provider will need to decide whether the risks of continuing opioid treatment while a patient is using illicit drugs outweigh the benefits to the patient in terms of pain control and improved function [48].

MEDICAL RECORDS

As noted, documentation is a necessary aspect of all patient care, but it is of particular importance when opioid prescribing is involved. All clinicians should maintain accurate, complete, and up-to-date medical records, including all written or telephoned prescription orders for opioid analgesics and other controlled substances, all written instructions to the patient for medication use, and the name, telephone number, and address of the patient’s pharmacy [1]. Good medical records demonstrate that a service was provided to the patient and that the service was medically necessary. Regardless of the treatment outcome, thorough medical records protect the prescriber.

PATIENT EDUCATION ON THE USE AND DISPOSAL OF OPIOIDS

Patients and caregivers should be counseled regarding the safe use and disposal of opioids. As part of its mandatory Risk Evaluation and Mitigation Strategy (REMS) for extended-release/long-acting opioids, the U.S. Food and Drug Administration (FDA) has developed a patient counseling document with information on the patient’s specific medications, instructions for emergency situations and incomplete pain control, and warnings not to share medications or take them unprescribed [16]. A copy of this form may be accessed online at http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM361110.htm.

When prescribing opioids, clinicians should provide patients with the following information [16]:

- Product-specific information
- Taking the opioid as prescribed
- Importance of dosing regimen adherence, managing missed doses, and prescriber contact if pain is not controlled
- Warning and rationale to never break or chew/crush tablets or cut or tear patches prior to use

- Warning and rationale to avoid other central nervous system depressants, such as sedative-hypnotics, anxiolytics, alcohol, or illicit drugs
- Warning not to abruptly halt or reduce the opioid without physician oversight of safe tapering when discontinuing
- The potential of serious side effects or death
- Risk factors, signs, and symptoms of overdose and opioid-induced respiratory depression, gastrointestinal obstruction, and allergic reactions
- The risks of falls, using heavy machinery, and driving
- Warning and rationale to never share an opioid analgesic
- Rationale for secure opioid storage
- Warning to protect opioids from theft
- Instructions for disposal of unneeded opioids, based on product-specific disposal information

There are no universal recommendations for the proper disposal of unused opioids, and patients are rarely advised of what to do with unused or expired medications [49]. According to the Office of National Drug Control Policy, most medications that are no longer necessary or have expired should be removed from their containers, mixed with undesirable substances (e.g., cat litter, used coffee grounds), and put into an impermeable, nondescript container (e.g., disposable container with a lid or a sealed bag) before throwing in the trash [50]. Any personal information should be obscured or destroyed. The FDA recommends that certain medications, including oxycodone/acetaminophen (Percocet), oxycodone (OxyContin tablets), and transdermal fentanyl (Duragesic Transdermal System), be flushed down the toilet instead of thrown in the trash [50]. Patients should be advised to flush prescription drugs down the toilet only if the label or accompanying patient information specifically instructs doing so.

The American College of Preventive Medicine has established best practices to avoid diversion of unused drugs and educate patients regarding drug disposal [49]:

- Consider writing prescriptions in smaller amounts.
- Educate patients about safe storing and disposal practices.
- Give drug-specific information to patients about the temperature at which they should store their medications. Generally, the bathroom is not the best storage place. It is damp and moist, potentially resulting in potency decrements, and accessible to many people, including children and teens, resulting in potential theft or safety issues.
- Ask patients not to advertise that they are taking these types of medications and to keep their medications secure.
• Refer patients to community “take back” services overseen by law enforcement that collect controlled substances, seal them in plastic bags, and store them in a secure location until they can be incinerated. Contact your state law enforcement agency or visit http://www.dea.gov to determine if a program is available in your area.

DISCONTINUING OPIOID THERAPY
The decision to continue or end opioid prescribing should be based on a physician-patient discussion of the anticipated benefits and risks. An opioid should be discontinued with resolution of the pain condition, intolerable side effects, inadequate analgesia, lack of improvement in quality of life despite dose titration, deteriorating function, or significant aberrant medication use [1; 10].

Clinicians should provide physically dependent patients with a safely structured tapering protocol. Withdrawal is managed by the prescribing physician or referral to an addiction specialist. Patients should be reassured that opioid discontinuation is not the end of treatment; continuation of pain management will be undertaken with other modalities through direct care or referral.

As a side note, cannabis use by chronic pain patients receiving opioid therapy has traditionally been viewed as a treatment agreement violation that is grounds for termination of opioid therapy. However, some now argue against cannabis use as a rationale for termination or substantial treatment and monitoring changes, especially considering the increasing legalisation of medical use at the state level [48].

CONSIDERATIONS FOR NON-ENGLISH-PROFICIENT PATIENTS
For patients who are not proficient in English, it is important that information regarding the risks associated with the use of opioids and available resources be provided in their native language, if possible. When there is an obvious disconnect in the communication process between the practitioner and patient due to the patient's lack of proficiency in the English language, an interpreter is required. Interpreters can be a valuable resource to help bridge the communication and cultural gap between patients and practitioners. Interpreters are more than passive agents who translate and transmit information back and forth from party to party. When they are enlisted and treated as part of the interdisciplinary clinical team, they serve as cultural brokers who ultimately enhance the clinical encounter. In any case in which information regarding treatment options and medication/treatment measures are being provided, the use of an interpreter should be considered. Print materials are also available in many languages, and these should be offered whenever necessary.

IDENTIFICATION OF DRUG DIVERSION/SEEKING BEHAVIORS
What is the most common source of nonmedical use of prescribed opioids?
• Selling medications
• Prescription forgery or alteration
• Injecting medications meant for oral use
• Obtaining medications from nonmedical sources
• Resisting medication change despite worsening function or significant negative effects
• Loss of control over alcohol use
• Using illegal drugs or non-prescribed controlled substances
• Recurrent episodes of:
  – Prescription loss or theft
  – Obtaining opioids from other providers in violation of a treatment agreement
  – Unsanctioned dose escalation
  – Running out of medication and requesting early refills

Behaviors with a lower level of evidence for their association with opioid misuse include [48; 54; 55]:
• Aggressive demands for more drug
• Asking for specific medications
• Stockpiling medications during times when pain is less severe
• Using pain medications to treat other symptoms
• Reluctance to decrease opioid dosing once stable
• In the earlier stages of treatment:
  – Increasing medication dosing without provider permission
  – Obtaining prescriptions from sources other than the pain provider
  – Sharing or borrowing similar medications from friends/family

Communication among providers and pharmacies can help to avoid inappropriate attainment of prescription drugs through “doctor shopping.” Prescribers should keep complete and up-to-date records for all controlled substance prescribing. When possible, electronic medical records should be integrated between pharmacies, hospitals, and managed care organizations [49]. If available, it is also best practice to periodically request a report from the state’s prescription reporting program to evaluate the prescribing of opioids to your patients by other providers [49].

When dealing with patients suspected of drug seeking/diversion, first inquire about prescription, over-the-counter, and illicit drug use and perform a thorough examination [49; 56]. Pill counting and/or UDT may be necessary to investigate possible drug misuse. Photo identification or other form of identification and social security number may be required prior to dispensing the drug, with proof of identity documented fully. If a patient is displaying suspicious behaviors, consider prescribing for limited quantities [56].

If a patient is found to be abusing prescribed opioids, this is considered a violation of the treatment agreement and the clinician must make the decision whether or not to continue the therapeutic relationship. If the relationship is terminated, it must be done ethically and legally. The most significant issue is the risk of patient abandonment, which is defined as ending a relationship with a patient without consideration of continuity of care and without providing notice to the patient. The American Medical Association Code of Ethics states that physicians have an obligation to support continuity of care for their patients. While physicians have the option of withdrawing from a case, they should notify the patient (or authorized decision maker) long enough in advance to permit the patient to secure another physician and facilitate transfer of care when appropriate [57]. Patients may also be given resources and/or recommendations to help them locate a new clinician.

Patients with chronic pain found to have an ongoing substance abuse problem or addiction should be referred to a pain specialist for continued treatment. Theft or loss of controlled substances is reported to the DEA. If drug diversion has occurred, the activity should be documented and a report to law enforcement should be made [58].

INTERVENTIONS FOR SUSPECTED OR KNOWN ADDICTION OR DRUG DIVERSION

There are a number of actions that prescribers and dispensers can take to prevent or intervene in cases of drug diversion. These actions can be generally categorized based on the various mechanisms of drug diversion.

Prevention is the best approach to addressing drug diversion. As noted, the most common source of nonmedical use of prescribed opioids is from a family member or friend, through sharing, buying, or stealing. To avoid drug sharing among patients, healthcare professionals should educate patients on the dangers of sharing opioids and stress that “doing prescription drugs” is the same as “using street drugs” [49]. In addition, patients should be aware of the many options available to treat chronic pain aside from opioids. To prevent theft, patients should be advised to keep medications in a private place and to refrain from telling others about the medications being used.
COMPLIANCE WITH STATE AND FEDERAL LAWS

In response to the rising incidence in prescription opioid abuse, addiction, diversion, and overdose since the late 1990s, the FDA has mandated opioid-specific REMS to reduce the potential negative patient and societal effects of prescribed opioids. Other elements of opioid risk mitigation include FDA partnering with other governmental agencies, state professional licensing boards, and societies of healthcare professionals to help improve prescriber knowledge of appropriate and safe opioid prescribing and safe home storage and disposal of unused medication [24].

Several regulations and programs at the state level have been enacted in an effort to reduce prescription opioid abuse, diversion, and overdose, including [59]:

- Physical examination required prior to prescribing
- Tamper-resistant prescription forms
- Pain clinic regulatory oversight
- Prescription limits
- Prohibition from obtaining controlled substance prescriptions from multiple providers
- Patient identification required before dispensing
- Immunity from prosecution or mitigation at sentencing for individuals seeking assistance during an overdose

CONTROLLED SUBSTANCES LAWS/RULES

The U.S. Drug Enforcement Agency (DEA) is responsible for formulating federal standards for the handling of controlled substances. In 2011, the DEA began requiring every state to implement electronic databases that track prescribing habits, referred to as PDMPs. Specific policies regarding controlled substances are administered at the state level [60].

According to the DEA, drugs, substances, and certain chemicals used to make drugs are classified into five distinct categories or schedules depending upon the drug's acceptable medical use and the drug's abuse or dependency potential [61]. The abuse rate is a determinate factor in the scheduling of the drug; for example, Schedule I drugs are considered the most dangerous class of drugs with a high potential for abuse and potentially severe psychologic and/or physical dependence.

STATE-SPECIFIC LAWS AND RULES

Most states have established laws and rules governing the prescribing and dispensing of opioid analgesics. It is each prescriber's responsibility to have knowledge of and adhere to the laws and rules of the state in which he or she prescribes.

CONCLUSION

Opioid analgesic medications can bring substantial relief to patients suffering from pain. However, the inappropriate use, abuse, and diversion of prescription drugs in America, particularly prescription opioids, has increased dramatically in recent years and has been identified as a national public health epidemic. A set of clinical tools, guidelines, and recommendations are now available for prescribers who treat patients with opioids. By implementing these tools, the clinician can effectively address issues related to the clinical management of opioid prescribing, opioid risk management, regulations surrounding the prescribing of opioids, and problematic opioid use by patients. In doing so, healthcare professionals are more likely to achieve a balance between the benefits and risks of opioid prescribing, optimize patient attainment of therapeutic goals, and avoid the risk to patient outcome, public health, and viability of their own practice imposed by deficits in knowledge.
Venous Disease and Ulcers

Audience
This course is designed for nurses in all care settings who may care for patients with venous disease or ulcers.

Course Objective
The purpose of this course is to enable nurses to accurately assess and treat venous disease and venous ulcers and to provide patient and family education for preventive care and lifestyle changes.

Learning Objectives
Upon completion of this course, you should be able to:
1. Identify the different components of the venous system, and explain the pathophysiology of venous insufficiency.
2. Discuss the epidemiology of venous disease.
3. Outline the signs and symptoms of venous disease.
4. Cite the various diagnostic tests used to identify and classify venous disease and ulcers.
5. Evaluate the role of compression therapy and surgical interventions in treating venous disease and venous ulcers.
6. Review the importance of patient education in preventing the reoccurrence of venous ulcers.

Faculty
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Faculty Disclosure
Contributing faculty, Maryam Mamou, BSN, RN, CRRN, CWOCN, has disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

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Division Planner Disclosure
The division planner has disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

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Sections marked with this symbol include evidence-based practice recommendations. The level of evidence and/or strength of recommendation, as provided by the evidence-based source, are also included so you may determine the validity or relevance of the information. These sections may be used in conjunction with the study questions and course material for better application to your daily practice.

INTRODUCTION
Venous insufficiency is the most prevalent vascular disorder and can result in significant morbidity, including lower extremity ulcers. Venous leg ulcers, also referred to as venous insufficiency ulcers, stasis ulcers, and varicose ulcers, are a major health problem in the United States. They are a common and disabling condition and often reoccur. The healing time is long—taking several weeks to several months; approximately 60% of venous ulcers remain unhealed after six months [1; 2]. As the population ages, the frequency of venous ulcers is also increasing. They are one of the most prevalent forms of chronic wounds, and healthcare professionals should have a clear understanding of their impact on patient care [1].

AN OVERVIEW OF LOWER EXTREMITY VENOUS ANATOMY
Veins are part of the circulatory system and are responsible for carrying blood from all parts of the body back to the heart. Whereas blood in the arteries is bright red in color, blood in the veins is dark red due to the high concentration of carbon dioxide it is carrying. In most instances, veins follow the same routes as their companion arteries [3].

The study of the circulatory system dates back to the time of Hippocrates, and it is said that he was one of the first to discover the connection between venous disease and ulceration formation [4]. However, the distinction between arteries and veins was not always clearly understood. During the Middle Ages, it was thought that veins and arteries formed two distinct conduit systems, with veins carrying liquids that provided nutrients to the body and being closely aligned with the liver [4]. This concept of venous circulation continued until the 1600s [4]. Though it was observed that both arteries and veins carried blood, it took years of research to fully understand how they functioned [4].

THE STRUCTURE OF VEINS
Similar to the other vessels in the circulatory system, the vein walls are composed of three layers. The innermost layer of epithelial tissue is the tunica intima, the tunica media is the middle layer, and the outer layer is the tunica externa. The tunica externa is made up of collagen and elastic fibers and is the thickest layer of the vein walls [3].

Vein walls vary in size, with the smallest veins having a diameter of 0.5 cm and the largest (the superior and inferior vena cavae) having a diameter of up to 3 cm [3]. Veins have the ability to distend to accommodate varying degrees of blood volume flowing through them; however, they do not have the capacity to withstand high pressures [3]. The lumen in veins is much larger than that found in the arterial system [3]. This is important because the size of the lumen determines the resistance to blood flow [3].

TYPES OF VEINS
Deep Venous System
Veins in the legs are divided into three major groups based on their relationship to the muscular fascia: deep veins, superficial veins, and perforator veins [5]. The deep venous system consists of the posterior and anterior veins and includes the common iliac veins, the femoral veins, and the popliteal veins [3]. These veins are located under the muscular fascia inside the muscle compartments of the leg, usually in close proximity to their companion arteries [5]. However, there is considerable variability in individual anatomy [6]. The deep veins are responsible for draining blood from the lower extremity muscles.
Superficial Venous System

The greater and lesser saphenous veins form the superficial venous system, also known as the saphenous system [5]. Superficial veins lie above the deep fascia and drain the cutaneous microcirculation [6]. The great saphenous veins are the longest veins in the body; they travel up from the dorsum of the foot to the groin and are located in the subcutaneous tissues [3]. Superficial veins are noticeable in some persons as a blue continuous line passing along the leg beneath the skin [3].

The Perforator Veins

The perforator veins are the branches that cross the muscular fascia to connect the deep veins with the superficial veins in a ladder-like system [5]. There are more than 90 perforator veins in a human leg [5]. The normal path of blood flow in the lower extremities is from the superficial to the deep veins via the perforator veins [7].

BICUSPID VALVES

Veins are equipped with flap-like bicuspid valves, which are made from the inner lining of the veins (i.e., the tunica intima) [3]. Blood is governed by the rule of gravity, and without intervention, it will flow downwards. The venous valves prevent the backward flow of blood in the veins by closing together in the middle of the vein to form a barrier [8]. The bicuspid valves in the veins of the lower extremities are opened when an individual is at rest in the supine position [6]. Valve closure occurs when the pressure gradient is reversed, following a brief period of antegrade flow.

The great saphenous veins are equipped with up to 20 valves along their entire course, the majority of which are found below the knee [3]. The perforator veins are also equipped with numerous valves to ensure one-way flow of blood from the superficial to the deep veins [6].

MUSCLE PUMPS

Which muscle pump is responsible for the greatest pressures in the lower extremities?

The leg muscles and the pumping action of the heart play a major role in venous blood flow, but the blood-holding capacity of the lower extremity veins when an individual is standing is regulated by two factors: the venous valves and the calf muscle pump [6]. Around 90% of venous blood return from the lower extremities flows through the deep veins and is facilitated by the action of muscle pumps in the foot, calf, and thigh [6].

Among these three pumps, the calf pump is the most important and is responsible for the greatest pressures [6]. During ambulation, this pump is responsible for propelling 70% of the blood out of the calf [8]. When the calf muscle pump contracts, blood is pushed out of the veins and the resting pressure in the veins decreases. Because blood flows from areas of high pressure to areas of low pressure, this decrease in the pressure gradient in the deep venous system after contraction allows blood to flow from the superficial veins to the deep veins via the perforating veins [6]. As long as the valves of the venous system are functioning correctly, there is little retrograde blood flow [9].

If the calf muscle pump is functioning below capacity or fails completely, high venous pressures will develop, which can ultimately lead to the development of varicose veins, edema, and venous ulcers. Many variables can adversely affect the contraction of the calf muscle pump, including vascular insufficiency, neurologic disease, injury, bone and joint conditions, and limited mobility [9]. Temporary or permanent immobilization resulting in an inability to contract the leg muscles causes sluggish circulation in the venous system and can lead to venous insufficiency [3].

LOWER EXTREMITY VENOUS CIRCULATION

The human heart is responsible for pumping blood throughout the circulatory system. Blood circulates through the capillaries, and then enters the venules, the small veins that carry the deoxygenated blood from the tissues. Venules join together to form the larger veins, which return the blood to the right side of the heart [3]. There is a small but significant pressure difference between the heart and the venous system, and when the left ventricle contracts, this generates sufficient pressure to assist with venous blood flow back to the heart [3].

The function of leg veins is to return blood from the lower extremities to the heart, and this is accomplished in conjunction with the muscles in the legs. The volume of blood that flows through the venous system back to the heart is referred to as venous return [3]. The normal blood pressure in veins is much lower than in arteries, and bleeding from a severed vein will be slow and steady, rather than the quick bursts seen with arterial bleeding [3]. The artery and companion vein(s) often share a vascular sheath, allowing arterial pulses to aid venous return.

Muscle pumps in the foot, calf, and thigh work together to drive blood out of the lower leg (against gravity) and back to the heart. As noted, the calf muscle pump is the most vital component of this process. Bicuspid valves prevent back-flow of blood to the foot and ankle.
PATHOPHYSIOLOGY OF VENOUS INSUFFICIENCY

Chronic venous insufficiency encompasses many different venous conditions that result from impaired venous return and resultant venous stasis. Malfunction of the venous valves, referred to as valvular incompetency, is the first step in the development of venous disease [10]. In valvular incompetency, the valves fail to close completely and allow retrograde blood flow, which results in venous hypertension. Chronic venous hypertension, the hallmark of chronic venous insufficiency, leads to the development of lower extremity complications [7].

The end result is pooling of blood (stasis) in the venous system, which can lead to initiation of the inflammatory process and on-going capillary damage [11]. With inflammation, there is activation of the white blood cells and endothelial damage, which are contributing factors to venous ulcer formation and delayed healing [11].

There are several reasons venous valves may not function properly, including congenital absence of the valves, venous thrombosis/phlebitis, and trauma [11]. Ambulation is necessary for contraction of leg muscles and activation of the calf muscle pump, and extended periods of immobility can lead to an increase in venous pressure.

EPIDEMIOLOGY OF VENOUS DISEASE

Chronic venous insufficiency is defined as persistent ambulatory venous hypertension of the lower extremities that can cause pain, skin changes, edema, and ulceration [12]. It is the most prevalent vascular disorder and, if left untreated, can result in the development of a venous ulcer. As noted, the most common cause of chronic venous insufficiency is venous reflux, particularly of the superficial deep veins [11]. Manifestations include telangiectasias, reticular veins, and varicose veins, the latter of which affect 25 million adults in the United States [12]. In addition, more than 6 million individuals in the United States have more advanced lower extremity venous disease, including venous ulcers [12]. Studies indicate there are 600,000 new lower extremity leg ulcers in the United States each year, and it is estimated that venous ulcers are responsible for up to 70% of wounds of the lower extremities [5; 9]. Up to 2% of adults will develop a venous ulcer at some point in their lives [2; 5]. In the long-term care setting, the prevalence of venous ulcers is higher, with an occurrence rate of approximately 2.5% among all new admissions [13].

SEX/GENDER

In the Edinburgh Vein Study, involving 1,566 subjects, the prevalence of chronic venous insufficiency was 9.4% in men and 6.6% in women [14]. However, research indicates that the female-to-male ratio of varicose vein prevalence is 3:1 [12]. Venous ulcers also occur more frequently in women than in men, with an overall occurrence rate for women of 1.42 per 100 person-years and 0.76 per 100 person-years for men [11; 13].

AGE

Chronic venous insufficiency becomes more common with advanced age. Data from the Edinburgh Vein Study indicate the prevalence rate doubled in men (21%) and women (12%) older than 50 years of age [14]. The likelihood of developing a venous ulcer also increases with age, possibly as a result of progression of the disease. In one study, nearly half of participants experienced deterioration (including skin changes) after 13 years [15]. Of persons with venous ulcers, approximately 22% develop their first ulcer by 40 years of age and 72% develop an ulcer by 60 years of age [9]. An increasing number of older adults have mixed venous and arterial disease, which presents more challenges for effective treatment [9].

RACE

Chronic venous insufficiency is more common in which racial group?

There is some evidence that chronic venous insufficiency is more common in white individuals than in racial/ethnic minorities [16; 17]. However, when present, venous disease in black patients is more likely to present at a more advanced stage at a younger age compared with white patients, resulting in increased ulcer debridement, deep vein thrombosis rates, and hospital charges [17].

COSTS

Due to the chronic nature of venous insufficiency and ulcers, they are costly. Patients may experience a significant socioeconomic impact as a result of direct care-related costs, disability, reduced productivity, and impaired quality of life [12]. In the United States, the approximate cost of venous ulcer care is estimated between $2 billion and $3.5 billion annually [5].
ASSESSMENT AND DIAGNOSIS

PATIENT HISTORY

When taking a patient history, it is important to explore risk factors for lower extremity venous disease [9]. Some of the more common prevailing risk factors are [5]:

- A history of deep vein thrombosis or leg ulcer(s)
- A family history of venous disease
- Multiple pregnancies, particularly in a short time span
- Older age
- Obesity
- Leg surgery or trauma
- Sedentary occupation and lack of exercise
- Drug injections into the veins of the lower extremities


Level of Evidence: Best Practice (Case series supplemented by the best opinion of a panel of experts)

A large number of those with venous disease also have one or several comorbidities, many of which are chronic conditions. Comorbid conditions have a negative impact on venous health and ulcer healing and should be thoroughly reviewed when assessing the patient and monitored throughout the course of treatment.

PHYSICAL EXAMINATION OF THE LOWER EXTREMITIES

Diagnosing lower extremity venous insufficiency relies mainly on clinical findings. A physical examination of both extremities should be done from mid-thigh level to the toes [5]. Patients will sometimes query why it is necessary to examine their “good leg,” and the best response is that a comparison between both legs will help to indicate the severity of the venous disease. If feasible, it is better to examine patients while they are standing [10].

Swelling in Lower Extremities

One of the early changes that individuals with venous insufficiency notice is swelling in their legs and a feeling of heaviness. Most patients will report that elevating their legs will reduce the swelling. Edema is an important finding in venous insufficiency, and the patient should be asked when he or she first noticed the swelling and how it has progressed over time. In venous disease, edema is usually first noticed around the ankles, and with time, it gradually progresses up the patient’s leg to include the calf area. Edema may be present for a considerable length of time before progressing, for example to a venous ulcer [5].

It is important to examine both extremities for the presence of edema. Chronic venous insufficiency will result in edema on the affected side, which progresses as the disease worsens. The sudden appearance of unilateral edema may be a sign of acute deep vein thrombophlebitis and requires immediate medical attention [7].

There are two forms of edema: pitting and non-pitting. Non-pitting edema presents as a swollen area that is hard to the touch. With pitting edema, pressure in the swollen area results in a persistent indentation. Pitting edema around the ankle that worsens through the day is a typical finding in advanced venous disease.

Serial bilateral ankle and calf measurements are useful to monitor the progress of edema. This consists of first measuring from the sole of the foot to just above the patient’s ankle, then measuring the circumference at this point on both ankles. This same process is repeated for the widest area of the patient’s calf on both extremities. In patients with edema, these measurements should be repeated at least weekly (with each wound assessment) using the same distance from the sole of the patient’s foot each time to accurately determine the progression of the edema.
Skin Changes

What is often the first and most common skin change associated with venous disease?

Chronic venous insufficiency affects the skin and fat tissue, and some individuals with venous disease have no symptoms other than skin changes accompanied by distended veins [18]. There is often thinning of the epidermis, and with longstanding venous disease, the texture of the skin on the lower legs changes, becoming shiny, indurated, and usually darker than the surrounding skin [10]. If there is no component of arterial disease present, the patient’s feet will feel warm to the touch and the dorsalis pedal and popliteal pulses will be palpable [18]. The presence of hair on the legs and feet is an indication of sufficient arterial supply and should be noted during the physical examination. Hemosiderin staining is a brownish or grayish discoloration of the skin caused by blood leaking into the tissues and breakdown of red blood cells [19]. Atrophie blanche is a change in skin texture and color attributed to venous insufficiency and presents as atrophic areas of white or pale skin [20].

Stasis dermatitis, also known as venous dermatitis or venous eczema, is dry, scaling skin of the lower extremities [18]. The first presentation is a reddish-brown skin discoloration, typically of the medial ankle. As the disease progresses, eczematous changes may be present, with weeping patches and plaques. Stasis dermatitis is often the first and most common skin change associated with venous disease. It is extremely pruritic (with insidious onset), which is a source of significant discomfort for patients.

Lipodermatosclerosis

Lipodermatosclerosis is an inflammation and hardening of the subcutaneous fat and dermal tissue found in longstanding venous insufficiency. It is caused by protein accumulation in the tissues, most noticeably in the “gaiter area” of the leg (between the knee and ankle) [18]. Lipodermatosclerosis presents as hard, waxy, hyperpigmented tissue with swelling of the surrounding areas. This has given rise to the description of a “bottle leg” formation [18].

Vein Abnormalities

Ankle flaring, a symptom of venous disease, presents as a cluster of distended small veins around the malleolus [5]. Telangiectasias (e.g., “spider veins”) and reticular veins are also common and present as dilated intradermal and subdermal venules. These findings are more common in women than men and can develop in the absence of more serious venous insufficiency [21].

Varicose veins are one of the most common signs of venous insufficiency. They are dilated, elongated, tortuous superficial veins that become progressively larger, typically 3 mm or greater in diameter [21]. In some cases, patients may experience superficial thrombophlebitis in these veins, but they are often asymptomatic aside from the appearance.

Assessing Pulses and Temperature in the Lower Extremities

During the physical examination, the femoral and pedal pulses should be assessed. The pedal pulses include the dorsalis pedal pulses, located between the first (great) toe and the second toe on the dorsum of the foot, and the posterior tibial pulse, located behind the medial malleolus. In younger patients, it may be possible to palpate these pulses; however, in older patients, use of a handheld Doppler is often necessary to detect a pulse beat [22].

