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Child Abuse Identification and Reporting: The New York Requirement

This course is approved by the New York State Education Department to fulfill the requirement for 2 hours of training in the Identification and Reporting of Child Abuse and Maltreatment. Provider #80673.

If you have already completed your one-time child abuse education requirement, you may use this course to meet 2 hours of your general CE requirement.

Audience

This course is designed for all New York dental professionals required to complete child abuse education.

Course Objective

The purpose of this course is to enable dental professionals to define child abuse and identify the children who are affected by violence. This course describes how a victim can be accurately diagnosed and identifies the community resources available in the state of New York for child abuse victims.

Learning Objectives

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

- 1. Summarize the historical context of child abuse.
- 2. Define child abuse and neglect and identify the different forms of child abuse and neglect.
- 3. Discuss the scope of child abuse and neglect in New York State and in the United States.
- 4. Describe warning signs and consequences of child abuse and neglect.
- 5. Review the mandatory reporting process and mandated reporters in New York State, including possible barriers to reporting suspected cases of child abuse.

Faculty

Alice Yick Flanagan, PhD, MSW, received her Master's in Social Work from Columbia University, School of Social Work. She has clinical experience in mental health in correctional settings, psychiatric hospitals, and community health centers. In 1997, she received her PhD from UCLA, School of Public Policy and Social Research. Dr. Yick Flanagan completed a year-long post-doctoral fellowship at Hunter College, School of Social Work in 1999. In that year she taught the course Research Methods and Violence Against Women to Masters degree students, as well as conducting qualitative research studies on death and dying in Chinese American families. (A complete biography can be found at NetCE.com/faculty.)

A full Works Cited list is available online at www.NetCE.com.

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Faculty Disclosure

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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Designations of Credit

NetCE designates this activity for 2 continuing education credits.

AGD Subject Code 155.

Special Approvals

This course is approved by the New York State Education Department to fulfill the requirement for 2 hours of training in the Identification and Reporting of Child Abuse and Maltreatment. Provider #80673.

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The purpose of NetCE is to provide challenging curricula to assist healthcare professionals to raise their levels of expertise while fulfilling their continuing education requirements, thereby improving the quality of healthcare.

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EVIDENCE PRACTICE RECOMMENDATION

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.

HISTORICAL CONTEXT

There is an established system in the United States to respond to reports of child abuse and neglect; however, this has not always been the case. This is not because child abuse, neglect, and maltreatment are new social phenomena. Rather, the terms "child abuse," "child neglect," and "child maltreatment" are relatively new, despite the fact that this social problem has existed for thousands of years [1]. Cruelty to children by adults has been documented throughout history and across cultures. In China, infant girls were often neglected during times of famine or sold during times of extreme poverty. There is also historical evidence that cultures have taken steps to stop child abuse and cruelty. For example, 6,000 years ago in Mesopotamia, orphans had their own patron goddesses for help and protection [2].

In many cases, the physical abuse of children has been linked to physical punishment. Throughout history, physical child abuse was justified because it was believed that severe physical punishment was necessary either to discipline, rid the child of evil, or educate [2; 13].

It was not until 1861 that there was a public outcry in the United States against extreme corporal punishment. This reform was instigated by Samuel Halliday, who reported the occurrence of many child beatings by parents in New York City [2].

Sexual abuse of children, particularly incest (defined as sex between family members), is very much a taboo. The first concerted efforts to protect children from sexual abuse occurred in England during the 16th century. During this period, boys were protected from forced sodomy and girls younger than 10 years of age from forcible rape [2]. However, in the 1920s, sexual abuse of children was described solely as an assault committed by "strangers," and the victim of such abuse was perceived as a "temptress" rather than as an innocent child [2].

The first public case of child abuse in the United States that garnered widespread interest took place in 1866 in New York City. Mary Ellen Wilson was an illegitimate child, 10 years of age, who lived with her foster parents [3]. Neighbors were concerned that she was being mistreated; however, her foster parents refused to change their behaviors and said that they could treat the child as they wished [2]. Because there were no agencies established to protect children specifically, Henry Berge, founder of the Society for the Prevention of Cruelty to Animals, intervened on Mary's behalf [3]. He argued that she was a member of the animal kingdom and deserved protection. The case received much publicity, and as a result, in 1874 the New York Society for the Prevention of Cruelty to Children was formed [3]. Because of this case, every state now has a child protective services (CPS) system in place. As a result of Berge's advocacy for children's safety, other nongovernmental agencies were formed throughout the United States, and the establishment of the juvenile court was a direct result of the Prevention of Cruelty to Children [13]. In 1912, the U.S. Children's Bureau was established to monitor and report on children's social and physical welfare [45]. The Bureau was the first formal federal government vehicle to address the welfare of children [45]. During this time, many states and counties had also established child welfare boards or departments. By 1919, all but three states had juvenile courts. However, many of these nongovernmental agencies could not sustain themselves during the Depression [13].

The topic of child abuse and neglect received renewed interest in the 1960s, when a famous study titled "The Battered-Child Syndrome" was published by Henry Kempe [1; 4]. In the study, researchers argued that the battered-child syndrome consisted of traumatic injuries to the head and long bones, most commonly to children younger than 3 years of age, by parents [1; 4]. The study was viewed as the seminal work on child abuse, alerting both the general public and the academic community to the problems of child abuse [1; 2]. This seminal study was the impetus to the adoption of a formal reporting system, and by 1967, all 50 states required physicians to report child abuse [14; 22]. In the early 1970s, Senator Walter Mondale noted that there was no official agency that spent its energies on preventing and treating child maltreatment [13]. Congress passed the Child Abuse Prevention and Treatment Act (CAPTA) of 1974, which targeted federal funds to improve states' interventions for the identification, reporting and training for child abuse [13; 22].

Today, child abuse and neglect are considered significant social problems with deleterious consequences. As noted, a system has been implemented in all 50 states to ensure the safety of children, with laws defining what constitutes abuse and neglect and who is mandated to report. In 2006, recognizing the role of physicians in the detection of child abuse, child abuse pediatrics became a board-certified subspecialty [46]. In 2010, additional prevention and treatment programs were funded through CAPTA, and in 2012, the Administration on Children, Youth, and Families began to focus on protective factors to child abuse and neglect [22].

DEFINITIONS OF CHILD ABUSE AND NEGLECT

The federal definition of child abuse is evident in CAPTA, published as a product of federal legislation. CAPTA defines a child to be any individual younger than 18 years of age, except in cases of sexual abuse. In cases of sexual abuse, the age specified by the child protection laws varies depending on the state in which the child resides [5]. CAPTA defines child abuse as, "any recent act or failure to act on the part of a parent or caretaker, which results in death, serious physical or emotional

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harm, sexual abuse, or exploitation, or an act or failure to act which presents an imminent risk of serious harm" [6]. The state of New York defines child abuse and neglect as follows [7]:

The term abuse encompasses the most serious harms committed against children. An "abused child" is a child whose parent or other person legally responsible for his/her care inflicts upon the child serious physical injury, creates a substantial risk of serious physical injury, or commits a sex offense against the child. Not only can a person be abusive to a child if they perpetrate any of these actions against a child in their case, they can be guilty of abusing a child if they allow someone else to do these things to that child.

FORMS OF CHILD ABUSE AND NEGLECT

There are several acts that may be considered abusive, and knowledge of what constitutes abuse is vital for healthcare providers and other mandated reporters. In this section, specific behaviors that fall under the category of abuse and neglect will be reviewed.

Physical Abuse

Physical abuse injuries can range from minor bruises and lacerations to severe neurologic trauma and death. Physical abuse is one of the most easily identifiable forms of abuse and the type most commonly seen by healthcare professionals. Physical injuries that may be indicative of abuse include bruises/welts, burns, fractures, abdominal injuries, lacerations/abrasions, and central nervous system trauma [8; 61].

Bruises and welts are of concern, particularly those that appear on:

- The face, lips, mouth, ears, eyes, neck, or head
- The trunk, back, buttocks, thighs, or extremities
- Multiple body surfaces

Patterns such as the shape of the article (e.g., a cord, belt buckle, teeth, hand) used to inflict the bruise or welt should be noted. Cigar or cigarette burns are common, and they will often appear on the child's soles, palms, back, or buttocks. Patterned burns that resemble shapes of appliances, such as irons, burners, or grills, are of particular concern.

Fractures that result from abuse might be found on the child's skull, ribs, nose, or any facial structure. These may be multiple or spiral fractures at various stages of healing. When examining patients, note bruises on the abdominal wall, any intestinal perforation, ruptured liver or spleen, and blood vessel, kidney, bladder, or pancreatic injury, especially if accounts for the cause do not make sense. Look for signs of abrasions on the child's wrists, ankles, neck, or torso. Lacerations might also appear on the child's lips, ears, eyes, mouth, or genitalia. If violent shaking or trauma occurred, the child might experience a subdural hematoma [8; 61].

Sentinel injuries are those minor injuries (e.g., bruises, intraoral injuries, fractures) that are recognized by providers or parents prior to the formal recognition of child abuse [47; 48]. It is crucial to monitor for these sentinel injuries.

Sexual Abuse

Sexual abuse is defined by CAPTA as [6]:

the employment, use, persuasion, inducement, enticement, or coercion of any child to engage in, or assist any other person to engage in, any sexually explicit conduct or simulation of such conduct for the purpose of producing a visual depiction of such conduct; or the rape, and in cases of caretaker or interfamilial relationships, statutory rape, molestation, prostitution, or other form of sexual exploitation of children, or incest with children.

Child sexual abuse can be committed by a stranger or an individual known to the child. Sexual abuse may be manifested in many different ways, including [9; 10]:

- Verbal: Obscene phone calls or talking about sexual acts for the purpose of sexually arousing the adult perpetrator
- Voyeurism: Watching a child get dressed or encouraging the child to masturbate while the perpetrator watches
- Commercial sexual exploitation and child sex trafficking: Involving the child in sexual acts for monetary profit
- Child pornography: Taking photos of a child in sexually explicit poses or acts
- Exhibitionism: Exposing his/her genitals to the child or forcing the child to observe the adult or other children in sexual acts
- Molestation: Touching, fondling, or kissing the child in a provocative manner; for example, fondling the child's genital area or long, lingering kisses
- Sexual penetration: The penetration of part of the perpetrator's body (e.g., finger, penis, tongue) into the child's body (e.g., mouth, vagina, anus)
- Rape: Usually involves sexual intercourse without the victim's consent and usually involves violence or the threat of violence

This definition is wide in scope and includes behaviors beyond touching, contact, or physical force. Instead, it encompasses sexual intent against an individual's will. It also takes into consideration consent, as there may be some who cannot consent due to age, disability, fear of harm, and/or state of consciousness or intoxication [62].

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Physical Neglect

Undoubtedly, the definition of neglect is an area of controversy. Some argue that neglect is a form of abuse, because neglect involves a caregiver having lower priority and value of the welfare of the child [49]. Some differentiate between the two terms by the fact that emotional abuse involves a commission of an act, while emotional neglect involves an omission [50].

Due to the ambiguity of definitions of child abuse and neglect, CAPTA provides minimum standards that each state must incorporate in its definition. Examples of child neglect may include [6; 11; 12]:

- Failure to provide adequate food, clothing, shelter, hygiene, supervision, education, and protection
- Refusal and/or delay in medical attention and care (e.g., failure to provide needed medical attention as recommended by a healthcare professional or failure to seek timely and appropriate medical care for a health problem)
- Abandonment, characterized by desertion of a child without arranging adequate care and supervision. Children who are not claimed within two days or who are left alone with no supervision and without any information about their parents'/caretakers' whereabouts are examples of abandonment.
- Expulsion or blatant refusals of custody on the part of parent/caretaker, such as ordering a child to leave the home without adequate arrangement of care by others
- Inadequate supervision (i.e., child is left unsupervised or inadequately supervised for extended periods of time)

In New York state, neglect also involves parents/caregivers who fail to exercise a minimum of care of minor who "misuses drugs and alcohol to the extent he/she loses self-control of his/her actions" [63].

Emotional Abuse/Neglect

The following behaviors constitute emotional abuse and neglect [6; 11; 12]:

- Verbal abuse: Belittling or making pejorative statements in front of the child, which results in a loss or negative impact on the child's self-esteem or self-worth
- Inadequate nurturance/affection: Inattention to the child's needs for affection and emotional support
- Witnessing domestic violence: Chronic spousal abuse in homes where the child witnesses the violence
- Substance and/or alcohol abuse: The parent/caretaker is aware of the child's substance misuse problem but chooses not to intervene or allows the behavior to continue

- Refusal or delay of psychologic care: Failure or delay in obtaining services for the child's emotional, mental, or behavioral impairments
- Permitted chronic truancy: The child averages at least five days per month of school absence and the parent/guardian does not intervene
- Failure to enroll: Failure to enroll or register a child of mandatory school age or causing the child to remain at home for nonlegitimate reasons
- Failure to access special education services: Refusal or failure to obtain recommended services or treatment for remedial or special education for a child's diagnosed learning disorder

In New York, emotional abuse entails the above behaviors or behaviors that impair emotional health or mental or emotional condition [63].

Enacted in 2015, the Justice for Victims of Trafficking Act includes an amendment to CAPTA, and several states now track data related to the numbers of victims of sex trafficking. In 2020, 35 states reported 953 victims of sex trafficking [15].

The Comprehensive Addiction and Recovery Act (CARA) of 2016 included an amendment to CAPTA to collect and report the number of infants with prenatal substance exposure. In 2020, 47 states reported this data and referred prenatal substance exposure cases to Child Protective Service agencies. There have been a total of 27,709 reports since passage of this Act [15].

EPIDEMIOLOGY OF CHILD ABUSE AND NEGLECT

NATIONAL PREVALENCE

In 2020, there were 3.9 million referrals to CPS agencies in the United States [15]. Almost 2.2 million were assessed to be appropriate for a response, and 27.6% of reports were made by health and mental or behavioral health professionals [15]. Girls tend to be victims at a slightly higher rate (8.9 per 1,000 girls) compared with boys (7.9 per 1,000 boys) [15]. More than a half (52%) of perpetrators are women, and the majority (83.2%) are between the ages of 18 and 44 years [15].

As of 2020, there were at least 3.1 million children referred to CPS agencies and who received an investigation and some form of response, and 8.4 of every 1,000 children in the United States were victims of abuse and/or neglect [15]. This is the unique rate, meaning each child is counted only once regardless the number of times a report may have been filed for abuse/neglect. The fatality rate for 2020 was 2.38 deaths per 100,000 children [15].

CHILD ABUSE VICTIMIZATION ACCORDING TO RACE/ETHNICITY, 2020		
Race/Ethnicity	Child Abuse Rate Per 1,000 Children	
Native American/Alaska Native	15.5	
African American	13.2	
Multi-race	10.3	
Pacific Islander	9.0	
White	7.4	
Hispanic	7.8	
Asian American	1.6	
Source: [15]	Table 1	

Research has shown that racial and ethnic minority children (particularly African American, Native American/Alaska Native, and multi-racial children) tend to have higher rates of reported child maltreatment compared to their white counterparts (*Table 1*) [15]. However, the lowest reported rate is among Asian American children [15].

NEW YORK STATE PREVALENCE

In 2020, the rate of child abuse and neglect in New York State was 14.8 per 1,000 children [15]. This translates to approximately 59,126 cases of child abuse and neglect in New York in 2020, a decrease of 9.2% compared with 2016 [15]. In terms of fatalities, 105 children in New York died in 2020 as a result of child abuse and neglect—a rate of 2.63 per 100,000 children [15]. This is greater than the national rate of 2.38 per 100,000 per children [15].

RECOGNIZING WARNING SIGNS

It is crucial that practitioners become familiar with the indications of child abuse and neglect. These factors do not necessarily conclusively indicate the presence of abuse or neglect; rather, they are clues that require further interpretation and clinical investigation. Some parental risk indicators include [8; 10; 12; 15; 16; 64]:

- Recounting of events that do not conform either with the physical findings or the child's physical and/or developmental capabilities
- Inappropriate delay in bringing the child to a health facility
- Unwillingness to provide information or the information provided is vague
- History of family violence in the home
- Parental misuse of substances and/or alcohol

- Minimal knowledge or concern about the child's development and care
- Environmental stressors, such as poverty, single parenthood, unemployment, or chronic illness in the family
- Unwanted pregnancy
- Early adolescent parent
- Expression that the parent(s) wanted a baby in order to feel loved
- Unrealistic expectations of the child
- Use of excessive physical punishment
- Healthcare service "shopping"
- History of parent "losing control" or "hitting too hard"
- Asks teacher to employ harsh disciplining for misbehaviors

Child risk indicators include [8; 10; 12; 16; 48; 64]:

- Multiple school absences
- Learning or developmental disabilities or special needs
- History of multiple, unexplained illnesses, hospitalizations, or accidents
- Poor general appearance (e.g., fearful, poor hygiene, malnourished appearance, inappropriate clothing for weather conditions)
- Begs for money or food
- Stress-related symptoms, such as headaches or stomachaches
- Frozen watchfulness
- Mental illness or symptoms, such as psychosis, depression, anxiety, eating disorders, or panic attacks
- Regression to wetting and soiling
- Sexually explicit play
- Excessive or out-of-the-ordinary clinging behavior
- Difficulties with concentration
- Disruptions in sleep patterns and/or nightmares
- Symptoms of wasting (i.e., unintended and significant weight loss), protruding ribs or bones, abdominal distension, edema, and sparse hair indicating nutritional neglect
- Abuses/mistreats pets

Some of the types of behaviors and symptoms discussed in the definitions of physical, sexual, and emotional abuse/neglect are also warning signs. For example, any of the injuries that may result from physical abuse, such as a child presenting with bruises in the shape of electric cords or belt buckles, should be considered risk factors for abuse.

CONSEQUENCES OF CHILD ABUSE

The consequences of child abuse and neglect vary from child to child; these differences continue as victims grow older. Several factors will mediate the outcomes. These factors include [17]:

- Severity, intensity, frequency, duration, and nature of the abuse and/or neglect
- Age or developmental stage of the child when the abuse occurred
- Relationship between the victim and the perpetrator
- Support from family members and friends
- Level of acknowledgment of the abuse by the perpetrator
- Quality of family functioning

In examining some of the effects of physical abuse, it is helpful to frame the consequences along a lifespan perspective [18]. During infancy, physical abuse can cause neurologic impairments. Most cases of infant head trauma are the result of child abuse [19]. Neurologic damage may also affect future cognitive, behavioral, and developmental outcomes. Some studies have noted that, in early childhood, physically abused children show less secure attachments to their caretakers compared to their nonabused counterparts [20].

By middle to late childhood, the consequences are more notable. Studies have shown significant intellectual and linguistic deficits in physically abused children [18]. Other environmental conditions, such as poverty, may also compound this effect. In addition, a number of affective and behavioral problems have been reported among child abuse victims, including anxiety, depression, low self-esteem, excessive aggressive behaviors, conduct disorders, delinquency, hyperactivity, and social detachment [8; 10; 12; 18].