It has been documented that individuals with venous disease and those who progress to venous ulceration have higher skin temperatures around the ankle than the general population [5]. A sudden elevation in temperature more than 4 degrees Fahrenheit may be indicative of a developing leg ulcer [5].

Venous Refill Time

Venous refill time should be assessed at presentation and regularly during treatment to get an overall measurement of venous reflux [24]. It is generally recorded as the number of seconds needed for the veins of the foot and lower leg to refill when the leg is in a dependent position.

Trendelenburg Tourniquet Test

In the past, the Trendelenburg tourniquet test (also referred to as the Brodie-Trendelenburg test) was used as a clinical exam technique to assess valve competency in the lower extremities and the severity of varicose veins. However, the results of this test are not considered reliable or accurate, and it has largely been replaced by duplex ultrasound testing [23].

NUTRITION ASSESSMENT

Unfortunately, nutritional status is not often assessed in patients with venous disease, and nutritional deficiencies are underdiagnosed and under-reported in this patient group [5]. A full nutritional assessment should be part of the initial patient evaluation.

Protein deficiency and inadequate calorie intake are common findings in patients with venous ulcers, and there is a correlation between protein deficiency and wound size at the 12-week mark [5]. Vitamin C deficits and low serum albumin levels are also common in persons with venous ulcers [5]. Resolution of these deficiencies should be included in the treatment plan, as venous ulcers will not heal in patients who are nutritionally compromised.
DIAGNOSTIC TESTING

The location and severity of venous reflux will help to determine the choice of treatment. Diagnostic testing used in the assessment of venous disease has been organized into three levels [24]. Level one is the patient work-up, which takes place during the initial intake process and includes the physical examination and continuous-wave, handheld Doppler studies [24]. All individuals who present with venous insufficiency should have a level one assessment. Level two encompasses more complex vascular laboratory studies, such as scanning, plethysmography, and venous pressure [24]. These studies will provide more detailed diagnostic information and further help to determine the course of treatment. Level three studies include phlebography and varicography and are done for more complex cases and as pre-operative preparation [24].

Duplex Ultrasound

What is the most reliable noninvasive test for diagnosing venous insufficiency?

Venous ultrasound is an important tool to determine the source of venous insufficiency [18]. A duplex ultrasound is used to locate malfunctioning perforator veins that may exist between the superficial and deep veins [10]. The American College of Phlebology has also recommended assessment of the patency and competency of the common and popliteal veins [25]. Duplex ultrasound is regarded as the most reliable noninvasive test for diagnosing venous insufficiency [5].

Photoplethysmography and Air Plethysmography

Photoplethysmography, which assesses the degree of venous reflux and measures venous filling times, may also be helpful. Normal venous refill time is 20 seconds or longer [5]. Shorter refill times are indicative of venous reflux or obstruction.

Air plethysmography testing is used to evaluate the degree of calf muscle pump impairment. A cuff surrounding the calf measures changes in limb volume during specific maneuvers (e.g., leg lift), allowing for assessment of outflow and filling rates. Normal venous filling occurs at a rate of <2 mL per second; rates greater than 4 mL per second indicate venous reflux and correlate with the level of venous insufficiency [12].

Venography

Computed tomographic or magnetic resonance venography is normally done to outline the venous system before surgical intervention is undertaken [5]. It will also give insight regarding obstructions or compression, if present.

Laboratory Studies

Laboratory studies used in the assessment of venous disease and to determine eligibility for treatment approaches include hemoglobin, hematocrit, and prothrombin time [5]. For patients on anticoagulant therapy, it is important to keep in mind that there may be increased bleeding from venous ulcers.

Ankle-Brachial Index Monitoring

All patients with venous insufficiency should have ankle-brachial index (ABI) studies done regularly, usually every three months [5]. The ABI is a noninvasive, indirect measurement of arterial blood flow to the lower extremities. Approximately 26% of those with venous problems also have arterial insufficiency, and the ABI value will help determine if the diagnosis is severe arterial disease, mixed arterial and venous pathology, or primarily venous disease [26; 27]. An ABI value greater than 0.8 indicates primarily venous disease, while a value of 0.5–0.8 suggests a mixed etiology [24]. An ABI value less than 0.5 points to severe arterial disease, and compression therapy is not recommended for these patients [5].

An ABI reading greater than 1.3 is indicative of incompressible blood vessels, usually found in patients with diabetes. This result is inaccurate and requires further testing (e.g., duplex ultrasound) to obtain a correct reading [26].

ABI testing is done by comparing the systolic blood pressures in the ankle to the systolic brachial blood pressures [28]. When obtaining an ABI reading, start by explaining the procedure to the patient and allowing him or her to rest in the supine position. The most accurate results are obtained when the patient is relaxed in a comfortable position with an empty bladder [26]. After about 15 minutes, take brachial blood pressure readings in both arms; the higher of the systolic pressure readings will be used to calculate the ABI value.

Next, place the blood pressure cuff around the ankle just above the malleolus. If there is a wound present, cover it with a dressing before applying the cuff. Apply ultrasound gel below the medial malleolus and move the handheld ultrasound probe slowly in a half circle around the ankle until a pulse is detected. Hold the probe at a 45-degree angle pointing upward to meet the blood flow. Inflate the blood pressure cuff until the audible pulse signal disappears, then slowly release the cuff until the pulse is heard again, indicating the systolic pressure. Complete this process for both ankles, again noting the highest systolic pressure reading.

To calculate the ABI value, divide the highest ankle systolic pressure by the highest brachial systolic pressure. For example, if the ankle systolic pressure is 90 mm Hg and the highest brachial systolic pressure is 100 mm Hg, this will result in an ABI of 0.9.

ABI testing should not be done for patients with severe foot or leg pain or suspected deep vein thrombosis, as there is a possibility of dislodging the clot [26]. In addition, patients who are unable to remain supine for the duration of the test are ineligible.
CEAP CLASSIFICATION

The clinical- etiology- anatomy-pathophysiology (CEAP) classification system is used to determine the severity of venous disease and was originally developed in 1994 by the American Venous Forum. It has since been updated and revised but continues to be the standard for classifying venous disease (Table 1) [11; 24; 29].

As the name implies, the CEAP classification system consists of four dimensions. The clinical dimension is probably the most widely used and encompasses what the veins look like. The etiology dimension describes the nature of the underlying cause of the venous insufficiency, while the anatomy dimension identifies the veins affected. Pathophysiology describes the cause of the condition—whether it is reflux, obstruction, or a combination of both [7; 29].

VENOUS ULCER ASSESSMENT

Diagnosing venous ulcers correctly is necessary to ensure that appropriate treatment is implemented [9]. These wounds should be clearly distinguished from other ulcers of the lower extremities, classified, and documented. The first step in this process is to obtain a complete clinical history from the patient, followed by a physical examination and full wound assessment [5].

Venous ulcers normally develop on the medial malleolus, ankle, or posterior calf; over a perforating vein; or along the route of the great or small saphenous veins. They do not occur above the knee or in the area of the forefoot [20; 22]. In appearance, the ulcers are usually irregular and shallow, with granulation tissue and fibrin evident in the wound bed [11].

A single ulcer or several wounds may be present. If left untreated, the ulcer can extend completely around the patient’s leg. The amount of drainage from a venous ulcer varies from mild to copious, and the periwound area is often macerated; scaling and crusting may also be present [5].

A venous ulcer is described as chronic when it persists for longer than three months. Ulcers that have been present for more than 12 months and are greater than 6 cm in diameter are regarded as having a poor prognosis for healing [11].

Wound Assessment

A complete assessment of the venous ulcer, including photographic documentation, should be done when a patient first presents and at all subsequent visits (ideally weekly). This is helpful in tracking healing progress and can provide positive reinforcement to patients who may find treatment long and arduous.

Wound assessment should take place in a private area that allows the patient to be positioned comfortably and has adequate lighting to provide for proper visualization of the wound, the periwound area, and the entire lower extremity.

A decrease in wound size is predictive of eventual full healing. If there are no changes in the wound dimensions after four weeks, a full review of the treatment plan is warranted [5]. Wounds that do not decrease in size by approximately 30% during the first four weeks of treatment have a 68% likelihood of not being healed within 24 weeks [5]. Leg ulcers that show no signs of improvement after six weeks of treatment should be biopsied to rule out malignancy or other causes that would prevent healing (e.g., collagen-vascular diseases, bacterial or fungal infection) [30].
During the assessment patients should be asked about chronic leg cramps and restless legs syndrome [18]. Chronic pain and insomnia should also be noted [18].

**Wound Measurement**

Accurate measurement of the wound is probably the most important feature of wound assessment [7]. It provides information on the initial size and progression or non-progression of healing, allowing for valuable feedback on the effectiveness of clinical interventions [31].

Wounds should always be measured in centimeters, using a plastic or paper ruler. Wound length is measured from head to toe; width is measured from hip to hip [32]. The depth of the wound can be obtained by gently inserting a sterile cotton-tipped applicator into the wound bed and marking it at skin level. The applicator is then measured using a metric ruler [32].

**Tunneling and Undermining**

Sinus tracts and undermining impair healing, and it is important to immediately identify their presence [31]. A sinus tract is a tunnel that extends from any part of the wound and can bore through subcutaneous tissue and muscle [31]. This tunnel creates dead space, which can result in abscess formation and further impede the healing process [31]. A sinus tract can be measured using a sterile cotton swab [31].

Undermining is defined as destruction of the tissue under the skin around the edges of the wound. The easiest way to measure and describe undermining is by using the face of the clock [31]. With the patient's head representing 12 o'clock, the area of undermining or probe the tunneling to ascertain the depth. For example, undermining along the right border would be recorded as extending from 1 o'clock to 5 o'clock with a depth of 4 cm [31]. It is important to check around the entire perimeter of the wound, as undermining can occur in more than one location.

**Wound Bed**

It is also vital to assess and document the appearance of the wound bed. If the wound bed has a mixture of tissue in it, this should be documented by an approximate percentage (e.g., the wound base is 75% granulation tissue and 25% slough). Granulation results in “beefy” red tissue with a shiny, moist granular appearance, while necrotic tissue is gray, brown, or black. Eschars are typically gray to black and dry or leathery in appearance [33]. Slough tissue is yellow/white to gray in color. It may be stringy or thick and appear as a layer over the wound bed [33]. The presence of thick slough or eschar is an indicator of arterial insufficiency [45]. Epithelial tissue will often begin to grow in from the edges over the wound surface. This tissue is generally pink and shiny. As a quick reference color guide, red is associated with normal healing, yellow indicates slough or dead tissue, and black is necrosis [33].

**Surrounding Skin**

The condition of the surrounding skin surface up to 4 cm from the edge of the wound circumferentially should also be assessed and documented. Its characteristics should be noted, particularly color and integrity [18]. Maceration from excessive drainage may indicate that the dressing used is not appropriate and a different product is needed. Circumferential redness up to 2 cm from the wound is indicative of cellulitis.

**TREATMENT**

Problems with venous circulation are not new, and reports of venous disease were recorded in the early days of medical practice. The first reported documentation of varicose veins and their treatment can be traced back to ancient Egypt [4]. In the Middle Ages, nuns discovered the benefits of massaging and applying tight wraps to legs with edema.

The earliest treatments for venous disease were vein stripping and ligation [4]. Today, treatment of venous disease is primarily surgical, and surgical intervention for varicose veins is one of the most frequently performed nonemergent surgical procedures in the United States [34].

If a venous ulcer has not yet developed, the primary goal of treatment of chronic venous insufficiency is to reduce venous hypertension and prevent ulceration. The plan of care for these patients will include weight management, compression therapy, leg elevation, setting realistic goals to become more physically active, and patient education. If an ulcer is present, the goal is to achieve complete healing and prevent ulcer reoccurrence.

Complete healing of a venous ulcer takes an average of 24 weeks. Nearly 15% of ulcers do not heal, and the five-year reoccurrence rate is up to 40% [24]. The selection of treatment options for patients with venous ulcers is often influenced by and modified because of the presence of other health issues. Diabetes, lymphedema, obesity, malnutrition, and intravenous drug use can all impact treatment efficacy and can lead to delayed healing [24]. When evaluating the treatment plan for a non-healing venous ulcer, one of the factors to re-assess is the presence of other health conditions and how well they are being managed.

A holistic approach is essential in treating venous disease and venous ulcers. Better healing outcomes are achieved when a multidisciplinary team approach is used along with evidence-based wound care [24]. The team involved in the treatment of venous disease should include physician specialists, podiatrists, surgeons, nurses who have training and/or experience in wound care, social workers, and discharge planners. The role of discharge planners and social workers in the care of these patients is often overlooked. However, the financial burden and lifestyle changes venous disease imposes on patients make assistance beyond physical care crucial to achieve successful outcomes.
There are five major treatment options for patients with venous disease [24]:

- Compression therapy
- Local wound care for venous ulcers
- Surgical interventions
- Medical treatment
- Advanced technology

As noted, conservative management is normally the first treatment option for patients without ulcers, including leg elevation, exercise, and compression therapy [21]. Treatment modalities generally focus on symptom management, such as reducing swelling or edema and eliminating lipodermatosclerosis [11; 21].

Leg elevation has been shown to be effective in reducing edema. Ideally, patients with leg edema should elevate their legs above the level of the heart for 30 to 45 minutes three to four times daily, unless there are medical contraindications to doing this [35]. Patients for whom this is not feasible should be encouraged to elevate their legs to a degree that is comfortable and to maintain that position for as long as possible.

MANAGING SYMPTOMS OF VENOUS DISEASE

Pain
Venous insufficiency-related pain does not radiate to other areas of the body and is not adversely affected by joint movement; the pain is localized to the area of venous disease and ulcer location, if present. Pain can reach a level of severity that makes walking difficult and eventually impossible. Numbness and tingling may also be present.

Pain associated with venous ulcers is usually described as moderate-to-severe stabbing, throbbing, or aching pain [9]. Patients state that pain worsens with prolonged standing, especially for long periods of time. Elevating the affected leg usually diminishes pain. It is reported that venous ulcer pain can linger for up to three months after wound healing [9]. Usual pain management techniques and pharmacology should be used to ensure patient comfort.

Pruritus
As discussed, stasis dermatitis, which occurs with longstanding venous disease, can be intensely pruritic, with some patients describing the sensation of itching as worse than the pain. However, scratching can lead to injury of already compromised skin surfaces and venous ulceration, with the possibility of infection, delayed healing, and scarring [36]. In addition, the amount of leg or foot itch is correlated with CEAP classification and degree of pain [36].

Patients with venous disease have identified itching as a factor that negatively impacts their quality of life [36]. Clinicians caring for patients with venous compromise should recognize that pruritus can pose a serious problem, and it should be included in the assessment process and addressed in the treatment plan [36].

Curative treatments are not always possible, but focusing on restoring the natural equilibrium of the skin should be the goal. Antihistamines can be used to decrease the sensation of itching, and emollient products can help to restore the skin’s natural barrier [36]. Topical steroid ointment may be used to reduce inflammation and alleviate itching, but in most cases, it should not be used for more than two weeks [5].

Nonpharmacologic interventions for managing pruritus include stress management training and guided imagery [36]. Validating patients’ experiences with itching and allowing them time to express their frustrations are also useful coping mechanisms.

COMPRESSION THERAPY
Compression therapy is still the mainstay of treatment of venous disease. Compression helps to heal venous ulcers more quickly by reducing edema in the affected extremity and increasing venous return toward the heart [9; 24]. As swelling in the extremity decreases, circulation to the skin surface provides improved oxygenation to promote healing [10]. Ambulatory patients should be encouraged to walk as much as possible after compression is applied in order to obtain maximum benefit from the therapy [10].

Several options are available for compression therapy, including elastic tubular support bandages, adhesive elastic wraps, hook-and-loop closure wraps, Unna boots, and multilayer compression (composed of two, three, or four layers of bandages) [13]. A multilayer, high-compression approach involving an elastic bandage provides better results for venous ulcer healing compared with non-elastic compression [44].

Since their conception, Unna boots have been the most widely used form of compression for venous ulcers [13]. The device is not actually a boot but a paste bandage impregnated with zinc oxide, glycerin, gelatin, and sometimes calamine [13]. This dressing applies compression via the slow drying and shrinkage of the bandage. Depending on facility protocol, the Unna boot is usually changed three days after the first application and weekly thereafter.
The Unna boot should be applied from just above the patient’s toes to approximately 1 inch below the knee. Different application methods may be used. The boot may be pleated as it is applied to avoid wrinkles and creases, or it can be cut through and applied in overlapping strips. With each spiral, there should be a 75% to 80% overlap. The gauge is then covered with an elastic, self-adhesive bandage with 50% overlap and 50% stretch to provide additional compression [18].

The Unna boot provides inelastic compression, meaning that the pressure gradient is high while the patient is walking but low (or lacking) when the patient is resting. As such, multilayer compression bandages may supply more effective compression for non-ambulatory patients than the Unna boot. The Unna boot also does not adapt to changes in the patient’s leg size, which can lead to complaints of pain and discomfort [11].

Multilayer bandages are often more effective in maintaining the pressure gradient beneath the compression. Multilayer compression includes an orthopedic wool bandage that is applied spirally around the patient’s leg. This helps to absorb drainage and protect boney prominences. The second layer is a cotton crepe bandage that is spirally wrapped around the patient’s leg. The third layer is an elastic bandage that conforms to the patient’s leg. This bandage may be applied in a spiral fashion (with 50% stretch and 50% overlap) or in a “figure eight” configuration that will increase the amount of compression applied. The fourth and final layer is an elastic cohesive bandage that is wrapped in a spiral fashion and holds the inner layers in place [13].

Applying Compression Bandages

Before applying compression bandages, it is important to explain the procedure to the patient and address any questions or concerns he or she may have. The patient’s ankle circumference should also be measured. If the circumference is less than 7.5 inches, extra padding should be added around the ankle area. This can be done using a piece of the first roll of orthopedic padding. As swelling decreases, it is important to recheck the ankle circumference weekly and to adjust the padding as necessary. A very thin extremity and boney prominences should also be protected with extra padding to prevent bruising when compression is applied.

The patient’s pain level should be taken into consideration when choosing compression therapy. Patients who are experiencing pain may better tolerate an inelastic support system to start, until pain and edema levels are under control [9].

Compression cannot be used for all patients with venous insufficiency; it is contraindicated for individuals with decompensated chronic congestive heart failure and those with mixed arterial and venous disease in which diminished arterial circulation is a significant risk factor [9]. Compression should not be used in any patient with an ABI less than 0.5 (i.e., with arterial disease). Carefully monitored, modified light compression (20–27 mm Hg at the ankle level) can be used in patients with an ABI of 0.6–0.8 [18].

In addition, many patients are unwilling to wear continuous compression. In these cases, intermittent pneumatic compression (IPC) may offer a viable alternative. IPC therapy uses an air pump and a “sleeve” with one or several bladders [24]. The sleeves are wrapped around the patient’s leg(s), and the air pump is used to inflate and deflate the bladders at set intervals [24]. Depending on the type of IPC used, there are variations in the compression cycles that can be set to meet the patient’s therapeutic needs [24]. IPC should not be used with patients who have edema related to chronic heart failure, active phlebitis, deep vein thrombosis, cellulitis, or wound infection [13].
The fourth layer is the cohesive compression bandage and should be applied with 50% stretch and 50% overlap. Two- and three-layer compression bandaging systems are applied in the same way.

Compression bandages can be left on for up to seven days. However, if wound drainage seeps through, the wrapping should be changed. During changes in bandaging, the wound is assessed and redressed.

Patient Teaching

The greatest risk factor with compression of any type is arterial occlusion, and patients and family/caretakers should be aware of this possible complication. Face-to-face teaching should be done after the compression is applied, and written instructions should be sent home with the patient along with contact information if problems arise. The following points should be included in compression instructions:

- If the patient experiences pain, tingling, or numbness in his/her foot or toes, if swelling develops, or if the toes become a blue/gray color, the compression should be removed immediately. If the tingling, numbness, pain, or discoloration continues after the compression is removed, the patient should return to the wound clinic or go to the emergency room.
- Patients should not stand or sit in the same position for more than 30 minutes without moving.
- Patients should be advised to keep the legs raised above the level of the heart as much as possible to decrease swelling.
- The compression wraps should be kept dry and clean. When showering, compression bandaging should be completely protected in a waterproof covering; baths may be preferred. If a compression wrap or Unna boot does get wet or damaged, it should be removed. If a wound is present, it should be covered with a clean dressing and the patient’s physician or clinic should be contacted.

Compression Stockings

What is the major drawback of compression stockings?

Comfortable compression stockings are effective in preventing the reoccurrence of venous ulcers and improving patient quality of life [10]. Patients should be advised to wear gradient elastic compression stockings, which provide more compression in the foot, with reduced levels of pressure moving up the leg [10]. Usually, the physician will recommend the best level of compression for the patient. The patient's legs should be measured at the ankle and calf level by a trained clinician to ensure that the stockings fit correctly.

Compression stockings are available in most large stores or pharmacies or mail ordered from several companies and can be worn with the patient's normal footwear. Patients and caretakers should be advised to buy at least two pairs of stockings to facilitate washing and drying. Manufacturer instructions should be followed for washing, but in most instances, hand-washing and air-drying are preferred. Lower levels of compression are better than no compression at all or stockings that are “left in the drawer” [9]. However, patients should be informed that nonmedical support hosiery and anti-embolism stockings (with a pressure gradient of 8–18 mm Hg) are not suitable for compression therapy and were not made for this purpose [5].

The major drawback is that people may find it difficult to don the stockings independently, especially if they have arthritis or neurologic deficits. There are stockings available with a side zipper that makes them easier to apply and remove, although they may be more expensive. It is also possible to purchase an inner silk lining sleeve to facilitate sliding the compression stocking on and off. Several brands of compression stockings also come with a wide band at the top, which provides a better grip [10]. Some people find that wearing rubber gloves helps to get the stockings on easily, but others do not find this helpful.

Compression stockings have been described as “operator dependent,” meaning they must be worn to be effective [10]. It should be emphasized to patients and caregivers that compression therapy is a lifetime commitment. Many patients may mistakenly believe that the stockings are only worn until swelling is abated, but all at-risk patients should continue to use them.

Patients and their families should also be educated about the correct use of compression. Compression stockings should be put on first thing in the morning, before the patient gets out of bed; patients should not wait until swelling is noticed to apply the stockings. It is not advisable to apply moisturizing lotion to the legs just before putting on the stockings, as this makes the skin sticky and can make it more difficult to get the stockings on [10].

Compression stockings should be replaced about every six months to maintain maximal level of compression. It is important to note that Medicare and most private insurances will only cover the cost of compression stockings if a venous ulcer is present; there is no reimbursement for compression therapy to prevent the reoccurrence of venous ulcers.
PENTOXIFYLLINE

Pentoxifylline (Trental), a derivative of xanthine, is an effective adjunct in the treatment of venous disease. It reduces blood viscosity and platelet adhesion and aggregation and increases fibrinolytic activity and microcirculation [11; 28]. When pentoxifylline is used in conjunction with compression, the healing rate of venous ulcers is significantly increased [37]. The recommended (off-label) dosage is 400 mg three times daily, and common side effects include nausea, gastrointestinal disturbances, dizziness, and headache [11; 28].

HORSE CHESTNUT SEED OIL

Horse chestnut seed oil has also been suggested to manage edema and relieve itching and other symptoms of chronic venous insufficiency, such as leg heaviness and pain [5]. The active ingredient in this herbal preparation is escin, a triterpenic saponin [38; 39]. Meta-analyses of horse chestnut seed extract (available as an oral tincture, tablets, or topical gel) have found that it is superior to placebo in reducing leg pain, edema, leg volume, leg circumference, and pruritus, but no differences were found when compared with traditional therapies (e.g., compression) [38; 40]. Potential adverse effects are typically mild (nausea, dizziness, headache), making horse chestnut seed extract a potentially attractive option for patients. However, the available evidence is limited, and larger randomized controlled studies are necessary to confirm the efficacy [38].

BIOENGINEERED THERAPY

Bioengineered therapy in conjunction with compression therapy is an option for the treatment of venous ulcers that have not healed after 30 days [30]. Single-layered and bilayered bioengineered skin cellular substitutes do not provide a graft covering to the wound, but rather donate multiple growth factors to the wound bed to stimulate healing [24]. The Wound Healing Society states that bilayered artificial skin in conjunction with compression therapy is better than compression and a simple dressing [41].

ULTRASOUND THERAPY

Low-frequency ultrasound therapy may be considered when wound healing fails to progress after four weeks of standard care [42]. In one clinical trial, this treatment decreased healing times for venous ulcers compared with usual care [30]. The assumed mechanism of action involves improvements in the microenvironment of the wound [30]. To date, there is no established standard for ultrasound therapy in the treatment of venous leg ulcers, but limited studies indicate that a minimum of two to three sessions per week is necessary in order to see results [42].

OPENING CLOSED WOUND EDGES

In full thickness wounds, the process of re-epithelialization occurs only from the wound edges, and undermining, tunneling, or rolled wound edges can inhibit wound healing. The simplest way to open closed wound edges is the treat them with silver nitrate sticks, known as AgNO3 cauterization. This requires a physician’s order and is achieved by rolling the moistened tip of a silver nitrate stick along the wound edge, which causes it to turn a grayish color and to slough off over several days [18]. Subsequent treatments may be necessary to open the complete circumference of the wound edges. A topical anesthetic may be applied 15 minutes prior to beginning the silver nitrate treatment in order to prevent associated pain [18].

SURGICAL TREATMENT OF VENOUS INSUFFICIENCY

The goal of surgical treatment of venous insufficiency is to either remove or permanently close non-working veins. There is some debate of whether venous surgery increases the healing rate of existing venous ulcers, but it has been proven to decrease the rate of ulcer recurrence, and it is considered definitive treatment for chronic venous insufficiency. One of the most problematic issues with venous ulcers is the recurrence rate, which can be more than 40% [2]. As such, prevention of ulcer occurrence is one of the most important aspects of treating venous insufficiency.

Venous Stripping

In the past, venous stripping was regarded as the “gold standard” for treatment for venous insufficiency. During this procedure, the problematic vein is removed through small incisions in the patient’s leg [19]. This results in elimination of venous reflux and stasis and eradication of the bulging vein [43].

Most commonly, venous stripping removes the saphenous vein. The procedure may be done with local or general anesthesia. A small incision is made in the groin, and second incision is made close to the knee. A wire stripper is inserted to disconnect the vein at both locations and remove the vein from its location [43]. Tiny incisions are made along the length of the patient’s leg in areas where there are bulging veins to facilitate removal of tributary varicose veins that were not directly attached to the saphenous vein [43]. The patient’s leg is then wrapped in compression bandages from the ankle to the thigh to decrease pain and minimize bruising. This compression is maintained in place for several days [43].

Other Approaches

Over the past decade, other procedures, such as venous ablation and foam sclerotherapy, have become popular in the treatment of venous disease, in many cases replacing venous stripping as the treatment of choice. These procedures are minimally invasive and result in less pain for the patient [21].
Venous Ablation
Venous ablation uses laser technology to destroy the inner lining of the saphenous vein and prevent blood flow. The procedure is done under local anesthesia, requires fewer incisions, and allows for a faster return to regular activities. It has a success rate of more than 90% [43].

Foam Sclerotherapy
Foam sclerotherapy may also be used to treat venous insufficiency. Ultrasound guidance is used to navigate a needle filled with the sclerosant drug and air (microfoam) to the appropriate location, where the mixture is injected directly into the vein [43]. This results in scarring of the inside of the saphenous vein and blocked circulation. It is done as an outpatient procedure and can be repeated, if needed.