Surprisingly, there has been little research on the effects of childhood physical abuse on adolescents [18]. However, differences have been noted in parents who abuse their children during adolescence rather than preadolescence. It appears that lower socioeconomic status plays a lesser role in adolescent abuse as compared to abuse during preadolescence [21]. In addition, parents who abuse their children during adolescence are less likely to have been abused as children themselves compared to those parents who abused their children during preadolescence [21]. It is believed that the psychosocial effects of physical abuse manifest similarly in late childhood and adolescence.

Research findings regarding the effects of childhood physical abuse on adult survivors have been less consistent. Some adult survivors function well socially and in terms of mental and physical health, while others exhibit depression, anxiety, post-traumatic stress, substance abuse, criminal behavior, violent behavior, and poor interpersonal relationships [17; 18]. A 2012 meta-analysis found that victims of child abuse were more likely to experience depression than non-abused counterparts, with the rates varying according to the type of abuse sustained (1.5-fold increase for physical child abuse, 2.11-fold increase for neglect, and 3-fold increase for emotional abuse) [24]. Similar results were found in a longitudinal study that compared a child welfare cohort to a group with no child welfare involvement. The child welfare group was twice as likely to experience moderate-to-severe depression and generalized anxiety compared with the control group [25].

Although not all adult survivors of sexual abuse experience long-term psychologic consequences, it is estimated that 20% to 50% of all adult survivors have identifiable adverse mental health outcomes [23]. In the Wisconsin Longitudinal Study, men who disclosed a history of childhood sexual abuse were more likely to have or develop depression, somatic symptoms, and increased levels of hostility [51]. Other possible psychologic outcomes include [10; 52]:

- Affective symptoms: Numbing, post-traumatic stress disorder, anxiety, depression, obsessions and compulsions, somatization
- Various health problems, including general pain and gastrointestinal symptoms
- Interpersonal problems: Difficulties trusting others, social isolation, feelings of inadequacy, sexual difficulties (e.g., difficulties experiencing arousal and orgasm), avoidance of sex
- Distorted self-perceptions: Poor self-esteem, self-loathing, self-criticism, guilt, shame
- Behavioral problems: Risk of suicide, substance abuse, self-mutilation, violence
- Increased risk-taking behaviors: Abuse of substances, cigarette smoking, sexual risk-taking

Adult male survivors of child sexual abuse are three times as likely to perpetrate domestic violence as non-victims. In addition, female survivors of child sexual abuse are more vulnerable to bulimia, being a victim of domestic violence, and being dependent on alcohol [28].

In more recent years, research has focused on the impact of adverse childhood experiences (ACEs) in general. ACEs are defined as potentially traumatic experiences that affect an individual during childhood (before 18 years of age) and increase the risk for future health and mental health problems (including increased engagement in risky behaviors) as adults [76]. Abuse and neglect during childhood are clear ACEs, but other examples include witnessing family or community violence; experiencing a family member attempting or completing suicide; parental divorce; parental or guardian substance abuse; and parental incarceration [76]. Adults who experienced ACEs are at increased risk for chronic illness, impaired health, violence, arrest, and substance use disorder [77; 78].

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The economic costs of non-fatal child maltreatment equate to \$210,012 per child victim, excluding the costs associated with adverse physical and mental health consequences and those incurred by the criminal justice and special education systems [53]. A 2017 study found a cost of more than \$400,000 per child abuse victim over the course of his or her lifetime [65].

REPORTING SUSPECTED CHILD ABUSE

MANDATED REPORTERS

In the state of New York, certain professionals are legally required or mandated to report any suspected cases of child abuse, maltreatment, and/or neglect that they encounter in their professional roles to the New York Statewide Central Register (SCR) of Child Abuse and Maltreatment. Reasonable cause for suspicion is based upon behaviors that have been observed or reported that cause the professional to believe that a specific circumstance might involve child abuse or neglect [26]. Child abuse laws in New York, and in all states, do not require reporters to have absolute proof of abuse [27]. Reporting suspected cases should be done in good faith, and mandatory reporting laws give the reporter immunity from criminal and civil liability regardless of the substantiation of abuse [16]. Good faith is defined as "the reporter, to the best of his or her knowledge, has reason to believe that the child in question is being subjected to abuse or neglect" [14]. However, if mandated reporters fail to report an incident of suspected child abuse or maltreatment, they may be charged with a Class A misdemeanor, subject to criminal penalties, and can be sued for monetary damages for any harm in a civil court [26]. It is vital to remember that mandated reporters are not required to provide absolute evidence; this is the responsibility of CPS [29].

The following individuals are classified as mandated reporters in the state of New York [26]:

- Physicians (including osteopaths)
- Registered physician's assistants
- Surgeons
- Medical examiners
- Coroners
- Dentists
- Dental hygienists
- Optometrists
- Chiropractors
- Podiatrists
- Medical residents
- Interns
- Psychologists
- Registered nurses

- Social workers
- Emergency medical technicians
- Licensed creative arts therapists
- Licensed marriage and family therapists
- Licensed mental health counselors
- Licensed psychoanalysts
- Hospital personnel engaged in the admission, examination, care, or treatment of persons
- Christian Science practitioners
- School officials
- Social services workers
- Day care center workers
- Providers of family or group family day care
- Any employees or volunteers in a residential care facility for children
- Any other childcare or foster care workers
- Mental health professionals
- Substance abuse counselors
- Alcoholism counselors
- Peace officers
- Police officers
- District attorneys or assistant district attorneys
- Investigators employed in the Office of the District Attorney
- Any other law enforcement officials

THE PROCESS OF REPORTING TO THE NEW YORK STATEWIDE CENTRAL REGISTER (SCR) OF CHILD ABUSE AND MALTREATMENT

When mandated reporters suspect a case of child abuse or maltreatment, they must report to the SCR at 1-800-635-1522. The general public can report suspected abuse by calling 1-800-342-3720 [38].

The SCR is open 24 hours per day, 7 days per week [26]. The mandated reporter is not obligated to contact the parents or the legal guardians of the child either before or after the call to SCR [26]. Good practice dictates that the reporter either seek consent or notify the parent(s) that essential information is being (and is required to be) shared, unless doing so would put the child's health or safety at risk. However, even if the parent does not consent, the mandated reporter is still obligated to contact the SCR [26]. (Additional child abuse hotline information may be found in the **Resources** section of this course.)

The worker who answers the phone will attempt to accumulate as much information from you as possible. According to the New York State Office of Children and Family Services, they will ask you the following types of questions [26; 38]:

- What is the nature and extent of the child's injuries, or the risk of harm to the child?
- Have there been any prior suspicious injuries to this child or his/her siblings?
- What is the child's name, home address, age?
- What is the name and address of the parent or other person legally responsible who caused the injury, or created the risk of harm to the child?
- What are the names and addresses of the child's siblings and parents if different from the information provided above?
- Do you have any information regarding treatment of the child, or the child's current whereabouts?

Within 48 hours of reporting the suspected abuse to SCR, the reporter must also complete and sign a written report (LDSS-2221A) and submit the report to the local department of social services (LDSS) that has been assigned to the investigation [26]. The forms may be accessed on the New York State of Children and Family Services website at https://ocfs.ny.gov/search/docs.php.

The CPS unit of the LDSS is required to begin an investigation of the reported abuse within 24 hours [26]. A CPS specialist will ask questions about the suspected abuse and the child. For example, the specialist will ask for the child's name, age, and home address, the name of the suspected person who inflicted the abuse, his or her address, and the nature of the abuse. The specialist should also evaluate the safety of the child named in the report as well as that of any other children in the home. If the child's safety is at risk, the specialist may take the child and other children in the home into protective custody to prevent further abuse or maltreatment. CPS has 60 days after receiving the report to determine whether it is "indicated" or "unfounded." CPS is obligated to inform the child's parents or other subject of the report of their rights, according to the New York State Social Services Law, and must inform the SCR of the determination of the investigation [26].

BARRIERS TO REPORTING

Studies have shown that many professionals who are mandated to report child abuse and neglect are concerned and/or anxious about reporting. Identified barriers to reporting include [29; 30; 31; 40; 54; 55]:

- Professionals may not feel skilled in their knowledge base about child abuse and neglect. In addition, they lack the confidence to identify sexual and emotional abuse.
- Professionals may be frustrated with how little they can do about poverty, unemployment, drug use, and the intergenerational nature of abuse.

- Although professionals understand their legal obligation, they may still feel that they are violating patient confidentiality.
- Many professionals are skeptical about the effectiveness of reporting child abuse cases given the bureaucracy of CPS and the large caseloads.
- Practitioners may be concerned that they do not have adequate or sufficient evidence of child abuse.
- Practitioners may have a belief that government entities do not have the right to get involved in matters within the family arena.
- There may be some confusion and emotional distress in the reporting process.
- Practitioners may fear that reporting will negatively impact the therapeutic relationship.
- Loyalty to the family
- Fear of driving the family away from seeking health, social, and mental health services
- Some professionals have concerns that there might be negative repercussions against the child by the perpetrator.
- Some simply underestimate the seriousness and risk of the situation and may make excuses for the parents.

The failure to identify and report child abuse may result in continued abuse of the child and potentially severe consequences. Improved and ongoing education about child abuse and maltreatment has been shown to improve identification and reporting rates among physicians and other professionals. The education should include [32]:

- Management and outcomes
- The role of the CPS investigator
- The role of the physician/other reporting professional
- The benefits of CPS involvement
- The benefits of mandated education on identification/ reporting
- The benefits of professional debriefing for the reporter
- The benefits of collaboration (e.g., with local emergency departments, pediatric specialists)

Other suggestions for improving reporting include [32]:

- Improving the relationship between CPS and medical providers
- Allowing certain registered professionals with demonstrated expertise in identifying/treating child abuse "flexible reporting options" (e.g., defer reporting when no immediate threat exists or make the report confidentially and defer an investigation until deemed necessary)
- Improving interaction with the legal system

ASSESSMENT GUIDELINES FOR PROFESSIONALS

Assessment for child abuse and neglect involves the systematic collection of data. Information should be obtained regarding the primary reason for the visit, family health history, the child's health history, history of illnesses, the parents' attitudes toward discipline, and the child's pattern of nutrition, sleep, and diet [16]. If abuse is a concern after the preliminary evaluation, consultation with a child abuse specialist, pediatric specialist, or pediatrician experienced in this area, if available, may be helpful in determining the best way to proceed with assessment [16].



The U.S. Preventive Services Task Force concludes that the current evidence is insufficient to assess the balance of benefits and harms of primary care interventions to prevent child maltreatment in children who do not have signs or symptoms of

maltreatment. However, children with signs or symptoms suggestive of maltreatment should be assessed or reported according to the applicable state laws.

(https://www.uspreventiveservicestaskforce.org/Page/ Document/RecommendationStatementFinal/childmaltreatment-primary-care-interventions. Last accessed February 1, 2023.)

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

It is important for professionals to ask questions in a nonjudgmental manner [33]. An environment where support and concern facilitate an open, trusting relationship between the parent and the practitioner should be created. By providing such an environment, the parent has the opportunity to voice concerns and ask for help. Questions that convey concern and may provide valuable information to the professional include, "Who helps you care for your children?" or "How do you discipline your children?" It may be necessary to interview the child and parent separately; however, by spending some time with the child and parent together, practitioners can observe interactions and communication.

Accuracy in record taking is also important. Be sure to record the date and time of the visit, the sources of any information, and the date, time, and place of the alleged abuse or assault [16; 34]. When talking to the child, the practitioner should use developmentally appropriate language that will be easily understood. Leading questions should be avoided [34]. Be sensitive to the fact that children often wonder if the abuse actually happened, as the abuser may behave as if nothing occurred [56]. Asking the following questions may be helpful when interacting with children [34; 35]:

- "Do you know why you are here today?"
- "Can you tell me what happened?"
- "How did it begin?"
- "What happened next?"
- "Where did this happen?"
- "Have you been hurt lately?"

It is important to note the child's demeanor during questioning. Some children may be protective of their abuser, openly fearful of their abuser, or may fear retribution for "telling." Strong nonverbal cues of anxiety and reluctance to answer questions about potential abuse are important considerations when a safety plan for the child is necessary [16; 33].

Supporting and facilitating the victim's emotions are also important. This helps to promote rapport between the interviewer and the child. One way of promoting the rapport is by expressing interest or care by saying: "I want to know more about how you are feeling" [65]. Certain feelings or events may be legitimized by confirming to the child that he/she is safe talking about bad things. Finally, the interviewer can reinforce these sentiments by thanking the child for expressing certain emotions [65].

Because studies have demonstrated a correlation between child abuse and domestic violence, there is a need for dual screening for both types of family violence [16; 20]. An estimated 75% of victims of domestic violence live in a household with at least one child younger than 18 years of age, and between 3.3 million and 10 million children witness domestic violence annually [36; 37]. When a woman presents with a child whom the professional suspects to be at risk for child abuse, the professional should ask the woman if she has ever been hurt or injured by her spouse/intimate partner. Professionals should minimize the discomfort associated with the questioning by first discussing the prevalence of domestic violence in intimate relationships and by stating that such questioning is commonly done [39]. Because of the sensitive nature of child abuse, it can evoke extreme emotions on the part of the professional. However, it is important to manage emotions when talking to children [57].

In cases of child sexual abuse, the child should be interviewed alone. The professional should try to keep a neutral tone of voice and manner. Open-ended, nonleading questions should be used. For example, the practitioner may ask: "Has anyone ever touched you in a way that you did not like or that made you feel uncomfortable?" Because the interview may be admissible in court, careful documentation of the questions and responses is important; the exchange should be documented verbatim [16].

SCREENING FOR ABUSE IN CHILDREN WITH SPECIAL NEEDS OR DISABILITIES

The rates of child maltreatment for children with disabilities are reportedly 1.7 to 7 times higher compared with children without disabilities [42]. In one study, researchers found that among substantiated reports of maltreatment among children, 22% of victims had some form of disability, most commonly an emotional disability [58]. A systematic review found that there was a prevalence rate of 20.4% for physical abuse, 13.7% for sexual abuse, and 26.7% for both forms of abuse combined among children with intellectual disabilities [66]. Children with disabilities can be more vulnerable to maltreatment if the parents/caregivers view the disability and its associated behaviors as "difficult," if the parents have unrealistic expectations of the child's behavior or abilities, if the parents are facing additional caregiver stress, or if the parent perceives the child as unable to defend him/herself [43]. Furthermore, they may be less likely to disclose the abuse because they not only do not realize they have been harmed or they have impaired communication skills [59].

To effectively interview a child with a disability, the practitioner should first obtain some preliminary data, including [33]:

- The child's primary disability
- Accompanying disabilities, if any
- How the disability affects the child's current functioning
- Whether the child is highly distractible
- What the appropriate method of communication will be (e.g., sign language, language board, facilitative communication) if communication is an issue
- What, if any, behavioral challenges (e.g., compulsive, withdrawal) the child has

Overall, when conducting an interview of a child with a disability or special need, the practitioner should work with someone to validate impressions or feelings about the child, develop and use a multidisciplinary resource team, be aware of the child's vulnerabilities (e.g., behavioral challenges, accompanying disabilities), and remember that he/she may be the first person able to stop the child from being further victimized [41]. When questioning the child, it is important to ask open-ended questions, as this approach maximizes recall. Some assume that children with disabilities will not be able to handle open-ended questions, but this is not trictly true [67]. When working with those with intellectual disabilities, interviewers should try shorter open-ended questions before falling back to closed-ended questions [67]. Scaffolding questions, or breaking up the tasks and gradually building up the questions with specific instructions and comprehension checks along the way, can also be beneficial [68]. Comprehension check questions can be as simple as: "Can you repeat the question I just asked?" or "I just asked you <insert question>, what does that question mean to you?" [68].

SCREENING FOR ABUSE IN NON-ENGLISH-PROFICIENT FAMILIES

Communication with children and families regarding the signs and history of abuse is a necessary step in obtaining an accurate diagnosis. When interviewing children for whom English is not their first language, they may switch back to their first language during the interview, even if they express the wish to have the interview conducted in English [69].

There will also be many occasions when an interpreter is warranted. Without an interpreter, children may experience additional stress, struggling to find the right words in English, which can result in more feelings of fear, disempowerment, and voicelessness [44].

It may be tempting to locate a practitioner who has some language ability to speak to the child and/or family member; however, this should be avoided if at all possible [44]. When looking for an interpreter in the community, it is important to consider if the interpreter and the family are acquainted, as this can cause an uncomfortable situation [69]. The language for screening for child abuse requires precision as well as sensitivity, and professional interpreters are recommended.

In this multicultural landscape, interpreters are a valuable resource to help bridge the communication and cultural gap between patients and practitioners [33]. 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. They should be familiar with both the nuances of the language and the cultural norms and value systems of the target community [44]. When providing care for children and parents for whom English is a second language, the consideration of the use of an interpreter and/or patient education materials in their native language may improve patient understanding and outcomes.

It is also vital to take into account interpreters' competence when working in the area of child abuse. Because of the sensitive nature of child abuse and the type of information being asked and recalled, interpreters should be well trained in communicating with victims and perpetrators [60].

INTERPROFESSIONAL COLLABORATIONS AND CHILD MALTREATMENT

Interprofessional collaboration, defined as a partnership or network of providers who work in a concerted and coordinated effort on a common goal for clients/patients and their families to improve health, mental health, social, and/or family outcomes, is a vital component in child abuse identification and intervention [70]. Positive outcomes with this approach have been demonstrated on individual and organizational levels, including increased patient/client safety and satisfaction and improved health outcomes and quality of life [71; 72; 73].

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#57533 Child Abuse Identification and Reporting: The New York Requirement

However, promoting interprofessional collaboration can be challenging, as it challenges the Western paradigm that focuses on individualism and working in a silo [74]. For example, physicians and other health professionals often do not ask their patients and family members about child abuse/neglect or about contact with the child welfare system. Even if this issue is not acute, knowledge of this background information can help to better understand the patient or family as a whole unit. Similarly, child welfare workers rarely engage with physicians, instead focusing primarily on their investigation [75].

Practitioners should work with each other to learn and understand each other's roles and traditions [79; 80]. In focus groups, physicians believed that child welfare workers were supposed to solve child abuse cases by providing social services and removing a child from the home, but did not appreciate the underlying complexities of child abuse and neglect. Child welfare workers overestimated physicians' understanding of the child welfare system [75].

Social workers are often an integral part of the interprofessional practice for child abuse and neglect, acting as a liaison between the families, healthcare workers, and outside entities [81]. When a family has to deal with an issue of suspected child abuse, social workers are able to intervene and offer tools to manage the crisis.

CONCLUSION

Child abuse and neglect are considered significant social problems with deleterious consequences. As noted, a system has been implemented in all 50 states to ensure the safety of children, with laws defining what constitutes abuse and neglect and who is mandated to report. Healthcare professionals, regardless of their discipline or field, are in a unique position to assist in the identification, education, and prevention of child abuse and neglect.

RESOURCES

American Academy of Pediatrics 345 Park Boulevard Itasca, IL 60143 800.433-9016 https://www.aap.org State Child Abuse Hotlines New York Statewide Central Register (SCR) of Child Abuse and Maltreatment General Public 1-800-342-3720

Onondaga County 315-422-9701

Childhelp

6730 N. Scottsdale Road, Suite 150 Scottsdale, AZ 85253 1-800-4-A-CHILD https://www.childhelp.org

Child Welfare Information Gateway

330 C Street SW Washington, DC 20201 1-800-394-3366 https://www.childwelfare.gov

Child Welfare League of America 727 15th Street NW, 12th Floor Washington, DC 20005 202-688-4200 https://www.cwla.org

National Council on Child Abuse and Family Violence P.O. Box 5222 Arlington, VA 22205 202-441-1304 https://www.preventfamilyviolence.org

New York State Office of Children and Family Services Child Protective Services Capital View Office Park 52 Washington Street Rensselaer, New York 12144 518-473-7793 https://ocfs.ny.gov/programs/cps

Prevent Child Abuse New York 4 Global View Troy, NY 12180 1-800-CHILDREN https://www.preventchildabuseny.org

COURSE TEST - #57533 CHILD ABUSE IDENTIFICATION AND REPORTING: THE NEW YORK REQUIREMENT

This is an open book test. A passing grade of at least 70% must be achieved in order to receive credit for this course.

This 2 CE Credit Hour activity must be completed by January 31, 2024.

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AGD SUBJECT CODE: 155.

- 1. The first child abuse case in the United States that garnered widespread interest involved Mary Ellen Wilson, a foster child in New York City. This case took place in
 - A) 1790.
 - B) 1866.
 - C) 1921.
 - D) 1965.

2. Child abuse is defined at the federal level by the

- A) Child Protective Services.
- B) Office of Child and Family Welfare.
- C) Child Abuse Prevention and Treatment Act.
- D) National Council on Child Abuse and Family Violence.

3. Which of the following injuries is NOT

- considered a possible indicator of physical abuse?
- A) Patterned burns
- B) Bruises on multiple body areas
- C) Abrasions to the knees and elbows
- D) Multiple or spiral fractures at various stages of healing

- 4. Child sexual abuse is categorized as exhibitionism if the act involves
 - A) obscene phone calls.
 - B) forcing a child to observe sexual acts.
 - C) watching a child get dressed or undressed.
 - D) touching, fondling, or kissing the child in a provocative manner.
- A child discloses that he has not gone to school for two weeks. When questioned regarding the reason for the absences, the child states that his parents do not feel like bringing him to school. This may be reported as which type of abuse?
 - A) Physical abuse
 - B) Financial abuse
 - C) Emotional abuse/neglect
 - D) This is not an abuse case.
- 6. More than one-quarter of child abuse reports are made by
 - A) parents.
 - B) teachers.
 - C) other children.
 - D) health and mental or behavioral health professionals.

#57533 Child Abuse Identification and Reporting: The New York Requirement

- 7. In 2020, how many children in New York died as a result of child abuse and neglect?
 - A) 7
 - B) 23
 - C) 46
 - D) 105
- 8. Which of the following is a parental risk indicator that may be present in cases of child abuse/neglect?
 - A) Multiple work absences
 - B) Poor general appearance
 - C) Disruptions in sleep patterns
 - D) Unwillingness to provide information
- 9. Of the following, who is legally mandated by the state of New York to report suspected cases of child abuse?
 - A) Peace officers
 - B) District attorneys
 - C) Registered nurses
 - D) All of the above

- 10. Patient A, a child 10 years of age, arrives at the emergency department with a burn. Upon intake, a registered nurse notices that the burn on the child's thigh resembles the face of an iron. In addition, the child has bruising on her upper arm. The nurse suspects abuse and therefore calls the toll-free number for mandated reporters to report the case. Which of the following steps must the nurse take following the report?
 - A) The nurse must contact a physician for a complete evaluation of the child, including assessment for sexual abuse.
 - B) The nurse should call a legal aid society to ask for a lawyer to represent her in the event he/she is held liable if the case is not substantiated.
 - C) This nurse should inform the mother that he/she will be contacting the appropriate agencies regarding suspected child abuse and maltreatment.
 - D) The nurse must complete and sign a written report (LDSS-2221A) within 48 hours and submit the report to the local department of social services (LDSS) that has been assigned to the investigation.

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Implicit Bias in Health Care

Audience

This course is designed for dental professionals working in all practice settings.

Course Objective

The purpose of this course is to provide dental professionals with an overview of the impact of implicit biases on clinical interactions and decision making.

Learning Objectives

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

- 1. Define implicit and explicit biases and related terminology.
- 2. Evaluate the strengths and limitations of the Implicit Association Test.
- 3. Describe how different theories explain the nature of implicit biases, and outline the consequences of implicit biases.
- 4. Discuss strategies to raise awareness of and mitigate or eliminate one's implicit biases.

Faculty

Alice Yick Flanagan, PhD, MSW, received her Master's in Social Work from Columbia University, School of Social Work. She has clinical experience in mental health in correctional settings, psychiatric hospitals, and community health centers. In 1997, she received her PhD from UCLA, School of Public Policy and Social Research. Dr. Yick Flanagan completed a year-long post-doctoral fellowship at Hunter College, School of Social Work in 1999. In that year she taught the course Research Methods and Violence Against Women to Masters degree students, as well as conducting qualitative research studies on death and dying in Chinese American families. (A complete biography can be found at NetCE.com/faculty.)

Faculty Disclosure

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

In the 1990s, social psychologists Dr. Mahzarin Banaji and Dr. Tony Greenwald introduced the concept of implicit bias and developed the Implicit Association Test (IAT) as a measure. In 2003, the Institute of Medicine published the report *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care* highlighting the role of health professionals' implicit biases in the development of health disparities [1]. The phenomenon of implicit bias is premised on the assumption that while wellmeaning individuals may deny prejudicial beliefs, these implicit biases negatively affect their clinical communications, interactions, and diagnostic and treatment decision-making [2, 3].

One explanation is that implicit biases are a heuristic, or a cognitive or mental shortcut. Heuristics offer individuals general rules to apply to situations in which there is limited, conflicting, or unclear information. Use of a heuristic results in a quick judgment based on fragments of memory and knowledge, and therefore, the decisions made may be erroneous. If the thinking patterns are flawed, negative attitudes can reinforce stereotypes [4]. In health contexts, this is problematic because clinical judgments can be biased and adversely affect health outcomes. The Joint Commission provides the following example [3]: A group of physicians congregate to examine a child's x-rays but has not been able to reach a diagnostic consensus. Another physician with no knowledge of the case is passing by, sees the x-rays, and says "Cystic fibrosis." The group of physicians was aware that the child is African American and had dismissed cystic fibrosis because it is less common among Black children than White children.

The purpose of this course is to provide health professionals an overview of implicit bias. This includes an exploration of definitions of implicit and explicit bias. The nature and dynamics of implicit biases and how they can affect health outcomes will be discussed. Finally, because implicit biases are unconscious, strategies will be reviewed to assist in raising professionals' awareness of and interventions to reduce them.

DEFINITIONS OF IMPLICIT BIAS AND OTHER TERMINOLOGIES

IMPLICIT VS. EXPLICIT BIAS

In a sociocultural context, biases are generally defined as negative evaluations of a particular social group relative to another group. Explicit biases are conscious, whereby an individual is fully aware of his/her attitudes and there may be intentional behaviors related to these attitudes [5]. For example, an individual may openly endorse a belief that women are weak and men are strong. This bias is fully conscious and is made explicitly known. The individual's ideas may then be reflected in his/her work as a manager.

FitzGerald and Hurst assert that there are cases in which implicit cognitive processes are involved in biases and conscious availability, controllability, and mental resources are not [6]. The term "implicit bias" refers to the unconscious attitudes and evaluations held by individuals. These individuals do not necessarily endorse the bias, but the embedded beliefs/ attitudes can negatively affect their behaviors [2; 7; 8; 9]. Some have asserted that the cognitive processes that dictate implicit and explicit biases are separate and independent [9].

Implicit biases can start as early as 3 years of age. As children age, they may begin to become more egalitarian in what they explicitly endorse, but their implicit biases may not necessarily change in accordance to these outward expressions [10]. Because implicit biases occur on the subconscious or unconscious level, particular social attributes (e.g., skin color) can quietly and insidiously affect perceptions and behaviors [11]. According to Georgetown University's National Center on Cultural Competency, social characteristics that can trigger implicit biases include [12]:

- Age
- Disability
- Education
- English language proficiency and fluency
- Ethnicity
- Health status
- Disease/diagnosis (e.g., HIV/AIDS)
- Insurance
- Obesity
- Race

- Sexual orientation, gender identity, or gender expression
- Skin tone
- Substance use

An alternative way of conceptualizing implicit bias is that an unconscious evaluation is only negative if it has further adverse consequences on a group that is already disadvantaged or produces inequities [6; 13]. Disadvantaged groups are marginalized in the healthcare system and vulnerable on multiple levels; health professionals' implicit biases can further exacerbate these existing disadvantages [13].

When the concept of implicit bias was introduced in the 1990s, it was thought that implicit biases could be directly linked to behavior. Despite the decades of empirical research, many questions, controversies, and debates remain about the dynamics and pathways of implicit biases [2].

OTHER COMMON TERMINOLOGIES

In addition to understanding implicit and explicit bias, there is additional terminology related to these concepts that requires specific definition.

Cultural Competence

Cultural competence is broadly defined as practitioners' knowledge of and ability to apply cultural information and appreciation of a different group's cultural and belief systems to their work [14]. It is a dynamic process, meaning that there is no endpoint to the journey to becoming culturally aware, sensitive, and competent. Some have argued that cultural curiosity is a vital aspect of this approach.

Cultural Humility

Cultural humility refers to an attitude of humbleness, acknowledging one's limitations in the cultural knowledge of groups. Practitioners who apply cultural humility readily concede that they are not experts in others' cultures and that there are aspects of culture and social experiences that they do not know. From this perspective, patients are considered teachers of the cultural norms, beliefs, and value systems of their group, while practitioners are the learners [15]. Cultural humility is a lifelong process involving reflexivity, self-evaluation, and self-critique [16].

Discrimination

Discrimination has traditionally been viewed as the outcome of prejudice [17]. It encompasses overt or hidden actions, behaviors, or practices of members in a dominant group against members of a subordinate group [18]. Discrimination has also been further categorized as lifetime discrimination, which consists of major discreet discriminatory events, or everyday discrimination, which is subtle, continual, and part of dayto-day life and can have a cumulate effect on individuals [19].

Diversity

Diversity "encompasses differences in and among societal groups based on race, ethnicity, gender, age, physical/mental abilities, religion, sexual orientation, and other distinguishing characteristics" [20]. Diversity is often conceptualized into singular dimensions as opposed to multiple and intersecting diversity factors [21].

Intersectionality

Intersectionality is a term to describe the multiple facets of identity, including race, gender, sexual orientation, religion, sex, and age. These facets are not mutually exclusive, and the meanings that are ascribed to these identities are inter-related and interact to create a whole [22].

Prejudice

Prejudice is a generally negative feeling, attitude, or stereotype against members of a group [23]. It is important not to equate prejudice and racism, although the two concepts are related. All humans have prejudices, but not all individuals are racist. The popular definition is that "prejudice plus power equals racism" [23]. Prejudice stems from the process of ascribing every member of a group with the same attribute [24].

Race

Race is linked to biology. Race is partially defined by physical markers (e.g., skin or hair color) and is generally used as a mechanism for classification [25]. It does not refer to cultural institutions or patterns. In modern history, skin color has been used to classify people and to imply that there are distinct biologic differences within human populations [26]. Historically, the U.S. Census has defined race according to ancestry and blood quantum; today, it is based on self-classification [26].

There are scholars who assert that race is socially constructed without any biological component [27]. For example, racial characteristics are also assigned based on differential power and privilege, lending to different statuses among groups [28].

Racism

Racism is the "systematic subordination of members of targeted racial groups who have relatively little social power...by members of the agent racial group who have relatively more social power" [29]. Racism is perpetuated and reinforced by social values, norms, and institutions.

There is some controversy regarding whether unconscious (implicit) racism exists. Experts assert that images embedded in our unconscious are the result of socialization and personal observations, and negative attributes may be unconsciously applied to racial minority groups [30]. These implicit attributes affect individuals' thoughts and behaviors without a conscious awareness.

#57000 Implicit Bias in Health Care

Structural racism refers to the laws, policies, and institutional norms and ideologies that systematically reinforce inequities resulting in differential access to services such as health care, education, employment, and housing for racial and ethnic minorities [31; 32].

MEASUREMENT OF IMPLICIT BIAS: A FOCUS ON THE IAT

Project Implicit is a research project sponsored by Harvard University and devoted to the study and monitoring of implicit biases. It houses the Implicit Association Test (IAT), which is one of the most widely utilized standardized instruments to measure implicit biases. The IAT is based on the premise that implicit bias is an objective and discreet phenomenon that can be measured in a quantitative manner. Developed and first introduced in 1998, it is an online test that assesses implicit bias by measuring how quickly people make associations between targeted categories with a list of adjectives [33]. For example, research participants might be assessed for their implicit biases by seeing how rapidly they make evaluations among the two groups/categories career/family and male/ female. Participants tend to more easily affiliate terms for which they hold implicit or explicit biases. So, unconscious biases are measured by how quickly research participants respond to stereotypical pairings (e.g., career/male and family/female). The larger the difference between the individual's performance between the two groups, the stronger the degree of bias [34; 35]. Since 2006, more than 4.6 million individuals have taken the IAT, and results indicate that the general population holds implicit biases [3].



Visit https://implicit.harvard.edu/implicit and complete an assessment. Does it reflect your perception of your own biases? Did you learn anything about yourself?

Measuring implicit bias is complex, because it requires an instrument that is able to access underlying unconscious processes. While many of the studies on implicit biases have employed the IAT, there are other measures available. They fall into three general categories: the IAT and its variants, priming methods, and miscellaneous measures, such as selfreport, role-playing, and computer mouse movements [36]. This course will focus on the IAT, as it is the most commonly employed instrument.

The IAT is not without controversy. One of the debates involves whether IAT scores focus on a cognitive state or if they reflect a personality trait. If it is the latter, the IAT's value as a diagnostic screening tool is diminished [37]. There is also concern with its validity in specific arenas, including jury selection and hiring [37]. Some also maintain that the IAT is sensitive to social context and may not accurately predict behavior [37]. Essentially, a high IAT score reflecting implicit biases does not necessarily link to discriminating behaviors, and correlation should not imply causation. A meta-analysis involving 87,418 research participants found no evidence that changes in implicit biases affected explicit behaviors [38].

EXTENT OF IMPLICIT BIASES AND RISK FACTORS

Among the more than 4 million participants who have completed the IAT, individuals generally exhibited implicit preference for White faces over Black or Asian faces. They also held biases for light skin over dark skin, heterosexual over gender and sexual minorities (LGBTQ+), and young over old [39]. The Pew Research Center also conducted an exploratory study on implicit biases, focusing on the extent to which individuals adhered to implicit racial biases [40]. A total of 2,517 IATs were completed and used for the analysis. Almost 75% of the respondents exhibited some level of implicit racial biases. Only 20% to 30% did not exhibit or showed very little implicit bias against the minority racial groups tested. Approximately half of all single-race White individuals displayed an implicit preference for White faces over Black faces. For single-race Black individuals, 45% had implicit preference for their own group. For biracial White/Black adults, 23% were neutral. In addition, 22% of biracial White/Asian participants had no or minimal implicit racial biases. However, 42% of the White/ Black biracial adults leaned toward a pro-White bias.

In another interesting field experiment, although not specifically examining implicit bias, resumes with names commonly associated with African American or White candidates were submitted to hiring officers [41]. Researchers found that resumes with White-sounding names were 50% more likely to receive callbacks than resumes with African Americansounding names [41]. The underlying causes of this gap were not explored.

Implicit bias related to sex and gender is also significant. A survey of emergency medicine and obstetrics/gynecology residency programs in the United States sought to examine the relationship between biases related to perceptions of leadership and gender [42]. In general, residents in both programs (regardless of gender) tended to favor men as leaders. Male residents had greater implicit biases compared with their female counterparts.

Other forms of implicit bias can affect the provision of health and mental health care. One online survey examining anti-fat biases was provided to 4,732 first-year medical students [43]. Respondents completed the IAT, two measures of explicit bias, and an anti-fat attitudes instrument. Nearly 75% of the respondents were found to hold implicit anti-fat biases. Interestingly, these biases were comparable to the scope of implicit racial biases. Male sex, non-Black race, and lower body mass index (BMI) predicted holding these implicit biases. Certain conditions or environmental risk factors are associated with an increased risk for certain implicit biases, including [44; 45]:

- Stressful emotional states (e.g., anger, frustration)
- Uncertainty
- Low-effort cognitive processing
- Time pressure
- Lack of feedback
- Feeling behind with work
- Lack of guidance
- Long hours
- Overcrowding
- High-crises environments
- Mentally taxing tasks
- Juggling competing tasks

THEORETIC EXPLANATIONS AND CONTROVERSIES

A variety of theoretical frameworks have been used to explore the causes, nature, and dynamics of implicit biases. Each of the theories is described in depth, with space given to explore controversies and debates about the etiology of implicit bias.

SOCIAL PSYCHOLOGICAL AND COGNITIVE THEORETICAL FRAMEWORKS

One of the main goals of social psychology is to understand how attitudes and belief structures influence behaviors. Based on frameworks from both social and cognitive psychology, many theoretical frameworks used to explain implicit bias revolve around the concept of social cognition. One branch of cognitive theory focuses on the role of implicit or nondeclarative memory. Experts believe that this type of memory allows certain behaviors to be performed with very little conscious awareness or active thought. Examples include tooth brushing, tying shoelaces, and even driving. To take this concept one step farther, implicit memories may also underlie social attitudes and stereotype attributions [46]. This is referred to as implicit social cognition. From this perspective, implicit biases are automatic expressions based on belonging to certain social groups [47]. The IAT is premised on the role of implicit memory and past experiences in predicting behavior without explicit memory triggering [48].

Another branch of cognitive theory used to describe implicit biases involves heuristics. When quick decisions are required under conditions of uncertainty or fatigue, and/or when there is a tremendous amount of information to assimilate without sufficient time to process, decision-makers resort to heuristics [49]. Heuristics are essentially mental short cuts that facilitate (usually unconscious) rules that promote automatic processing [50]. However, these rules can also be influenced by socialization factors, which could then affect any unconscious or latent cognitive associations about power, advantage, and privilege. Family, friends, media, school, religion, and other social institutions all play a role in developing and perpetuating implicit and explicit stereotypes, and cognitive evaluations can be primed or triggered by an environmental cue or experience [51]. When a heuristic is activated, an implicit memory or bias may be triggered simultaneously [47]. This is also known as the dual-process model of information processing [50].