Subfascial Endoscopic Perforator Surgery
Subfascial endoscopic perforator surgery (SEPS) is a minimally invasive procedure that alleviates perforator disease, which is characterized by perforator vein incompetence and resultant venous reflux. The procedure involves disconnection of abnormal perforator veins. In addition to improving venous sufficiency, SEPS may increase venous ulcer healing when used along with compression therapy [5; 30]. SEPS has low rates of infection and is instrumental in reducing ulcer reoccurrence [30].

LOCAL WOUND CARE
General principles of wound care should be implemented when treating a venous ulcer. Ulcers should be cleaned when first diagnosed and then with every dressing change. The purpose of wound cleaning is to remove nonadherent debris from the wound bed in order to promote healing and make the wound less susceptible to bacterial overgrowth and infection. While cleaning the wound, it is necessary to minimize trauma to the wound bed and healthy tissue.

If debridement is needed, for example, if infection is present, sharp surgical debridement under local anesthesia is in most instances the best option. Depending on the size of the wound this can be done either in the outpatient wound clinic or in the surgical center. Regular (weekly) debridement is routinely done to maintain the wound in a healing state and to prevent the build-up of biofilm on the wound surface.

Wound dressings are a pivotal aspect of wound care. Dressings insulate the wound from the external environment, provide a barrier to prevent infection, maintain a moist environment, wick fluid from areas of tunneling, and absorb drainage [18]. Ideally, a wound dressing should also provide for gaseous exchange, allowing oxygen, carbon dioxide, and water vapor to pass in and out through the dressing [7].

Several wound dressing options are available. Bacterial colonization and infection are frequently found in venous ulcers, and antimicrobial dressings such as cadexomer iodine have showed good results in treating these wounds. Oral antibiotics are only indicated when cellulitis is present.

Silver dressings are a good choice and work well under compression. Foam dressings have been shown to reduce pain and decrease leakage and wound odor. While these dressings can be applied under compression, thicker versions (4–7 mm) may cause indentations at the foam edge [5; 42]. Tapering the edges of foam dressings may help ameliorate this problem.

Availability and cost should also be kept in mind when selecting a dressing. Certain dressing types may not be covered by private insurances or Medicare.

SKIN CARE
Increased swelling in the affected leg causes small slits and breaks in the skin, often with copious amounts of weeping. Skin care can help prevent breaks in the skin, but it can also introduce additional risks in some patients. Patients with venous ulcers are particularly susceptible to contact reactions, and even topical antibiotics can cause sensitivity reactions in susceptible patients. Other products associated with stasis dermatitis include creams and gels containing lanolin and perfumes [5]. Care should be taken when choosing and applying topical lotions and medications to avoid the possibility of allergic reactions and the development of contact dermatitis, as this significantly increases the risk of venous ulceration [26].

Maintaining skin cleanliness and moisturizing frequently can protect skin integrity. The skin should be cleaned with water and a gentle soap, preferably a pH-balanced cleanser. Alkaline products remove skin lipids, which increases water loss and weakens the barrier function of the skin. Hot water for bathing and scrubbing and using harsh cleaning agents should also be avoided. A soft cloth should be used to pat rather than rub the skin dry. The nurse or physician should be notified of any redness, discoloration, or skin breakdown.
It is important to individualize the frequency of skin cleansing based on the patient’s age, skin texture, and dryness or excessive oiliness of the skin. A daily bath may not be needed for all patients.

PATIENT AND FAMILY EDUCATION

What should be included in patient education for individuals with venous disease and/or ulcers?

It is not uncommon for individuals with venous disease to delay seeking treatment, often due to misconceptions regarding their condition. Many people believe that their symptoms are not serious enough to warrant medical attention. Patient will frequently treat wounds at home for weeks, and sometimes months, before seeking medical care. But this can lead to an increased risk of non-healing and difficult-to-heal venous ulcers. Varicose veins are often regarded as a cosmetic problem—an unsightly consequence of aging, but not a threat to well-being. These myths can be successfully addressed through patient education.

Most people are not aware that without treatment venous insufficiency will progress and can have debilitating consequences. Men are more likely than women to present with advanced stages of venous disease because they are less likely to seek early treatment for lower extremity pain and swelling [18].

Patients with venous ulcers and their caregivers should be taught how to assess the wound with each dressing change done in the home. This should include the signs of wound infection, such as changes in the amount of wound drainage, odor, and the color of the wound bed (e.g., changing from a bright red to a dark ruddy color). Changes in the periwound area, including alterations in appearance, swelling, tenderness, and pain level, are also important to note. The occurrence of any of these symptoms should prompt the patient and/or caregiver to contact his or her physician immediately.

An honest discussion should be held with the patient and significant others about what treatment is going to entail, including the necessity for weekly visits to the wound clinic for debridement and dressings changes. If a patient has difficulty keeping appointments, treatment will not be successful and healing may not be achieved.

It is vital to listen carefully to patients’ concerns about treatment. Patients may be worried about missing work, transportation to appointments, wound care at home, and/or the cost of supplies. All members of the team caring for the patient should be aware of the concerns and support the patient to explore solutions. The input of the team social worker and/or case manager is particularly important at this time.

Many individuals with venous disease do not have sufficient knowledge to manage their condition successfully in the long term. The focus should be extended beyond wound healing and to making changes to maintain a healthy lifestyle. If a patient smokes, the benefits of smoking cessation for wound healing should be discussed. Weight management, safe exercise (e.g., walking), and prevention of trauma to the lower extremities should be explored with the patient/family. Concrete suggestions are better than general recommendations. For example, a patient may be instructed to take a brisk walk every day, not to cross his/her legs, and not to stand for more than 30 minutes at a time.

For patients who are unable to walk, an alternative exercise is sitting in a rocking chair and using the feet to push back while rocking steadily. This helps to increase calf muscle pump function and also provides ankle flexion exercise [5]. Non-ambulatory patients should be encouraged to do this several times per day.

More attention is now being paid to the impact that venous disease and especially venous ulcers have on the quality of life for patients. Those with venous disease often have a less favorable perception of their overall health status than those who do not have venous problems, especially if edema and changes in skin texture are present [22]. Patients with venous ulcers report having less vitality, and leg pain may cause isolation and depression. Financial concerns related to treatment and care are a major source of worry and anxiety for many patients. Interestingly, successful healing of a venous ulcer does not always lead to a patient reporting an improvement in perceived quality of life [22].

Questions related to quality of life issues should be included in the initial patient assessment and with all follow-up visits. Inquiries should be specific and directed to what, if any, changes venous disease and venous ulceration (if present) have necessitated in their usual daily activities, including work, recreational activities, and social interactions [22].

CONCLUSION

As clinicians and educators, nurses play a vital role in the care of patients with venous disease and venous ulcers. We are ideally placed to build therapeutic relationships with patients that can translate into more positive healing outcomes.
Influenza: A Comprehensive Review

Audience
This course is designed to help nurses and other healthcare professionals understand influenza and their role in its prevention.

Course Objective
The purpose of this course is to help healthcare professionals minimize the burden of influenza on their patients and their communities. Information is included to help healthcare professionals accept the importance of influenza vaccine in lessening the impact of the disease on their patients, preventing complications and hospitalizations, and saving healthcare dollars.

Learning Objectives
Upon completion of this course, you should be able to:

1. Articulate the history and burden of influenza on the community.
2. Explain the types of influenza viruses, including the H and N designations.
3. Describe the symptoms, transmission, and diagnosis of influenza.
5. Identify complications of influenza.
6. Articulate the effectiveness and importance of the influenza vaccines.
7. Implement a system to increase vaccine administration to vulnerable patients.
8. Describe the best method of hand hygiene and other ways of protecting against influenza.
9. List the current antiviral medications available and their use.
10. Teach family members how to care for people with the flu, including interventions for non-English-proficient patients and caregivers.
11. Identify the significance of avian and swine influenza, particularly issues related to pandemic disease.

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Faculty Disclosure
Contributing faculty, Elizabeth T. Murane, PHN, BSN, MA, has disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

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INTRODUCTION

Influenza is a disease that is often accepted as “a part of life.” While considered bothersome, it is not perceived to be a “serious” disease. However, new diseases, such as sudden acute respiratory syndrome (SARS), make headlines because of hospitalizations and fatalities. Much effort and money is expended to contain or find a way to prevent new diseases like SARS, but little notice is given to the fact that in the United States, influenza and pneumonia hospitalize more than 200,000 people and cause an average of 49,000 deaths each year [1; 2]. The cost of a flu epidemic is estimated to be $12 billion [3]. The pain and suffering caused by influenza is not considered when discussing costs [3; 4]. Between 1957 and 1986, 19 different annual influenza epidemics in the United States caused up to 40,000 deaths per year. Direct annual costs for medical care alone were between $1 billion and $3 billion [4]. A study based on 2010 Census data found that the annual economic costs of influenza varied from $13,900 to $957.5 million across U.S. counties, with a median of $2.47 million [5]. It has been estimated that the economic costs of the next influenza pandemic in the United States will be $713 million to $166.5 billion in direct healthcare costs (e.g., outpatient visits, hospitalization) alone [6]. Large amounts of time, energy, and money have been spent to find a vaccine against SARS while the flu vaccine, though not perfect, is markedly underused.
In 2014, pneumonia/influenza was listed as one of the top 10 causes of death in all age groups, except for children younger than 1 year of age [7]. As the cause of death, pneumonia/influenza ranked sixth in children 1 to 9 years of age, eighth in those 10 to 24 years of age, tenth in those 25 to 64 years of age, and sixth in those 85 years of age and older. When all age groupings were combined, pneumonia/influenza ranked eighth as a leading cause of death, ahead of nephritis and intentional self-harm (9th and 10th, respectively) [7].

Influenza is the only communicable disease still listed as a leading cause of death in the United States.

In this course, the term “influenza” is defined strictly as an acute viral respiratory illness caused by influenza A or B, occurring in seasonal outbreaks and periodic epidemics and characterized by the abrupt onset of systemic symptoms (e.g., malaise, fever, myalgia, headache) and cough. (Note: This is not to be confused with the gastroenteritis syndrome of nausea, vomiting, and diarrhea often erroneously referred to as “flu.”) Influenza occurs mainly in winter months (October to March) in temperate climates north of the equator. In the United States, “flu season” usually begins in November, peaks in late December or January, and is generally over by March. However, earlier outbreaks in October can also occur and peak activity may continue as late as March.

Surveillance conducted by the Centers for Disease Control and Prevention (CDC) of laboratories and outpatient facilities in 2015–2016 showed that influenza activity peaked in mid-March, one of the later season peaks on record. For example, in 2012–2013, influenza activity peaked much earlier (late December) [9; 10]. In 2010, the CDC distributed a health advisory via the Health Alert Network that H3N2 influenza was detected in a number of U.S. states. The last significant outbreak (319 cases) was reported in 2012 [181]. Each summer some localized outbreaks and sporadic cases occur. Often there is no history of recent travel or epidemiologic links between such outbreaks. It was expected that the viruses causing these cases would be antigenically similar to A/Hong Kong/4801/2014 (H3N2)-like, a component in the 2017–2018 vaccine [182].

In contrast, the 2009 H1N1 (swine flu) virus was isolated by Francis. Swine influenza viruses (closely related to human influenza viruses) were isolated in 1930 [14]. Smith, Andrews, and Laidlaw in ferrets. In 1936, influenza B virus was isolated by Francis. Influenza A virus was first isolated in 1933 by Smith, Andrews, and Laidlaw in ferrets. In 1936, influenza B virus was isolated by Francis. Swine influenza viruses (closely related to human influenza viruses) were isolated in 1930 [14]. In that same decade, researchers discovered that influenza virus could be grown in embryonated chicken eggs. These discoveries led to the development of inactivated (killed) vaccines [3].

All age groups are susceptible to influenza, but children have the highest infection rate. Rates of serious illness and death from seasonal influenza are higher among those who are 65 years of age and older with medical conditions that place them at increased risk for complications from influenza. Approximately 90% of the 49,000 annual fatalities resulting from influenza occur in those who are 65 years of age or older [3]. However, much media attention is directed to fatalities among children. Pediatric deaths increased markedly during the 2009–2010 H1N1 (swine flu) pandemic, with 276 deaths reported [12]. Particularly during pandemics, the burden of disease borne by younger individuals; in the 2009 H1N1 pandemic, which caused illness in 60 million Americans, 90% of hospitalizations and deaths were in persons younger than 65 years of age [5].

The economic burden of influenza on the community, the potential excess mortality among vulnerable members of the population, and the benefit to be derived from simple preventive measures and regular immunization are often underrecognized by the public and medical professionals alike. One study reported that increasing the annual percentage of adults receiving the influenza vaccine from 37% to 90% would save 12,000 lives each year [13]. Studies of influenza mortality between 1976 and 1999 show that influenza A (H3N2), a swine flu, had a 57% mortality rate for the flu seasons between 1976 and 1990 and a 90% rate between 1990 and 1999 [8].

### HISTORY

For many years, where was the proposed influenza epicenter thought to be?

The term “influenza” originated in Italy sometime in the 15th century from an epidemic that was attributed to the “influence of the stars.” In 1580, there was a worldwide epidemic that, from written description, was most likely caused by the influenza virus. Several other pandemics have occurred throughout the centuries. The most famous of these pandemics, the “Spanish flu,” lasted for 10 months in 1918–1919 and resulted in an estimated 21 million deaths worldwide, with approximately 500,000 of these deaths in the United States [3]. Other more recent pandemics include the “Asian flu” (1957), “Hong Kong flu” (1968), “Swine flu” (1976), and “Swine flu” (2009).

Influenza A and B are the two virus types that cause disease in humans. Influenza A virus was first isolated in 1933 by Smith, Andrews, and Laidlaw in ferrets. In 1936, influenza B virus was isolated by Francis. Swine influenza viruses (closely related to human influenza viruses) were isolated in 1930 [14].
For many years, the proposed influenza epicenter has been thought to be Southeast Asia. Farming practices there bring pigs, fowl, and people into close contact, allowing swine, avian, and human flu viruses to mix. The cycle is thought to be birds to pigs to humans. Now it is clear that this cycle can occur at any place in the world where there is the domestication of animals [14].

**INFLUENZA VIRUS**

**INFLUENZA VIRUS TYPES**

Influenza belongs to the orthomyxovirus family and consists of a single-stranded, helically shaped ribonucleic acid (RNA) virus. There are three types of influenza viruses designated A, B, and C. The differentiation is made by the type of proteins within the nucleus, specifically antigenic properties in their internal nucleocapsid and matrix proteins. The individual types have different effects on the humans who become infected.

Influenza type A is the virus that causes moderate-to-severe illness in all age groups and is highly infectious, with an attack rate of 10% to 20%. It also causes influenza in pigs, birds, and other animals. There are several subtypes of influenza A.

Influenza type B generally causes milder disease. It primarily affects children but has also caused outbreaks in military camps and occasionally in long-term care facilities. It does not cause illness in animals and birds and, as a result, tends to be more stable with less antigenic change. Subtypes have not been defined for influenza B.

Influenza type C is rarely ever reported, probably because any disease it causes is usually subclinical or mild. It does not affect animals and birds. Because type A influenza virus causes more severe illness and also occurs in animal and birds, this course will focus on influenza A.

**INFLUENZA A SUBTYPES AND ANTIGENIC SHIFT**

What is antigenic shift?

Influenza A subtypes are defined by the occurrence of the glycoproteins hemagglutinin (H) and neuraminidase (N), which are surface antigens on the virus. The hemagglutinins H1, H2, and H3 are involved in attaching the virus to cells. The neuraminidases N1 and N2 facilitate virus penetration into cells. There are 15 different subtypes of hemagglutinins and 9 different subtypes of neuraminidases leading to several possible combinations, which are indicated in the name of the virus (e.g., H1N2, H2N3). Many combinations of the various hemagglutinin and neuraminidase antigen subtypes are possible. However, H1N1, H1N2, H2N2, and H3N2 have historically occurred in humans.

Pigs are susceptible to three of the same subtypes of influenza. Historically, they have not been infected by the H2N2 subtype. Wild waterfowl, in contrast, appear to acquire all influenza A subtypes. An additional difference is that the virus causes respiratory illness in humans, pigs, and other mammals but infects the gastrointestinal tract in wild birds without causing disease. However, the virus is shed in the bird droppings, leading to the contamination of water supplies, barnyards, farms, fields, and animal food supplies.

The genes of influenza viruses are carried on eight separate segments of RNA rather than on one long single molecule. This means that if two or more subtypes of influenza virus infect the same cell in a host, these viruses can exchange RNA segments during replication and create viruses with new gene combinations. This reassortment is termed “antigenic shift.” It often occurs in pigs and is the source of influenza epidemics because the human population has little immunity to the new subtype that results.

In comparison, “antigenic drift” refers to changes in the surface glycoproteins. This does not result in a new subtype but does influence the choice of the particular influenza viral subtypes for the annual influenza vaccine. Depending on the degree of antigenic drift, immunity developed to one virus may be adequate to protect against the related virus. In other situations, the drift has resulted in enough change that there is little protection.

In the past, the influenza subtypes present in birds did not directly infect humans. A different host was usually required to complete the shift from an avian subtype to a subtype capable of infecting humans. This host has been the pig, which can be infected with avian, human, and swine influenza viruses. A possible scenario is that the food or water supply of the pig is contaminated by bird feces containing a subtype or subtypes of influenza A. The pig also acquires different influenza subtypes from other pigs and/or humans. Reassortment of the viral RNA occurs in the pig host, thus infecting other pigs. Farm workers catch the new subtype from the pigs and develop highly contagious influenza because they do not have immunity against this new subtype. Thus, a new influenza strain is launched [14]. It is possible that antigenic shift could occur in a person who acquires a strain from a bird and also has a human strain. Realignment of H and N in the person’s cells would result in a new strain. This new strain could become a pandemic if there is very little or no immunity in the human population and there is efficient, effective transmission from person to person [3].

Major pandemics of 1889–1891, 1918–1920, 1957–1958, and 1968–1969 have resulted from antigenic shifts. Characteristics of a pandemic are high attack rates in all age groups and a high mortality rate. Historically, pandemics have moved along trade routes, with rapidity of spread matching available transportation methods [3]. Rapid movement of people...
around the world by aircraft and fewer border restrictions by partners such as the European Union allow new influenza subtypes to spread more quickly. However, cooperation among the World Health Organization (WHO), the CDC in the United States, and the European Centre for Disease Prevention and Control, which was established in 2005, has contributed to slowing the spread of the virus. Also, minimizing the transmission of influenza virus from any of the hosts to any of the other hosts (e.g., birds, pigs, humans) will decrease the antigenic shift and lessen the development of new subtypes to which the population has not developed immunity [14].

Research has shown that work-related travel rates affect the spread of influenza more than geographical distance or air travel [15]. Based on 30 years of weekly data, influenza imported into a state with many inflows and outflows of workers, such as California, spreads much faster than if it enters a less-connected state, such as Wyoming. Epidemics also tend to start and spread from more populated states. This information is especially important in the event of the appearance of a new virus to which most of the population is susceptible. It usually takes five to seven weeks for annual influenza disease to spread across the continent. However, if a new strain originates in a highly connected state, it could spread to all states within two to four weeks. The study also revealed that adults, not children, are responsible for the transmission of influenza across regions because they travel farther and more frequently. One proposed intervention is to limit interregional travel to slow the spread [15].

**VIRUS NAMING**

The name of each influenza virus is developed following this formula [3]:

- Virus type (A or B): A/
- Geographic origin (place where virus was first isolated): Wuhan/
- Strain number: 395/
- Year of isolation: 95/
- Virus subtype (based on combination of hemagglutinin [H] and neuraminidase [N] antigens): (H3N2)

This was the principal virus isolated in the United States during most of the 1997–1998 influenza season.

Thus A/New Caledonia/20/99/(H1N1) would be read influenza A, which was first isolated in New Caledonia, strain number 20, isolated in 1999, with hemagglutinin subtype 1 antigen and neuraminidase subtype 1 antigen.

**INFLUENZA DISEASE**

As discussed, a brief definition for influenza is “respiratory illness with fever.” This is a quick way for healthcare providers who are participating in the annual surveillance of influenza activity to categorize each of their patients. Approximately 1000 sentinel medical practitioners in the United States participate in the U.S. Influenza Sentinel Provider Surveillance System by providing statistics about the number of “respiratory illness with fever” cases that have been seen each week. These figures are collected weekly by designated local health departments and reported to the CDC by the corresponding state health department. The CDC compiles and publishes these figures, which give a current view and contribute to a historical picture of influenza activity for that week. Monitoring and analyzing these figures also alerts medical professionals to changes in patterns. Any change in the historical pattern is especially important in early detection of a biologic change, whether introduced naturally or by terrorist activity. Several biologic agents that could be used by a terrorist first manifest their presence with flu-like symptoms.

**SYMPTOMS AND SIGNS**

**What is the usual incubation period of influenza in adults?**

Uncomplicated influenza is characterized by an abrupt onset of:

- Constitutional symptoms: Fever, chills, myalgia, headache, severe and persistent malaise, eye pain, light sensitivity, and substernal burning in the chest
- Respiratory symptoms: Nonproductive cough, sore throat, and rhinitis

Initially, there are more constitutional than respiratory symptoms. If there are no complications, the chest is usually clear to auscultation.

Children may also experience any of the accompanying effects of fever, such as listlessness, irritability, anorexia, and convulsions. In addition, otitis media, nausea, vomiting, and diarrhea are frequently reported in children with influenza [8]. Pneumonia and encephalopathy are serious complications in children with influenza [17]. Elderly patients may exhibit confusion in addition to other symptoms.

The patient with influenza usually appears febrile and fatigued with hot, moist skin, a flushed face, and red watery eyes. More than half of patients infected with the influenza virus will have nasal discharge with obstruction and pharyngeal redness. Younger patients may have nontender cervical lymphadenopathy [18].
Influenza onset is so abrupt that many patients can pinpoint the hour in which they became ill. This is an important feature that helps distinguish influenza from other diseases with flu-like symptoms. The fever is generally 101 to 102 degrees F (38.3 to 39 degrees C). Children may run higher fevers. Patients may complain of body aches. Myalgia often localizes in the back muscles. These systemic symptoms usually last from two to three days and may persist as long as five days. Most systemic symptoms respond to antipyretics and analgesics. It is important to remember that any medications containing aspirin should never be used in children or teenagers because of the risk of Reye syndrome [3]. This will be discussed in more detail later in this course.

Uncomplicated influenza is generally a self-limiting disease. Recovery is usually rapid, but most patients experience a decrease in strength or energy for a week or more after recovery (Figure 1).

TRANSMISSION

Influenza is highly contagious, with an attack rate of 10% to 20% from the day before symptoms begin through approximately five days after onset in adults. It is spread from person to person through coughing and sneezing by the infected individual. Influenza can be spread by the airborne route, which means that a person coughing in the room can transmit the virus to others in the room without close personal contact. This is in contrast to droplet transmission in which heavier particles (droplets) are transmitted to those with close contact (less than 3–6 feet, depending on the organism). Droplet transmission also probably occurs in influenza. Airborne transmission is especially significant in congregate situations like institutions, daycare facilities, airplanes, and cruise ships [19].

As noted, the influenza virus may be transmitted between humans and pigs. More than 25 examples of transmission from pigs to humans have been documented in the medical literature [14]. It is assumed that many more undocumented cases occur in individuals who work with swine. Usually, this swine-human connection is missed because the flu seasons in both pigs and people overlap. However, this connection should not be minimized. Its influence in antigenic drift or shift and the introduction of new subtypes is important to traditional transmission patterns.

Contaminated hands are a frequent source of transmission and infection. Contagious individuals cough or sneeze into their hands and deposit virus on whatever they touch. Or, they cough or sneeze the virus into the air, which settles on objects in the area. Others handle these objects and then touch their eyes, nose, or mouth and are infected. Following an incubation period of one to four days (average: two days), the individual develops symptoms. Another major factor in the spread of influenza is that it is transmitted to others before infected individuals even realize that they are sick [20].

Children are another source of infection, as they can be contagious for 10 or more days. In addition, young children can shed virus for up to six days before illness onset [16]. This is one reason to discourage the practice of kissing infants and children on the mouth.
DIAGNOSTIC TESTS FOR INFLUENZA

Obviously, an accurate diagnosis of influenza on the basis of symptoms alone is difficult. The quickest way to decide if the patient has influenza, or some other disease, is to use a rapid diagnostic test for influenza. However, medical practitioners should be aware that false-negative and false-positive results do occur. Within three to four days after onset of influenza, the virus can be found from throat and/or nasopharyngeal swabs. Highest viral shedding occurs during the first four days of illness. Nasopharyngeal specimens generally are more accurate. There are several rapid diagnostic tests available, and these tests can usually detect the influenza virus within 15 minutes [22; 23]. The specimen to collect and the information provided by the results vary according to the test being used. These various rapid diagnostic tests for influenza A are 65% to 95% accurate [21]. The accuracy rate depends on the particular rapid diagnostic test used and collection of the specimen at the optimum time [22]. Other factors that may improve the accuracy of these tests include knowledge that influenza is circulating in the community and obtaining the specimen from a patient within the first four days of illness [23]. The package insert should always be consulted as to the percentage of inaccurate results for the specific test. The rapid diagnostic test, therefore, can leave the medical practitioner with the need to base decisions about diagnosis and treatment on his or her clinical judgment [22]. Recent immunization with intramuscular (IM) influenza vaccine will not affect a rapid diagnostic test. Intranasal vaccine will affect any serology test; however, the intranasal vaccine is no longer recommended [8; 24]. Not all patients with influenza symptoms require a rapid diagnostic test. They should be done only if the results will help with the diagnosis and/or influence treatment decisions [23]. In an institutional setting, such as a nursing home, use of a rapid test combined with a viral culture will help provide more effective treatment and allow for rapid prevention and control measures [21].

Culture of the virus takes a minimum of 48 hours. Another one to two days are needed to identify the virus type. Viral culture can take as long as 10 days to complete. Obviously, these tests provide information as to the virus responsible for the illness but are not practical for individual case management. Knowing the virus or viruses responsible, however, allows more accurate planning for vaccine preparations. This information also helps evaluate the effectiveness of the formulation used in the current vaccine [3].

There are several ways that the influenza diagnosis can be confirmed [23; 25]:

- Rapid test
- Viral culture
- Direct or indirect immunofluorescent antibody staining
- Reverse transcriptase polymerase chain reaction
- Immunohistochemical analysis of tissues collected during autopsy
- Paired serology (comparison of antibody levels during acute and convalescent—two to three weeks later—phases). Antibodies in the convalescent specimen should be at least four times greater than in the acute specimen to confirm influenza.

For more information on available tests, please refer to the CDC’s website at http://www.cdc.gov/flu/professionals/diagnosis/index.htm. Monitoring the status of influenza circulating in the community through the information provided by the CDC can also assist the practitioner in the diagnosis [23].

INFLUENZA-LIKE ILLNESSES

Making the correct diagnosis when a patient presents with flu-like symptoms is becoming more critical. The purpose of the discussion below is to highlight the importance of making a careful observation of the patient and obtaining an accurate history of the illness.

INFLUENZA COMPARED TO THE COMMON COLD

Because both influenza and the common cold are caused by viruses that affect the respiratory tract, distinguishing between them is important. Adults rarely develop fever with a cold (coryza) but usually have a fever of 101 to 102 degrees F (38.3 to 39 degrees C) with the flu. Headaches, muscle aches, and extreme exhaustion are mild or nonexistent with a cold but are usual and severe with the flu. The prodromal signs of sneezing, runny nose, and sore throat signal that a cold is developing and may be present for one or more days before onset. These symptoms may occur with influenza but usually occur concurrently with the sudden onset rather than signaling an approaching illness. The flu develops suddenly, without warning. Like influenza, a cold may have a dry (nonproductive) cough. Some use a “rule of thumb” to distinguish between a cold, in which symptoms are from the neck up, and influenza, which is systemic (Table 1).

OTHER FLU-LIKE ILLNESSES

Which influenza-type illnesses peak in the winter?

There are many other illnesses that initially look like influenza. For discussion and consideration in making a diagnosis, these diseases are sometimes grouped into influenza-like illnesses (ILI). Adults will average one to three ILI a year. Children can average three to six ILI in a year. The common cold is one of these, and the differences between influenza and colds have been discussed above. Other bacteria that cause ILI are Chlamydia pneumoniae, Mycoplasma pneumoniae, Streptococcus pneumoniae, and Legionella pneumophila. In addition, respiratory syncytial virus (RSV) has similar symptoms.
None of these ILIs are as significant as biologic agents that may be used by a terrorist, such as anthrax, ricin, plague, and smallpox, all of which may present with influenza-like symptoms. However, they are a significant source of disease and should be considered when deciding if a patient has influenza or something else. Because bacterial diseases are treatable with antibiotics, but influenza is not, an accurate diagnosis is important. Much of the overuse of antibiotics occurs when patients request them for any illness or when careful diagnosis is not made between viral and bacterial diseases.

It may be helpful to consider the time of year in which the diagnosis is being made. Generally, pneumococcal disease peaks in the winter, as does influenza and RSV. Mycoplasma and legionellosis are more common during the summer and fall. Rhinoviruses and parainfluenza virus peak during the fall and spring. Adenoviruses circulate throughout the year [21]. Information on the presence of influenza and predominant strains in the community can usually be found from the surveillance system maintained by the local health department [16].

Other information to consider is that, in healthy individuals, influenza is a self-limiting disease that strikes suddenly with most of its fury, maintains that level of illness for three to five days, and then shows improvement, even though the aftereffects of weakness and tiredness may persist for a week or more. In most other ILI diseases the patient’s condition continues to worsen.

These last two considerations are not meant to figure in the diagnosis but to guide thinking about the patient’s illness. For instance, if a greater than usual number of cases of ILI are being seen and it is the wrong time of year for influenza, another disease or a terrorist attack should be considered.

Some studies have been conducted on the use of clinical definitions for influenza-like illness. The results were [22]:

- Fever, cough, and acute onset accurately predict influenza 30% of the time in nonhospitalized older patients.
- Fever, cough, and illness of less than seven days in hospitalized older patients with chronic cardiopulmonary disease accurately predict influenza 73% of the time.
- Fever, but not cough, in vaccinated older persons with chronic lung disease was 54% specific for influenza.

**COMPLICATIONS OF INFLUENZA**

Complications of influenza leading to hospitalizations and death are greater in persons 50 years of age and older, in young children, in pregnant women in the second and third trimester, and in persons of any age with underlying medical conditions. Laboratory data for the 2015–2016 influenza season indicated that 85 children younger than 18 years of age had influenza-related deaths [9]. Since becoming a nationally notifiable condition in 2004–2005, the number of annual pediatric deaths has ranged from 37 to 171, excluding the 2009–2010 H1N1 epidemic, which will be discussed later in this course.
PNEUMONIA

The major complication of influenza is pneumonia, and three types have been well-described in association with influenza epidemics: primary influenza (viral) pneumonia, secondary bacterial pneumonia, and mixed influenza/bacterial pneumonia. The incidence and mortality are highest in the elderly and in persons with underlying chronic illness, especially those with heart, lung, and renal diseases. However, in pandemic periods, half the deaths from pneumonia are seen in persons younger than 65 years of age [18].

Primary influenza pneumonia is the least common but most devastating form. It arises when the virus directly invades lung parenchyma and tends to present early as a rapidly deteriorating illness with high fever, profound dyspnea, and progressive respiratory failure. Patients with conditions that cause elevated left atrial pressures, such as heart failure and third-trimester pregnancy, are particularly at risk. Chest radiographs show bilateral diffuse reticulonodular opacities and basal (lower lobe) consolidation. Mortality is high.

Secondary bacterial pneumonia is the most common type and constitutes the major cause of excess morbidity and mortality in the elderly. The typical clinical presentation is a patient who appears to be convalescing from influenza only to experience an exacerbation of symptoms with renewed fever, worsening cough, purulent sputum, pleuritic chest pain, and radiographic evidence of a localized pulmonary infiltrate. The pathogens most often responsible are Streptococcus pneumoniae (50%), Staphylococcus aureus (20%), and Haemophilus influenzae. A number of factors affecting lung defense mechanisms are at play in the pathogenesis of bacterial superinfection, including [18]:

- The prime target cell for influenza virus in humans is the ciliated epithelial cell of the tracheobronchial tree.
- Damage to this epithelium leads to impaired mucociliary clearance of any potential pathogens that happen to be colonizing the upper respiratory tract.
- Alveolar macrophage phagocytosis is transiently impaired.

As might be expected, mixed influenza/bacterial pneumonia is a third type encountered during influenza outbreaks. This type of patient is vulnerable to severe, direct infection of the lung and happens, at the same time, to be colonized by a virulent respiratory bacterial pathogen (e.g., pneumococcus or staphylococcus).

Signs that a patient has developed pneumonia are [18]:

- Symptoms continue after the expected five to seven days
- Symptoms worsen after the patient has started to improve
- Fever returns and is higher than with the initial illness
- Dyspnea
- Productive cough
- Abnormal x-ray (pulmonary infiltrates)
- Rales on auscultation

REYE SYNDROME

Influenza virus and acetylsalicylic acid interact to produce what condition?

An unfortunate complication of influenza in patients younger than 18 years of age is Reye syndrome. Much education for parents has focused on the danger of giving aspirin to anyone younger than 18 years of age with a fever. This education has led to a decrease in Reye syndrome. Unfortunately, acetylsalicylic acid or salicylic acid is a component in some over-the-counter preparations and may be unintentionally given to a child with a fever. Influenza virus, especially influenza A virus, and varicella (chicken pox) interact with acetylsalicylic acid to produce Reye syndrome. Symptoms are nausea and vomiting, decreased consciousness and/or convulsions caused by cerebral edema, hypoglycemia, and liver failure. Parents must be reminded to read the labels of all medications and that aspirin is listed as acetylsalicylic acid [18].

MYOSITIS AND RHABDOMYOLYSIS

Myositis (inflammation of muscle tissue) and rhabdomyolysis (involving striated muscle tissue) can be complications of influenza. These complications occur most often in children and are manifested by extreme muscle tenderness, especially in the legs. Myoglobinuria may lead to renal failure in these patients. Serum creatinine phosphokinase (CPK) is markedly increased [18].

STAPHYLOCOCCUS AUREUS SUPERINFECTION

Influenza can be complicated by Staphylococcus aureus, leading to pneumonia as discussed above. Superinfection with S. aureus, leading to bacteremia, endocarditis, or epidural abscess, can also occur following influenza. Influenza B and S. aureus have led to toxic shock.

CARDIAC COMPLICATIONS

Other less common complications from influenza are myocarditis (inflammation of the cardiac tissues), and pericarditis (inflammation of the pericardial lining). A study conducted in Australia from 2008 to 2010 showed that recent influenza vaccination was significantly protective against acute myocardial infarction [26].
PULMONARY COMPLICATIONS
Besides the more common complication of bacterial or viral pneumonia, influenza can lead to the worsening of chronic bronchitis and other chronic pulmonary diseases.

CENTRAL NERVOUS SYSTEM COMPLICATIONS
Encephalitis, postencephalitic Parkinson disease, transverse myelitis, Guillain-Barré syndrome (GBS), and possibly amyotrophic lateral sclerosis have followed cases of influenza. There has been research suggesting that cases of Parkinson disease resulted from the “Spanish flu” pandemic of 1918–1919 [55; 56; 57; 58; 59; 60].

Any person with a serious medical condition can be placed in jeopardy by influenza, not only from the complications listed above, but also from exacerbation of the underlying condition [18].

INFLUENZA VACCINE
Who does the ACIP recommend should receive routine annual influenza vaccination?

Influenza vaccine is the primary preventive measure against the virus. It is efficacious in preventing influenza. Among those at higher risk, it lessens the severity of the illness, decreases complications, reduces hospitalizations, and lowers the fatality rate. It is disappointing that a vaccine with such benefits and few side effects is not used more widely. In 2010, the CDC approved the Advisory Committee on Immunization Practices (ACIP) recommendation that all individuals 6 months of age and older should receive the influenza vaccine. This recommendation was based on the fact that historically targeting at-risk groups for influenza vaccination has not proven to be as effective as immunizing everyone. With a highly communicable disease like influenza, children are the most likely to contract and spread the infection. Nearly all children must be immune to achieve community (herd) immunity [4]. The ACIP reaffirmed its recommendation of routine annual influenza vaccination for all persons 6 months of age or older who do not have contraindications (i.e., universal vaccination) [8].

In July 2010, the CDC published its recommendation that administration of the flu vaccine should begin as soon as the vaccine is received [4]. The CDC and the ACIP repeat this recommendation for the 2017–2018 flu season [8]. This decision was based on clinical trials that suggest protection from the influenza viruses covered by the vaccine lasts six to eight months and may last up to one year in college students. Because those 50 years of age and older have a diminished response to the vaccine, the immunity probably does not last as long [8].

A variety of vaccines are available for the 2017–2018 flu season, including trivalent and quadrivalent preparations (inactivated and recombinant) [8].

HIGH-DOSE INFLUENZA VACCINE
A vaccine containing an increased amount of the hemagglutinin antigen of the influenza virus was licensed by the U.S. Food and Drug Administration (FDA) in 2009 [4]. It is a single-dose, inactivated, trivalent, injectable vaccine sold under the brand name, Fluzone High-Dose, manufactured by Sanofi-Pasteur. This high-dose vaccine was developed for individuals 65 years of age and older who are at a greater risk of hospitalization and death from seasonal flu and are known to develop lower antibody titers to the influenza virus. The vaccine is available for the 2017–2018 flu season [8].

Preliminary clinical trials showed no preference for the new vaccine over other inactivated trivalent influenza vaccines. All were equally safe and equally effective at producing immunity [4]. However, the high-dose formulation resulted in significantly higher hemagglutination inhibition titers against each strain than the standard formulation [8]. A 2014 trial showed that recipients had 25% greater protection against influenza illness. A comparison between the standard and high-dose flu vaccines showed that in each 0.5-mL dose the standard vaccine contained 45 mcg (15 mcg of each of the three strains) while the high-dose vaccine had 180 mcg (60 mcg of each strain) [8].

As with the standard vaccine, the high-dose should not be given to anyone with a known severe reaction to egg proteins or other components of the vaccine. Vaccination with the high-dose formulation produced more frequent injection site reactions and systemic adverse events than the standard formulation, but typically they were mild and transient [4; 8].

HIGH-RISK GROUPS WHO SHOULD RECEIVE THE INFLUENZA VACCINE
In the event of a vaccine shortage, the following high-risk groups should receive the vaccination first.

Persons 50 years of age and older have the highest fatality and hospitalization rate from influenza and its complications. Of the 49,000 annual deaths, 90% of them occur in those 65 years of age and older. In addition, 57% of the hospitalizations are in this age bracket [16]. Those who are between 50 and
64 years of age are high risk because of the high prevalence of chronic diseases in this population. These patients often do not receive the vaccine because the publicity about the need to receive the vaccine has tended to focus on those 65 years of age and older. Only 48.1% of persons 50 to 64 years of age receive the vaccination; the vaccination rate among persons 65 years of age and older is 69.1% [183]. In addition, Medicare pays for the vaccine after the person reaches 65 years of age. Therefore, individuals who fall into the 50 to 64 age group may be disinclined to receive the vaccine.

**Persons with chronic health problems who are 6 months of age or older are at high risk for complications from influenza or exacerbation of their condition.** Such chronic conditions include:

- Cardiac disease, such as congestive heart failure
- Pulmonary disease, such as chronic obstructive pulmonary disease, cystic fibrosis, or asthma
- Renal disease
- Diabetes and other metabolic diseases
- Hepatic disorders
- Neurologic disorders
- Anemia and blood disorders, such as sickle cell disease

**Persons with compromised immune systems from any cause—human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS), autoimmune conditions, cancer, long-term steroid treatment, and medications—should receive the inactivated vaccine [8].** Because the vaccine is inactivated (killed), it can and should be given to immunosuppressed people. However, because of the depressed immune system of this group of people, the expected antibody response may not be obtained. HIV-infected patients with minimal AIDS-related symptoms and high CD4 T-lymphocyte cell counts have been shown to develop substantial antibody titers against influenza. For those with more advanced HIV disease and low CD4 T-cell counts, the vaccine might not induce protective antibody titers, and a second dose has not been shown to increase the titer. Some studies have shown that there is a temporary (two- to four-week) increase in replication of the influenza virus and aspirin that can lead to Reye syndrome.

**Persons with conditions or diseases that may compromise respiratory function or increase the risk of aspiration should also be vaccinated against influenza to prevent any possible complications or damage.**

All healthcare providers should receive the influenza vaccine annually. Additionally, healthcare facilities are encouraged to make available the vaccine to their workers. In its 2012 recommendations, the ACIP encouraged healthcare facilities to obtain a signed declination form from healthcare workers who refuse influenza vaccination [63]. Those who refuse vaccination may be required to wear a mask during influenza season. This issue is not specifically discussed in the 2017–2018 recommendations [8].

**Persons who reside in skilled nursing facilities (nursing homes) or other chronic care facilities are at high risk for influenza-related problems because of their weakened physical state and close living arrangements.**

**Persons 6 months to 18 years of age on long-term aspirin therapy should be immunized against influenza because of the interaction of the influenza virus and aspirin that can lead to Reye syndrome.**

**Women who are pregnant during influenza season have the same complication and hospitalization rate from influenza as persons with chronic diseases and, therefore, should receive the vaccine. This would include women who will deliver from the beginning of October through the end of May. Increased severity of influenza among pregnant women was reported during the pandemics of 1918–1919, 1957–1958, and 2009–2010 [8]. Severe infections among postpartum women also were observed in the 2009–2010 pandemic, and 56 deaths (36 during the third trimester) were reported among 280 pregnant women admitted to intensive care units.** Although there are some recommendations that a woman should not receive the influenza vaccine before the 14th week of gestation, the ACIP and the American Congress of Obstetricians and Gynecologists (ACOG) recommend influenza vaccination for all women who are or will be pregnant during the influenza season, regardless of trimester [8; 64]. There is a coincidental association of spontaneous abortion, which is common in the first trimester. Also, many practitioners avoid any exposure to vaccines during the first trimester. However, no adverse fetal effects have been associated with influenza immunization [8; 65]. Infants born to women who contracted the 1918 flu during their second and third trimesters had higher rates of cardiovascular disease at 60 to 82 years of age [66]. For men this rate of increase was 23.1%; for women it was 17%. In addition, individuals exposed prenatally were less successful economically and educationally. Studies of other influenza pandemics have shown schizophrenia risk is three times higher in those exposed to influenza in utero [66]. This information should help healthcare workers to recognize the importance of immunizing pregnant women.
All children 6 to 59 months of age, especially children 6 to 23 months of age, even without any chronic conditions, should receive the annual influenza immunization because they are at a substantially increased risk for influenza-related hospitalizations [8]. Many of the hospitalizations are due to dehydration that can occur rapidly in a child who has a fever and will not drink fluids. The hospitalization rate in this age group matches the hospitalization rate for other groups at high risk for complications and death from influenza. At this point, these higher hospitalization rates cannot be totally assigned to influenza because RSV circulates at the same time. Since 2003, the Vaccines for Children (VFC) program has covered the cost of the influenza vaccine for all eligible children 6 to 23 months of age and all eligible children 2 to 18 years of age who are household contacts of a child 0 to 23 months of age [16]. The ACIP, the American Academy of Pediatrics, the ACOG, and the American Academy of Family Physicians (AAFP) published the Recommended Immunization Schedule for Persons Age 0 Through 18 Years, which includes a recommended yearly influenza immunization for all children 6 months of age and older [8; 67]. Data from two studies showed that a side benefit from the influenza vaccine has been a reduction in otitis media [8].

Other groups who should receive vaccine during a shortage include American Indians/Alaskan Natives; the morbidly obese (body mass index ≥40); household contacts/caregivers of children younger than 6 months of age for whom there is no vaccine; and persons with medical conditions that put them at higher risk for severe complications from influenza [8].

Before 2004, influenza-related deaths in children were not on the list of deaths that should be reported. When it became apparent that a significant number of children were dying, the CDC requested that all influenza-related deaths of children younger than 18 years of age be reported to the appropriate state health department. Any postmortem tissue specimens that were collected or autopsy reports that were completed were also asked to be sent to the CDC [25]. However, in the subsequent years there have been even more deaths of children. As noted, in the 2015–2016 flu season, there were 85 deaths among persons younger than 18 years of age [9]. During the 2009 H1N1 pandemic, 32% of hospitalizations and 10% of deaths (approximately 1,250 deaths) were children younger than 18 years of age [68].

Data from the Internet Panel Survey of healthcare personnel indicated that only 49% of healthcare workers were immunized against influenza, in spite of the fact that vaccination reduced work absenteeism and resulted in fewer deaths among nursing home residents [69]. In the 2011–2012 season, only 67% were immunized. That percentage rose to 72% during the 2012–2013 season and then to 79% in the 2015–2016 season [70; 87]. Studies have also shown that ill workers account for as much as 60% of corporate healthcare costs. To respond to these situations, many companies now offer free influenza vaccinations and expanded telecommuting options [71]. The Healthy People 2020 objective is a 90% vaccination rate, but obviously 100% coverage is preferable [82].

The public continues to follow the example of their healthcare providers. Although approximately 218 million Americans could have benefited from the influenza vaccine in the 2007–2008 flu season, millions of unused doses were destroyed [72]. To emphasize the importance of flu vaccinations, the CDC has established the National Influenza Vaccination Week. In 2016, the week is scheduled for December 4 through 10 [73]. While meaningful improvements in vaccination coverage have been observed in children over the past seven flu seasons (from 44% to 60%), a significant increase has not occurred in the adult population (from 40.4% to 41.7%) [184].

**OTHER GROUPS ADVISED TO RECEIVE THE INFLUENZA VACCINE**

Persons who provide essential services, such as law enforcement personnel and firefighters, should be immunized. This is especially important in a pandemic situation. Students living in dormitories should receive the vaccine in order to avoid disruption of their studies.

Travelers should be evaluated for influenza immunization when “travel shots” are being recommended. Influenza in temperate climates occurs in the winter months (October through March in the Northern hemisphere; April through September in the Southern hemisphere); it occurs year-round in tropical climates. People taking a cruise could be infected with influenza at any time of the year because many of the service crew members are from tropical areas and a cruise ship is a closed community, which helps to assist in the spread of the virus [65].

The need for healthcare workers to be immunized against influenza cannot be overemphasized. All healthcare workers should receive the influenza vaccine. Not only does it protect the patient, but it also protects the healthcare worker. Healthcare workers who have been immunized tend to remember to advise their patients to get the immunization. This can strengthen the advice by example and can also provide anecdotal reassurance about the pain or side effects experienced. Studies have shown that residents in long-term care facilities have fewer deaths from influenza when their caregivers have been immunized against influenza [16].
GROUPS WHO SHOULD NOT RECEIVE THE INFLUENZA VACCINE

Persons with a severe allergic reaction to eggs should not be given most types of influenza vaccine [8]. A person with a severe hypersensitivity to eggs may develop an anaphylactic reaction (e.g., sudden sense of great uneasiness or anxiety, pounding headache, hypotension, urticaria, dyspnea). Most influenza vaccines are grown in eggs, and although they go through a purification process, a small amount of egg protein remains. This minute amount could trigger a reaction in those who are severely allergic to eggs. A dislike for eggs, mild gastrointestinal symptoms, or hives (alone, without other, more severe symptoms) following ingestion of eggs is not a contraindication for the inactivated influenza vaccine. Usually, asking a person receiving the influenza vaccine for the first time if they can eat soft-cooked eggs without a problem is a quick screening tool and an adequate precaution. In 2013, the FDA approved the first vaccine that is not grown in eggs, eliminating any risk for those with severe allergic reactions to eggs. The only vaccine considered to be egg-free is Flublok, a trivalent recombinant influenza vaccine; however, this vaccine is only approved for adults 18 years of age and older [8; 185]. (Note: persons who have experienced only hives after exposure to egg may receive any appropriate influenza vaccine.)

According to the Institute for Clinical Systems Improvement, contraindications to influenza vaccination include severe allergic reaction to any component of the vaccine, including egg protein, or after previous dose of any influenza vaccine. (https://guideline.gov/summaries/summary/36813. Last accessed October 25, 2016.)

**Level of Evidence:** Consensus Statement and/or Expert Opinion

Persons with acute respiratory or other active infections or illnesses should be advised to wait until they have recovered to receive the vaccine [8].

Persons with a history of GBS are more prone to another episode of this syndrome [8]. Because GBS is such a rare condition, it is impossible to know if the influenza vaccine is involved in its occurrence. During the 1976 swine flu epidemic, there was an increase of GBS (1 additional case per 100,000 vaccinated) in those who had received the vaccine [8]. However, an increased incidence of GBS following administration of other influenza vaccine formulations since 1976 is extremely low (1 additional case per 1 million vaccinated). According to the package insert for Fluzone, for patients who have recovered from GBS, it is better to err on the side of caution and avoid giving them the influenza vaccine until more information is available [65]. The Epidemiology and Prevention of Vaccine-Preventable Diseases, known as the “Pink Book,” states that persons who have developed GBS within six weeks of receiving the influenza vaccine would be wise to avoid a subsequent flu shot [3; 8]. However, the recommendation of the ACIP is that recovered GBS persons with risk factors that increase their vulnerability to the complications of influenza should receive the vaccine because the risk of complications is greater than the risk of a recurrence of GBS [8].

Persons with an allergic reaction to dry natural latex rubber should be evaluated before being given the vaccine because the stopper in some of the vials contains dry natural latex rubber [8]. According to data provided to CDC, Fluvirin and Flud (manufactured by Seqirus) are the only vials that are expected to possibly contain latex.

Note: Influenza immunization is NOT contraindicated in breastfeeding mothers. In fact, it should be encouraged because the mother could transmit influenza to her vulnerable infant if she gets the disease [8]. She could also be liable to a decreased milk supply because of decreased fluid intake and fever and would have the added burden of infant care and breastfeeding while experiencing exhaustion and other flu symptoms.

**MANUFACTURE OF THE VACCINE**

Because of antigenic drift, each year the ACIP and the FDA must decide which influenza strains to include in the formulation of the season’s vaccine. Because the formulation changes each year to provide protection against the expected circulating strains, an annual influenza immunization is needed. Obviously, the point is to include the strains that will be expected to spread globally. There are two type A strains included in the trivalent formulations, because type A influenza strains are usually those that lead to more complications, hospitalizations, and deaths. The third strain included is always a type B; the quadrivalent formulation includes a second type B strain. In the 2003–2004 influenza season, the expected dominant strain killed the embryonated egg where the virus was grown due to the virulence of the strain [17]. A virus that was close to the expected circulating strain was chosen instead. However, the match was not close enough to the circulating strain for the vaccine to be as effective as it usually is. To the credit of the ACIP, this was only the second mismatch in 15 years [74; 75]. In some cases, antibodies produced against one strain can overcome another strain, but the strains must be closely related. Antibodies produced by the strains in the 2003–2004 formulation were not close enough to the dominant circulating strain to destroy it, so people who had received the vaccine still developed influenza. In fact, the choice of which strains to include is based on the current knowledge as to which will be the most virulent strains in circulation. Due to the fact that there are only three strains in the vaccine and there are multiple influenza strains, people who are vaccinated can still develop illness from a strain of influenza virus that was not included in the vaccine.
Another extremely significant factor in the choice of a strain is the ability to grow the strain so that the vaccine can be produced in millions of doses. When vaccine distribution is delayed, it is often due to the fact that one particular strain would not reproduce well or quickly enough. As noted, some strains kill the culture medium.

Trivalent formulations for the 2017–2018 influenza season are A/Michigan/45/2015/(H1N1)pdm09-like, A/Hong Kong/4801/2014 (H3N2)-like, and B/Brisbane/60/2008-like (Victoria lineage). Quadrivalent vaccines will include an additional vaccine virus strain, B/Phuket/3073/2013-like (Yamagata lineage) [8].

Production of influenza vaccine involves the following steps [65]:

1. The chosen strains of influenza virus are incubated in fertilized chicken eggs.
2. Fluids containing the virus are harvested.
3. The virus is inactivated (killed) by formaldehyde.
4. The virus is concentrated.
5. The virus is chemically disrupted to produce a “split virus.” (All influenza vaccine used in the United States is split virus.)
6. Further purification of the virus by chemical means is done.
7. The virus is suspended in sodium phosphate-buffered isotonic sodium chloride solution.
8. No antibiotics are used in the preparation of influenza vaccine.

Thimerosal is a preservative used in multi-dose vials to inhibit bacterial growth that might occur because of multiple introductions of needles to withdraw individual doses. It is a compound containing 49.6% mercury. Because of the allegation that thimerosal is connected to conditions such as autism and the fact that there have been warnings to avoid fish that has a high mercury content, thimerosal has been removed from most childhood vaccines. Vaccines without thimerosal are packaged in single-dose vials. However, thimerosal is still used in multi-dose vials (5-mL dose vials) and in one brand (Fluvirin) of single-dose prefilled syringes of influenza vaccine [8]. There are 25 mcg of mercury in each 0.5-mL dose of vaccine. One should note that there have been no studies proving any link between mercury poisoning and autism. Thimerosal is made from ethyl mercury, which is different from methyl mercury, the compound named in the government warning about consumption of or exposure to mercury [74].

Influenza vaccine without thimerosal has been made each year and should be used for those who have a severe allergic reaction to thimerosal. One hundred thirty million doses of thimerosal-free vaccine will be available for the 2017–2018 flu season [76].

These production methods have been used for decades and do not apply some of the modern technology available in the production of vaccines against other organisms, such as hepatitis A or hepatitis B. As noted, most influenza vaccine is incubated in fertilized chicken eggs. It takes one egg to produce one dose. More than 80 million doses are made for annual distribution in the United States alone. The number of chickens and eggs needed for this production is almost beyond comprehension. Also sobering is the thought of what would happen if one or more of the major flocks used for producing the eggs for the vaccine became infected with an avian influenza, which would require destruction of the flock(s).

Another issue involved is the amount of time required to produce the annual influenza vaccine—about six to eight months. Any new strain of influenza could circulate around the world much faster than the vaccine could be produced, resulting in a pandemic. Experimentation is being conducted on faster ways to produce the vaccine. Some companies are experimenting with caterpillar cells to incubate the virus. Experiments have indicated that the vaccine can be produced more quickly and that it would be available to protect people against emerging strains. Phase I trials indicated that the vaccine incubated in caterpillar cells is safe. In a clinical trial of 400 elderly people, the vaccine stimulated the production of nearly twice the number of antibodies as the vaccine produced using eggs. In addition, there were no adverse effects. Phase II trials in 400 elderly participants showed that 97% of them developed antibodies if the highest dose of the vaccine was used [77; 78].

Another approach being explored in influenza vaccine production is to genetically engineer cells to replicate continuously. Such a process would lead to faster production and a more consistent vaccine [79]. One example of this is the Flublok vaccine, which uses protein-producing machines to make hundreds of copies of hemagglutinin, the small piece of the influenza virus needed for immunity [80]. Flublok is available for the 2017–2018 influenza season.