BEHAVIORAL OR FUNCTIONAL PERSPECTIVES

Behavioral or functional theorists argue that implicit bias is not necessarily a latent or unconscious cognitive structure. Instead, this perspective recognizes implicit bias as a group-based behavior [52]. Behavior is biased if it is influenced by social cues indicating the social group to which someone belongs [52]. Social cues can occur rapidly and unintentionally, which ultimately leads to automatic or implicit effects on behavior. The appeal of a behavioral or functional approach to implicit bias is that it is amoral; that is, it is value- and judgment-free [52]. Rather than viewing implicit bias as an invisible force (i.e., unconscious cognitive structure), it is considered a normal behavior [53].

NEUROSCIENTIFIC PERSPECTIVES

Implicit bias has neuroscientific roots as well and has been linked to functions of the amygdala [2; 54]. The amygdala is located in the temporal lobe of the brain, and it communicates with the hypothalamus and plays a large role in memory. When situations are emotionally charged, the amygdala is activated and connects the event to memory, which is why individuals tend to have better recall of emotional events. This area of the brain is also implicated in processing fear. Neuroscientific studies on implicit biases typically use functional magnetic resonance imaging (fMRI) to visualize amygdala activation during specific behaviors or events. In experimental studies, when White research subjects were shown photos of Black faces, their amygdala appeared to be more activated compared to when they viewed White faces [55]. This trend toward greater activation when exposed to view the faces of persons whose race differs from the viewer starts in adolescence and appears to increase with age [54]. This speaks to the role of socialization in the developmental process [54].

It may be that the activation of the amygdala is an evolutionary threat response to an outgroup [56]. Another potential explanation is that the activation of the amygdala is due to the fear of appearing prejudiced to others who will disapprove of the bias [56]. The neuroscientific perspective of implicit bias is controversial. While initial empirical studies appear to link implicit bias to amygdala activation, many researchers argue this relationship is too simplistic [2].

STRUCTURAL OR CRITICAL THEORY

Many scholars and policymakers are concerned about the narrow theoretical views that researchers of implicit bias have taken. By focusing on unconscious cognitive structures, social cognition and neuroscientific theories miss the opportunity to also address the role of macro or systemic factors in contributing to health inequities [9; 57]. By focusing on the neurobiology of implicit bias, for example, racism and bias is attributed to central nervous system function, releasing the individual from any control or responsibility. However, the historical legacy of prejudice and bias has roots in economic and structural issues that produce inequities [58]. Larger organizational, institutional, societal, and cultural forces contribute, perpetuate, and reinforce implicit and explicit biases, racism, and discrimination. Psychological and neuroscientific approaches ultimately decontextualize racism [9; 57].

In response to this conflict, a systems-based practice has been proposed [59]. This type of practice emphasizes the role of sociocultural determinants of health outcome and the fact that health inequities stem from larger systemic forces. As a result, medical and health education and training should focus on how patients' health and well-being may reflect structural vulnerabilities driven in large part by social, cultural, economic, and institutional forces. Health and mental health professionals also require social change and advocacy skills to ensure that they can effect change at the organizational and institutional levels [59].

Implicit bias is not a new topic; it has been discussed and studied for decades in the empirical literature. Because implicit bias is a complex and multifaceted phenomenon, it is important to recognize that there may be no one single theory that can fully explain its etiology.

CONSEQUENCES OF IMPLICIT BIASES

HEALTH DISPARITIES

Implicit bias has been linked to a variety of health disparities [1]. Health disparities are differences in health status or disease that systematically and adversely affect less advantaged groups [60]. These inequities are often linked to historical and current unequal distribution of resources due to poverty, structural inequities, insufficient access to health care, and/or environmental barriers and threats [61]. Healthy People 2030 defines a health disparity as [62]:

...a particular type of health difference that is closely linked with social, economic, and/or environmental disadvantage. Health disparities adversely affect groups of people who have systematically experienced greater obstacles to health based on their racial or ethnic group; religion; socioeconomic status; gender; age; mental health; cognitive, sensory, or physical disability; sexual orientation or gender identity; geographic location; or other characteristics historically linked to discrimination or exclusion.

As noted, in 2003, the Institute of Medicine implicated implicit bias in the development and continued health disparities in the United States [1]. Despite progress made to lessen the gaps among different groups, health disparities continue to exist. One example is racial disparities in life expectancy among Black and White individuals in the United States. Life expectancy for Black men is 4.4 years lower than White men; for Black women, it is 2.9 years lower compared with White women [63]. Hypertension, diabetes, and obesity are more prevalent in non-Hispanic Black populations compared with non-Hispanic White groups (25%, 49%, and 59% higher, respectively) [64]. In one study, African American and Latina women were more likely to experience cesarean deliveries than their White counterparts, even after controlling for medically necessary procedures [65]. This places African American and Latina women at greater risk of infection and maternal mortality.

Gender health disparities have also been demonstrated. Generally, self-rated physical health (considered one of the best proxies to health) is poorer among women than men. Depression is also more common among women than men [66]. Lesbian and bisexual women report higher rates of depression and are more likely than non-gay women to engage risk behaviors such as smoking and binge drinking, perhaps as a result of LGBTQ+-related stressors. They are also less likely to access healthcare services [67].

Socioeconomic status also affects health care engagement and quality. In a study of patients seeking treatment for thoracic trauma, those without insurance were 1.9 times more likely to die compared with those with private insurance [68].

CLINICAL DECISIONS AND PROVIDER-PATIENT INTERACTIONS

In an ideal situation, health professionals would be explicitly and implicitly objective and clinical decisions would be completely free of bias. However, healthcare providers have implicit (and explicit) biases at a rate comparable to that of the general population [6; 69]. It is possible that these implicit biases shape healthcare professionals' behaviors, communications, and interactions, which may produce differences in help-seeking, diagnoses, and ultimately treatments and interventions [69]. They may also unwittingly produce professional behaviors, attitudes, and interactions that reduce patients' trust and comfort with their provider, leading to earlier termination of visits and/or reduced adherence and follow-up [7].

In a landmark 2007 study, a total of 287 internal medicine physicians and medical residents were randomized to receive a case vignette of an either Black or White patient with coronary artery disease [70]. All participants were also administered the IAT. When asked about perceived level of cooperativeness of the White or Black patient from the vignette, there were no differences in their explicit statements regarding cooperativeness. Yet, the IAT scores did show differences, with scores showing that physicians and residents had implicit preferences for the White patients. Participants with greater implicit preference for White patients (as reflected by IAT score) were more likely to select thrombolysis to treat the White patient than the Black patient [70]. This led to the possible conclusion that implicit racial bias can influence clinical decisions regarding treatment and may contribute to racial health disparities. However, some argue that using vignettes depicting hypothetical situations does not accurately reflect real-life conditions that require rapid decision-making under stress and uncertainty.

PATIENTS' PERCEPTIONS OF CARE

It has been hypothesized that providers' levels of bias affect the ratings of patient-centered care [34]. Patient-centered care has been defined as patients' positive ratings in the areas of perception of provider concern, provider answering patients' questions, provider integrity, and provider knowledge of the patient. Using data from 134 health providers who completed the IAT, a total of 2,908 diverse racial and ethnic minority patients participated in a telephone survey. Researchers found that for providers who scored high on levels of implicit bias, African American patients' ratings for all dimensions of patient-centered care were low compared with their White patient counterparts. Latinx patient ratings were low regardless of level of implicit bias.

A 2013 study recorded clinical interactions between 112 low-income African American patients and their 14 non-African American physicians for approximately two years [71]. Providers' implicit biases were also assessed using the IAT. In general, the physicians talked more than the patients; however, physicians with higher implicit bias scores also had a higher ratio of physician-to-patient talk time. Patients with higher levels of perceived discrimination had a lower ratio of physician-to-patient talk time (i.e., spoke more than those with lower reported perceived discrimination). A lower ratio of physician-patient talk time correlated to decreased likelihood of adherence.

Another study assessed 40 primary care physicians and 269 patients [72]. The IAT was administered to both groups, and their interactions were recorded and observed for verbal dominance (defined as the time of physician participation relative to patient participation). When physicians scored higher on measures of implicit bias, there was 9% more verbal dominance on the part of the physicians in the visits with Black patients and 11% greater in interactions with White patients. Physicians with higher implicit bias scores and lower verbal dominance also received lower scores on patient ratings on interpersonal care, particularly from Black patients [72].

In focus groups with racially and ethnically diverse patients who sought medical care for themselves or their children in New York City, participants reported perceptions of discrimination in health care [73]. They reported that healthcare professionals often made them feel less than human, with varying amounts of respect and courtesy. Some observed differences in treatment compared with White patients. One Black woman reported [73]:

When the doctor came in [after a surgery], she proceeded to show me how I had to get up because I'm being released that day "whether I like it or not"... She yanked the first snap on the left leg...So I'm thinking, 'I'm human!' And she was courteous to the White lady [in the next bed], and I've got just as much age as her. I qualify on the level and scale of human being as her, but I didn't feel that from the doctor.

Another participant was a Latino physician who presented to the emergency department. He described the following [73]:

They put me sort of in the corner [in the emergency department] and I can't talk very well because I can't breathe so well. The nurse comes over to me and actually says, "Tu tiene tu Medicaid?" I whispered out, "I'm a doctor...and I have insurance." I said it in perfect English. Literally, the color on her face went completely white...Within two minutes there was an orthopedic team around me...I kept wondering about what if I hadn't been a doctor, you know? Pretty eye opening and very sad.

These reports are illustrative of many minority patients' experiences with implicit and explicit racial/ethnic biases. Not surprisingly, these biases adversely affect patients' views of their clinical interactions with providers and ultimately contribute to their mistrust of the healthcare system.

DEVELOPMENTAL MODEL TO RECOGNIZING AND REDUCING IMPLICIT BIAS

There are no easy answers to raising awareness and reducing health providers' implicit bias. Each provider may be in a different developmental stage in terms of awareness, understanding, acceptance, and application of implicit bias to their practice. A developmental model for intercultural sensitivity training has been established to help identify where individuals may be in this developmental journey [74; 75]. It is important to recognize that the process of becoming more self-aware is fluid; reaching one stage does not necessarily mean that it is "conquered" or that there will not be additional work to do in that stage. As a dynamic process, it is possible to move back and forth as stress and uncertainty triggers implicit biases [74]. This developmental model includes six stages:

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- Denial: In this stage, the individual has no awareness of the existence of cultural differences between oneself and members of other cultural groups and subgroups. Individuals in this stage have no awareness of implicit bias and cannot distinguish between explicit and implicit biases.
- Defense: In this stage, the person may accept that implicit biases exist but does not acknowledge that implicit biases exist within themselves.
- Minimization: An individual in this stage acknowledges that implicit biases may exist in their colleagues and possibly themselves. However, he or she is uncertain of their consequences and adverse effects. Furthermore, the person believes he or she is able to treat patients in an objective manner.
- Acceptance: In the acceptance stage, the individual recognizes and acknowledges the role of implicit biases and how implicit biases influence interactions with patients.
- Adaptation: Those in the adaptation stage self-reflect and acknowledge that they have unrecognized implicit biases. Not only is there an acknowledgement of the existence of implicit bias, these people begin to actively work to reduce the potential impact of implicit biases on interactions with patients.
- Integration: At this stage, the health professional works to incorporate change in their day-to-day practice in order to mitigate the effects of their implicit biases on various levels—from the patient level to the organization level.

CREATING A SAFE ENVIRONMENT

Creating a safe environment is the essential first step to exploring issues related to implicit bias. Discussions of race, stereotypes, privilege, and implicit bias, all of which are very complex, can be volatile or produce heightened emotions. When individuals do not feel their voices are heard and/or valued, negative emotions or a "fight-or-flight" response can be triggered [76]. This may manifest as yelling, demonstrations of anger, or crying or leaving the room or withdrawing and remaining silent [76].

Creating and fostering a sense of psychological safety in the learning environment is crucial. Psychological safety results when individuals feel that their opinions, views, thoughts, and contributions are valued despite tension, conflict, and discomfort. This allows the individual to feel that their identity is intact [76]. When psychological safety is threatened, individuals' energies are primarily expended on coping rather than learning [76]. As such, interventions should not seek to confront individuals or make them feel guilty and/or responsible [77]. When implicit bias interventions or assessments are planned, facilitators should be open, approachable, non-threatening, and knowledgeable; this will help create a safe and inclusive learning environment [77]. The principles of respect, integrity, and confidentiality should be communicated [77]. Facilitators who demonstrate attunement, authenticity, and power-sharing foster positive and productive dialogues about subjects such as race and identity [76]. Attunement is the capacity of an individual to tacitly comprehend the lived experiences of others, using their perspectives to provide an alternative viewpoint for others. Attunement does not involve requiring others to talk about their experiences if they are not emotionally ready [76]. Authenticity involves being honest and transparent with one's own position in a racialized social structure and sharing one's own experiences, feelings, and views. Being authentic also means being vulnerable [76]. Finally, power-sharing entails redistributing power in the learning environment. The education environment is typically hierarchical, with an expert holding more power than students or participants. Furthermore, other students may hold more power by virtue of being more comfortable speaking/interacting [76]. Ultimately, promoting a safe space lays a foundation for safely and effectively implementing implicit bias awareness and reduction interventions.

STRATEGIES TO PROMOTE AWARENESS OF IMPLICIT BIAS

As discussed, the IAT can be used as a metric to assess professionals' level of implicit bias on a variety of subjects, and this presupposes that implicit bias is a discrete phenomenon that can be measured quantitatively [79]. When providers are aware that implicit biases exist, discussion and education can be implemented to help reduce them and/or their impact.

Another way of facilitating awareness of providers' implicit bias is to ask self-reflective questions about each interaction with patients. Some have suggested using SOAP (subjective, objective, assessment, and plan) notes to assist practitioners in identifying implicit biases in day-to-day interactions with patients [80]. Integrating the following questions into charts and notes can stimulate reflection about implicit bias globally and for each specific patient interaction:

- Did I think about any socioeconomic and/or environmental factors that may contribute to the health and access of this patient?
- How was my communication and interaction with this patient? Did it change from my customary pattern?
- How could my implicit biases influence care for this patient?

When reviewing the SOAP notes, providers can look for recurring themes of stereotypical perceptions, biased communication patterns, and/or types of treatment/interventions proposed and assess whether these themes could be influenced by biases related to race, ethnicity, age, gender, sexuality, or other social characteristics.

A review of empirical studies conducted on the effectiveness of interventions promoting implicit bias awareness found mixed results. At times, after a peer discussion of IAT scores, participants appeared less interested in learning and employing implicit bias reduction interventions. However, other studies have found that receiving feedback along with IAT scores resulted in a reduction in implicit bias [81]. Any feedback, education, and discussions should be structured to minimize participant defensiveness [81].

INTERVENTIONS TO REDUCE IMPLICIT BIASES

Interventions or strategies designed to reduce implicit bias may be further categorized as change-based or control-based [58]. Change-based interventions focus on reducing or changing cognitive associations underlying implicit biases. These interventions might include challenging stereotypes. Conversely, control-based interventions involve reducing the effects of the implicit bias on the individual's behaviors [58]. These strategies include increasing awareness of biased thoughts and responses. The two types of interventions are not mutually exclusive and may be used synergistically.

PERSPECTIVE TAKING

Perspective taking is a strategy of taking on a first-person perspective of a person in order to control one's automatic response toward individuals with certain social characteristics that might trigger implicit biases [82]. The goal is to increase psychological closeness, empathy, and connection with members of the group [4]. Engaging with media that presents a perspective (e.g., watching documentaries, reading an autobiography) can help promote better understanding of the specific group's lives, experiences, and viewpoints. In one study, participants who adopted the first-person perspectives of African Americans had more positive automatic evaluations of the targeted group [83].

interactive activity -

Consuming media that presents a viewpoint and life experience different from your own can help minimize implicit biases. Visit the following sites and consider how they might challenge or expand your perception of each group. Internet searches can help identify many more options for various social groups.

Think Out Loud Podcast

Young Black people share their experiences growing up in Portland, Oregon.

https://podcasts.apple.com/us/podcast/youngblack-people-share-their-experiences-growing/ id274122573?i=1000496652363

George Takei: Growing Up Asian-American

This PBS clip is a brief introduction, and the subject can be further explored in Takei's book *They Called Us Enemy*.

https://www.pbs.org/wnet/pioneers-of-television/video/george-takei-growing-up-asian-american

Seattle Public Library LGBTQ Staff Picks

A reading list including books and films focusing on LGBTQ+ life, culture, history, and politics. https://www.spl.org/programs-and-services/socialjustice/lgbtq/lgbt-staff-picks

EMPATHY INTERVENTIONS

Promoting positive emotions such as empathy and compassion can help reduce implicit biases. This can involve strategies like perspective taking and role playing [77]. In a study examining analgesic prescription disparities, nurses were shown photos of White or African American patients exhibiting pain and were asked to recommend how much pain medication was needed; a control group was not shown photos. Those who were shown images of patients in pain displayed no differences in recommended dosage along racial lines; however, those who did not see the images averaged higher recommended dosages for White patients compared with Black patients [84]. This suggests that professionals' level of empathy (enhanced by seeing the patient in pain) affected prescription recommendations.

In a study of healthcare professionals randomly assigned to an empathy-inducing group or a control group, participants were given the IAT to measure implicit bias prior to and following the intervention. Level of implicit bias among participants in the empathy-inducing group decreased significantly compared with their control group counterparts [85].

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INDIVIDUATION

Individuation is an implicit bias reduction intervention that involves obtaining specific information about the individual and relying on personal characteristics instead of stereotypes of the group to which he or she belongs [4; 82]. The key is to concentrate on the person's specific experiences, achievements, personality traits, qualifications, and other personal attributes rather than focusing on gender, race, ethnicity, age, ability, and other social attributes, all of which can activate implicit biases. When providers lack relevant information, they are more likely to fill in data with stereotypes, in some cases unconsciously. Time constraints and job stress increase the likelihood of this occurring [69].

MINDFULNESS

Mindfulness requires stopping oneself and deliberately emptying one's mind of distractions or allowing distractions to drift through one's mind unimpeded, focusing only on the moment; judgment and assumptions are set aside. This approach involves regulating one's emotions, responses, and attention to return to the present moment, which can reduce stress and anxiety [86]. There is evidence that mindfulness can help regulate biological and emotional responses and can have a positive effect on attention and habit formation [4]. A mindfulness activity assists individuals to be more aware of their thoughts and sensations. This focus on deliberation moves the practitioner away from a reliance on instincts, which is the foundation of implicit bias-affected practice [4; 87].

Mindfulness approaches include yoga, meditation, and guided imagery. Additional resources to encourage a mindfulness practice are provided later in this course.