Other experimentation is being done using DNA-based approaches to develop a broadly protective vaccine that utilizes influenza virus proteins from multiple strains. Several companies are working to develop new ways to grow the antigens that cause the immune system to fight infection [79; 81]. Using the reverse genetics method, in which genomes of the influenza viruses are manipulated in order to transfer genes between viral strains, seed viruses for vaccine manufacture can be rapidly generated. In addition, highly pathogenic influenza viruses can be altered so that they are safer for vaccine manufacturers to handle [81].
Another method of vaccine development, cell culture, has been well tolerated and has successfully led to antibody development in trials. Some research has shown that vaccines developed based on cell culture have been efficacious against all strains of influenza A, including H5N1 [81]. Using cell-based vaccines creates a more consistent manufacturing process and could reduce production time to 9 to 12 weeks. Although there are some side effects from cell-based vaccines, including headaches and injection site reactions, they appear to have a similar tolerability profile to egg-based vaccines [27].

In another area, one small study has been conducted that indicates that mild exercise before having a flu shot may make the vaccine more effective. Lifting weights before a flu shot increased antibody response in women but reduced the response in men. However, the cell-mediated response in men was increased by weight lifting. The researchers suggest that exercise increases the number of immune cells in muscle tissues, which in turn increases activity in the lymph nodes and creates a more efficient immune response [29; 30].

HANDLING AND STORAGE OF THE VACCINE

The following information pertains to the egg-based vaccine in use. As is the case for all vaccines, the package insert should be consulted for proper handling and storage in order to preserve its effectiveness. Influenza vaccine should be stored at a temperature of 36 to 46 degrees F (2 to 8 degrees C) [8]. It should be transported in insulated containers with cold packs; however, it should not be directly in contact with the cold packs nor should it be placed anywhere in a refrigerator where it can be frozen. Freezing destroys the effectiveness of influenza vaccine. The vaccine can tolerate being out of the refrigerator while an influenza clinic is being prepared or conducted. However, only enough vaccine for the first half hour should be taken from the refrigerator at a time. When immunizing individual patients in an office setting, the vaccine vial should be returned to the refrigerator as soon as the dose has been withdrawn.

It is important that the temperature of the vaccine storage refrigerator be checked and recorded each morning before starting to dispense immunizations and each evening before leaving for the day. Older refrigerators can develop cold spots where items can freeze, or they may not maintain a constant temperature. All inactivated vaccines, like influenza vaccine, are destroyed by freezing. Large bottles of water should be kept in the refrigerator at all times to help maintain an even temperature and to preserve cold longer in case of a power outage. Some live vaccines, such as chickenpox and oral polio (no longer used in the United States), must be kept frozen. Vaccine should never be stored on the shelves in the door as the temperature there is erratic.

Recommended vaccines for the 2017–2018 flu season are Fluad, Fluarix Quadrivalent, Flublok, Fluzone High-Dose, Fluzone Intradermal Quadrivalent, Fluzone Quadrivalent, Flucelvax Quadrivalent, Fluvirin, Afluria, and Flulaval Quadrivalent (Table 2). Children younger than 18 years of age should not receive Flublok (IM) or Afluria Quadrivalent [8]. FluMist is available but is not recommended for the 2017–2018 flu season [8].

Fluad is an adjuvanted trivalent inactivated influenza vaccine that was licensed November 2015 for adults 65 years of age and older [8]. The adjuvant, a squalene-based oil-in-water emulsion, effectively boosts the immune response in older individuals.

In May 2016, the FDA licensed Flucelvax Quadrivalent, a cell culture-based inactivated influenza vaccine [8]. The vaccine is prepared from virus propagated in adult canine kidney cells rather than in hen’s eggs.

Monitoring the 2010 influenza season in Australia produced data indicating that Afluria (marketed as Fluvax in the Southern Hemisphere) was associated with increased frequency of fever and febrile seizures in children 6 months through 4 years of age when compared to previous years [33]. Generally, the fever occurs 4 to 24 hours after the vaccine is given [33]. It would be prudent to instruct the parents or caregivers of these children to monitor the child’s temperature and give nonaspirin fever-reducing medication as needed. In some public health immunization clinics, parents are instructed to give a dose of a fever-reducing medication to the child as soon as they get home, as a preventive measure. In a 2009 clinical trial in the United States, increased fever was noted among recipients of Afluria 6 months through 8 years of age. For the 2010–2011 influenza season, the U.S. Department of Health and Human Services Vaccine Adverse Event Reporting System (VAERS) and Vaccine Safety Datalink reviewed adverse event reports carefully for febrile seizures in children younger than 9 years of age [33].

ADMINISTERING THE VACCINE

The influenza vaccine discussed in this section is for IM use only; the intranasal and intradermal preparations are discussed later in the course. The IM vaccine is for all people 6 months of age or older. In order to assure that the vaccine is given IM, it is necessary to use needles of the proper length. Vaccine that is administered subcutaneously because of improper technique or a needle that is too short is ineffective.

The recommended site for adults and for children 3 years of age and older is the deltoid muscle [8]. A 1-inch needle will reach the deltoid in most children and adults. Some patients with large arms will need a 1.5-inch needle. One should be careful to make sure that the patient’s sleeve can go high enough so that the needle can be inserted in the middle of the arm, about 1.5 inches below the top of the shoulder.
<table>
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<th>Trade Name</th>
<th>Manufacturer</th>
<th>Supplied As</th>
<th>Mercury</th>
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<td>IM</td>
<td>Inactivated</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.0 mL multi-dose vial</td>
<td>24.5 mcg per 0.5 mL</td>
<td>18 to 64 years (jet injector)</td>
<td>IM</td>
<td>Inactivated</td>
</tr>
<tr>
<td>Afluria Quadrivalent</td>
<td>Seqirus</td>
<td>0.5 mL prefilled syringe</td>
<td>0</td>
<td>≥18 years</td>
<td>IM</td>
<td>Inactivated</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.0 mL multidose vial</td>
<td>24.5 mcg per 0.5 mL</td>
<td>≥18 years (needle and syringe)</td>
<td>IM</td>
<td>Inactivated</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.0 mL multidose vial</td>
<td>24.5 mcg per 0.5 mL</td>
<td>18 to 64 years (jet injector)</td>
<td>IM</td>
<td>Inactivated</td>
</tr>
<tr>
<td>Fluad</td>
<td>Seqirus</td>
<td>0.5 mL prefilled syringe</td>
<td>0</td>
<td>≥65 years</td>
<td>IM</td>
<td>Adjuvanted inactivated</td>
</tr>
<tr>
<td>Flublok</td>
<td>Protein Sciences</td>
<td>0.5 mL single-dose vial</td>
<td>0</td>
<td>≥18 years</td>
<td>IM</td>
<td>Recombinant</td>
</tr>
<tr>
<td>Flublok Quadrivalent</td>
<td>Protein Sciences</td>
<td>0.5 mL prefilled syringe</td>
<td>0</td>
<td>≥18 years</td>
<td>IM</td>
<td>Recombinant</td>
</tr>
</tbody>
</table>

*The composition of vaccines varies among different products.

*Increased risk of fever/febrile seizures in children younger than 5 years of age.

Source: [8]  Table 2
Usually the firmness of the deltoid can be felt in that area. In patients who are very thin, it is wise to squeeze the deltoid between the thumb and finger to avoid hitting the bone. Administration of the vaccine distal in the deltoid is more painful. The posterior portion of the arm should not be used.

In children younger than 3 years of age, the deltoid is usually not big enough to receive the vaccine. The vastus lateralis muscle should be used [8]. This is the muscle on the outer aspect of the child’s thigh and can usually be palpated. At times, when the infant kicks, the outline of the muscle can be seen. Two key elements to administering an injection to a child are to have the child properly and quickly restrained. An assistant, either the parent or a helper, should position the child so that the leg or arm where the injection will be given will not move. The upper body, the leg not being used for the shot, and the foot of the leg being used should be held tightly by the parent. Young children 3 years of age and older should sit sideways on the parent’s lap so that the child’s legs can be clamped between the parent’s knees. The arm that will not be used for the injection should go around the parent’s waist and be clamped under the parent’s arm. The hand of the arm being used for the injection should be held by the parent. The person giving the vaccination should have all injections prepared so that they can be administered quickly. It is also good to distract the older child by having them blow, count, or see how loudly they can say “ouch.”

Children should receive split-virus vaccine. This is not an issue in the United States as all vaccines are split-virus. Because some influenza vaccine comes in multidose vials, a small amount of thimerosal is in the vaccine [8]. For parents who are unwilling to accept the studies showing no connection between thimerosal and autism or other negative health effects, several thimerosal-free preparations are available [8; 65].

FluMist, Fluarix, Flulaval (single-dose), Fluzone (single-dose), and Affuria do not contain thimerosal. There are additional vaccines in use with reduced or no thimerosal. Information on the amount of thimerosal present in each vaccine dose is available on the CDC website [8].

Children younger than 9 years of age receiving influenza vaccine for the first time should receive two doses, one month apart. The dose for a child is age-related [35]. Children from 6 to 35 months of age should be given 0.25 mL administered IM with a 1-inch needle in the outer aspect of the thigh. If it is the first time the child has received a flu shot, a second 0.25 mL dose IM should be given one month later [35]. The Fluzone quadrivalent vaccine (Sanofi Pasteur) is available in a 0.25 mL single-dose prefilled syringe and contains no thimerosal [8]. In subsequent years, the child will receive only one influenza vaccine each year. Children 3 years of age and older should be given 0.5 mL IM using a 1-inch needle in the deltoid. Children who are 3 to 8 years of age receiving influenza vaccine for the first time will need a second vaccine in one month. These second doses in those not previously immunized against influenza are given to maximize a satisfactory antibody response to all antigens in the vaccine. Preferably, both doses should be given before December [8; 36; 74]. Late-season immunization is acceptable and should be encouraged for those who have not received the vaccine [63].

As an inactivated vaccine, influenza can be administered with other vaccines if required. Separate needles and separate sites should always be used. In fact, for patients 65 years of age or older who have never received the immunization against pneumococcal disease, that vaccine should be given at the same visit. This is also an excellent time to check on the status of the patient’s tetanus immunization. Tetanus vaccine should be given every 10 years, a fact that is often forgotten in adults, especially older individuals.

All patients or their parent/guardian must receive the Vaccine Information Statement (VIS) appropriate to the vaccine being administered. The patient signs that he or she has read the VIS. The record the patient signs must contain the date that the VIS was provided to the patient. Many people think that they are signing permission for the vaccine to be given. Actually, they are signing that they have read the VIS [37].

Children younger than 18 years of age should not be given any vaccines without a parent/guardian present. Grandparents who are not legal guardians frequently bring children to immunization clinics. A written permission from the child’s parent/guardian should be presented to the staff before the vaccine is administered.

**SIDE EFFECTS OF THE INFLUENZA VACCINE**

The most common side effect following influenza immunization is a local reaction—soreness, redness, or induration at the injection site—that occurs in 15% to 20% of the recipients. Generally, these effects last only one or two days. Some people (<1%) experience fever, chills, malaise, and myalgias, usually within 6 to 12 hours. This effect occurs most often in those receiving the vaccine for the first time. As with the local reaction, these systemic reactions last only one to two days. In a comparative study with a placebo, the systemic reactions occurred as often with the placebo as with the influenza injection. Neurologic reactions to influenza do occur, but they are rare [8].

A certain percentage of people will be incubating an influenza virus when they receive the influenza injection. When they have symptoms of influenza within a few days of vaccination, they are certain it is the result of the flu shot. Healthcare workers should try to reassure their patients that the vaccine cannot be responsible because the virus in it is split and dead.
Immediate severe allergic reactions can occur after administration of influenza vaccine. These reactions are probably due to hypersensitivity to a component of the vaccine, usually a severe egg allergy. As noted, this concern may be eliminated with new technologies that have become available. The CDC recommends that all patients receiving the influenza vaccine, especially for the first time, should be carefully screened for severe egg allergy. However, the American Academy of Allergy, Asthma, and Immunology and the American College of Allergy, Asthma, and Immunology updated their practice parameter in 2017 and now assert that any appropriate, licensed influenza vaccine may be safely used for persons with egg allergy of any severity, eliminating the need for careful prescreening [186]. If a person has a severe allergic reaction to thimerosal, a thimerosal-free vaccine (e.g., Fluzone, Fluarix) should be used. For those allergic to eggs but who have factors that increase their risk of complications from influenza infection, protocols to vaccinate them are available. Flublok may be used in these patients as it is egg-free [8]. A sheet with the symptoms of anaphylaxis and the dosage of therapeutic epinephrine should be posted near the preloaded epinephrine syringe and should be readily available and known to all staff. In addition, crushable packets of ammonia should be available in any area in which immunizations will be administered. It should be noted that anaphylactic reactions are extremely rare. Patients, especially teenagers, may faint and the crushed ammonia passed quickly under the nose is enough to revive them. Never ignore a patient who verbalizes fear of shots or mentions that they have fainted in the past. Make sure such a patient is seated or lying down if in an exam room. Reassure the patient and administer the vaccine as quickly as possible. Position your body in such a way as to be able to support the patient if he or she begins to faint.

ADVERSE EVENTS

Adverse events are any unusual conditions, such as fever, dizziness, behavior change, or serious allergic reactions (e.g., difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, tachycardia), following influenza vaccine. The National Childhood Vaccine Injury Act of 1986 mandates that healthcare providers report adverse events following vaccination to VAERS. Providers are additionally encouraged to report any clinically significant adverse event following vaccination to VAERS [8]. Any person can report an adverse event following the administration of any vaccine by calling VAERS or by obtaining a form online. Adverse events usually occur within 48 hours of vaccine administration. However, GBS may occur as long as six weeks after administration. The VAERS form will ask for detailed information on the vaccine, such as lot number, administration site, administrator, and date. Patients to whom influenza vaccine is administered should be instructed to call a physician if there is an adverse event. Careful investigation follows the receipt of a VAERS report. The provider is notified of the results of the investigation usually several months after the report was made. Therefore, it is important to keep a copy of the report in the patient’s file and a copy in a special file for VAERS reports. As the report is investigated, the provider may be contacted for clarification or additional information.

EFFECTIVENESS OF THE INFLUENZA VACCINE

The effectiveness of any vaccine depends upon the age and immunocompetence of the person receiving the vaccine. Most children and young adults receiving the vaccine have a good antibody response to the strains included in the vaccine and develop titers sufficient to protect them against those strains. For healthy adults younger than 65 years of age, if the vaccine strains match the circulating strains, illness will be prevented in 70% to 90% of those adults. In children, various studies have shown that children as young as 6 months of age develop antibodies. Children at high risk to develop complications with influenza may have a lower antibody response than healthy children. Also, children receiving the vaccine in the second year exhibit lower attack rates. Otitis media rates are lowered in some studies but not in others. Overall, because the vaccine is beneficial to children in preventing disease and lowering hospitalization rates, the ACIP recommends a yearly influenza immunization for all children 6 months of age and older [4; 8].

In adults 60 years of age and older who are not institutionalized, a randomized trial showed that the vaccine was 58% effective against influenza respiratory illness. Efficacy might be lower in those older than 70 years of age. However, the vaccine appears to be effective in preventing secondary complications, hospitalization, and death among older adults, both those who are healthy and those with chronic medical conditions. Among noninstitutionalized older adults, the vaccine prevented hospitalization for pneumonia and influenza 30% to 70% of the time. Among institutionalized older adults, the vaccine can be 50% to 60% effective in preventing hospitalization or pneumonia and 80% effective in preventing death even though it is only 20% to 40% effective in preventing respiratory illness among this population [8]. Overall, in those 65 years of age and older, influenza immunizations have reduced hospitalization by 70% and death by 85% [36].

COST-EFFECTIVENESS OF THE INFLUENZA VACCINE

In preventing illness among younger workers, the vaccine may help reduce economic losses caused by absenteeism. Decreasing hospitalization rates of healthy infants and toddlers, of older noninstitutionalized and institutionalized adults, and of persons with chronic conditions is cost-effective. Studies have demonstrated that influenza-related hospitalizations are decreased 40% to 42% overall with vaccination, that there is a 25% decrease in antibiotic usage for secondary illness associated with influenza, and that there is possibly a decrease in lost workdays. A 2014 study found that a vaccinated child’s risk of being hospitalized due to influenza
was reduced 74%; for individuals 50 years of age or older, flu-related hospitalization risk was reduced 57% [84]. These statistics indicate a significant annual savings of healthcare dollars for each person who received influenza vaccine. In an era of escalating healthcare costs and increasing antibiotic resistance, these are important figures [8].

**INTRADERMAL INFLUENZA VACCINE**

In 2011, the FDA approved a new version of Fluzone to be administered intradermally via microinjection system [34]. The vaccine is packaged in 0.1 mL single-dose, prefilled syringes, and it contains no preservative [8; 39]. The microinjection consists of an ultra-thin needle 0.06 inches (1.5 mm) in length, or less than one-tenth the length of the standard needles used for the traditional IM route [34]. The system deposits the vaccine into the dermal layer of the skin, where dendritic cells generate an immune response. Research indicates that use of the intradermal route results in an immune response as good as or better than IM administration using a lower dose of hemagglutinin (9 mcg of hemagglutinin for each influenza strain compared to 15 mcg) [40; 41]. As such, this route may be preferred when sparing vaccine is advised.

Fluzone intradermal is recommended for use in adults 18 to 64 years of age [8; 39]. Initial research indicates that it may also be effective in older adults (60 to 95 years of age), but more research is necessary before Fluzone intradermal can be recommended for this group [42]. Potential adverse effects associated with intradermal administration are similar to those seen with IM administration, although local injection site reactions may be more common and more visible [34; 40]. The most common injection-site reactions are erythema (>75%), swelling (≥50%), induration (≥50%), pain (≥50%), and pruritus (>40%); all of these reactions occur more often with intradermal than with IM administration, with the exception of pain, which occurs at similar rates in both [34]. Due to the small size of the needle, it may also be useful for patients with fear or anxiety related to injections or needles.

**NASAL SPRAY INFLUENZA VACCINE**

Live attenuated influenza vaccines (LAIVs) have been in development in the United States since the 1960s [43; 44]. FluMist (a LAIV trivalent formulation), manufactured by MedImmune, LLC, was originally approved in June 2003. FluMist quadrivalent LAIV contains two subtype A strains and two subtype B strains. It was approved by the FDA in February 2012 and was first available for the 2013–2014 flu season [45; 46]. All LAIV available in the United States for the 2017–2018 flu season will be the quadrivalent formulation [8]. FluMist, which is delivered intranasally, is licensed only for healthy, nonpregnant persons 2 to 17 years of age. Live vaccines are unsuitable for healthcare workers that care for immunocompromised patients [8].

However, LAIV (Flumist) is not recommended by the CDC and the ACIP and should not be used for the 2017–2018 flu season. Data from the 2015–2016 flu season showed a 3% overall efficacy rate (A and B viruses combined) of LAIV in children and adolescents (who were the primary recipients of the vaccine) compared to a 63% efficacy rate of inactivated influenza vaccine [8]. Department of Defense data also showed no significant protection from the FluMist vaccine in children 2 to 17 years of age, particularly against H1N1 and other A-type viruses, which were the most abundant circulating strains in the 2012–2013 and 2015–2016 seasons. Information provided to the CDC/ACIP by the manufacturer for the 2017–2018 season showed that this year’s formulation efficacy is expected to be similarly poor [8]. Patients (including children) who received LAIV for the 2017–2018 season should be revaccinated with any other available product at any time (as all other vaccines are inactivated) in order to achieve adequate protection against influenza [83].

**PROMOTING THE USE OF INFLUENZA VACCINE**

The Healthy People Year 2020 objectives are to [82]:

- Increase influenza vaccination levels to 90% or higher among high-risk groups
- Have 90% of residents in long-term care facilities receive the vaccine
- Increase influenza vaccination levels to 80% among healthy children and adults younger than 65 years of age

Among high-risk people 65 years of age and older, the overall influenza vaccination rate is 67%. However, people of color have much lower rates [36].

There are several other high-risk groups, discussed previously in this course, that fall far short of the 90% influenza immunization rate goal. According to data from the National Health Interview Survey, only 39% of high-risk people 18 to 64 years of age were immunized against influenza in 2008 [82]. Since 1999, in years without vaccine shortages, immunization levels have ranged between 63% to 66% for high-risk individuals [70; 87].

**FACTORS INFLUENCING INFLUENZA IMMUNIZATION**

One of the major factors influencing people with conditions that put them at high-risk for complications, hospitalization, and death from influenza is the misconception that the flu shot will give them the flu. This misconception is fueled by the fact that, in such a large cohort receiving the influenza immunization, a certain percentage will already be incubating the flu. When the symptoms of influenza appear one day or so after getting the shot, the natural assumption is that the illness came from the shot. Some take the opposite view that the flu shot will protect them against colds, so they are disappointed the “the flu shot didn’t work” when they get a cold [84].
Another factor is that patients rely on their physician’s advice. Unfortunately, physicians may not specifically suggest that their patients get the influenza vaccine. This leads the patient to think that it is not important or it would have been mentioned.

Cost may be a prohibitive factor for those too young for Medicare, which covers influenza and pneumococcal immunizations. Some people may assume that the influenza immunization is effective for several years. Others feel that a healthy person should not take anything, like a flu shot, that might make them sick. Some patients do not realize how effective the influenza vaccine is in preventing complications, hospitalizations, deaths, and actual influenza disease when the vaccine antigens correspond to the circulating antigens.

Probably one of the biggest factors affecting influenza immunization rates is the fact that influenza is so common—a true illustration of “familiarity breeds contempt.” Few are aware of the number of hospitalizations and deaths and the economic burden associated with influenza. Media attention focuses on deaths from SARS or other diseases while influenza kills far more each year.

**IMPROVING INFLUENZA VACCINE USAGE**

**Start Administration As Soon As Vaccine is Available**

Now that studies have shown that the immunity produced by the vaccine lasts several months, the ACIP recommends that influenza immunizations start as soon as the vaccine is available. Thus patients who are seen infrequently by their healthcare providers can receive the vaccine when they have an appointment and avoid a special visit just for the immunization. Providers should offer the vaccine to all patients, especially children 6 months to 8 years of age, as soon as they have a supply. The CDC also recommends that the offer of the vaccine and its refusal be documented in the patient’s medical record [8].

**The Role of the Healthcare Provider**

**What is the most effective way to increase the use of influenza vaccine?**

One of the major factors in increasing the number of administrations of influenza vaccine is the involvement of the medical practitioner providing care in a variety of settings, such as physicians’ offices, clinics, outpatient rehabilitation programs, or any place where there is contact between medical providers and their patients. To encourage practitioner involvement, providers should be informed of the reimbursement for the vaccine and its administration by Medicare and Medicaid and should be instructed as to billing methods, especially roster billing.

The majority of flu shots given are administrated by the person’s personal healthcare provider, and studies have shown that a healthcare provider's recommendation plays a critical role in a patient’s decision to get a seasonal flu vaccine [85]. As many as 75% of patients at high risk for influenza or for death from a complication of influenza have seen a healthcare provider in the last year. One of the most effective methods of encouraging a high-risk patient to receive the flu shot is a verbal recommendation from the patient’s physician [85].

To ensure that high-risk patients receive the recommendation, a variety of reminder techniques might be employed, such as placing stickers on the charts of high-risk patients, creating computer-generated lists of patients not scheduled to be seen, sending reminders via email or regular mail, and telephoning patients. Educational efforts by public health departments through media and personnel could encourage high-risk people to ask their healthcare provider for the flu shot [86]. Beginning in September, emergency rooms and walk-in clinics should display posters and educational materials about the need for the flu shot and either provide the vaccine or provide information about where it may be obtained [16].

Influenza immunization is also recommended for all people who have contact with high-risk populations. Obviously, this includes all healthcare professionals, a group for which the ACIP recommends annual influenza vaccination [8]. According to results of a survey conducted by the CDC among 2,258 self-selected healthcare personnel, 79% of survey participants reported having had an influenza vaccination for the 2015–2016 season, a significant increase from 67% during the 2011–2012 season [70; 87]. Vaccination coverage was highest among hospital-based healthcare personnel (91.2%) and lowest among healthcare personnel at long-term care facilities (69.2%). Coverage was also higher in occupational settings that offered no-cost, onsite vaccination for one or more days compared with settings that did not offer no-cost coverage. Vaccination coverage was 85.8% overall among healthcare personnel in all occupational settings who reported an employer mandate to receive vaccination [70; 87].

Immunization lowers worker absenteeism and transmission to vulnerable patients. Those who supervise or manage other healthcare personnel should set an example for their staff and patients by making sure to get a flu shot each year. It seems that those who have received the vaccine are more aware of the need to inform patients of the value of the flu shot, and their example is an encouragement.

As noted, LAIV should not be used to immunize contacts of severely immunocompromised patients unless no contact for seven days following receipt of LAIV can be assured [8]. There have been no reported instances in which a healthcare professional immunized with LAIV has transmitted influenza to a patient. Unvaccinated healthcare workers are more likely to transmit the virus [88]. To encourage more healthcare professionals and allied personnel to get the flu shot, it should be provided at the work site free of charge [16].
Standing Orders
Implementation of standing orders in acute care hospitals is another way to help increase influenza vaccine coverage. Patients who are hospitalized as flu season approaches, or during flu season, should have their records checked for chronic illness that is impacted by influenza and for influenza vaccine status. Those who have risk factors for complications and have not received the influenza immunization should receive the flu shot before discharge, as covered by the standing order. Such standing orders would have to be developed and implemented by the medical board of the hospital. All medical personnel connected with the hospital should be made aware of the standing order and reminded by posters or other means during influenza season. A study of Medicare patients hospitalized during flu season showed that only 31.6% had received the flu vaccine before admission, 1.9% during admission, and 10.6% after admission [43].

In long-term care facilities, there should be a standing order for each patient to receive a flu shot in October. When a patient is admitted to the facility, the attending medical professional and family member(s) should be informed of the standing order. If there is a reason that the patient should not receive the influenza vaccine, the physician can so order or the family member can so request. All residents should be immunized on the same day, if possible, before flu season. Those admitted after this day should receive the vaccine upon admission [43]. One study showed that only 62% of residents in nursing homes received influenza immunization in spite of its demonstrated effectiveness in preventing complications, hospitalization, and death in long-term care patients. Another study showed that if 80% or more of the residents in the facility were immunized against influenza, hospitalization from all causes was reduced regardless of the vaccination status of the individual resident [89]. As noted, another protective measure for residents of institutions is the care providers to receive an influenza immunization.

Home healthcare agencies should also have protocols in place to immunize patients under their care during the flu season and to inform the in-home caregivers of their need to be immunized. Staff members with patient contact should also be immunized [43].

All healthcare providers of patients in hospitals, long-term care facilities, and home health agencies should be aware that the Centers for Medicare and Medicaid Services has removed the physician signature requirement for the administration of influenza and pneumococcal vaccines to patients covered by Medicare and Medicaid [43].

The Role of Community Agencies
Religious meeting places are a point of contact for many groups. Patient education materials can be included in the organization’s bulletin. In some areas, the local public health department will provide an influenza immunization clinic in conjunction with a religious service.

Reminder posters and educational materials can also be displayed at banks, grocery stores, and community centers. These materials are available from the local public health department or on the CDC website. Organizations such as Lions, Kiwanis, Rotary, and the AARP, that are interested in controlling the cost of health care, should be enlisted to help encourage their friends and neighbors to be immunized against influenza.

Many public health departments provide influenza immunizations in community settings, such as churches, community centers, meetings of minority groups, airports, and malls—any place where a clinic can be temporarily set up. Some even provide “drive-up clinics” where the person does not need to get out of the car to receive the flu shot. These clinics are especially helpful for a person who cannot wait in line or walk easily.

OTHER METHODS TO PREVENT INFLUENZA
The primary and most effective way to prevent influenza is vaccination. However, in cases when antigens of the vaccine are not close enough to the circulating antigen, when there is a shortage of vaccine, or when a new strain has emerged and is circulating before the vaccine can be made and distributed, people will have to resort to other ways to protect themselves from infection.