Goldstein has developed the STOP technique as a practical approach to engage in mindfulness in any moment [88]. STOP is an acronym for:

- Stop
- Take a breath
- Observe
- Proceed

inter*active* Pactivity

Visit the following website to view a short animated video on the STOP technique. After viewing the video, consider how you can incorporate the technique into your work. https://elishagoldstein.com/short-animated-stoppractice-elisha-goldstein-phd Mindfulness practice has been explored as a technique to reduce activation or triggering of implicit bias, enhance awareness of and ability to control implicit biases that arise, and increase capacity for compassion and empathy toward patients by reducing stress, exhaustion, and compassion fatigue [89]. One study examined the effectiveness of a loving-kindness meditation practice training in improving implicit bias toward African Americans and unhoused persons. One hundred one non-Black adults were randomized to one of three groups: a six-week loving-kindness mindfulness practice, a six-week loving-kindness discussion, or the waitlist control. The IAT was used to measure implicit biases, and the results showed that the loving-kindness meditation practice decreased levels of implicit biases toward both groups [90].

There is also some novel evidence that mindfulness may have neurologic implications. For example, one study showed decreased amygdala activation after a mindfulness meditation [91]. However, additional studies are required in this area before conclusions can be reached.

COUNTER-STEREOTYPICAL IMAGING

Counter-stereotypical imaging approaches involve presenting an image, idea, or construct that is counter to the oversimplified stereotypes typically held regarding members of a specific group. In one study, participants were asked to imagine either a strong woman (the experimental condition) or a genderneutral event (the control condition) [92]. Researchers found that participants in the experimental condition exhibited lower levels of implicit gender bias. Similarly, exposure to female leaders was found to reduce implicit gender bias [93]. Whether via increased contact with stigmatized groups to contradict prevailing stereotypes or simply exposure to counterstereotypical imaging, it is possible to unlearn associations underlying various implicit biases. If the social environment is important in priming positive evaluations, having more positive visual images of members in stigmatized groups can help reduce implicit biases [94]. Some have suggested that even just hanging photos and having computer screensavers reflecting positive images of various social groups could help to reduce negative associations [94].

EFFECTIVENESS OF IMPLICIT BIAS INTERVENTIONS

The effectiveness of implicit bias trainings and interventions has been scrutinized. In a 2019 systematic review, different types of implicit bias reduction interventions were evaluated. A meta-analysis of empirical studies published between May 2005 and April 2015 identified eight different classifications of interventions [13]:

- Engaging with others' perspectives, consciousnessraising, or imagining contact with outgroup: Participants either imagine how the outgroup thinks and feels, imagine having contact with the outgroup, or are made aware of the way the outgroup is marginalized or given new information about the outgroup.
- Identifying the self with the outgroup: Participants perform tasks that lessen barriers between themselves and the outgroup.
- Exposure to counter-stereotypical exemplars: Participants are exposed to exemplars that contradict negative stereotypes of the outgroup.
- Appeal to egalitarian values: Participants are encouraged to activate egalitarian goals or think about multiculturalism, cooperation, or tolerance.
- Evaluative conditioning: Participants perform tasks to strengthen counter-stereotypical associations.
- Inducing emotion: Emotions or moods are induced in participants.
- Intentional strategies to overcome biases: Participants are instructed to implement strategies to over-ride or suppress their biases.
- Pharmacotherapy

Interventions found to be the most effective were, in order from most to least, [13]:

- Intentional strategies to overcome biases
- Exposure to counter-stereotypical exemplars
- Identifying self with the outgroup
- Evaluative conditioning
- Inducing emotions

In general, the sample sizes were small. It is also unclear how generalizable the findings are, given many of the research participants were college psychology students. The 30 studies included in the meta-analysis were cross-sectional (not longitudinal) and only measured short-term outcomes, and there is some concern about "one shot" interventions, given the fact that implicit biases are deeply embedded. Would simply acknowledging the existence of implicit biases be sufficient to eliminate them [95; 96]? Or would such a confession act as an illusion to having self-actualized and moved beyond the bias [95]?

Optimally, implicit bias interventions involve continual practice to address deeply habitual implicit biases or interventions that target structural factors [95; 96].

ROLE OF INTERPROFESSIONAL COLLABORATION AND PRACTICE AND IMPLICIT BIASES

The study of implicit bias is appropriately interdisciplinary, representing social psychology, medicine, health psychology, neuroscience, counseling, mental health, gerontology, LGBTQ+ studies, religious studies, and disability studies [13]. Therefore, implicit bias empirical research and curricula training development lends itself well to interprofessional collaboration and practice (ICP).

One of the core features of IPC is sharing—professionals from different disciplines share their philosophies, values, perspectives, data, and strategies for planning of interventions [97]. IPC also involves the sharing of roles, responsibilities, decision making, and power [98]. Everyone on the team employs their expertise, knowledge, and skills, working collectively on a shared, patient-centered goal or outcome [98; 99].

Another feature of IPC is interdependency. Instead of working in an autonomous manner, each team member's contributions are valued and maximized, which ultimately leads to synergy [97]. At the heart of this are two other key features: mutual trust/respect and communication [99]. In order to share responsibilities, the differing roles and expertise are respected.

Experts have recommended that a structural or critical theoretical perspective be integrated into core competencies in healthcare education to teach students about implicit bias, racism, and health disparities [100]. This includes [100]:

- Values/ethics: The ethical duty for health professionals to partner and collaborate to advocate for the elimination of policies that promote the perpetuation of implicit bias, racism, and health disparities among marginalized populations.
- Roles/responsibilities: One of the primary roles and responsibilities of health professionals is to analyze how institutional and organizational factors promote racism and implicit bias and how these factors contribute to health disparities. This analysis should extend to include one's own position in this structure.
- Interprofessional communication: Ongoing discussions of implicit bias, perspective taking, and counter-stereotypical dialogues should be woven into day-to-day practice with colleagues from diverse disciplines.
- Teams/teamwork: Health professionals should develop meaningful contacts with marginalized communities in order to better understand whom they are serving.

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Adopting approaches from the fields of education, gender studies, sociology, psychology, and race/ethnic studies can help build curricula that represent a variety of disciplines [78]. Students can learn about and discuss implicit bias and its impact, not simply from a health outcomes perspective but holistically. Skills in problem-solving, communication, leadership, and teamwork should be included, so students can effect positive social change [78].

CONCLUSION

In the more than three decades since the introduction of the IAT, the implicit bias knowledge base has grown significantly. It is clear that most people in the general population hold implicit biases, and health professionals are no different. While there continue to be controversies regarding the nature, dynamics, and etiology of implicit biases, it should not be ignored as a contributor to health disparities, patient dissatisfaction, and suboptimal care. Given the complex and multifaceted nature of this phenomenon, the solutions to raise individuals' awareness and reduce implicit bias are diverse and evolving.

RESOURCES

American Bar Association Diversity and Inclusion Center Toolkits and Projects

https://www.americanbar.org/groups/diversity/resources/ toolkits

National Implicit Bias Network

https://implicitbias.net/resources/resources-by-category

The Ohio State University

The Women's Place: Implicit Bias Resources https://womensplace.osu.edu/resources/implicit-biasresources

The Ohio State University

Kirwan Institute for the Study of Race and Ethnicity http://kirwaninstitute.osu.edu

University of California, Los Angeles Equity, Diversity, and Inclusion: Implicit Bias https://equity.ucla.edu/know/implicit-bias

University of California, San Francisco, Office of Diversity and Outreach Unconscious Bias Resources https://diversity.ucsf.edu/resources/unconscious-biasresources

Unconscious Bias Project https://unconsciousbiasproject.org

MINDFULNESS RESOURCES

University of California, San Diego Center for Mindfulness https://medschool.ucsd.edu/som/fmph/research/mindfulness

University of California, Los Angeles Guided Meditations https://www.uclahealth.org/marc/mindful-meditations

Mindful: Mindfulness for Healthcare Professionals https://www.mindful.org/mindfulhome-mindfulness-for-

healthcare-workers-during-covid

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COURSE TEST - #57000 IMPLICIT BIAS IN HEALTH CARE

This is an open book test. A passing grade of at least 70% must be achieved in order to receive credit for this course.

This 3 CE Credit Hour activity must be completed by August 31, 2024.

Accreditations & Approvals: NetCE is an ADA CERP Recognized Provider.

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Designations of Credit: NetCE designates this activity for 3 continuing education credits. AGD Subject Code: 149.

AGD SUBJECT CODE: 149

- 1. Dr. X, a physician, acknowledges that she still has a lot to learn about different racial and ethnic minority groups. She is willing to learn from her patients and assume the role of learner. Dr. X is demonstrating
 - A) diversity.
 - B) reflexivity.
 - C) explicit bias.
 - D) cultural humility.
- 2. What tool is used to quantitatively measure implicit bias?
 - A) IAT
 - B) SOAP
 - C) STOP
 - D) fMRI
- 3. Which of the following is NOT a risk factor in triggering implicit biases for health professionals?
 - A) Uncertainty
 - B) Cognitive dissonance
 - C) Time pressure to make a rapid decision
 - D) Heavy workload and feeling behind schedule

- 4. How might critical theory or a structural perspective be integrated into the values and ethics of interprofessional collaboration and practice?
 - A) Advocate for more neurologic imaging studies to examine how implicit bias affects the brain.
 - B) Analyze how communications should reflect autonomous decision-making in its role in racism.
 - C) The ethical responsibility is to advocate for policies that perpetuate and reinforce implicit biases.
 - D) The role of health professionals is to focus less on the unconscious and instead emphasize explicit bias as the behaviors.
- 5. Which of the following statements regarding health disparities is FALSE?
 - A) Health disparities are linked to disadvantaged groups.
 - B) Health disparities refer to differences in health status and disease that are tied to structural inequities.
 - C) There are no differences in life expectancies among African Americans and White Americans.
 - D) The Institute of Medicine has implicated implicit bias in the development and continuance of health disparities.

Test questions continue on next page 🔶

- 6. An implicit bias training is offered at a hospital, and a total of 50 health professionals attend. During the breakout session, training participants are assigned to discussion groups. One nurse agrees that implicit bias is prevalent, but she is quite sure she does not hold any implicit biases. Which developmental stage might this nurse be in?
 - A) Defense
 - B) Minimization
 - C) Structural competence
 - D) Counter-stereotype acceptance
- 7. If psychological safety is threatened, what might be a potential outcome in implicit bias training?
 - A) Recriminations
 - B) Self-confessions of guilt
 - C) Health disparities increase
 - D) Learning may be compromised
- 8. As part of an implicit bias training, participants watch a film about an African American man's experiences navigating the health system and are asked to enter the protagonist's lived reality. What type of intervention is this?
 - A) Priming
 - B) Attunement
 - C) Control strategies
 - D) Perspective taking

- 9. Mr. A, a social worker, attempts to record personal information about his patients and not simply social characteristics. For example, he writes, "Patient is an elderly Hispanic woman, age 79 years. She lives with her daughter and is an avid pianist." What is this an example of?
 A) STOP
 - B) Priming
 - C) Power-sharing
 - D) Individuation
- 10. All of the following are concerns with research conducted to examine the effectiveness of implicit bias reduction interventions, EXCEPT:
 - A) The studies conducted to examine implicit bias reduction interventions utilize cross-sectional and not longitudinal designs.
 - B) The studies conducted to examine implicit bias reduction interventions may not be generalizable to the general population.
 - C) The studies conducted to examine implicit bias reduction interventions have measured long-term but not immediate outcomes.
 - D) Study samples have tended to include psychology students and it is not clear whether findings can be applied to other populations.

Go to NetCE.com/NYDN23 and click on the Get Started button. Enter the Customer ID and Quick Code found on the back of your booklet, then transfer your test answers and complete the course evaluation.

Responsible and Effective Opioid Prescribing

This course meets the New York prescriber requirement for 3 hours of education in pain management, palliative care, and addiction.

Audience

This course is designed for dental 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 dental professionals 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.
- 5. Describe the available treatment modalities for opioid use disorder.

Faculty

Mark Rose, BS, MA, LP, is a licensed psychologist in the State of Minnesota with a private consulting practice and a medical research analyst with a biomedical communications firm. Earlier healthcare technology assessment work led to medical device and pharmaceutical sector experience in new product development involving cancer ablative devices and pain therapeutics. Along with substantial experience in addiction research, Mr. Rose has contributed to the authorship of numerous papers on CNS, oncology, and other medical disorders. (A complete biography can be found at NetCE.com/faculty.)

Faculty Disclosure

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

Division Planner

William E. Frey, DDS, MS, FICD

Director of Development and Academic Affairs Sarah Campbell

Division Planner/Director Disclosure

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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

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-oflife 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

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 patients with pain, and how these potentially problematic behavioral responses to opioids both resemble and differ from physical dependence and pseudodependence. 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 extent of opioid analgesic use in the United States in the 2000s was 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. In 2017, 20% of adults are prescribed an opioid such as oxycodone and hydrocodone for chronic pain, and sales of opioid analgesics totaled approximately \$7 billion in 2016 [10; 33].

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]. A study using data from 2005 to 2015 showed opioid prescribing in 57 million visits from adolescents and young adults, representing a prescribing rate of nearly 15% in emergency departments and nearly 3% in outpatient clinical settings [36]. During the course of the study, emergency department prescribing decreased slightly while outpatient clinical setting prescribing remained the same [36]. 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. In 2016–2017, there were 127,101 nonmedical opioid emergency department visits [39]. While this number is an improvement from previous years, nonmedical use accounts for 47.6% of all emergency department visits related to opioids [39].

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

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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].

In 2016, the CDC issued updated guidance on the prescription of opioids for chronic pain [10]. The guideline addresses when to initiate or continue opioids for chronic pain; opioid selection, dosage, duration, follow-up, and discontinuation; and assessing risk and addressing harms of opioid use. In addition, the CDC further updated guidance against the misapplication of this guideline in 2019, noting that some policies and practices attributed to the guideline were inconsistent with the recommendations [40].

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. Several nonpharmacologic approaches are therapeutic complements to pain-relieving medication, lessening the need for higher doses and perhaps minimizing side effects. These interventions can help decrease pain or distress that may be contributing to the pain sensation. Approaches include palliative radiotherapy, complementary/alternative methods, manipulative and body-based methods, and cognitive/behavioral techniques. The choice of a specific nonpharmacologic intervention is based on the patient's preference, which, in turn, is usually based on a successful experience in the past.

Implantable intrathecal opioid infusion and/or spinal cord stimulation may be options for severe, intractable pain. Both options require that devices or ports be implanted, with associated risks. With intrathecal opioid infusion, the ability to deliver the drug directly into the spine provides pain relief with significantly smaller opioid doses, which can help to minimize side effects (e.g., drowsiness, dizziness, dry mouth, nausea,

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vomiting, and constipation) that can accompany systemic pain medications that might be delivered orally, transdermally, or through an IV [43]. However, use of opioid infusion has traditionally been limited to cancer pain. With spinal cord stimulation therapy, the most challenging aspect is patient selection. In order for patients to be considered for spinal cord stimulation, other options should have been ineffective or be contraindicated. Spinal cord stimulation is indicated for severe neuropathic pain persisting at least six months [91].

If opioids 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., \leq 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 patients who are opioid-naïve, start at the lowest possible dose and titrate to effect. Dosages for patients who are opioidtolerant 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 \geq 50 mg morphine equivalent dose (MED) per day. Decisions to titrate dose to \geq 90 mg MED/day should be avoided or carefully justified [10; 40].

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/extendedrelease 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 lifelimiting 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; 30; 34; 35]. 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; 42]. 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; 42]. As a result, many clinicians, especially primary care physicians, do not feel confident about their ability to manage pain in their patients [37; 42].

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]. Morphine, buprenorphine, oxycodone, hydromorphone, 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 patients who are opioid-naïve or who have 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*) [17; 28]. 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].

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

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- 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 comanagement 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 tools used 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; 28].



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://painphysicianjournal.com/2012/july/2012;%20 15;S67-S116.pdf. Last accessed April 28, 2021.)

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.)

RISK ASSESSMENT TOOLS

Opioid Risk Tool (ORT)

The Opioid Risk Tool (ORT) is a five-item, patient-administered 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].

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RISK STRATIFICATION FOR PATIENTS PRESCRIBED OPIOIDS

Low Risk
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
Medium Risk
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
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
High Risk
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
HIV = human immunodeficiency syndrome, MRI = magnetic resonance imaging.
Source: [17; 28] Table 1

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 [18, 19].

Screening Instrument or Substance Abuse Potential (SISAP)

The Screening Instrument or Substance Abuse Potential (SISAP) tool is a self-administered, five-item questionnaire addressing history developed used to predict the risk of opioid misuse. The SISAP is used to identify patients with a history of alcohol/substance abuse and improve pain management by facilitating focus on the appropriate use of opioid analgesics and therapeutic outcomes in the majority of patients who are

not at risk of opioid abuse, while carefully monitoring those who may be at greater risk [18].

CAGE and CAGE-AID

The original CAGE (Cut down, Annoyed, Guilty, and Eyeopener) 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) Score

The Diagnosis, Intractability, Risk, and Efficacy (DIRE) risk assessment score is a clinician-rated questionnaire that is used to predict patient compliance with long-term opioid therapy [18; 21]. Patients scoring lower on the DIRE tool are poor candidates for long-term opioid analgesia.
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

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 A's" [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; 29]:

- 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

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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; 29]:

- 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?

PATIENT RISK LEVEL AND FREQUENCY OF MONITORING					
Monitoring Tool		Patient Risk Level			
	Low	Medium	High		
Urine drug test	Every 1 to 2 years	Every 6 to 12 months	Every 3 to 6 months		
State prescription drug monitoring program	Twice per year	Three times per year	Four times per year		
Source: [47]			Table 2		

- 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 patients being treated for chronic pain. 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 patients with chronic pain receiving opioid therapy, and the Pain Assessment and Documentation Tool (PADT) was designed to address these shortcomings [46]. The PADT is a cliniciandirected 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," patientadministered 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 "onthe-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.

CONCURRENT USE OF BENZODIAZEPINES

In 2019, 16% of persons who died of an opioid overdose also tested positive for benzodiazepines, a class of sedative medication commonly prescribed for anxiety, insomnia, panic attack, and muscle spasm [44]. Benzodiazepines work by raising the level of the neurotransmitter gamma-aminobutyric acid (GABA) in the brain. Common formulations include diazepam, alprazolam, and clonazepam. Combining benzodiazepines with opioids is unsafe because both classes of drug cause central nervous system depression and sedation and can decrease respiratory drive—the usual cause of overdose fatality. Both classes have the potential for drug dependence and addiction. The CDC recommends that healthcare providers avoid prescribing benzodiazepines concurrently with opioids whenever possible [10]. If a benzodiazepine is to be discontinued, the clinician should taper the medication gradually, because abrupt withdrawal can lead to rebound anxiety and complications such as hallucinations, seizures, delirium tremens, and, in rare instances, death. A commonly used tapering schedule is a reduction of the benzodiazepine dose by 25% every one to two weeks [10].

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 https:// www.fda.gov/media/114694/download.

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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, gastro-intestinal 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 FDA, 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 [31; 50]. The FDA provides a free toolkit of materials (e.g., social media images, fact sheets, posters) to raise awareness of the serious dangers of keeping unused opioid pain medicines in the home and with information about safe disposal of these medicines. The Remove the Risk Outreach toolkit is updated regularly and can be found at https://www.fda.gov/drugs/ensuring-safe-use-medicine/ safe-opioid-disposal-remove-risk-outreach-toolkit [31]. Patients should be advised to flush prescription drugs down the toilet only if the label or accompanying patient information specifically instructs doing so.