HANDWASHING
Good handwashing is difficult to practice, is rarely known or taught, and is one of the single most effective ways to prevent transmission of many diseases, including influenza. Everyone knows to wash their hands before eating and after using the restroom. However, few do little more than remove obvious dirt. Good handwashing involves removing the skin oils where organisms can remain even when the hands look clean. A quick pass under the water faucet and fast dry with a towel removes visible dirt, but the oils and organisms remain.

To effectively remove the oils and organisms, the process should take at least 20 seconds (e.g., the amount of time that it takes to sing “Twinkle, Twinkle Little Star”). The hands should be soaped and rubbed vigorously for 15 seconds to create a good lather and to assure that all parts of each hand are soaped and rubbed well. Then the hands should be rinsed thoroughly and dried, preferably with a paper towel. The towel should be used to turn off the water and then properly thrown away. Such handwashing removes the oils that harbor the organisms, but 20 seconds can seem like a long time in the busy life of a healthcare provider. If there is no visible dirt or contamination, a waterless hand sanitizer with at least 60% alcohol can be used between patients.
However, nothing is as good as washing well with soap and water. Some mistakenly think that hot water must be used to kill the organisms. Water hot enough to kill organisms would be too hot to touch. Warm water mainly adds to comfort and hopefully encourages better washing technique. Careful attention to handwashing and cleansing may result in chapped skin, so the medical professional should find the proper lotions to care for his/her hands [90; 91].

**AVOID TOUCHING EYES, NOSE, OR MOUTH**
The eyes, nose, and mouth are entryways for bacteria and viruses. Everyone tends to unconsciously touch their eyes, nose, and mouth when going about their activities. Because organisms are not visible and hand washing is often less than adequate, infection occurs. Though difficult, the person trying to prevent illness should make a conscious effort to avoid touching his/her face [92].

**PROPER COVER FOR A COUGH OR SNEEZE**

What is appropriate cough etiquette?

Covering a cough or sneeze is of primary importance however it is done [93]. Ideally, disposable paper tissues will be readily available during cold and flu season and used to cover the nose and mouth when coughing or sneezing. Patients and children should be instructed that, when this is not possible, they should cough or sneeze into their upper sleeve or elbow instead of into their hands. This will avoid contaminating the hands with an offending virus or bacteria [93]. In those instances when coughs and sneezes are covered with only the bare hands, the hands should be cleaned with soap and water or with an alcohol-based hand sanitizer as soon as possible to prevent transfer of the organisms to another person. Coughing, sneezing, or blowing nasal secretions into a cloth handkerchief is not recommended as this results in creating a moist, viable culture that is then carried in the pocket or purse, potentially resulting in prolonged episodes of re-infection or transfer from cross-contamination.

**AVOID PEOPLE WITH RESPIRATORY SYMPTOMS**

During cold and flu season, trips to the store, school, church, and workplace bring contact with those who are coughing and sneezing. If at all possible, avoid close contact. This is an excellent time to consciously work on keeping your hands away from your face. Good handwashing should be done as soon as possible after contact with someone exhibiting symptoms of respiratory illness. Help the immune system to overcome the organisms by getting enough rest, drinking six to eight glasses of water per day, and eating fresh fruits and vegetables [94]. Healthcare providers can lessen the spread of influenza by utilizing proper cough etiquette, providing tissues and safe disposal, using rapid diagnostic tests and antiviral chemoprophylaxis for suspected flu in healthcare workers, and recommending that influenza sufferers stay home [95].

**ANTIVIRAL MEDICATIONS AS PREVENTION**

Antiviral medications can also be used to prevent influenza. Three of the four antiviral drugs used to treat illness due to influenza can also be used to prevent it, although this is complicated by growing resistance to available agents. Amantadine (Symmetrel) and rimantadine (Flumadine) have been approved for treatment and prevention, but both of these agents have also been associated with decreasing effectiveness due to viral resistance and are no longer recommended for these uses [45; 96; 97]. Oseltamivir (Tamiflu) is an effective treatment of uncomplicated acute illness due to influenza A and B viruses in adults and children older than 2 weeks of age, and it is approved as a preventive treatment in persons 1 year of age and older. In 2007, the Japanese Ministry of Health, Labor, and Welfare issued a warning that oseltamivir may cause psychiatric problems and suicide in patients 10 to 19 years of age [98]. This warning has been the subject of much controversy, and no such warning has been issued in the United States. Zanamivir (Relenza) is approved for prophylaxis in persons 5 years of age and older; ACIP recommends that prophylaxis with zanamivir be considered for individuals at high risk of influenza complications, for unvaccinated healthcare workers exposed to influenza, and for eligible residents of institutions that house high-risk patients when outbreak control is needed [45].

A physician’s order is required to obtain any of the antivirals. In the past, amantadine and rimantadine prevented influenza A illness 70% to 90% of the time [16]. However, the increasing incidence of amantadine- and rimantadine-resistant strains of influenza in the United States has made these medications less effective [96]. Therefore, they are no longer recommended for treatment or prophylaxis of circulating influenza A strains [45; 97].

Antiviral medications can make a person less contagious to others, so they are prescribed for contacts of people who are at high risk for complications from the flu. A subclinical infection may develop in a patient taking an antiviral. This allows the body to make antibodies against the virus. If any antiviral medication is to be totally effective, it must be taken as long as influenza is active in the community. Some studies indicate that taking an antiviral during peak influenza activity in a community is also effective. Of course, the less expensive single application vaccine is the best choice in preventing influenza in contacts of high-risk persons. However, in situations in which the individual has a hypersensitivity to one of components of the vaccine, or the needed two weeks to develop immunity are not available before contact, an antiviral medication can be used. Another reason to use an antiviral prophylaxis would be if the available vaccine does not match the circulating virus.
Antivirals are also used in closed environments, such as institutions or cruise ships, to control flu outbreaks. In such cases, it is best to combine the vaccine with an antiviral to provide protection for those exposed but who have not developed illness until the vaccine can stimulate the immune system to make protective antibodies. This also avoids the protracted use of the antiviral medication. The antiviral will not interfere with the antibody response elicited by the vaccine [3; 16; 99].

**ANTIVIRAL MEDICATIONS**

Which antiviral medications are approved to treat influenza A and B?

The antiviral medications zanamivir and oseltamivir are also used to treat acute illness due to influenza (Table 3). To be effective, any of these medications must be started within 48 hours of symptom onset. Generally, a course of one of these antivirals will reduce the illness by one to two days, prevent serious complications, and make the patient less contagious to others. These medications are effective only against influenza viruses and will not affect the common cold or other ILI of viral origin [16; 99; 100]. All require a prescription from a physician.

According to the Advisory Committee on Immunization Practices, antiviral treatment is recommended as early as possible for any patient with confirmed or suspected influenza who is hospitalized, is at higher risk for influenza complications, or has severe, complicated, or progressive illness. (https://guideline.gov/summaries/summary/25627. Last accessed October 25, 2016.)

**ZANAMIVIR**

Zanamivir belongs to the antiviral group of neuraminidase inhibitors. It is effective against both influenza A and B and was approved in 1999 to treat uncomplicated illness due to influenza virus in adults and children 7 years of age and older. The dosage is 10 mg twice daily by inhalation for five days. Doses should be 12 hours apart. It may also be used to prevent influenza virus in adults and children 5 years of age and older. The dosage is two 10-mg inhalations once daily for seven days after last known exposure [45; 101].

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### COMPARISON OF ANTIVIRALS USED IN INFLUENZA

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Zanamivir</th>
<th>Oseltamivir</th>
<th>Peramivir</th>
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<tbody>
<tr>
<td>Type of antiviral</td>
<td>Neuraminidase inhibitor</td>
<td>Neuraminidase inhibitor</td>
<td>Neuraminidase inhibitor</td>
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<tr>
<td>Effective for type</td>
<td>Influenza types A and B</td>
<td>Influenza types A and B</td>
<td>Influenza types A and B</td>
</tr>
<tr>
<td>Route of administration</td>
<td>Inhaled</td>
<td>Oral</td>
<td>IV</td>
</tr>
</tbody>
</table>
| Age that can receive     | Treatment: 7 years of age and older  
Prevention: 5 years of age and older | Treatment: 1 year of age and older  
Prevention: 13 years of age and older | Treatment: 18 years of age and older  
Prevention: NA |
| Action                   | Decrease symptoms           | Decrease symptoms         | Decrease symptoms          |
| Side effects             | Throat/tonsil pain, nasal symptoms, diarrhea, nausea, headache, cough | Nausea and vomiting | Diarrhea |
| Sold as                  | Relenza                     | Tamiflu                   | Rapivab                    |

*Peramivir efficacy is based on clinical trials in which the predominant influenza virus type was influenza A; a limited number of subjects infected with influenza B virus were enrolled.

**Level of Evidence**: Consensus Statement and/or Expert Opinion

**Source**: [45; 96; 97]  

Table 3
Zanamivir can lead to a decrease in respiratory function and bronchospasm. It is not recommended for patients with asthma, obstructive pulmonary disease, or other chronic lung diseases. More common (>10%) side effects include headache, throat/tonsil discomfort or pain, nasal signs and symptoms, and cough. Other effects that occur in less than 10% of patients include diarrhea, nausea, headache, dizziness, nasal infections, sinusitis, and bronchitis [45]. Some allergic responses of oropharyngeal or facial edema have also occurred [16; 22; 100; 102].

**OSEL TAMIVIR**

Oseltamivir also is a neuraminidase inhibitor and effective against both influenza A and B viruses. It is marketed as Tamiflu, which should not be confused with Theraflu. Like zanamivir, it was approved in 1999. It can be used as treatment in adults and children who have been symptomatic for no more than two days. The treatment dosing for adults and children 13 years of age and older is 75 mg twice daily. The treatment dosing for children younger than 13 year of age is weight dependent [101]:

- 3 mg twice daily for children aged 2 weeks to younger than one year
- 30 mg twice daily for children aged 1 year and older who weigh ≤15 kg
- 45 mg twice daily for children who weigh >15 kg and up to 23 kg
- 60 mg twice daily for children who weigh >23 and up to 40 kg
- 75 mg twice daily for children who weigh >40 kg

Oseltamivir can also be used as a preventive in anyone 1 year of age or older, but such usage should be rare [97]. The dose is 75 mg twice daily by mouth for adults and once daily for children and adolescents who weigh more than 40 kg (88 lbs.) [45]. Studies have shown that oseltamivir reduces the incidence of complications that may require antibiotics. Although the neuraminidase inhibitors promote a drug-resistant mutant of the virus, less resistance appears to occur with oseltamivir than with zanamivir. The reported side effects with oseltamivir are nausea and vomiting, which are lessened if the medication is taken with food [8; 16; 22; 100; 102].

Since 2005, some resistance to all of the antivirals has been documented. However, the 2009 H1N1 outbreak remained sensitive to oseltamivir except in a few cases [8]. Serious reactions to the four antiviral medications should be reported to the FDA MedWatch program.

**PERAMIVIR**

Approved in 2014, peramivir is a neuraminidase inhibitor for use in patients 18 years of age or older with acute uncomplicated influenza who have shown symptoms for no longer than two days [45; 97]. Peramivir injection preparation is a 200 mg/20 mL single-use vial, stored at 59 to 86 degrees F (15 to 30 degrees C). After being diluted, it should either be administered immediately or refrigerated and administered within 24 hours [159]. Peramivir is typically given in a single 600-mg dose; the dose should be adjusted based on renal function. The most common side effect is diarrhea (8%) [45]. An efficacy study showed that overall symptoms were relieved 21 hours sooner in participants given peramivir compared to those given placebo [32]. Efficacy studies have primarily been conducted in patients with A type influenza viruses, and it is effective for 2009 H1N1 [45; 159].

**AMANTADINE AND RIMANTADINE**

Amantadine was approved in 1966 as a treatment for uncomplicated respiratory tract illness caused by influenza. It belongs to a group of chemically related drugs called adamantanes (tricyclic amines) and is effective only against influenza A viruses. Rimantadine, approved in 1993, is also in the adamantanes group. Therefore, it is also only effective against influenza A. However, circulating influenza A (H3N2) and 2009 H1N1 viruses are resistant to adamantanes. As a result, these medications are no longer recommended for the treatment or prophylaxis of influenza A [45; 103].

**TREATMENT OF ACUTE ILLNESS RESULTING FROM INFLUENZA**

All treatment with either oseltamivir or zanamivir should begin within 48 hours of symptom onset to be effective [104]. In most individuals without underlying medical conditions, influenza is a self-limiting disease. Recovery usually occurs after one week, although fatigue and malaise may persist two or more weeks. The decision to use an antiviral is influenced by the type of work the patient does. In an epidemic or pandemic, persons providing critical services should be treated because shortening their absence by one or two days is important. For other personnel, the decision should be based on the comparison between the wages that would be lost and the cost of the medication [100]. If an outbreak of influenza occurs in an institution, antiviral medications should be used for both treatment and prophylaxis [104].

Some people may desire treatment because of upcoming plans or because they do not like to be sick. These individuals should be encouraged to obtain the annual influenza vaccine in the future, as disease that develops in spite of the vaccine is usually milder unless the vaccine strains do not match the circulating strains.
Antiviral treatment is recommended as soon as possible for patients with confirmed or suspected influenza who have severe, complicated, or progressive illness or who require hospitalization. It is also recommended for outpatients with confirmed or suspected influenza who are at higher risk for influenza complications on the basis of their age or underlying medical conditions [96; 104]. Antiviral treatment also may be considered on the basis of clinical judgment for any outpatient with confirmed or suspected influenza who does not have known risk factors for severe illness if treatment can be initiated within 48 hours of illness onset.

Pregnancy should not be considered a contraindication to the use of oseltamivir or zanamivir. Pregnant women are known to be at higher risk for complications from infection with seasonal influenza viruses, and if influenza is confirmed or suspected in these patients, it should be treated with oseltamivir or zanamivir; fever should be treated with acetaminophen [101]. Because antivirals have a potential but unknown risk during pregnancy, it is important to continue to vaccinate pregnant women. The seasonal flu shot has been given to pregnant women for many years without any harm to the women or their fetuses. Vaccines that contain thimerosal can be initiated within 48 hours of illness onset.

OBSERVATIONS INDICATING URGENT MEDICAL HELP IS NEEDED

By keeping a written record of observations, a patient’s subtle changes become more apparent, and the information will also help a physician. As discussed, there are many diseases that initially present like influenza or conditions that can be complicated by influenza; therefore, each person with influenza should be watched. The patient with influenza usually starts to improve after a few days. Patients and/or caregivers should be given a list of symptoms that indicate when a physician should be notified (Appendix 3). Any difficulty in breathing, a fever that is not responding to antipyretics, change in mental state, inability to maintain hydration, or worsening of symptoms should be reported to a physician, or the patient should be taken to the emergency room if a physician is unavailable.

The healthcare professional should review the following items with influenza patients or their family member(s), so a physician can be notified appropriately and promptly [105]:

- High or prolonged fever
- Breathing (fast or difficult with retractions in children, or cyanosis, labored breathing, shortness of breath, or pain or pressure in the chest in adults)
- Inadequate fluid intake (e.g., fewer wet diapers, darker urine)
- Changes in mental status (e.g., hard to arouse, confusion, too irritable to be comforted)
- Fainting or near-fainting, seizures
- Severe or persistent vomiting
- Worsening of a chronic disease
- Worsening of influenza symptoms, increasing weakness
- Any rash or jaundice
- Dry cough that becomes productive

CARE OF THE INFLUENZA PATIENT

AT HOME

What are important points in the care of the influenza patient?

Family members or friends should be located to care for the high-risk patient who lives alone. With enough community support (e.g., home health, neighbors, "Meals on Wheels"), a patient might be able to remain alone, but it would require careful planning and coordination among all involved. During an epidemic or a pandemic, it may be necessary to set up temporary facilities, such as a shelter for medically fragile patients, to provide care. A normally healthy adult living alone may only need help in the form of shopping.

Points in the care of the patient include: careful observation, providing symptomatic relief, help with activities of daily living, helping the patient remain hydrated, and emotional support (Appendix 1).

PREVENTIVE MEASURES FOR THE CAREGIVER

Attention should also be given to the person(s) caring for the influenza patient in the home to protect him/her from the disease. This would include influenza immunization, with or without an antiviral medication for two weeks, instruction on effective handwashing, wearing a mask when providing care or when the patient is coughing, getting adequate rest, consuming five to nine or more fruits, fruit juices, and vegetables each day, and drinking eight glasses of water every day (Appendix 2).

SELF-CARE

Of course, the most important aspect of self-care is obtaining the immunization. However, should one develop influenza and not be at high risk for complications, there are a few general steps to speed recovery and protect others [105]:

- Consider obtaining an antiviral if flu is in the first or second day of illness.
- Stay home to protect others from infection.
- Get plenty of rest.
- Drink plenty of liquids.
- Do not drink alcohol or use tobacco products.
- Consider over-the-counter medications to relieve the symptoms.
- Cover coughs and sneezes.
- Wash hands well and frequently, especially after coughing or sneezing.
THE INFLUENZA PATIENT IN THE HOSPITAL, MEDICAL OFFICE, OR CLINIC

Infection control procedures should be followed carefully as soon as any contact with an influenza patient occurs so that transmission can be prevented. In order to protect staff, posters prominently displayed or warning signs at the sign-in desk should request that the staff be informed if the patient has any respiratory symptoms.

Patient education posters about flu, the vaccine, and cough etiquette should be displayed in emergency rooms, waiting rooms, exam rooms, elevators, and other appropriate traffic areas used by patients and visitors. Messages should be brief but clear. Pictures could also be included for children who cannot read or for non-English speakers. All education materials should be provided in the major languages of the community.

As a result of the evolving racial and immigration demographics in the United States, interaction with patients for whom English is not a native language is inevitable. Because patient education is such a vital aspect of the prevention and treatment of influenza, it is each practitioner’s responsibility to ensure that information and instructions are explained in such a way that allows for patient understanding. When there is an obvious disconnect in the communication process between the practitioner and patient due to the patient’s lack of proficiency in the English language, an interpreter is required.

In this multicultural landscape, interpreters are a valuable resource to help bridge the communication and cultural gap between clients/patients and practitioners. Interpreters are more than passive agents who translate and transmit information back and forth from party to party. When they are enlisted and treated as part of the interdisciplinary clinical team, they serve as cultural brokers, who ultimately enhance the clinical encounter.

Educational materials might include:

- Cough etiquette
- Cover your cough.
- Use a tissue.
- Throw the tissue away in the wastebasket.
- Wash your hands.
- Tissues and wastebaskets should be easily accessed.
- Handwashing
- Use soap.
- Rub your hands well to make a good lather.
- Rub your hands for 15 seconds.
- Rinse well.
- Dry with a paper towel.
- Turn off water with a paper towel.
- Throw the paper towel in the wastebasket.

If no facilities to wash hands are available, alcohol-based hand cleaner should be available.

When influenza is present in the community, patients who are coughing should be given a mask and asked to sit in a separate area. If a separate area is not available, they should be at least 3 feet away from other people. Masks can be the surgical masks with ties or procedural masks with ear loops. They do not need to be respirator N95 masks.

Staff involved with patients who have respiratory symptoms with fever should follow droplet precautions as developed at their work place. For all patient contact, a mask (surgical or procedural) should be worn. Hands should be washed thoroughly following contact. During an epidemic, staff circulating between floors in the hospital should be limited [106].

AVIAN INFLUENZA

What elements are needed for an avian influenza pandemic to occur?

The influenza viruses that are carried by birds, both domesticated and wild, rarely have infected humans. This is partly due to the fact that avian influenza (AI) viruses attach to receptors found on bird cells but not found on human cells. Human viruses prefer the receptors found in the human respiratory tract. Pigs have receptors used by avian, swine, and human influenza viruses and have traditionally been the link between avian and human influenza viruses. Because pigs acquire all three types of viruses, reassortment/antigenic shift of the hemagglutinin and neuraminidase proteins occurs in the pig host, which then transmits the new strain to humans or other pigs [14; 107].

However, there now exists evidence that avian influenza can spread directly to humans [107]. In 2004, areas of Asia experienced large-scale outbreaks of avian influenza, specifically the H5N1 virus, in poultry. The virus went on to infect humans, with a high mortality rate. The number of countries, people, and animals affected by the virus reached unprecedented levels. In 2006, the CDC summarized the H5N1 outbreak. Wild birds and poultry had been infected in Asia, parts of Europe, the Middle East, and Africa. Human infections continued to be reported in China, Egypt, Indonesia, Azerbaijan, Cambodia, and Djibouti. There were some probable human-to-human transmissions of H5N1, but these were rare. As of October 2016, there had been more than 850 human cases of H5N1 since 2003, with a continued fatality rate of approximately 53% [108; 109]. In 2013, an outbreak of H7N9 virus in China spread to humans, with 14 reported infections and 6 deaths in the first two months [110]. Both the CDC and the WHO have reported that there is a strong threat of a future pandemic of avian influenza and that preparedness is vital [111; 112].
Although influenza A viruses can infect all birds, domestic poultry flocks are more vulnerable to infections that can reach epidemic proportions. Generally, domesticated fowl transmit the virus in saliva, nasal secretions, and feces. However, it is thought that the fecal-oral route is the common way the virus is spread among flocks. Wild birds rarely become sick but are a source of infection through their droppings because they carry the virus in their intestines. Free-roaming domestic fowl are at more risk from wild bird droppings than housed flocks. Both food and water supplies can be contaminated by droppings or sharing with wild birds. At first it was thought that wild birds spread the virus from farm to farm, but further study indicated that people and equipment probably spread the virus to domesticated flocks [113; 114].

AI viruses are classified as low pathogenic and high pathogenic based on their genetic sequence and the resulting illness in birds. Low pathogenic AI has been detected in wild birds, mostly ducks, geese, and gulls, since 1975 [115]. Low pathogenic AI virus causes only ruffled feathers and a reduction in egg production. Fortunately, most AI viruses are low pathogenic; however, in six to nine months, they can mutate to high pathogenic. High pathogenic AI viruses, first noted in 1878 in Italy, are highly contagious, spread rapidly, and are almost 100% fatal. Fowl can die the same day that they first exhibit symptoms [115; 116; 117].

Whenever an AI virus infects a human directly, there is much concern. Humans rarely have any immunity to AI viruses. Medical resources around the world quickly mobilize when there is a case of AI that skips reassortment in swine and directly infects a human. Fowl within a 2-mile (3-kilometer) radius of the source bird/flock are killed in order to contain the virus. An AI virus in humans usually produces upper respiratory disease and conjunctivitis. The infected humans and their contacts are watched closely for secondary transmission. For a pandemic to follow, these factors are needed:

- Humans do not have immunity to the virus
- Direct transmission from bird to human
- Sustainable transmission from human to human
- Movement of infected/contagious individuals to other geographic locations

Once a new pandemic influenza virus emerges, it generally circulates for many years [113; 116]. Researchers at the University of Wisconsin, Madison, have been combining H5N1 with a seasonal flu strain (H3N2). As a result, they have found such reassortment flu viruses are highly pathogenic; 22 were more pathogenic for mice than the original H5N1, and three caused extremely severe disease [118].

AVIAN INFLUENZA VIRUSES

The hemagglutinin antigens that historically have caused human influenza are H1, H2, and H3. Although all known hemagglutinin subtypes occur in birds, H5, H7, and H9 have been implicated more in recent outbreaks. Various combinations with the neuraminidase antigens occur. All of these AI viruses are type A, as B and C do not infect birds. Some of the cases focused on in the past decades have included the following [111; 119; 120; 125]:

- H5N1 – Hong Kong, 1997, first documented human infection–18 hospitalized, 6 deaths, 1.5 million chickens culled
- H9N2 – Hong Kong, 1999, 2 mild cases in children, several in mainland China
- H7N2 – Virginia, 2002, 4.7 million chickens and turkeys culled
- H7N7 – Netherlands, 2003, 80 poultry workers, 3 family members infected (79 eye infections, 6 influenza-like), one veterinarian death due to acute respiratory distress syndrome and complications
- H5N1 – Hong Kong/China, 2003, 2 ill, death
- H9N2 – Hong Kong, 2003, 1 case confirmed in a child
- H5N1 – Asia, 2004–2005 (H5N1 had been found in Asian chickens April, 2003), 112 confirmed cases, 57 deaths; too widespread to cull all fowl
- H7N3 – British Columbia, 2004, 2 ill
- H5N2 – Taiwan, 2004, low pathogenic, no human illness
- H7N2 – Delaware, 2004, no human illness
- H5N2 – Texas, 2004, no human illness
- H5N1 – Russia/Romania/Turkey/Azerbaijan/Egypt, 2006, some human illness, unknown deaths
- H7N9 – China, 2013–2017, 1,222 confirmed cases, 40% mortality rate

Fortunately, although in some of these outbreaks bird-to-human transmission did occur, human-to-human transmission has been extremely rare. Limited transmission possibly did occur between humans in the Netherlands, but no sustainable transmission occurred, so an epidemic or pandemic did not follow. There were 14 cases and 12 deaths (11 children) from H5N1 virus in Vietnam. The viruses isolated from those who expired in Vietnam were mostly resistant to amantadine and rimantadine. Studies are continuing as to the effectiveness of oseltamivir and zanamivir against H5N1 viruses. There is some evidence that the 2004 H5N1 virus in Asia is sensitive to oseltamivir [113; 114; 116; 121]. However, some evidence of resistance to oseltamivir has been reported in highly pathogenic avian influenza H5N1 viruses isolated from human cases [122]. Most of the 2004 H5N1 outbreaks were controlled by veterinarian officials or spontaneously died out. However, H5N1 continues to fulminate in poultry in Egypt [123].
**AVIAN INFLUENZA AND HUMANS**

Most cases of AI in humans have resulted from contact with infected poultry or contaminated surfaces. It is also possible for the virus to become aerosolized and then land on exposed surfaces of the mouth, nose, or eyes. Aerosolized virus could also be inhaled directly into the lungs. Eating poultry products has not been associated with the development of AI. Influenza viruses are destroyed by adequate heat. Because of the pathogens found in poultry, all patients should be reminded to cook all poultry, including eggs, thoroughly. Chicken should be cooked until the internal temperature reaches 180 degrees F. All utensils and surfaces that have come in contact with raw poultry should be washed well with soap and water immediately following use. A separate cutting board should be used to cut raw poultry. In order to retard bacterial or viral replication, all poultry products should be defrosted in the refrigerator, not at room temperature.

Some patients might become concerned about contaminated poultry products from other countries entering our food supply. Some countries will not permit poultry to be imported from countries in which there were detections of AI, such as China’s ban of U.S. chicken in 2015. However, the risk of AI spreading through the global chicken industry is low because most chickens on the international market are killed and frozen or chilled. All documented transmission to date has been from live birds [124; 125].

Humans have no immunity to AI viruses, so illness tends to be severe and the fatality rate high. Prevention is difficult because the viruses tend to be highly contagious. Because of the mobile nature of people and efficient, rapid transport, any virus can spread quickly around the world. The current manufacturing process of influenza vaccine requires several months. The elements are all in place for a pandemic.

In 2007, a team of scientists at the National Institute of Allergy and Infectious Diseases reported that it had developed a way to generate vaccines and therapeutic antibodies that could target constantly mutating influenza viruses, such as H5N1. The team focused on mutations that enable H5N1 hemagglutinin protein to better recognize and enter human cells and those mutations that will elicit antibodies. This information will enable researchers to consider how to design potential vaccines that will protect people from future emerging AI virus mutants, possibly helping to contain a pandemic in its early stages [126].

In order to understand how influenza viruses mutate, researchers have been working to synthesize the hemagglutinin responsible for the 1918 influenza (“Spanish flu”) pandemic. The success of this endeavor was reported in 2004, and scientists have since discovered how subtle alterations enabled the virus to move from birds to people [127]. The H5N2 avian influenza virus continues to be monitored around the world by scientists. It is highly virulent but has not been transmitted person to person yet [4; 112]. In 2015, H5N2 avian influenza virus (along with H5N8 and H5N1) were found in more than 200 bird samples, indicating the likelihood that 40 million farm and backyard birds have been infected in 20 states [48].

**PREVENTING OR LESSENING THE EFFECTS OF A PANDEMIC**

**Vaccine Development**

As with the development of all vaccines, the first step is to isolate the organism. In the case of AI, various research centers and companies around the world are working to make a vaccine. The first step is to isolate the virus (e.g., the H5N1 influenza A virus in 2004). Next, the virus is dismantled so the most virulent elements can be excluded. Then the virus is reassembled without those virulent elements, and attempts are made to produce it [124]. As noted, the virus has been isolated and the virulent elements have been identified to allow vaccine development to proceed. In 2006, a new recombinant H5N1 virus became available for distribution to companies interested in pandemic vaccine development [128]. In 2007, GlaxoSmithKline received a contract from the U.S. Department of Health and Human Services to manufacture 22.5 million doses of AI vaccine in addition to the 5 million doses ordered in 2006 [129]. Research to find novel media or methods (rather than using eggs) is ongoing [130].

In 2007, the FDA approved the first human vaccine for the AI virus H5N1 [131]. This vaccine is intended for individuals 18 to 64 years of age who could be at an increased risk of exposure to the H5N1 influenza virus. The vaccine is not available commercially, but rather has been purchased by the federal government to be distributed if necessary. The vaccine consists of two 1-mL IM doses given 21 to 35 days apart (optimum: 28 days). There is thimerosal in this vaccine [45; 131]. Because this vaccine has been approved by the FDA and found to be safe and effective, it is no longer considered experimental. Therefore, it can be used during a pandemic without the time-consuming protocol and signed informed consent necessary for an experimental drug or vaccine [131]. In 2013, the first adjuvanted H5N1 vaccine, Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted, was approved for individuals 18 year of age and older. The vaccine is not for commercial use, but at least 20 million doses are stocked at the Strategic National Stockpile for emergency release [53].
Antiviral Stockpile

Another plan is to gather a supply of effective antiviral medications to use not only to treat AI but also to use as a preventive treatment if a vaccine is not available. As discussed, some testing of the four antivirals available has been done with the H5N1 virus, which produced mass illness in Asia in 2004. So far, only oseltamivir was shown to be effective. More research is needed [114]. Some have suggested combining probenecid and oseltamivir to enhance effectiveness and to stretch limited oseltamivir supplies [132].

It is not known if other AI strains will be sensitive to oseltamivir or to any of the other antivirals. The suggestion has been made to stockpile antivirals so they would be available in a pandemic. Logically, it would make sense to include the effective antiviral medications in the Strategic National Stockpile and use the same distribution system and overall protocol in managing them [133].

Increased Interaction Between Veterinary and Human Disease Experts

Because of the rapid spread of avian influenza among flocks in Asia in the spring of 2004, the need for more involvement and communication between animal and human experts became apparent. No reporting of animal diseases is required by the WHO. However, the Global Early Warning System combines and coordinates the disease intelligence mechanisms of the United Nations Food and Agriculture Organization, the World Organization for Animal Health, and the WHO to provide the international community with information about the prediction, prevention, and control of animal disease threats [134]. In addition, the World Organization for Animal Health monitors avian influenza outbreaks in its member countries (including the United States) [28]. Human medical practitioners are not trained in the subtle indications of animal illnesses, nor are they usually aware of early indications that an epidemic is developing. Veterinary expertise is also needed to institute the best measures for containing the illness and limiting transmission not only to animals but to humans as well [135].

Travelers

During the outbreaks of AI in poultry in Asia during 2003–2004, people were not restricted from traveling to outbreak areas because of the limited transmission to humans. However, the following recommendations were sent to embassies and Americans living abroad [136]:

- Practice frequent and careful handwashing with soap and water or with a hand cleanser if soap and water are unavailable.
- Avoid bird markets and poultry yards where AI is most likely to be transmitted.

Travelers should be immunized with the current influenza vaccine against human influenza strains before traveling and should be reminded that winter (i.e., flu season) occurs in the Southern Hemisphere when the Northern Hemisphere is experiencing summer.

Limiting Introduction of Avian Influenza to Other Countries

The CDC has developed guidelines for airline personnel with a suspected case of AI on board an international flight originating in an area in which AI has been reported [137]:

- As much as possible, airline staffs are to keep the sick person separated from close contact with others.
- A surgical or procedural mask should be provided to limit the amount of droplets coughed into the air. If the passenger cannot wear the mask, anyone assisting him/her should be masked.
- Staff should teach the passenger cough etiquette if it is not being practiced.
- Disposable gloves are to be worn for any contact with body fluids, and hands are to be washed well when gloves are removed.

The captain is to report the illness to the nearest U.S. Quarantine Station if the aircraft is coming to the United States. The Quarantine Station will coordinate appropriate medical assistance when the plane lands and will notify the appropriate CDC staff.

In addition, general precautions of handwashing and covering coughs are, as always, important. Should flight personnel or ground staff become ill and believe they have been exposed to AI, they should notify their employer. If they are away from home, they should obtain local medical help. On any visit to a medical practitioner, they should inform the staff of the possible exposure to AI [137].

Limiting Continuing Disease and Transmission Among Fowl

The major way to limit disease and transmission among domesticated fowl is to destroy all diseased birds and their flockmates. Because the virus appears to be carried by people and machines, possibly on shoes and tires, to surrounding areas, the recommendation is that all fowl in a 2-mile (3-kilometer) radius of the diseased flock be culled. Obviously, no shipping of live poultry from the infected areas should occur.
Those culling the flocks are vulnerable to infection because they will be dealing with diseased birds, exposed to their feces, or inhaling dust/dirt contaminated with the feces. Therefore, cullers must have personal protective equipment: coveralls or a surgical gown with long sleeves and an impermeable apron, heavy duty rubber gloves or disposable nitrile or vinyl gloves, rubber boots or disposable shoe covers, N95 respirator masks, and safety goggles. Frequent effective handwashing is important. All cullers should have received the current influenza vaccine so they will not acquire the circulating influenza and provide an opportunity for reassortment with the AI strain. Cullers should be monitored by the local health department and be provided information on the ways to prevent infection. They should be instructed when to call the practitioner and to always tell the practitioner that they have been exposed to AI. Persons who are at high risk for complications from influenza should not be employed as cullers. Medical personnel who have contact with cullers should make sure that the cullers have received the current influenza vaccine, understand the symptoms of the flu, realize that eye infections are common, and understand the importance of following the protective guidelines, including how to effectively wash their hands. The CDC states that treatment with an antiviral may be considered for workers involved with culling flocks of known infected birds, but does not recommend routine use of chemoprophylaxis of workers involved in culling non-infected birds as a preventative measure [31; 138]. Whether personal protective equipment was used correctly, the type of exposure, and risk of complications from illness should be part of clinical decision making. Oseltamivir or zanamivir (one dose twice daily) is recommended versus the typical antiviral regimen (once daily dose) for exposed individuals who require chemoprophylaxis [31].

Those who dispose of the carcasses and those who are cleaning and disinfecting the environment where the flocks were housed are also at risk. The viruses can survive for varying periods of time, in some cases up to weeks or months, depending upon the temperature and humidity. For personal protection, those who dispose of the carcasses should follow the same recommendations as the cullers [31; 138].

All workers involved in eradication efforts should be monitored for respiratory symptoms, fever, and conjunctivitis for one week after the last involvement with the diseased birds or their environment. If they seek medical care, they should be instructed to tell the practitioner that they were working with birds that had AI. Other than seeing the practitioner, all symptomatic personnel should stay home until their temperature has been normal for 24 hours. To protect their families, they should cover all coughs and dispose of the tissues safely, wash their hands well, and try to limit any face-to-face contact with others [151].

In handling environmental cleanup, it is important to note that the virus is killed by heating to 56 degrees C (132.8 degrees F) for three hours or to 60 degrees C (140 degrees F) for 30 minutes. Formalin and iodine compounds will also kill AI. When the temperature is cool, the virus can survive for three months in contaminated manure. It can survive for four days at 22 degrees C (71.6 degrees F) in water and for more than 30 days at 0 degrees C (32 degrees F) [116].

The culling of millions of birds has an economic impact on the owners and countries in which the culling must be done. However, the more widespread the virus is in any country or countries, the more opportunity there is for transmission to humans. Each AI in a human increases the possibility that co-infection with a human influenza virus can occur leading to reassortment of the antigens and a new virulent influenza virus that can be transmitted person-to-person [116].

Limiting Transmission of Influenza by Medical Treatment

If a patient is known to have or suspected of having respiratory AI, he or she should be segregated in the waiting room, be provided with a surgical or procedural mask, be given tissues and a way to dispose them, and not be kept in the waiting room for an extended period.

A nasopharyngeal swab or aspirate should be collected and sent to the local public health laboratory. It is important to keep the local health authorities aware of any such suspected illness so that the full use of available resources can be made, if necessary. The specimen should then be forwarded to the state laboratory for reverse transcription-polymerase chain reaction (RT-PCR) for influenza A analysis and, if possible, for H1 and H3 analysis. Should the state not have the capacity to perform these tests, or if the tests are positive, the specimen should be sent to the CDC. Only a level 3+ laboratory should attempt to isolate the virus. Blood should be collected and stored locally for an acute (within one week of symptom onset) and convalescent (after three weeks of symptom onset) specimen to test for AI antibodies [38].

Medical practitioners should also be alert to ask all patients with respiratory symptoms and fever if they have traveled to any area in which AI is reported [139].

Increase Detection and Surveillance Systems

Early detection is another way to handle AI so that proper containment procedures can be initiated as soon as possible. As discussed, both the CDC and the WHO are working to increase surveillance in countries around the world [134; 140]. Hopefully, all countries will be able to detect and acknowledge the presence of a disease before it becomes widespread and the death toll escalates [116].
SWINE INFLUENZA

As discussed, pigs represent an important link in the interspecies transmission of influenza and in the creation of new virus types. In addition, swine influenza has the potential to cause significant disease in humans, although it is difficult to predict the potential impact of swine influenza in humans. Because most individuals, with the possible exception of those with regular contact with pigs, do not have immunity to these viruses, the potential for pandemic exists.

Swine influenza is usually caused by the H1N1 subtype, but other swine influenza A viruses do occur, including H1N2, H3N1, and H3N2 [141]. Although swine flu viruses do not normally infect humans, sporadic human infections have occurred. When this occurs, these viruses are called “variant viruses” and are denoted by adding the letter “v” to the virus subtype designation. Human infections with H1N1v, H3N2v, and H1N2v viruses have been detected in the United States [141]. Pigs may become infected with more than one virus subtype simultaneously; in these cases, genes from the viruses may mix and create a new “reassortment” virus [142]. The main swine influenza viruses circulating in U.S. pigs in the past decade include triple reassortant (tr) H1N1, trH3N2, and trH1N2 [141].

Among pigs, swine influenza is a highly contagious acute respiratory disease. In many countries, including the United States, swine populations are routinely vaccinated against the prevalent subtypes. Vaccination of pigs, while not sufficient to produce sterilizing immunity, can reduce the levels of virus shed by the animals and reduce the potential for human exposure and infection [143].

In 2009, an outbreak of H1N1 influenza A (hereafter referred to as 2009 H1N1), popularly referred to as the “swine flu,” occurred. Tests showed this virus was similar to influenza viruses normally occurring in pigs in North America. However, with more extensive testing, scientists learned that there were two genes present that typically occur in pigs in Europe and Asia. In addition, there were also avian and human genes. A quadruple reassortment virus was the result [11; 144].

It should be noted that the so-called Spanish Influenza of 1918–1919 was also an H1N1 virus. The hemagglutinin gene in 2009 H1N1 influenza apparently descended from the avian-origin 1918 pandemic influenza virus; however, laboratory testing showed that 2009 H1N1 did not have any 1918-like markers that had been associated with increased risk of severe disease, nor did it have genetic markers that were previously associated with high death rates in people infected with the avian influenza A (H5N1) virus in other countries [144].

The 2009 H1N1 virus was first detected in the United States in April 2009. Laboratory testing at the CDC confirmed infection with the virus in two patients, 8 and 10 years of age, who lived 130 miles apart, who had no contact with pigs, and who had no known connection to one another. Sporadic reports of human infection with North American-lineage swine influenza virus in the United States had been reported from December 2005 to January 2009, but the detection of infection in the two children raised concern that a novel swine-origin influenza virus had made its way into the human population and that human-to-human transmission of the virus had occurred. By September 2009, more than 99% of the circulating viruses were 2009 H1N1 [144].

The 2009 H1N1 virus was not a new subtype, but many humans had no pre-existing antibody to it (especially those younger than 65 years of age). The virus quickly spread worldwide, and on June 11, 2009, the WHO declared it a worldwide pandemic [144]. The 2009 H1N1 virus remained the predominant circulating virus for the entire 2009–2010 influenza season [11; 145]. On June 23, 2010, the public health emergency for 2009 H1N1 expired in the United States, and the WHO declared the pandemic over on August 10, 2010 [146].

Data from past pandemics show that influenza activity occurs in waves. A second wave of 2009 H1N1 occurred in the fall of 2010 and peaked in the first three weeks of October [8]. Experts believe that 2009 H1N1 will continue to circulate for some time as a typical winter flu, as it did extensively in 2012–2013 and 2015–2016. It is included in the formulation of the 2017–2018 vaccine [8].

TRANSMISSION

Like all flu viruses, 2009 H1N1 is mainly spread among people by coughing, sneezing, talking, and occasionally via fomites. It is not spread by food or by eating pork or pork products. There have been no cases acquired from influenza-contaminated drinking water. Chlorine treatment of drinking water has been shown to inactivate the highly pathogenic H5N1 virus, and H1N1 would be similarly affected. A documented case of influenza from any water exposure (drinking or recreational) has not occurred.

Pets, such as dogs, cats, and ferrets, can be infected with H1N1 from close contact with a sick human. All available information indicates that H1N1-infected dogs, cats, and ferrets do not transmit the illness to humans. So far, there is no H1N1 vaccine for animals. Most recover with supportive care [11].
When a swine influenza virus does become a source of widespread human illness, the transmission patterns change. Instead of being mainly limited to swine contact, the virus will spread by human-to-human contact. According to the CDC, available data indicate that the 2009 H1N1 virus is transmitted in ways similar to other influenza viruses, primarily via large-particle respiratory droplet transmission [92]. Because humans have little to no immunity to influenza viruses of swine origin, transmission may be common.

H1N1 survives on surfaces, including kitchen counters, door knobs, desk tops, and other fomites, for two to eight hours. Individuals can pick up the virus when they touch contaminated objects and unconsciously then touch their eyes, mouth, or nose. Thus it is vital for people to learn to keep their hands away from their mouths, eyes, and nose and to frequently wash their hands well with soap and water or use an alcohol-based hand sanitizer. An alcohol-based product, bleach solution, or hot, soapy water can be used to clean surfaces [148]. One positive result of the H1N1 pandemic, as indicated in a study conducted in Hong Kong, was that people were washing their hands more frequently and wearing face masks when having ILI or in public areas [149].

A major transmission concern with 2009 H1N1 was regarding newborns whose mothers had the virus. The CDC and State Health Departments strongly recommended vaccination for this population because of demonstrated risks to both infants and pregnant women. However, many disregarded the recommendation. It was then decided that infant and mother should be separated until the mother had been on antivirals for at least 48 hours, was afebrile for 24 hours without antipyretics, and could control her cough and respiratory secretions. Before visiting the infant, the mother was instructed to clean her hands well with soap and water or an alcohol-based hand sanitizer, wear a face mask, and observe respiratory/cough etiquette. If her gown had been contaminated with byproducts of coughing or sneezing, she was instructed to change to a fresh gown. Following these guidelines, the mother was then allowed to hold, feed, and care for the infant [8].

PREVENTION

Like seasonal influenza, vaccination is the most important preventive measure. Other common sense preventive steps (e.g., appropriate cough cover, correct disposal of used tissues, adequate rest, good fluid intake, staying home when ill) should also be practiced.

Vaccine

The CDC identified five groups who were given first priority vaccination [144; 150]:

- Pregnant women
- Persons who live with or provide care for infants younger than 6 months of age
- Healthcare and emergency medical services personnel
- Children and young adults 6 months to 24 years of age
- Persons 25 to 64 years of age at higher risk for influenza-related complications

The ACIP also recommended that local public health authorities and healthcare practitioners have flexibility to determine how quickly and when to expand vaccination to other groups [144]. The priority patients were vaccinated as soon as the vaccine was available. The CDC recommended that children younger than 10 years receive two doses of influenza vaccine [144]. For the 2017–2018 flu season, the ACIP recommends that children 6 months through 8 years of age who are receiving influenza vaccine for the first time be given two doses at least four weeks apart [8].

SYMPTOMS

Similar to seasonal flu, H1N1 symptoms include chills, fever, myalgia, fatigue, headache, cough, sore throat, and rhinitis. But unlike seasonal flu, there may be vomiting and diarrhea in some people. Others may have respiratory symptoms without fever [11; 152].

DIAGNOSIS

Unless it becomes a pandemic, swine influenza infection in humans generally goes undistinguished from typical human influenza as a result of the overlapping flu seasons and the relatively mild clinical presentation. The disease is diagnosed by analysis of a sputum sample collected in the first four to five days of illness, when an individual is most likely to be shedding the virus [153]. In June 2010, the FDA authorized the CDC Influenza 2009 A (H1N1)pdm Real-Time RT-PCR panel (IVD) to detect human infections with 2009 H1N1. This test replaced the previous real-time RT-PCR diagnostic test authorized by the FDA in April 2009, just as the WHO declared that a pandemic was imminent [144; 154]. There are now several RT-PCT and other molecular assays available to differentiate 2009 H1N1 [155].

In the case of the 2009 H1N1 virus, the CDC recommends that clinicians not routinely test for the virus when it is known to occur in the community, but that testing be prioritized in people who are hospitalized with suspected flu and in people for whom a diagnosis of flu would help their physician make decisions about their care [155]. As the 2009–2010 H1N1 epidemic progressed, it became apparent that those younger than 65 years of age were at greatest risk (Table 4) [8].
While most swine influenza cases were sufficiently mild to resolve spontaneously, antiviral medications were used if treatment was indicated. The specifically recommended agents were determined based on clinical and epidemiologic assessment of the virus. For example, in the case of the 2009 H1N1 outbreak in North America, the virus’s susceptibility profile indicated that the preferred antivirals would be oseltamivir or zanamivir [156].

During the 2009–2010 H1N1 pandemic, the CDC recommended antiviral treatment for all persons with suspected or confirmed influenza requiring hospitalization [145]. In addition, early empiric treatment with oseltamivir or zanamivir was considered for persons with suspected or confirmed influenza who were at higher risk for complications, including [145]:

- Children younger than 2 years of age
- Persons 65 years of age or older
- Pregnant women and women up to two weeks postpartum (including following pregnancy loss)
- Persons of any age with certain chronic medical or immunosuppressive conditions
- Persons younger than 19 years of age who are receiving long-term aspirin therapy

The recommended treatment for adult and adolescent patients was either 75 mg oseltamivir twice per day or 10 mg (two 5-mg inhalations) of zanamivir twice daily [45; 145]. Children 7 years of age and older may be treated with the adult dose of zanamivir. However, calculating oseltamivir doses for children is more complicated and has been the source of medical errors [157]. It is important to note that while healthcare providers in the United States generally write prescriptions for liquid medications in milliliters, oseltamivir is dosed in milligrams [157]. For infants 2 weeks of age or older, the oseltamivir dosage is 3 mg/kg twice daily [45]. For children between 1 and 12 years of age, dosage is based on weight [45; 145]:

- <15 kg (<33 lbs.): 30 mg twice daily
- >15 kg to 23 kg (>34 lbs. to 51 lbs.): 45 mg twice daily
- >23 kg to 40 kg (>51 lbs. to 88 lbs.): 60 mg twice daily
- >40 kg (>88 lbs.): 75 mg twice daily

Treatment should continue for five days [45]. Pregnancy is not considered a contraindication to the use of oseltamivir or zanamivir.

As of 2015, 2009 H1N1 was susceptible to both oseltamivir and zanamivir, with a few exceptions [96; 103]. Those resistant to oseltamivir have been sensitive to zanamivir. Sporadic oseltamivir-resistant 2009 H1N1 virus infections have been identified, but the public health impact has been limited [103]. As of 2015, no evidence existed of ongoing transmission of oseltamivir-resistant 2009 H1N1 virus strains worldwide [103].

**INVESTIGATIONAL DRUGS**

A study at Utah State University examined the use of oseltamivir combined with T-705 (favipiravir), an antiviral in late-stage development by Toyama Chemical of Japan, on mice [158; 160]. This combination was effective against H1N1, N3N2, and H5N1 influenzas. The study indicated that two antivirals may be a better strategy for treatment of humans with influenza. Favipiravir is a viral RNA polymerase inhibitor with a novel mechanism of action, inhibiting viral gene replication within infected cells to prevent their propagation [160].

### DISTRIBUTION OF 2009 H1N1 AND SEASONAL INFLUENZA BY AGE GROUP

<table>
<thead>
<tr>
<th>Influenza Type</th>
<th>0 to 17 Years</th>
<th>18 to 64 Years</th>
<th>0 to 64 Years</th>
<th>65 Years and Older</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cases</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2009 H1N1</td>
<td>33%</td>
<td>57%</td>
<td>90%</td>
<td>10%</td>
</tr>
<tr>
<td>Seasonal</td>
<td>—</td>
<td>—</td>
<td>&lt;10%</td>
<td>90%</td>
</tr>
<tr>
<td><strong>Hospitalizations</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2009 H1N1</td>
<td>32%</td>
<td>58%</td>
<td>90%</td>
<td>10%</td>
</tr>
<tr>
<td>Seasonal</td>
<td>—</td>
<td>—</td>
<td>40%</td>
<td>60%</td>
</tr>
<tr>
<td><strong>Deaths</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2009 H1N1</td>
<td>10%</td>
<td>77%</td>
<td>87%</td>
<td>13%</td>
</tr>
<tr>
<td>Seasonal</td>
<td>—</td>
<td>—</td>
<td>10%</td>
<td>90%</td>
</tr>
</tbody>
</table>

Source: [8; 150]  

Table 4
INFLUENZA PANDEMIC

Should methods for containment of a new avian or swine influenza virus fail, a worldwide epidemic or pandemic could follow. Because the population has no immunity to the new strain, millions of people could be infected and several million could die. The 1918 pandemic afflicted 20% to 40% of the world's population and caused 50 million deaths, at least 675,000 of which were in the United States [161]. As a comparison, “seasonal” flu generally affects less than 20% of the population [162]. The WHO estimates that there would be 233 million outpatient visits, 5.2 million hospitalizations, and 7.4 million deaths globally within a very short period of time were a pandemic to occur [163]. Waves of the outbreak could occur in any given community for approximately six to eight weeks, then reoccur months later, affecting the global population for one to two years [161]. The resulting strain on resources would be far more severe than a terrorist attack that is localized to one or a few areas and lasting from a few minutes to hours. However, planning for a bioterrorist attack and an influenza pandemic have many similarities, and each can enhance the other [164].

As became clear in 2009, the government has decided that it will not close our borders if pandemic flu occurs elsewhere. Challenges to closing the borders are numerous, and the disease will inevitably infect the United States regardless of border closures. In the event of a pandemic, attempts will be made to limit those who might be infected from entering the country [165].

Medical practitioners, emergency departments, and clinics, especially walk-in facilities, will be the first contacts in a pandemic. Having a high index of suspicion is vital to help slow the spread of the disease. Checking the CDC weekly influenza reports will help to clarify suspicions [166]. Experience during the 2004 SARS outbreak in Toronto showed that, once SARS was recognized, infection control measures worked well to protect the medical community and facilities. The public health infrastructure was active, strong, and responsive, ensuring that public health in a major urban center was also protected [167].

The WHO has defined phases for a pandemic that reflect a global risk assessment of each influenza virus with pandemic potential [168]:

- **Interpandemic phase:** The period between influenza pandemics
- **Alert phase:** Influenza caused by a new subtype has been identified in humans, and the population has little or no immunity to the virus. This may be a precursor to a pandemic.
- **Pandemic phase:** A period of global spread of human influenza caused by a new subtype with sustained person-to-person transmission. Multiple cases occur in the same geographic area.
- **Transition phase:** As assessed global risk reduces, de-escalation of global actions may occur, and reduction in response activities may be appropriate.

The CDC has developed guidelines for public response in a pandemic situation. These stress that people should stay away from crowds, avoid close contact with anyone at work or school, stay home if they or anyone in the household is sick, wash hands frequently, practice covering all coughs and sneezes, and dispose of tissues safely.

Many people think they will be protected in a crowd if they wear a mask, but there is little scientific data proving that masks protect against the flu. Industrial masks/N95 respirators should be considered for caregivers. N95 masks must fit closely (no air leaks) to be effective. Masks that become damp or wet cease to be protective. Proper disposal of a mask is imperative, as it has the potential to become a source of infection rather than protection [106; 169].

**PLANNING FOR A PANDEMIC**

In planning for the inevitable pandemic, five areas should be covered. These include: surveillance and laboratory issues, communication, community services, medical care, and vaccines and drugs. In September 2006, the California Department of Health Services developed the Pandemic Influenza Preparedness and Response Plan [170]. The plan was then revised in 2007. The 2007 plan includes sections on pandemic influenza surveillance and epidemiology, laboratory testing capacity, healthcare planning, infection control in the healthcare setting, case management, vaccine programs, antiviral drug programs, community disease control and prevention, and risk communication. These sections cover the responsibilities of the medical community (health practitioners, hospitals, and clinics) and public health departments and include prevention and mitigation plans [170].

**Surveillance and Laboratory Issues**

This area includes establishing global and local data collection systems in order to determine expected disease rates in humans and animals so that an increase is recognized as quickly as possible. It also includes developing laboratory infrastructure and expertise to handle specimens correctly and accurately. The CDC is a WHO Collaborating Center that plays a major role in identifying antigenically drifted seasonal and novel influenza A viruses that possibly have pandemic potential [171]. The CDC's Influenza Division conducts surveillance throughout the year and collects and analyzes influenza viruses from around the world for antigenic (immune response), antiviral susceptibility, epidemiology, and genetic characterizations.
Communication
The second planning area is communication among all those who will be involved in a response on local, state, and federal levels. The Federal Emergency Management Agency requires that all planning for various hazards/disasters/terrorist acts follow the Incident Command System (ICS) [172]. This system provides a structure for the flow of information to the participants providing the response and back to those in authority. An influenza pandemic would require multiple agencies, organizations, and community groups to effectively respond, so in many areas, they would be under the local ICS.

In addition, communication includes relaying accurate, frequent, concise, and timely information to the public by a primary spokesperson. Health experts should use interactions with media personnel to provide educational points about the transmission, prevention, and symptoms of influenza. Such points, referred to as “sound bites,” are brief, accurate, in common language, and important.

Another area of communication is between individual healthcare providers and patients. Having patient educational materials prepared before the flu season will assist patients to remember what they have been told and increase their participation in preventing the flu, as well as caring for themselves or someone else with the flu. The U.S. Chamber of Commerce has also developed a pamphlet for business owners that lists steps that can be taken to protect employees and to help keep businesses operating in the case of an outbreak [173].

Community Services
One of the facets of a pandemic is the social disruption caused by the illness of so many employees. Therefore, the third area in any preparedness plan is maintenance of community services from healthcare providers, ambulance personnel, police, fire fighters, utility workers, and truck drivers—all the services that are called on daily to maintain life in our communities. This may involve providing vaccine first to healthcare professionals and those responsible for essential services in the community. Some services and work may be done via telecommuting so that more people can stay at home and lessen their exposure to the influenza virus.