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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 https://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 patients physically dependent on opioids 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 patients with chronic pain 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 legalization 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

Research has more closely defined the location of prescribed opioid diversion into illicit use in the supply chain from the manufacturer to the distributor, retailer, and the end user (the pain patient). This information carries with it substantial public policy and regulatory implications. The 2019 National Survey on Drug Use and Health asked non-medical users of prescription opioids how they obtained their most recently used drugs [51]. Among persons 12 years of age or older, 38.6% obtained their prescription opioids from a friend or relative for free, 34.7% got them through a prescription from one doctor (vs. 17.3% in 2009-2010), 9.5% bought them from a friend or relative, and 3.2% took them from a friend or relative without asking [51]. Less frequent sources included a drug dealer or other stranger (6.5%); multiple doctors (2.0%); and theft from a doctor's office, clinic, hospital, or pharmacy (0.9%) (vs. 0.2% in 2009-2010) [51].

As discussed, UDTs can give insight into patients who are misusing opioids. A random sample of UDT results from 800 patients treated for pain at a Veterans Affairs facility found that 25.2% were negative for the prescribed opioid while 19.5% were positive for an illicit drug/unreported opioid [52]. Negative UDT results for the prescribed opioid do not necessarily indicate diversion, but may indicate the patient halted his/her use due to side effects, lack of efficacy, or pain remission. The concern arises over the increasingly stringent climate surrounding clinical decision-making regarding aberrant UDT results and that a negative result for the prescribed opioid or a positive UDT may serve as the pretense to terminate a patient rather than guide him/her into addiction treatment or an alternative pain management program [53].

In addition to aberrant urine screens, there are certain behaviors that are suggestive of an emerging opioid use disorder. The most suggestive behaviors are [48; 54; 55]:

- 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

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.

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Communication among providers and pharmacies can help to avoid inappropriate attainment of prescription drugs through "doctor shopping." Prescribers should keep complete and up-todate 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].

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].

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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 Administration (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.

MANAGEMENT OF OPIOID USE DISORDER

Management of opioid dependence entails different methods to achieve different goals, depending on the health situation and treatment history of the patient. These treatment approaches include [62]:

- Crisis intervention: Directed at immediate survival by reversing the potentially lethal effects of overdose with an opioid antagonist.
- Harm reduction: Intended to reduce morbidity and mortality associated with use of dirty needles and overdose.

- Detoxification/withdrawal: Aims to remove the opioid of abuse from the patient's body, either through gradual taper and substitution of a long-acting opioid or through ultra-rapid opioid detoxification.
- Maintenance treatment or opioid (agonist) replacement therapy: Aimed at reduction/elimination of illicit opioid use and lifestyle stabilization. Maintenance follows detox-ification/withdrawal, whereby the patient is tapered from short-acting opioids and introduced to a long-acting opioid agonist, such as methadone or buprenorphine. Patients remain on agonist therapy short-term, long-term, or indefinitely depending on individual needs.
- Abstinence-oriented therapy: Treatment directed at cure. The patient is tapered off of short-acting opioids during the detoxification/withdrawal process and may be placed on an opioid antagonist with the goal of minimizing relapse.

All treatment approaches share the common goal of improving health outcomes and reducing drug-related criminality and public nuisance [62].

CRISIS INTERVENTION

In response to acute overdose, the short-acting opioid antagonist naloxone is considered the criterion standard. Naloxone is effective in reversing respiratory depression and coma in patients who have overdosed. There is no evidence that subcutaneous or intramuscular use is inferior to intravenous naloxone. This prompted discussion of making naloxone available to the general public for administration outside the healthcare setting to treat acute opioid overdose, and in 2014, the FDA approved naloxone as an autoinjector dosage form for home use by family members or caregivers [63]. The autoinjector delivers 0.4 mg naloxone intramuscularly or subcutaneously. The autoinjector comes with visual and voice instruction, including directs to seek emergency medical care after use [63]. In 2015, the FDA approved intranasal naloxone after a fasttrack designation and priority review. Intranasal naloxone is indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. It is available in a ready-to-use 2-mg, 4-mg, or 8-mg single-dose sprayer [64; 65; 87].

HARM REDUCTION

Harm reduction measures are primarily employed to minimize the morbidity and mortality from opioid abuse and to reduce public nuisance [20; 66]. As a part of this effort, measures to prevent and minimize the frequency and severity of overdoses have been identified. Enrollment in opioid substitution therapy, with agents such as methadone and buprenorphine, substantially reduces the risk of overdose as well as the risk for infection and other sequelae of illicit opioid use [20; 66].

DETOXIFICATION AND WITHDRAWAL

The process of tapering patients with opioid dependence from agonist therapy is often referred to as detoxification, or more accurately, medically supervised withdrawal [67; 68]. Its purpose is to eliminate physical dependence on opioid medications. It can be considered the medically supported transition to a medication-free state or to antagonist therapy. A careful and thorough review of the risks and benefits of detoxification should be provided, and informed consent obtained from patients prior to choosing this option [68; 69]. Detoxification alone should not be considered a treatment and should only be promoted in the context of a well-planned relapse-prevention program [62; 68].

Discontinuation of opioid use must be implemented slowly and cautiously to avoid a marked abstinence syndrome. Withdrawal symptoms may not begin for days after abrupt discontinuation of methadone or buprenorphine given their longer half-lives. Protracted abstinence, or post-acute withdrawal, may last for several months and is characterized by asthenia, depression, and hypotension. Post-acute withdrawal is more likely to occur with methadone than other opioids [67].

The three primary treatment modalities used for detoxification are opioid agonists, non-opioid medications, and rapid and ultra-rapid opioid detoxification [67]. The most frequently employed method of opioid withdrawal is a slow, supervised detoxification during which an opioid agonist, usually methadone, is substituted for the abused opioid [70]. Methadone is the most frequently used opioid agonist due to the convenience of its once-a-day dosing [67]. Methadone is highly bound to plasma proteins and accumulates more readily than heroin in all body tissues. Methadone also has a longer half-life, approximately 22 hours, which makes withdrawal more difficult than from heroin. Substitution therapy with methadone has a high initial dropout rate (30% to 90%) and an early relapse rate. Alternative pharmacologic detoxification choices include clonidine (with or without methadone), midazolam, trazodone, or buprenorphine [70].

Many opioid withdrawal symptoms, such as restlessness, rhinorrhea, lacrimation, diaphoresis, myosis, piloerection, and cardiovascular changes, are mediated through increased sympathetic activation, the result of increased neuron activity in the locus coeruleus. Non-opioid agents (such as clonidine), which inhibit hyperactivation of noradrenergic pathways stemming from the locus coeruleus nucleus, have been used to manage acute withdrawal [70; 71]. The first non-opioid treatment approved for the management of opioid withdrawal symptoms is lofexidine [86]. In studies, lofexidine resulted in less severe withdrawal symptoms and greater treatment retention than placebo.

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However, some withdrawal symptoms, including anxiety and myalgias, are resistant to clonidine; benzodiazepines and nonsteroidal anti-inflammatory agents may be necessary to treat these symptoms. To mitigate withdrawal symptoms and assist in detoxification, alpha2-agonists, opioid agonist-antagonists, benzodiazepines, and antidepressants have been used [70].

Following detoxification, patients may feel exhausted and weak. Other complications, such as slight variations in hemodynamic status and gastrointestinal tract symptoms, follow quickly and may take several days to resolve. Muscle cramps and low back pain can be treated with nonsteroidal anti-inflammatory drugs. However, the newer cyclooxygenase-2 (COX-2) inhibitors may be advantageous because they produce fewer gastrointestinal side effects [70]. Insomnia is a frequent aspect of acute and protracted withdrawal, as opioids disrupt the normal sleep-wake cycle and many addicts require narcotics to sleep. Although long-term disruption of the normal sleep-wake cycle cannot be corrected rapidly, melatonin (3 mg), benzodiazepines, or antihistamines can be used with beneficial effects. Hypnosis and relaxation techniques are nonpharmacologic methods that may also be used [70]. Psychosocial treatments offered in addition to pharmacologic detoxification treatments positively impact treatment retention and completion, results at followup, and compliance [72; 73].

AGONIST REPLACEMENT OR ABSTINENCE THERAPY

Two principle treatment modalities are offered for patients with opioid dependence: agonist maintenance or detoxification followed by outpatient or residential drug-free treatment. Both can be effective, with no clear indication for each, although agonist maintenance leads to greater treatment retention [74]. A reasonable approach is initial outpatient or residential treatment referral for patients relatively new to treatment, with agonist maintenance appropriate for patients with history of treatment failures, greater disease severity, or a history of drug overdoses. Naltrexone is best reserved for patients with strong legal incentives to abstain, family involvement to monitor treatment, or concurrent enrollment and involvement in a psychosocial intervention [75].

At present, there are no direct interventions that are capable of reversing the effects of drugs of dependence on learning and motivation systems [76]. Instead, the management of opioid dependence often consists of pharmacotherapy with methadone and buprenorphine, which do not eliminate physical dependence on opioids. These medications instead reduce the use of illicit opioids and produce very strong positive health outcomes as measured by decreased mortality, improved mental and physical health, and reduced risk of disease transmission [76]. Considering the high rate of relapse after detoxification, maintenance therapy with methadone or buprenorphine is currently considered to be the first-line treatment for patients with opioid dependence [62].

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Any treatment for opioid dependence must take into consideration the chronic relapsing nature of opioid dependence, characterized by a variable course of relapse and remission in many patients. Treatments should emphasize patient motivation, psychoeducation, continuity of care, integration of pharmacotherapy and psychosocial support, and improved liaison between the treatment staff and the judicial system. Pharmacotherapy must be offered in a comprehensive healthcare context that also addresses the psychosocial aspects of dependence [62]. Patients who are dependent on opioids frequently suffer from physical and psychiatric disorders, and targeted interventions of psychiatric comorbidity are essential in improving treatment outcome for these patients [62]. Polysubstance abuse is the rule rather than the exception in opioid dependence, and concurrent use of other substances should be carefully monitored and treated when necessary [62]. Incarceration should never automatically result in discontinuation of an existing treatment; imprisonment offers a window of opportunity to initiate or restart treatment with a necessary continuation after release [62].

Agonist Replacement Therapy

The goal of opioid replacement therapy is to reduce illicit drug use and associated health risks, with secondary goals of reducing unsafe sexual practices, improving vocational and psychosocial functioning, and enhancing quality of life [67]. The theoretical basis of opioid replacement stems from the finding that chronic opioid use results in an endogenous opioid deficiency as a result of the down-regulation of opioid production. This creates overwhelming cravings and necessitates interventions that shift the patient's attention and drive from obsessive preoccupation with the next use of opioids to more adaptive areas of focus, such as work, relationships, and non-drug leisure activities [67].

The neurobiologic changes resulting from prolonged opioid exposure provide a rationale for specific pharmacotherapies, such as long-acting opioid agonists, that are aimed at stabilizing these complex systems [77]. Opioid agonist maintenance treatment stabilizes brain neurochemistry by replacing short-acting opioids, which can create rapid changes in opioid levels in the serum and brain, with a long-acting opioid that has relative steady-state pharmacokinetics. Opioid agonist maintenance treatment is designed to have minimal euphoric effect, block the euphoria associated with administration of exogenous opioids (competitive antagonism), eliminate the risk of infectious disease and health consequences associated with injection drug use, and prevent opioid withdrawal [77].

Successful maintenance treatment entails stabilization of opioid dependence through opioid receptor occupation. Positron emission tomography studies have revealed that only 25% to 35% of brain opioid receptors are occupied during steady-state methadone maintenance, suggesting that unoccupied opioid receptors disrupted during cycles of opioid abuse could normalize during methadone maintenance [67]. Additionally,

opioid replacement therapy blocks much of the euphoria from illicit heroin use. Long-term opioid agonist treatment also has a positive impact on public health, through significantly reducing overdose deaths, criminal activity, and the spread of infectious disease [67].

As of 2019, there were 1,691 treatment programs including opioid replacement therapy in the United States [78]. However, this represents only an estimated 19% of all patients with opioid use disorder. Although some have criticized the practice of methadone and buprenorphine therapy on the grounds that one opioid is merely being substituted for another, the clinical benefits strongly support this treatment modality [67]. When compared to active street heroin users, these benefits include a four-times lower HIV seroprevalence rates, 70% fewer crime-days per year, and a one-year mortality rate of 1% (versus 8%) [79].

Abstinence-Oriented Therapies

The primary goal of abstinence-oriented interventions is cure, which is defined as long-term, stable abstinence from all opioids. Abstinence is achieved in two phases: detoxification and relapse prevention. Outcomes in abstinence-oriented programs are generally poor [62].

The primary goal of pharmacotherapy during detoxification is to alleviate opioid withdrawal severity and associated distress/ medical complications and to enhance patient motivation to continue treatment. Withdrawal can also be reduced by psychosocial measures, such as contingency management or counseling, and as discussed, the addition of psychosocial therapy to pharmacologic treatment increases efficacy. Buprenorphine and clonidine are both used to manage withdrawal symptoms, but buprenorphine's advantages, compared with clonidine, are related to its favorable side effect profile and positive effects on well-being and psychosocial variables [62].

12-Step/Self-Help Programs

Twelve-step programs for opioid abuse and dependence include Narcotics Anonymous (NA), Heroin Anonymous (HA), and Methadone Anonymous (MA) and are modeled after Alcoholics Anonymous (AA), an abstinence-based support and self-improvement program that is based on the 12-step model of recovery. AA has helped hundreds of thousands of alcoholics achieve sobriety [80]. The 12-step model emphasizes acceptance of dependence as a chronic, progressive disease that can be arrested through abstinence but not cured. Additional elements include spiritual growth, personal responsibility, and helping other addicted persons. By inducing a shift in the consciousness of the addict, 12-step programs offer a holistic solution and are a resource for emotional support [80]. Although research on efficacy and patient outcomes in NA and MA is very limited, many prominent researchers emphasize the important role ongoing involvement in 12-step programs plays in recovery from substance abuse [81].

The understanding of drug dependence as a chronic and relapsing disorder has helped professionals gain a better comprehension of the vital role played by 12-step programs. Every patient attempting to recover from a substance use disorder will encounter a time when he or she faces urges to use without the resources or assistance of healthcare professionals. Twelve-step programs are not considered treatment, nor are they intended as substitutes for treatment. Instead, they are organizations that provide ongoing and indefinite support in the achievement and maintenance of abstinence and in personal growth and character development [81].

Part of the effectiveness of NA, HA, and MA is related to their ability to provide a competing and alternative reinforcer to drug use. Involvement in 12-step programs can enhance the quality of social support and the social network of the member, a potentially highly reinforcing aspect the person stands to forfeit if they resume drug using. Other reinforcing elements of 12-step involvement include recognition for increasingly durable periods of abstinence and frequent awareness of the consequences of drug and alcohol use through attendance of meetings [82]. Research shows that establishing a pattern of 12-step program attendance early in treatment predicts the level of ongoing involvement. Emphasis and facilitation of early engagement in a 12-step program involvement are key [83].

STIGMA OF ADDICTION

Many terms used in discussions of opioid use and misuse may have ambiguous meanings, and the absence of consensus in the terminology and definitions of substance use, substance use disorders, and addiction has led to considerable confusion and misconceptions. These misconceptions may be harbored by clinicians, patients, family members, and the public and can negatively impact patient interaction, assessment, treatment, and outcomes. This, coupled with pervasive stereotypes about what an opioid addict "looks" like, can negatively impact willingness to receive treatment or seek help and impair the patient's self-worth and mental health. Correction of these erroneous beliefs and attitudes is important, as is the use of nonpejorative and nonstigmatizing language when describing opioid analgesics, the patients who need them, and patients who develop aberrant behaviors or addiction involving opioids [32; 42]. It is important for all healthcare professionals to remember that addiction can affect any patients, regardless of age, sex, socioeconomic status, education, ability, or race.

#55151 Responsible and Effective Opioid Prescribing

PROGNOSIS OF TREATMENT FOR OPIOID USE DISORDER

The relapse rate among patients receiving treatment for opioid dependence and other substance abuse is high (25% to 97%), comparable to that of other patients with chronic relapsing conditions, including hypertension and asthma [84]. Many cases of relapse are attributable to treatment noncompliance and lack of lifestyle modification [85].

Duration of agonist replacement therapy is usually recommended as a minimum of one year, and some patients will receive agonist replacement therapy indefinitely. Longer durations of treatment are associated with higher rates of abstinence from illicit opioids [76].

Much remains unknown about patient outcomes following termination of long-term opioid replacement therapy. Some patients aim to achieve total abstinence from all opioids, but little is known about patient characteristics and strategies used among those who remain abstinent. It is likely that at least some of the patients who remain abstinent from all opioids do so with the help of a 12-step support program, such as NA [76].

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.

COURSE TEST - #55151 RESPONSIBLE AND EFFECTIVE OPIOID PRESCRIBING

This is an open book test. A passing grade of at least 70% must be achieved in order to receive credit for this course.

This 3 CE Credit Hour activity must be completed by April 30, 2024.

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DESIGNATIONS OF CREDIT: NETCE DESIGNATES THIS ACTIVITY FOR 3 CONTINUING EDUCATION CREDITS.

AGD SUBJECT CODE: 340.

1. Inappropriate opioid analgesic prescribing for pain is defined as

- A) non-prescribing.
- B) inadequate prescribing.
- C) continued prescribing despite evidence of ineffectiveness of opioids.
- D) All of the above

2. When opioids are used for acute pain, clinicians should prescribe

- A) the highest safe dose.
- B) extended-release opioids.
- C) a quantity no greater than that needed for the expected duration of severe pain.
- D) All of the above
- 3. A patient prescribed opioids for chronic pain who is 65 years of age and displays high levels of pain acceptance and active coping strategies is considered at what level of risk for developing problematic opioid behavioral responses?
 - A) Low
 - B) Medium
 - C) High
 - D) Severe

- 4. The Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R)
 - A) consists of 5 items.
 - B) is patient administered.
 - C) diagnoses depression in the past month.
 - D) assesses the likelihood of current substance abuse.
- 5. Which of the following is NOT one of the5 A's of monitoring chronic opioid response?A) Analgesia
 - A) Analgesia
 D) A sector and a sec
 - B) Acceptance
 - C) Affect (i.e., patient mood)
 - D) Aberrant drug-related behaviors
- 6. For patients considered at medium risk for misuse of prescription opioids, urine drug testing should be completed every
 - A) 6 to 12 weeks.
 - B) 3 to 6 months.
 - C) 6 to 12 months.
 - D) 1 to 2 years.

#55151 Responsible and Effective Opioid Prescribing

- 7. Which of the following statements regarding the disposal of opioids is TRUE?
 - A) Patients are almost always advised of what to do with unused or expired medications.
 - B) There are no universal recommendations for the proper disposal of unused opioids.
 - C) According to the FDA, most medications should be flushed down the toilet instead of thrown in the trash.
 - D) All of the above
- 8. The most common source of nonmedical use of prescribed opioids is from
 - A) a friend or relative for free.
 - B) a prescription from one doctor.
 - C) purchase from a drug dealer or other stranger.
 - D) theft from a doctor's office, clinic, hospital, or pharmacy.

- 9. Which of the following behaviors is the most suggestive of an emerging opioid use disorder?A) Asking for specific medications
 - B) Injecting medications meant for oral use
 - C) Reluctance to decrease opioid dosing once stable
 - D) Stockpiling medications during times when pain is less severe
- 10. Which government agency is responsible for formulating federal standards for the handling of controlled substances?
 - A) Institutes of Medicine
 - B) U.S. Drug Enforcement Administration
 - C) Office of National Drug Control Policy
 - D) U.S. Department of Health and Human Services

Go to NetCE.com/NYDN23 and click on the Get Started button. Enter the Customer ID and Quick Code found on the back of your booklet, then transfer your test answers and complete the course evaluation.

This course is approved by the New York State Education Department of Health to fulfill the requirement for Infection Control Training as mandated by Chapter 786 of the Laws of 1992. Provider #OT10781.

If you have already completed infection control within the last four years, you may use this course to meet 5 hours of your general CE requirement.

Audience

This course is designed for dental professionals in New York required to complete education to enhance their knowledge of infection control.

Course Objective

The purpose of this course is to provide a review of current infection control practices and accepted standards, with an emphasis on the application of infection control standards and practices in dental care settings.

Learning Objectives

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

- 1. Discuss the standards of professional conduct associated with infection control in the healthcare setting.
- 2. Outline the infectious disease process.
- 3. Describe various practices that can result in exposure to bloodborne pathogens.
- 4. Identify effective strategies to prevent or control infection, including precautions, isolation techniques, hand hygiene, standards for cleaning, and safe injection practices.
- 5. Describe the role of surveillance and reporting in an effective infection control program.
- 6. Discuss the impact of communicable diseases in healthcare professionals, including the necessity for preplacement evaluations, periodic health assessments, education, and postexposure prophylaxis.
- 7. Evaluate the impact and appropriate response to sepsis.

Faculty

Lori L. Alexander, MTPW, ELS, MWC, is President of Editorial Rx, Inc., which provides medical writing and editing services on a wide variety of clinical topics and in a range of media. A medical writer and editor for more than 30 years, Ms. Alexander has written for both professional and lay audiences, with a focus on continuing education materials, medical meeting coverage, and educational resources for patients. (A complete biography can be found at NetCE.com/faculty.) **Carol Shenold, RN, ICP**, graduated from St. Paul's Nursing School, Dallas, Texas, achieving her diploma in nursing. Over the past thirty years she has worked in hospital nursing in various states in the areas of obstetrics, orthopedics, intensive care, surgery and general medicine. (A complete biography can be found at NetCE.com/faculty.)

Faculty Disclosure

Contributing faculty, Lori L. Alexander, MTPW, ELS, MWC, has disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

Contributing faculty, Carol Shenold, RN, ICP, 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

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INTRODUCTION

The development of formal infection control programs in hospitals and other healthcare facilities was spurred by the Joint Commission accreditation standards for infection control, published in 1976. According to the standards, accredited facilities should have a program for the surveillance, prevention, and control of healthcare-associated infections (HAIs) [1]. The most important aspect of infection control is establishing multidisciplinary programs that promote teamwork and foster an organizational culture centered on patient safety.

HAIs are one of the leading causes of death and increased morbidity for hospitalized patients and are a significant problem for healthcare providers [2]. Historically, these infections have been known as nosocomial infections or hospital-acquired infections because they develop during hospitalization. As health care has increasingly expanded beyond hospitals into outpatient settings, nursing homes, long-term care facilities, and even home care settings, the more appropriate term has become healthcare-acquired or healthcare-associated infection.

Many factors have contributed to an increase in HAIs. Advances in medical treatments have led to more patients with decreased immune function or chronic disease. The increase in the number of these patients, coupled with a shift in health care to the outpatient setting, yields a hospital population that is both more susceptible to infection and more vulnerable once infected. In addition, the increased use of invasive devices and procedures has contributed to higher rates of infection [3].

According to data published in 2014, HAIs develop in an estimated 1 in 25 hospitalized patients (excluding skilled nursing facilities); this number varies from year to year and had previously been estimated at a high of 1 in 10 [1; 4; 5; 6]. HAI data from the Centers for Disease Control and Prevention (CDC) indicate that the number is higher, at 1 in 31 patients [5]. Based on CDC-sponsored hospital surveillance data from 2018, an estimated 633,000 hospitalized patients develop an HAI each year [7]. These infections are the cause of approximately 72,000 deaths and add approximately \$28.4 to \$33.8 billion in direct medical costs annually [4; 6; 8].

Between January 2015 and December 2017, the most common types of HAIs were surgical site infections (42.4%), catheterassociated urinary tract infections (29.7%), central-line-associated bloodstream infections (25.3%), and ventilator-associated pneumonia (2.6%) [9]. Of the 355,633 reported pathogens, *Escherichia coli* was the most common pathogen across all HAIs, accounting for nearly 18% of reported infections [9].

As HAIs have become a cause for increasing concern, many national organizations, state departments of health, and professional organizations have taken additional steps to prevent or control infection in the healthcare environment. According to data from the CDC, these steps appear to be working. The

2020 National and State Healthcare-Associated Infections (HAI) Progress Report provides national- and state-level data about HAI incidence across four healthcare settings: acute care hospitals, critical access hospitals, inpatient rehabilitation facilities, and long-term acute care hospitals [10]. The progress report includes data gathered by the CDC's National Healthcare Safety Network (NHSN), a national HAI surveillance system that gathers data from more than 25,000 hospitals and other healthcare facilities.

Prior to 2020, the prevalence of HAIs had been declining, the result of an ongoing national collaborative effort. However, an analysis of NHSN data from acute care hospitals in 12 U.S. states found that rates of central-line-associated bloodstream infections, catheter-related urinary tract infections, and ventilator-associated events increased significantly compared with 2019, largely as a result of the COVID-19 pandemic [11]. The analysis showed that national standard infection ratios for central-line-associated bloodstream infections initially declined in the first quarter of 2020 compared with the first quarter of 2019, but then rose by 27.9%, 46.4%, and 47.0% in the second, third, and fourth quarters of the year, respectively. Ventilator-associated events rose by 44.8% in the fourth quarter of 2020 compared with the same period for 2019 [11]. While acknowledging that 2020 was an unprecedented time for hospitals, the authors of the analysis emphasized the continued need for regular review of HAI surveillance data to identify gaps in prevention [11].

STANDARDS OF PROFESSIONAL CONDUCT

The increased focus on healthcare quality over the past decade has highlighted the need to prevent HAIs as part of overall efforts to enhance patient safety. These efforts have been developed by healthcare quality agencies, professional associations, advocacy organizations, healthcare regulating bodies, and policymakers [12; 13; 14; 15; 16; 17; 18; 19]. Prevention of HAIs and of methicillin-resistant Staphylococcus aureus (MRSA) infection are listed among safe healthcare practices established by the Agency for Healthcare Research and Quality (AHRQ) and the National Quality Forum, and prevention of HAIs was noted by the Institute of Medicine (IOM) to be one of 20 priority areas for enhancing the quality of health care [12; 13; 18]. In 2004, the Institute for Healthcare Improvement (IHI) established the 100,000 Lives Campaign as a challenge to save 100,000 patient lives through six healthcare interventions, three of which were related to HAIs: preventing central-line infections, surgical site infections, and ventilator-associated pneumonia [14]. Building on the success of the 100,000 Lives Campaign, the IHI established the 5 Million Lives Campaign in December 2006, adding six more interventions, one of which is to reduce MRSA infection [14]. In 2010, the Centers for Medicare & Medicaid Services (CMS) launched the Partnership for Patients with the goal of reducing all HAIs 40% compared to 2010 and reducing readmissions due to HAIs by 20% by focusing on transitions from one care setting to another [20]. According to data from the AHRQ, successful reductions in HAIs helped prevent 20,500 hospital deaths and saved \$7.7 billion in healthcare costs from 2014 to 2017 [20].

Regulatory bodies have also focused on HAIs. Goal 7 of the National Patient Safety Goals developed by the Joint Commission is to reduce the risk of HAIs in hospitals as well as ambulatory care/office-based surgery, long-term care, and assisted living settings [19]. Perhaps the most aggressive campaign against HAIs has come from CMS, which has suspended reimbursement of hospital costs related to three categories of HAIs it considers "reasonably preventable:" catheter-related urinary tract infection, vascular catheter-associated infection, and various surgical site infections [16; 17; 21]. However, studies have shown that this policy has not been a contributor to any decrease in the rate of HAIs, and a survey indicated that adherence to only a few prevention strategies has increased as a result of the policy [22; 23]. The policy also has the potential to lead to increased unnecessary use of antimicrobials in an effort to prevent infections [24]. Additionally, one study found that many acute care hospitals commonly listed the reimbursement restricted HAIs as "present on admission," which mitigated the impact intended by CMS [25].

The New York Codes, Rules, and Regulations require that certain healthcare professionals who may influence the control and prevention of HAIs complete training or education regarding infection control and barrier precautions [26]. New York State has also established professional standards of conduct to ensure that infection prevention and control practices are adhered to. According to the Rules of the Board of Regents: Part 29, "failing to use scientifically accepted infection prevention techniques appropriate to each profession for the cleaning and sterilization or disinfection of instruments, devices, materials and work surfaces, utilization of protective garb, use of covers for contamination-prone equipment and the handling of sharp instruments" is considered unprofessional conduct [27]. Appropriate infection control techniques include, but are not limited to, wearing appropriate personal protective equipment, adhering to recommendations for Universal and Standard Precautions, following sterilization and disinfection standards, and using the correct equipment in the correct way [27].

Healthcare professionals have the responsibility to adhere to scientifically accepted principles and practices of infection control in all healthcare settings and to oversee and monitor those medical and ancillary personnel for whom the professional is responsible [27]. Healthcare professionals are expected to use scientifically accepted infection prevention techniques appropriate to each profession for handwashing; aseptic technique; cleaning and sterilization or disinfection of instruments, devices, materials, and work surfaces; use of protective garb; use of covers for contamination-prone equipment; and handling of sharp instruments [26; 27; 28].

CONSEQUENCES OF NONCOMPLIANCE WITH GUIDELINES

The results of the CDC Study of Efficacy of Nosocomial Infection Control suggested that 6% of all HAIs could be prevented by minimal infection control efforts and 32% by "well organized and highly effective infection control programs" [29; 30]. A later review estimated that as many as 65% to 70% of cases of catheter-associated infections and 55% of cases of surgical site infections are preventable [31].

Evidence-based guidelines are at the heart of strategies to prevent and control HAIs and drug-resistant infections and address a wide range of issues from architectural design of hospitals to hand hygiene. These guidelines have been developed primarily by the CDC and the World Health Organization (WHO), infection-related organizations, and other professional societies. Some specialty organizations and quality improvement groups have summarized the guidelines for easier use in practice [2; 28; 32; 33; 34; 35; 36; 37; 38; 39; 40; 41; 42; 43; 44; 45; 46; 47; 48; 49; 50; 51; 52; 53]. Adherence to individual guidelines varies but, in general, is low. Historically, 87% of hospitals have failed to implement all of the recommended guidelines for preventing HAIs [54]. Hand hygiene is the most basic and single most important preventive measure, yet compliance rates among healthcare workers have averaged only 30% to 50% [3; 25; 42; 55; 56; 57; 58]. Decreasing the number of HAIs will require research to better understand the reasons behind lack of compliance with guidelines and to develop strategies that target those reasons.

In addition, there are professional consequences for New York healthcare professionals who do not adhere to appropriate infection control efforts. Healthcare professionals who fail to use scientifically accepted barrier precautions and stateestablished infection control practices may be subject to charges of professional misconduct [59]. The Office of Professional Medical Conduct may investigate on its own any suspected professional misconduct and is required to investigate each complaint received regardless of the source. The charges must state the substance of the alleged misconduct and the material facts (but not the evidence). A hearing may be called, if warranted. The results of the hearing (i.e., findings, conclusions, determinations, order) will be made public upon issuance. Any professional found guilty of misconduct shall be subject to penalties, including [60]:

- Censure and reprimand
- Suspension of license or limitation of license to a specified area or type of practice
- Revocation of license
- Annulment of license or registration
- Limitation on registration or issuance of any further license
- A fine not to exceed \$10,000 upon each specification of charges of which the respondent is determined to be guilty

- A requirement that a licensee pursue a course of education or training
- A requirement that a licensee perform up to 500 hours of public service in a manner and at a time and place as directed

METHODS OF COMPLIANCE

The education and training of healthcare personnel are prerequisites for ensuring that Standard Precautions are understood and practiced. Education on the principles and practices for preventing transmission of infectious agents should begin during training in the health professions and be provided to anyone who has an opportunity for contact with patients or medical equipment. Education programs for healthcare personnel have been associated with sustained improvement in adherence to best practices [28].

Adherence to recommended infection control practices decreases transmission of infectious agents in healthcare settings; however, several observational studies have shown limited adherence to recommended practices by healthcare personnel. Improving adherence to infection control practices requires a multifaceted approach that incorporates continuous assessment of both the individual and the work environment. It also requires that the organizational leadership make prevention an institutional priority and integrate infection control practices into the organization's safety culture [28, 61, 62].

THE INFECTIOUS DISEASE PROCESS

A comprehensive description of the pathogenesis of infection is beyond the scope of this course. However, a broad overview of pathogen-host interaction will aid in the understanding of how infection develops in the healthcare setting.

A healthy human body has several defenses against infection: the skin and mucous membranes form natural barriers to infection, and immune responses (nonspecific and specific) are activated to resist micro-organisms that are able to invade. The skin can effectively protect the body from most micro-organisms unless there is physical disruption. For example, the human papillomavirus can invade the skin, and some parasites can penetrate intact skin, but bacteria and fungi cannot [63]. Other disrupters of the natural barrier are lesions (e.g., chapped, abraded, affected by dermatitis), injury, or in the healthcare setting, invasive procedures or devices [64].

In addition to breaks in the skin, other primary entry points for micro-organisms are mucosal surfaces, such as the respiratory, gastrointestinal, and genitourinary tracts [65]. The membranes lining these tracts comprise a major internal barrier to microorganisms due to the antimicrobial properties of their secretions. The respiratory tract filters inhaled micro-organisms, and mucociliary epithelium in the tracheobronchial tree moves them out of the lung. In the gastrointestinal tract, gastric acid, pancreatic enzymes, bile, and intestinal secretions destroy

harmful micro-organisms. Nonpathogenic bacteria (commensal bacteria) make up the normal flora in the gastrointestinal tract and act as protectants against invading pathogenic bacteria. Commensal bacteria are a source of infection only if they are transmitted to another part of the body or if they are altered by the use of antibiotics [2].

HAIs are commonly caused by bacteria, but can also be caused by viruses, fungi, and parasites. These types of infection occur less frequently and often do not carry the same risks of morbidity and mortality as bacterial infections. Viral infections are more common in children than in adults and carry a high epidemic risk [1]. Fungal infections frequently occur during prolonged treatment with antibiotics and in patients who have compromised immune systems [2]. Various pathogens have different levels of pathogenicity, virulence, and infectivity.

The transmission of infection follows the cycle (the "cycle of infection") that has been described for all diseases, and humans are at the center of this cycle [2; 66]. In brief, a micro-organism requires a reservoir (a human, soil, air, or water), or a host, in which to live. The micro-organism also needs an environment that supports its survival once it exits the host and a method of transmission. Inherent properties allow micro-organisms to remain viable during transmission from a reservoir to a susceptible host, another essential factor for transmission of infection. The primary routes of transmission for infections are through the air, blood (or body fluid), contact (direct or indirect), fecal-oral route, food, animals, or insects. Once inside a host, micro-organisms thrive because of adherent properties that allow them to survive against mechanisms in the body that act to flush them out. Bacteria adhere to cell surfaces through hair-like projections, such as fibrillae, fimbriae, or pili, as well as by proteins that serve as adhesions [65]. Fimbriae and pili are found on gram-negative bacteria, whereas other types of adhesions are found with both gram-negative and gram-positive bacteria. Receptor molecules in the body act as ligands to bind the adhesions, enabling bacteria to colonize skin and mucous membranes. The virulence of the micro-organism, the integrity of the skin and membrane barriers, and patient status will determine whether colonization is followed by invasive infection. With colonization, there is no damage to local or distant tissues and no immune reaction; with infection, bacterial toxins that break down cells and intracellular matrices are released, causing damage to local and distant tissues and prompting an immune response in the host. Bacteria continue to thrive within a host through strategies that enable them to acquire iron for nutrition and to defend against the immune response. These virulence factors enhance a micro-organism's potential for infection by interrupting or avoiding phagocytosis or living inside phagocytes [65].

A healthcare environment increases the risk of infection for two primary reasons. First, it is likely that normally sterile body sites will become exposed, allowing pathogens to cause infection through contact with mucous membranes, nonintact skin, and internal body areas [66]. Second, the likelihood of a susceptible host is high due to the vulnerable health status of patients. Especially in an era of decreased hospital stays and increased outpatient treatments, it is the sickest patients who are hospitalized, increasing the risk not only for infection to develop in these patients but also for their infection to be more severe and to be transmitted to others.

Infection is transmitted in a healthcare environment primarily through exogenous and endogenous modes. Exogenous transmission is through patient-to-patient or staff-to-patient contact. Patients who do not have infection but have bacterial colonization can act as vectors of transmission. Staff members can also act as vectors because of colonization or contamination. Endogenous infection occurs within an individual patient through displacement of commensal micro-organisms.

Factors specifically related to the healthcare environment are not common causes of HAIs [2; 67; 68]. However, consideration should be given to the prevention of infection with environmental pathogens. The CDC revised guideline related to environmental factors for infection provides clear recommendations for infection control measures according to several environment-related categories, including air (normal ventilation and filtration, as well as handling during construction or repair), water (water supply systems, ice machines, hydrotherapy tanks and pools), and environmental services (laundry, housekeeping) [41].

In general, the spread of infectious disease is prevented by eliminating the conditions necessary for the micro-organism to be transmitted from a reservoir to a susceptible host. This can be accomplished by:

- Destroying the micro-organism
- Blocking the transmission
- Protecting individuals from becoming vectors of transmission
- Decreasing the susceptibility of potential hosts

Antiseptic techniques and antibiotics will kill micro-organisms, while proper hand hygiene will block their transmission. Gloves, gowns, and masks remove healthcare professionals from the transmission cycle by protecting them from contact with micro-organisms. Contact Precautions and isolation techniques help patients avoid being vectors of transmission. Lastly, ensuring that patients and healthcare professionals are immune or vaccinated can help decrease the availability of potential hosts.