Medical Care
Medical care is the fourth area that will be heavily impacted in a pandemic. The local health officer in most jurisdictions has the legal authority to isolate those with symptoms and quarantine those who have been exposed, as needed, to slow the spread of the disease. Equipment and care may have to be prioritized. In a pandemic, multiple geographic areas are impacted, so obtaining help from another area probably will not be possible. Some hospitals, health departments, and other medical facilities are developing lists of physicians and nurses who are either retired or no longer practicing but who would be available to assist during a crisis if needed [174].

Starting in the 2000–2001 flu season, Ontario, Canada, offered influenza vaccine to all its residents to lessen the impact on hospitals. This universal vaccination program reduced the number of cases by 61% and influenza mortality by 28% [8].

If all available hospital beds in the area are in use, it may be necessary to set up a shelter for medically fragile people. Local health departments have plans and agreements with the American Red Cross and other organizations to establish shelters. Normally, these shelters are for people who have been displaced/evacuated because of a natural event (e.g., fire, flood, earthquake). A shelter for medically fragile people has additional equipment and staffing needs. Such a shelter would be for people who require help with medical treatment, such as wound care, medications, and IVs. People who are too sick to care for themselves and who have no one to care for them would be appropriate referrals for a medically fragile shelter [175].

Vaccines and Drugs
The final area to be addressed is the supply and delivery of vaccines and drugs. The objectives of planning are to reduce morbidity and mortality, make sure essential services are available, reduce the economic impact, and equitably distribute the resources [164]. Those with high risk of complications from the flu are generally the first to receive the vaccine if a shortage is anticipated or production is slow. In a pandemic, the decision may be made that healthcare professionals and others providing essential services would be the first recipients of vaccine. Because the vaccine would be completely new to a person’s immune system, two doses 30 days apart may be needed to produce immunity, as is the current practice for children 6 months through 8 years of age receiving influenza vaccine for the first time [8].

Nonpharmacologic Interventions
During the influenza pandemic in 1918, large public gatherings continued to be permitted in some areas, most notably in Philadelphia, which served to spread the epidemic and led to a death rate of 719 per 100,000. Cities that had enforced a shutdown of schools, churches, and other gatherings slowed the spread and experienced a death rate of 347 per 100,000. Quarantine, school closings, and public meeting bans cut peak death rates 30% to 50% [176].
In 2007, the federal government established that, in the case of a severe influenza outbreak, schools should be closed for up to three months; sports events, movies, church, and other public gatherings and events should be canceled; working hours should be staggered to decrease the number of commuters using public transportation at any one time; and the use of public transport should be discouraged [177]. Sick people and their families, even healthy members, should stay home 7 to 10 days. Issues of other gathering places, such as daycare centers and malls, will also need to be addressed. Parents should prevent their children from gathering. Measures of isolation (isolating ill patients) and quarantine (isolating exposed persons) should be used to slow the spread of influenza [178]. State borders and airports would not be closed because of the need to transport food and other supplies [177; 178].

In New York City, the plan emphasizes the importance of early detection. A monitoring system that tracks 60,000 pieces of information (e.g., ambulance runs, emergency room visits, pharmacy sales) has been developed [179].

A cooperative research project between Azusa Pacific University in California and National Chung Sing University in Taiwan is researching traditional Chinese herbal treatments and their effects on influenza virus subunits to develop alternative treatments, especially for countries in which vaccines or pharmaceutical treatments will be unavailable in a pandemic [180].

### CHALLENGES OF A PANDEMIC

For medical care providers, an influenza epidemic presents many challenges. These would be compounded by the increased number of cases in a pandemic. A group in Los Angeles studied the impact on emergency departments and outpatient facilities during seven influenza epidemics. Some of the lessons learned in order to better cope with an increased number of patients were that [147]:

- Elective surgery should be reduced or eliminated.
- Facilities should work with licensing agencies, fire marshals, and other regulators to relax staff-patient ratios and/or bed capacity limitations.
- Additional staff resources for epidemics should be developed.
- Walk-in influenza clinics should be established to triage and treat patients at lower cost.
- Methods to identify additional needed equipment should be developed.

During the SARS outbreak, nurses at Stanford University Medical Center set up receiving areas to prescreen hundreds of patients before they entered the emergency department. Those with ILI were diverted to negative pressure rooms for further testing. Screening questions were used to triage the patients [147]. Table 5 provides a list of questions that could be asked of patients to elicit extra information that may assist in a more rapid diagnosis. These questions should be asked in the receiving area of the hospital, clinic, or office in order to minimize the introduction of highly contagious organisms.

<table>
<thead>
<tr>
<th>ASSESSMENT OF A PATIENT WITH INFLUENZA-LIKE ILLNESS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is this the time of year when influenza is expected?</td>
</tr>
<tr>
<td>2. Has the patient done any traveling in the last 10 days? If yes, find out where so the practitioner can relate to any known SARS, avian flu, or other outbreaks in the area. Did the patient travel in an airplane or on a cruise ship?</td>
</tr>
<tr>
<td>3. Can the patient pinpoint an exact time when the illness began?</td>
</tr>
<tr>
<td>4. Has the patient had any recent contact with any farm animals, such as pigs, cows, chickens, turkeys, ducks, or other birds?</td>
</tr>
<tr>
<td>5. In the last few days, has the patient been around anyone who is sick? If yes, find out who was sick, type of contact, when it was, and symptoms of the person who was sick.</td>
</tr>
<tr>
<td>6. Is the patient getting sicker or feeling just as bad as when he or she first became ill? Or perhaps feeling a bit better?</td>
</tr>
<tr>
<td>7. Has the patient been in any place in the mountains? Did he or she notice any signs warning about plague? What did the patient do there—camp, hike, etc.?</td>
</tr>
<tr>
<td>8. Has the patient consumed any raw/unpasteurized milk in the last month?</td>
</tr>
<tr>
<td>9. If ricin toxin is suspected, find out the patient’s activities in the last 24 hours.</td>
</tr>
</tbody>
</table>

When asking a patient or family member when a symptom began, or other information that depends on recalling one’s activities, it is helpful to have a calendar and to refer any symptom to some event that would be easily remembered; for example, “Your sister visited on Tuesday. Did you have the fever then?”

**Table 5**

Source: Author
This receiving area would also be a place where educational materials could be provided for the “worried well.” In an office situation, it might be possible to set up a small table outside the office door to screen patients and distribute masks and educational materials. Some public health department plans include supplying public health staff to emergency rooms to help answer questions and educate the worried well, allowing the hospital staff to assist in the care of those critically ill.

**CONCLUSION**

Influenza, with its complication, pneumonia, is the only infectious disease that remains one of the top 10 killers in the United States. An effective vaccine to prevent influenza has been available for decades but is underused by both the general public and healthcare professionals. As a result, the economic burden of influenza is billions of dollars, including the inefficient use of healthcare resources.

The threat of biologic weapons has made the control of influenza imperative as many of the possible biologic agents initially may be misdiagnosed as influenza because of similar symptoms. Added to the perils facing the world is the expected pandemic of influenza as the result of the introduction of an avian or swine influenza virus to which humans have no immunity.

**GLOSSARY OF TERMS**

**Antigenic drift:** Change in an influenza virus that allows it to resist the immunity developed against it. Antigenic drift is a factor behind the need for an annual influenza vaccine.

**Antigenic shift:** Reassortment of RNA segments involving hemagglutinin and neuraminidase antigens from two different influenza A types in one host cell to create a new influenza type.

**Antiviral:** A medication that will kill or weaken a virus.

**Avian, or bird, influenza (AI):** Influenza caused by viruses that occur naturally among wild birds. The low pathogenic variety is common in birds and causes few problems. High pathogenic AI is deadly to domestic fowl and may be transmitted to humans, resulting in high morbidity and mortality rates due to lack of immunity.

**Case definition:** A standardized precise description of a disease to assist in accurate data collection. Generally, there are 3 levels in a case definition: suspect, probable, and confirmed. Description for each level is particular to the disease being defined based on clinical symptoms and laboratory findings.

**Epidemic:** An increase in the expected number of cases of a particular disease. The amount of increase needed to declare an epidemic depends upon the disease involved.

**Hemagglutinin:** A surface antigen on the influenza A virus indicated in the name of the virus by a capital H followed by the subtype number.

**Influenza:** Respiratory illness with fever.

**Isolation:** Separation of a person with a contagious disease from the public.

**Neuraminidase:** A surface antigen on the influenza A virus indicated in the name of the virus by a capital N followed by the subtype number.

**Quarantine:** Restriction of a well person who has been exposed to a known infectious organism.

**Pandemic:** Epidemic of a disease that is worldwide.

**Split virus:** Chemical alteration of a virus for use in a vaccine. All influenza vaccine in the United States is split virus.

**RESOURCES**

- **Association for Professionals in Infection Control and Epidemiology**
  [http://www.apic.org](http://www.apic.org)
- **Association of State and Territorial Health Officials**
  [http://www.astho.org](http://www.astho.org)
- **Centers for Disease Control and Prevention**
  [http://www.cdc.gov/flu](http://www.cdc.gov/flu)
  [http://www.cdc.gov/vaccines](http://www.cdc.gov/vaccines)
  [http://www.cdc.gov/flu/weekly/fluactivitysurv.htm](http://www.cdc.gov/flu/weekly/fluactivitysurv.htm)
- **National Institute of Allergy and Infectious Diseases**
- **U.S. Food and Drug Administration**
  [http://www.fda.gov](http://www.fda.gov)
- **U.S. Food and Drug Administration/MedWatch**
- **Vaccine Adverse Event Reporting System**
  [https://vaers.hhs.gov](https://vaers.hhs.gov)
- **World Health Organization Global Influenza Programme**
  [http://www.who.int/influenza/en](http://www.who.int/influenza/en)
APPENDIX 1

HOME CARE OF AN INFLUENZA PATIENT

1. Monitor the patient for improvement or worsening of symptoms. Write down the date and time of all observations: temperature, coughing, sneezing, amount the patient has had to drink and eat.

2. Supportive care
   - Over-the-counter medicines that bring fever down (no aspirin in anyone younger than 8 years of age)
   - Pain relievers (e.g., medications, carefully monitored heating pads)
   - Back or leg rubs
   - Cough medications, as ordered and needed
   - Cool cloth to the head
   - Limited light in the room
   - An encouraging, positive, but not overly exuberant attitude

3. Maintain the patient's fluid intake with water, juices, popsicles, ice cubes, tea, coffee, or broths. Milk may be appealing to some patients.

4. Provide any foods that are appealing to the patient. However, fluid intake is more critical than solid food intake.

5. Provide tissues and a disposal place that the patient can reach, such as a wastebasket or paper bag pinned to the bed.

6. Assist the patient to the bathroom, if needed.

7. Continue any routine medications, if possible. Check with the physician if the patient cannot take or vomits the medications or if the medication needs to be taken with food and the patient is not eating.

8. Persons on insulin should have their blood sugar carefully monitored. Blood sugar may go up because of the disease process or go down because of poor food intake.

9. Keep the patient oriented as to time of day and date by telling him/her the time (and day, if needed) whenever they awake. Napping can lead to disorientation, especially in the elderly patient. Some patients may also need to be reminded where they are.

10. Provide a way for the patient to summon help, such as a bell, whistle, or some other method.

Source: Author
APPENDIX 2

CARING FOR YOURSELF TO PREVENT THE FLU

1. Get the flu shot.
2. Wash your hands frequently. Use soap, make a good lather, rub lather all over your hands for 15 seconds, rinse well, and dry with a paper towel or with your own towel at home. The process should take at least 20 seconds and should be completed:
   • After shaking hands
   • After being around someone who is coughing/sneezing
   • After caring for someone who is sick
   • As soon as you get home
3. Avoid touching your mouth, nose, or eyes.
4. Wear a mask when you take care of someone with the flu.
5. Get seven to eight hours rest in 24 hours.
6. Drink at least six to eight glasses of water each day. Sodas do not count. If one is tiring of water, putting it in a colored glass may help. Also, room temperature water is easier to drink in quantities than cold water.
7. Eat at least five or more servings of fruits and vegetables each day.
8. If caring for someone, get away from the house for a period of time each day, even just to go to the store or take a walk.
9. Avoid alcohol and tobacco.

Source: Author
APPENDIX 3

WHEN TO CALL THE DOCTOR

Phone Number _______________________

Usually the person with the flu gets very sick suddenly, stays very sick for a few days, and then starts to feel better. The flu can cause other problems. Below is a list of symptoms and signs that indicate that a person needs help from a physician.

As you take care of the person, write down the date and time when you take the temperature or notice a new sign or symptom. If you are having trouble getting the patient to drink fluids, write down the time the person had a drink and how much they drank. The following signs should be reported to a physician immediately.

**Fever**

The temperature stays above 102 degrees F in spite of the person taking medicine to bring the fever down.

(Never give aspirin to anyone younger than 18 years of age.)

**Breathing**

The person says or looks like he or she is having trouble breathing. The person is short of breath. The child is breathing very fast. The chest between the ribs or above the collar bone retracts when the child takes a breath. The person, especially if a child, looks a little blue.

**Fluids**

The person will not drink water, juice, or any fluid or suck popsicles or ice. The infant has less than 6 wet diapers in 24 hours. The urine is very dark and there is not much of it. If the skin on the forearm is pinched up, it slowly returns to normal. The eyes are sunken in and the mouth is dry. The person keeps vomiting or retching.

**Changes in Mental State**

The person is hard to wake up. No matter what you try, the child/infant cannot be comforted. The person is confused or seeing things. The person has fainted or nearly fainted. The person has a convulsion.

**Change in Condition**

Any worsening of the flu symptoms, as individuals with the flu will start to feel better after three to five days.

Any worsening of any health problem (e.g., chest pain, swelling of the feet).

**Rash**

May indicate an allergy to a medicine or a disease other than the flu.

*Source: Author*
## POSTOPERATIVE COMPLICATIONS
### #30762 • 15 ANCC Hours / 1 PHArm Hour
**By Mail – $66 • Online/eBook – $60**

**Purpose:** The purpose of this course is to provide nurses and all allied health professionals who care for postsurgical patients the knowledge necessary to recognize and manage common postoperative complications, improving patient care and outcomes.

**Faculty:** Susan Engman Lazear, RN, MN

**Audience:** This course is designed for all nurses and allied professionals involved in the care of patients who undergo surgical procedures, especially those who work in the preoperative area, the operating room, or the postanesthesia unit in hospitals or free-standing surgical centers.

**Additional Approval:** AACN Synergy CERP Category A, CCMC

## OSHA AND HEALTHCARE FACILITIES
### #31232 • 5 ANCC Hours
**By Mail – $26 • Online/eBook – $20**

**Purpose:** The purpose of this course is to provide information that will allow facilities to more easily comply with the broad spectrum of rules covered by the OSHA regulations.

**Faculty:** Carol Shenold, RN, ICP

**Audience:** This course is designed for healthcare staff in all specialties.

**Additional Approval:** AACN Synergy CERP Category B

## NEWBORN ASSESSMENT
### #32262 • 10 ANCC Hours
**By Mail – $46 • Online/eBook – $40**

**Purpose:** The purpose of this course is to provide an overview of a newborn assessment for all nurses, especially those who either presently care for newborns or those who come in contact with them occasionally.

**Faculty:** Nicole F. Keehn, RN, MSN, PsyD; Katrina Lieben, MSN, CNM

**Audience:** This course is designed for all medical-surgical nurses and ancillary nursing personnel involved in the assessment of newborns.

**Additional Approval:** AACN Synergy CERP Category A

## DIABETIC HYPOGLYCEMIA
### #34652 • 5 ANCC / 5 PHArm Hours
**By Mail – $26 • Online/eBook – $20**

**Purpose:** The purpose of this course is to provide nurses and healthcare professionals with a foundation of understanding hypoglycemia in order to assure the highest quality of care is provided to patients.

**Faculty:** Diane Thompson, RN, MSN, CDE, CLNC

**Audience:** This course is designed for nurses in any healthcare venue and dietitians with a desire to better understand the causes, recognition, and treatment of hypoglycemia in a variety of settings.

**Additional Approval:** AACN Synergy CERP Category A, CCMC

## DIABETES PHARMACOLOGY
### #35322 • 10 ANCC / 10 PHArm Hours
**By Mail – $46 • Online/eBook – $40**

**Purpose:** The purpose of this course is to meet the needs of nursing professionals seeking a better understanding of the actions, dosages, onset of action, and adverse effects of diabetes medications in order to provide optimal care to their patient population.

**Faculty:** Diane Thompson, RN, MSN, CDE, CLNC

**Audience:** This course is designed for nurses in any practice setting with a desire to familiarize themselves with the medications used in the treatment of type 2 diabetes.

**Additional Approval:** AACN Synergy CERP Category A, CCMC

## FORENSIC NURSING: AN OVERVIEW
### #37102 • 2 ANCC Hours
**By Mail – $16 • Online/eBook – $10**

**Purpose:** Forensic nurses are an important link between the medical and legal worlds. The purpose of this course is to inform nursing professionals about forensic evidence collection and documentation, being mindful of preserving evidence while managing critically injured patients, and making referrals to or requesting the assistance of forensic specialists.

**Faculty:** Michelle Booth, RN, BSN

**Audience:** This course is designed for all nurses involved in the assessment and care victims, including sexual assault nurse examiners and other forensic nursing specialists.

**Additional Approval:** AACN Synergy CERP Category A

**Special Approval:** This course is designed to fulfill the Texas requirement for 2 hours of continuing nursing education in the area of forensic evidence collection.
Course Availability List (Cont’d)

RESPIRATORY CARE: ARTIFICIAL AIRWAYS, MECHANICAL VENTILATION, AND CHEST TUBES
#38800 • 3 ANCC Hours
By Mail – $46 • Online/eBook – $40
Purpose: The purpose of this course is to reinforce nurses’ knowledge and skills related to the care of patients with artificial airways and/or chest tubes in order to improve outcomes and patient quality of life.
Faculty: Jane C. Norman, RN, MSN, CNE, PhD
Audience: This course is designed for nurses working in critical care and general and specialty medical-surgical units in which patients require assistance maintaining a patent airway and respiration.
Additional Approval: AACN Synergy CERP Category A

CLINICAL MANAGEMENT OF ATRIAL FIBRILLATION
#90822 • 10 ANCC / 4 PHARM Hours
By Mail – $46 • Online/eBook – $40
Purpose: The purpose of this course is to provide a basic review of current treatment options for the management of atrial fibrillation and indications for use, risks, and criteria for evaluating the treatment’s efficacy.
Faculty: Karen Majorowicz, RN, ARNP
Audience: This course is designed for physicians, physician assistants, nurses, and other healthcare professionals working in an adult healthcare setting, where they are likely to encounter patients who are (or should be) receiving medical intervention for control of atrial fibrillation.
Additional Approval: AACN Synergy CERP Category A, CCMC

PATHOPHYSIOLOGY: THE RESPIRATORY SYSTEM
#38820 • 15 ANCC / 6 PHARM Hours
By Mail – $66 • Online/eBook – $60
Purpose: As health care becomes more complex, it is essential that the theoretical concepts of the basis of illness (pathophysiology) be well understood. The purpose of this course is to reinforce the scientific rationales for the interventions nurses perform and the decisions nurses make as patients move through the ever-changing struggle with their respiratory illness.
Faculty: Jane C. Norman, RN, MSN, CNE, PhD
Audience: This course is designed for nurses working in critical care and general and specialty medical-surgical units in which patients with multiple organ system problems are found.
Additional Approval: AACN Synergy CERP Category A

CANCER SCREENING
#91991 • 10 ANCC Hours
By Mail – $46 • Online/eBook – $40
Purpose: The purpose of this course is to concisely provide the evidence-based guidelines and recommendations for cancer screening in order to improve healthcare professionals’ adherence and ultimately increase overall screening rates, leading to improvements in public health.
Faculty: Lori L. Alexander, MTPW, ELS, MWC
Audience: This course is designed for physicians, physician assistants, and nurses who may intervene to improve cancer screening rates.
Additional Approval: AACN Synergy CERP Category A

ISCHEMIC STROKE
#90282 • 10 ANCC / 5 PHARM Hours
By Mail – $46 • Online/eBook – $40
Purpose: The purpose of this course is to provide needed information about the roles of diagnosis and screening, evaluation of individuals with suspected stroke, immediate treatment of stroke, and the elements of effective rehabilitation programs so that healthcare professionals may implement the necessary interventions appropriately.
Faculty: Lori L. Alexander, MTPW, ELS, MWC
Audience: This course is designed for physicians, nurses, and physician assistants in the primary care setting. Neurologists and other healthcare practitioners will also benefit from this course.
Additional Approval: AACN Synergy CERP Category A, CCMC

CARE OF THE PEDIATRIC TRAUMA PATIENT
#92072 • 15 ANCC Hours
By Mail – $66 • Online/eBook – $60
Purpose: As injury remains a leading cause of mortality and morbidity among children, the purpose of this course is to allow healthcare professionals to provide timely care to pediatric trauma patients and to assist parents and caregivers in recognizing measures that prevent this type of injury.
Faculty: Susan Engman Lazar, RN, MN
Audience: This course is designed for all healthcare professionals involved in the care of pediatric patients, especially those in trauma care centers.
Additional Approval: AACN Synergy CERP Category A

OPTIMIZING OPIOID SAFETY AND EFFICACY
#95140 • 15 ANCC / 15 PHARM Hours
By Mail – $66 • Online/eBook – $60
Purpose: The purpose of this course is to provide clinicians with the information necessary to choose the appropriate opioid agents for their patients, with a resultant improvement in patients’ quality of life and compliance with prescribed treatments.
Faculty: Mark Rose, BS, MA
Audience: This course is designed for physicians, physician assistants, nurses, and other healthcare professionals involved in the care of patients who may benefit from the use of opioids to address pain.
Additional Approval: AACN Synergy CERP Category A

Prices are subject to change. Visit www.NetCE.com for a list of current prices.
## MEDICAL MARIJUANA AND OTHER CANNABINOIDS

**#95171 • 5 ANCC / 5 PHARM Hours**

**Purpose:** The purpose of this course is to provide healthcare professionals with unbiased and evidence-based information regarding the use of marijuana and other cannabinoids for the treatment of medical conditions.

**Faculty:** Mark Rose, BS, MA

**Audience:** This course is designed for physicians, nurses, physician assistants, social workers, therapists, and counselors in the primary care setting involved in the care of patients who use or who are candidates for the therapeutic use of marijuana and other cannabinoids.

**Additional Approval:** AACN Synergy CERP Category A

## ALZHEIMER DISEASE

**#96152 • 15 ANCC Hours**

**Purpose:** In order to increase and maintain a reasonable quality of life for patients with Alzheimer disease throughout the course of the disease, caregivers must have a thorough knowledge and understanding of the disease. The purpose of this course is to provide clinicians with the skills to care for patients with Alzheimer disease in any setting as part of the interdisciplinary team.

**Faculty:** Joan Needham, MSEd, RNC

**Audience:** This course is designed for clinicians who come in contact with patients with Alzheimer disease in hospitals, long-term care facilities, home health care, and the office.

**Additional Approval:** AACN Synergy CERP Category A, CCMC

## ANXIETY DISORDERS

**#96180 • 15 ANCC / 10 PHARM Hours**

**Purpose:** The purpose of this course is to provide healthcare professionals with the knowledge and skills necessary to appropriately identify and treat patients with anxiety disorders.

**Faculty:** Mark Rose, BS, MA

**Audience:** This course is designed for health and mental health providers involved in the identification, treatment, and care of patients with anxiety disorder.

**Additional Approval:** AACN Synergy CERP Category A

## HUMAN TRAFFICKING AND EXPLOITATION

**#96311 • 5 ANCC Hours**

**Purpose:** As human trafficking becomes an increasingly more common problem in the United States, healthcare and mental health professionals will require knowledge of human trafficking patterns, the health and mental health needs of human trafficking victims, and successful interventions for victims. The purpose of this course is to increase the level of awareness and knowledge about human trafficking and exploitation so health and mental health professionals can identify and intervene in cases of exploitation.

**Faculty:** Alice Yick Flanagan, PhD, MSW

**Audience:** This course is designed for physicians, nurses, social workers, psychologists, therapists, mental health counselors, and other members of the interdisciplinary team who may intervene in suspected cases of human trafficking and/or exploitation.

**Additional Approval:** AACN Synergy CERP Category B

## SUICIDE ASSESSMENT AND PREVENTION

**#96440 • 6 ANCC Hours**

**Purpose:** The purpose of this course is to provide health and mental health professionals with an appreciation of the impact of depression and suicide on patient health as well as the skills necessary to identify and intervene for patients at risk for suicide.

**Faculty:** Mark Rose, BS, MA

**Audience:** This course is designed for physicians, nurses, psychologists, social workers, therapists, counselors, and other healthcare professionals who may identify persons at risk for suicide and intervene to prevent or manage suicidality.

**Additional Approval:** AACN Synergy CERP Category A

## SEXUAL ASSAULT: EVALUATION AND CARE

**#97021 • 3 ANCC Hours**

**Purpose:** The purpose of this course is to address knowledge gaps, enhance clinical examination and management skills, and improve treatment outcomes for victims of sexual assault.

**Faculty:** John M. Leonard, MD

**Audience:** This course is intended for physicians, nurses, psychologists, social workers, therapists, counselors, and other healthcare professionals who may be called upon to provide care to victims of sexual assault.

**Additional Approval:** AACN Synergy CERP Category A

## PARKINSON DISEASE

**#98770 • 10 ANCC / 5 PHARM Hours**

**Purpose:** The purpose of this course is to provide needed information about the assessment and treatment of Parkinson disease so healthcare professionals may implement the necessary interventions appropriately.

**Faculty:** Mark Rose, BS, MA

**Audience:** This course is designed for all healthcare providers in the primary care setting who may encounter patients with Parkinson disease.

**Additional Approval:** AACN Synergy CERP Category A

**Special Approval:** This course fulfills the Texas requirement for 2 hours of education relating to geriatrics for those whose practice includes a geriatric population.
ATTENTION TEXAS NURSES,

You may have some questions about your continuing education requirements. We’re here to help!

Texas nurses may choose to meet their continuing competency requirement for license renewal by completing 20 contact hours of approved continuing nursing education (CNE). Nurses who choose to complete 20 contact hours must complete courses within their current area of practice. If you do not have a current area of practice, you must refer to your prior area of practice.

GERIATRIC REQUIREMENT

As part of the 20 contact hours, nurses whose practice includes older adult or geriatric populations must complete at least two contact hours of CNE in geriatrics every two-year renewal cycle. Featured course #99352 Aging and Long-Term Care is designed to meet this requirement.

NURSING JURISPRUDENCE AND ETHICS

All nurses are required to complete two contact hours in Nursing Jurisprudence and Nursing Ethics every third renewal cycle. These two hours may be included in the 20 hours of required CNE. Our course #31131 Texas Nursing Jurisprudence and Ethics meets the requirement and is featured in this booklet on page 1.

FORENSIC EVIDENCE COLLECTION

Nurses employed in an emergency room setting must complete a one-time requirement of two hours of CNE relating to forensic evidence collection. Our course #37102 Forensic Nursing: An Overview will meet this requirement and is advertised for sale on page 93 of our Course Availability List or online at www.NetCE.com.

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For more information about your license renewal requirements, contact the Texas Board of Nursing at (512) 305-7400.
You may complete all five courses or any combination of these five courses for a maximum payment of $21 (or pay the individual course price, whichever is less).

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#38630 Venous Disease and Ulcers — If you answered yes to question #13, what change(s) do you plan to make in your practice?

#94422 Influenza: A Comprehensive Review — If you answered yes to question #13, what change(s) do you plan to make in your practice?

May we contact you later regarding planned changes in your nursing practice as a result of these activities?  

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#99352 • Aging and Long-Term Care • 3 Contact Hours
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#38630 • Venous Disease and Ulcers • 5 Contact Hours
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