HIGH-RISK PRACTICES: EXPOSURE TO BLOODBORNE PATHOGENS

Healthcare professionals, emergency response personnel, and public safety personnel may be exposed to a variety of bloodborne pathogens, including human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV). Exposure may occur percutaneously, parenterally, or through contact with mucous membranes and nonintact skin [69].

PERCUTANEOUS EXPOSURE

Percutaneous exposures may occur through the handling, disassembly, disposal, or reprocessing of contaminated needles and other sharp objects. They may also be related to the performance of procedures in which there is poor visualization (e.g., blind suturing, placing the nondominant hand next to or opposing a sharp, or performing procedures where bone spicules or metal fragments are produced). Data from the CDC National Surveillance System for Hospital Health Care Workers (NaSH) have shown that approximately 70% of percutaneous injuries occur during use of a sharp, 15% occur after use and before disposal, and 3% occur during or after disposal [70].

PARENTERAL EXPOSURE

Parenteral exposures (i.e., injection with infectious material) may occur during administration of parenteral medications, sharing of blood monitoring devices (e.g., glucometers, lancets), or infusion of contaminated blood products or fluids. Generally, these exposures are the result of poor adherence to Standard Precautions and infection control guidelines.

MUCOUS MEMBRANE AND NONINTACT SKIN EXPOSURE

Mucous membrane and nonintact skin exposures may occur when blood or body fluids come in direct contact with the eyes, nose, mouth, or other mucous membranes via contaminated hands, open skin lesions, or splashes or sprays of blood or body fluids (e.g., during irrigation or suctioning). Again, following established infection control guidelines greatly reduces the risk of this type of exposure.

PRECAUTIONS AND ISOLATION TECHNIQUES

The CDC guideline for isolation precautions in hospitals, last updated in 2007, synthesizes a variety of recommendations for precautions based on the type of infection, the route of transmission, and the healthcare setting [28]. As defined by the CDC, Standard Precautions represent measures that should be followed for all patients in a healthcare facility, regardless of diagnosis or infection status. Standard Precautions apply to blood; all body fluids, secretions, and excretions except sweat, regardless of whether they contain visible blood; nonintact skin; and mucous membranes [28]. For patients who are known to have or are highly suspected to have colonization or infection, Contact Precautions should be followed. This type of precaution is designed to reduce exogenous transmission of micro-organisms through direct or indirect contact from healthcare professionals or other patients. Airborne Precautions are used for patients who have or are highly suspected of

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having infection that is spread by airborne droplet nuclei, such as tuberculosis, measles, or varicella. Droplet Precautions target infections that are transmitted through larger droplets generated through talking, sneezing, or coughing, such as invasive *Haemophilus influenzae* type b disease, diphtheria (pharyngeal), pertussis, group A streptococcal pharyngitis, influenza, mumps, and rubella [28].



The Infectious Diseases Society of America and Society for Healthcare Epidemiology of America recommend patients with suspected *Clostridioides difficile* infection should be placed on preemptive contact precautions pending the *C. difficile* test

results if test results cannot be obtained on the same day.

(https://www.idsociety.org/practice-guideline/ clostridium-difficile. Last accessed March 11, 2022.)

Strength of Recommendation/Level of Evidence: Strong recommendation, moderate-quality evidence

The CDC guideline includes descriptions of all the elements involved in the four types of precautions, including hand hygiene; the use of personal protection equipment (i.e., gloves, gown, face protection); placement of the patient; handling of patient-care equipment; and environmental services and occupational health. New elements of Standard Precautions added to the 2007 guideline include infection control practices (i.e., use of masks) for special lumbar puncture procedures, safe injection practices (discussed later in this course), and respiratory hygiene/cough etiquette [28]. Recommendations in this area address the importance of educating healthcare professionals about adherence to measures to control the transmission of respiratory pathogens, especially during seasonal outbreaks of viral respiratory tract infections. In addition, the guideline states that efforts should be made to contain respiratory secretions in patients and other individuals who have signs and symptoms of a respiratory infection, beginning at the point of initial encounter in a healthcare setting. Signs should be posted to instruct patients and visitors with symptoms of respiratory infection to cover their mouths/noses when coughing or sneezing, to use and dispose of tissues, and to perform hand hygiene after contact with respiratory secretions. Masks should be offered to coughing patients and other individuals with symptoms, and such persons should be encouraged to maintain an ideal distance of at least 3 feet from others in common waiting areas.

The following descriptions of precautions are summarized from the 2007 guideline for isolation precautions [28]. Although the 2007 guideline is the most recent version, guidance regarding Ebola virus precautions and isolation has been updated and will be discussed briefly [71].

STANDARD PRECAUTIONS

Hand Hygiene

The guideline includes recommendations found in the CDC guideline on hand hygiene [42]. Hand hygiene guidelines will be discussed in length later in this course.

Gloves

Wear gloves (clean, nonsterile gloves are adequate) when touching blood, body fluids, secretions, excretions, and contaminated items. Latex or nitrile gloves are preferable for clinical procedures that require manual dexterity and/or will involve more than brief patient contact. Put on clean gloves just before touching mucous membranes and nonintact skin. When worn in combination with other personal protective equipment, don gloves last.

Change gloves between tasks and procedures on the same patient after contact with material that may contain a high concentration of micro-organisms. Remove gloves promptly after use, before touching noncontaminated items and environmental surfaces and before going to another patient, and wash hands immediately to avoid transfer of micro-organisms to other patients or environments. Avoid contamination of clothing and skin when removing gloves. Do not reuse gloves or wash gloves for subsequent reuse.

Mask, Eye Protection, Face Shield

Wear a mask and eye protection or a face shield to protect mucous membranes of the eyes, nose, and mouth during procedures and patient-care activities that are likely to generate splashes or sprays of blood, body fluids, secretions, or excretions.

Gowns

Wear a gown (a clean, nonsterile gown is adequate) to protect skin and to prevent soiling of clothing during procedures and patient-care activities that are likely to generate splashes or sprays of blood, body fluids, secretions, or excretions. Select a gown that is appropriate for the activity and amount of fluid likely to be encountered. Remove a soiled gown as promptly as possible (turning outer "contaminated" side of the gown inward), roll gown into a bundle, and discard appropriately. Wash hands to avoid transfer of micro-organisms to other patients or environments. Do not reuse gowns, even for repeated tasks with the same patient.

Patient Placement

Use a private room for a patient who contaminates the environment or who does not (or cannot be expected to) assist in maintaining appropriate hygiene or environmental control. If a private room is not available, consult with infection control professionals regarding patient placement or other alternatives.

Patient-Care Equipment

Handle used patient-care equipment soiled with blood, body fluids, secretions, and excretions in a manner that prevents skin and mucous membrane exposures, contamination of clothing, and transfer of micro-organisms to other patients and environments. Ensure that reusable equipment is not used for the care of another patient until it has been cleaned and reprocessed appropriately. Ensure that single-use items are discarded properly.

Environmental Control

Ensure that the hospital has adequate procedures for the routine care, cleaning, and disinfection of environmental surfaces, beds, bedrails, bedside equipment, and other frequently touched surfaces, and ensure that these procedures are being followed.

Linen

Handle, transport, and process used linen soiled with blood, body fluids, secretions, and excretions in a manner that prevents contamination of air, surfaces, and individuals.

Occupational Health and Bloodborne Pathogens

Take care to prevent injuries when using needles, scalpels, and other sharp instruments or devices; when handling sharp instruments after procedures; when cleaning used instruments; and when disposing of used needles. Never recap used needles, or otherwise manipulate them using both hands, or use any other technique that involves directing the point of a needle toward any part of the body. Rather, use either a one-handed "scoop" technique or a mechanical device designed for holding the needle sheath. Do not remove used needles from disposable syringes by hand, and do not bend, break, or otherwise manipulate used needles by hand. Place used disposable syringes and needles, scalpel blades, and other sharp items in appropriate puncture-resistant containers, which are located as close as practical to the area in which the items were used, and place reusable syringes and needles in a puncture-resistant container for transport to the reprocessing area.

Use mouthpieces, resuscitation bags, or other ventilation devices as an alternative to mouth-to-mouth resuscitation methods in areas where the need for resuscitation is predictable.

CONTACT PRECAUTIONS

Patient Placement

Place the patient in a private room. When a private room is not available, place the patient in a room with a patient(s) who has active infection with the same micro-organism but with no other infection (cohorting). When a private room is not available and cohorting is not achievable, consider the epidemiology of the micro-organism and the patient population when determining patient placement. Consultation with infection control professionals is advised before patient placement.

Gloves and Handwashing

In addition to wearing gloves as outlined under Standard Precautions, wear gloves (clean, nonsterile gloves are adequate) when entering the room. During the course of providing care for a patient, change gloves after having contact with infective material that may contain high concentrations of microorganisms (e.g., fecal material, wound drainage). Remove gloves before leaving the patient's room, and wash hands immediately with an antimicrobial agent or a waterless antiseptic agent. After glove removal and handwashing, ensure that hands do not touch potentially contaminated environmental surfaces or items in the patient's room, to avoid transfer of microorganisms to other patients or environments.

Gown

In addition to wearing a gown as outlined under Standard Precautions, wear a gown (a clean, nonsterile gown is adequate) when entering the room if you anticipate that your clothing will have substantial contact with the patient, environmental surfaces, or items in the patient's room, or if the patient is incontinent or has diarrhea, an ileostomy, a colostomy, or wound drainage not contained by a dressing. Remove the gown before leaving the patient's environment. After gown removal, ensure that clothing does not contact potentially contaminated environmental surfaces, to avoid transfer of micro-organisms to other patients or environments.

Patient Transport

Limit the movement and transport of the patient from the room to essential purposes only. If the patient is transported out of the room, ensure that precautions are maintained to minimize the risk of transmission of micro-organisms to other patients and contamination of environmental surfaces or equipment.

Patient-Care Equipment

When possible, dedicate the use of noncritical patient-care equipment to a single patient (or cohort of patients infected or colonized with the pathogen requiring precautions) to avoid sharing between patients. If use of common equipment or items is unavoidable, then adequately clean and disinfect them before use for another patient.

AIRBORNE PRECAUTIONS

All precautions described for airborne pathogens are in addition to Standard Precautions.

Patient Placement

Place the patient in a private room that has (1) monitored negative air pressure in relation to the surrounding areas; (2) 6 to 12 air changes per hour; and (3) appropriate discharge of air outdoors or monitored high-efficiency filtration of room air before the air is circulated to other areas in the hospital. Keep the room door closed and the patient in the room. When a private room is not available, place the patient in a room with a

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patient who has active infection with the same micro-organism, unless otherwise recommended, but with no other infection. When a private room is not available and cohorting is not desirable, consultation with infection control professionals is advised before patient placement.

Respiratory Protection

Wear respiratory protection (N95 respirator) when entering the room of a patient with known or suspected infectious pulmonary tuberculosis. Susceptible persons should not enter the room of patients known or suspected to have rubeola (measles) or varicella (chickenpox) if other immune caregivers are available. If susceptible persons must enter the room of a patient known or suspected to have rubeola or varicella, they should wear respiratory protection (N95 respirator). Persons immune to rubeola or varicella need not wear respiratory protection.

Patient Transport

Limit the movement and transport of the patient from the room to essential purposes only. If transport or movement is necessary, minimize patient dispersal of droplet nuclei by placing a surgical mask on the patient, if possible.

DROPLET PRECAUTIONS

All precautions described for droplet pathogens are in addition to Standard Precautions.

Patient Placement

Place the patient in a private room. When a private room is not available, place the patient in a room with a patient(s) who has active infection with the same micro-organism but with no other infection. When a private room is not available and cohorting is not achievable, maintain spatial separation of at least 3 feet between the infected patient and other patients and visitors. Special air handling and ventilation are not necessary, and the door may remain open.

Masks

In addition to wearing a mask as outlined under Standard Precautions, wear a mask when working within 3 feet of the patient. (Logistically, some hospitals may want to implement a policy of wearing a mask to enter the room.)

Patient Transport

Limit the movement and transport of the patient from the room to essential purposes only. If transport or movement is necessary, minimize patient dispersal of droplets by placing a surgical mask on the patient, if possible.

HAND HYGIENE

Hand hygiene is the most important preventive measure in hospitals, and the Joint Commission mandates that hospitals and other healthcare facilities comply with the Level I recommendations in the CDC guideline for hand hygiene [42]. The CDC guideline states the specific indications for

SUMMARY OF CDC RECOMMENDATIONS FOR HAND HYGIENE

Indications for Hand Hygiene

Wash hands with nonantimicrobial or antimicrobial soap and water when they are visibly dirty, contaminated, or soiled. If hands are not visibly soiled, use an alcohol-based handrub for routinely decontaminating hands.

Specific Indications

Wash hands before patient contact and before putting on gloves for insertion of invasive devices that do not require surgery (e.g., urinary catheters, intravascular devices).

Wash hands after:

- Contact with a patient's skin
- Contact with body fluids or excretions, nonintact skin, or wound dressings
- Removing gloves

Recommended Handrub Technique

Apply to palm of one hand, rub hands together, covering all surfaces until dry.

Recommended Handwashing Technique

- Wet hands with water, apply soap, and rub hands together for at least 15 seconds.
- Rinse and dry with disposable towel.
- Use towel to turn off faucet.

Fingernails and Artificial Nails

Keep tips of natural nails to a length of ¼ inch. Do not wear artificial nails during direct contact with high-risk patients (e.g., patients in intensive care unit or operating room).

Use of Gloves

Use gloves when there is potential for contact with blood or other potentially infectious materials, mucous membranes, or nonintact skin. Change gloves after use for each patient.

Source: [42]

washing hands, the recommended hand hygiene techniques, and recommendations about fingernails and the use of gloves (*Table 1*) [42]. The guideline also provides recommendations for surgical hand antisepsis, selection of hand-hygiene agents, skin care, educational and motivational programs for healthcare professionals, and administrative measures.

Despite the simplicity of the intervention, its substantial impact, and wide dissemination of the guideline, compliance with recommended hand hygiene has ranged from 16% to 81%, with an average of 30% to 50% [3; 42; 54; 56; 57; 58]. Among the reasons given for the lack of compliance are inconvenience, understaffing, and damage to skin [1; 42; 56; 72]. The development of effective alcohol-based handrub solutions addresses these concerns, and studies have demonstrated that these solutions have increased compliance [57; 73; 74]. The CDC guideline recommends the use of such solutions on the basis of several advantages, including [42]:

- Better efficacy against both gram-negative and gram-positive bacteria, mycobacteria, fungi, and viruses than either soap and water or antimicrobial soaps (e.g., chlorhexidine)
- More rapid disinfection than other handhygiene techniques

- Less damaging to skin
- Time savings (18 minutes compared with 56 minutes per 8-hour shift)

The guideline suggests that healthcare facilities promote compliance by making the handrub solution available in dispensers in convenient locations (e.g., entrance to patients' room, at the bedside) and provide individual pocket-sized containers [42]. In one small survey of hand hygiene practices, healthcare workers indicated that they would be more likely to clean their hands as recommended if alcohol-based handrub solution was located near the patient [75]. The handrub solution may be used in all clinical situations except for when hands are visibly dirty or are contaminated with blood or body fluids. In such instances, soap (either antimicrobial or nonantimicrobial) and water must be used.

However, there are many other reasons for lack of adherence to appropriate hand hygiene, including denial about risks, forgetfulness, and belief that gloves provide sufficient protection [1; 42; 56]. These reasons demand education for healthcare professionals to emphasize the importance of hand hygiene. Also necessary is research to determine which interventions are most likely to improve hand-hygiene practices, as no studies have demonstrated the superiority of any intervention [76].

Table 1

Single interventions are unlikely to be effective [76]. Studies indicate that multimodal interventions (e.g., education, observation, provision of supplies, administrative support, reminders, surveillance, performance feedback) may be more effective in raising compliance [76; 77; 78].

Several single-institution studies have demonstrated that appropriate hand hygiene reduces overall rates of HAIs, including those caused by MRSA and vancomycin-resistant enterococci [57; 58; 73; 74]. However, rigorous evidence linking hand hygiene alone with the prevention of HAIs is lacking, making it difficult to evaluate the true impact of hand hygiene alone in reducing HAIs [79]. One challenge in evaluating the impact of hand hygiene is that a variety of methodologies (e.g., surveys, direct observation, measurement of product use) have been used to assess compliance, each with its own advantages and disadvantages [80]. Measuring the effect of appropriate hand hygiene alone is also difficult because the intervention is often one aspect of a multicomponent strategy to reduce infection [58]. Lastly, as noted previously, the development of HAIs is complex, with many contributing factors [58]. Although more research is needed to assess the individual impact of appropriate hand hygiene, this basic prevention measure is the essential foundation of an effective infection control strategy and is an element of every infection control guideline [2; 28; 36; 37; 39; 40; 42; 43; 44; 47; 49].

EBOLA VIRUS

Care of patients with Ebola requires Standard, Contact, and Airborne Precautions. Duration of these measures is determined on a case-by-case basis, in conjunction with local, state, and federal health authorities. A single-patient room with the door closed is preferred. A log of all people entering the patient's room is required. Avoid entry of visitors into the patient's room except as needed for the patient's well-being and on a case-by-case basis. Any visits should be scheduled and controlled. Barrier protections against blood and body fluids should be used upon entry into the room (i.e., gloves, fluid-resistant or impermeable gown, face/eye protection with masks, goggles or face shields). Additional protective wear (i.e., double gloves, leg and shoe coverings) should be used during the final stages of illness when hemorrhage may occur. The use of dedicated disposable medical equipment is preferred for patient care. All nondedicated, nondisposable equipment should be cleaned and disinfected after use. Disinfection of environmental surfaces should be conducted using a U.S. Environmental Protection Agency (EPA)-registered hospital disinfectant. Selection of a disinfectant product with a higher potency than is normally required for an enveloped virus is recommended. If possible, needles, sharps, and aerosolgenerating procedures should be avoided as much as possible, and the number of procedures and tests should be limited. All needles and sharps should be handled with extreme care and disposed in puncture-proof, sealed containers. Ebola virus is

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classified as a Category A infectious substance regulated by the U.S. Department of Transportation's (DOT) Hazardous Materials Regulations (HMR, 49 C.F.R., Parts 171-180). Any item transported offsite for disposal that is contaminated or suspected of being contaminated with a Category A infectious substance must be packaged and transported in accordance with the HMR. Public health officials should be notified immediately if Ebola is suspected [28; 71; 81; 82].

STANDARDS FOR EQUIPMENT AND ENVIRONMENTAL SERVICES

The infection control manual should contain details on cleaning and disinfecting equipment and the healthcare environment. The procedures should follow those set forth by the CDC in its guidelines for environmental infection control and for disinfection and sterilization [37; 41]. These procedures are related to the routine cleaning, disinfection, and reprocessing of equipment; the cleaning and disinfection of environmental surfaces; the cleaning of spills of blood and other body fluids; the cleaning and maintenance of laundry and bedding, carpeting, and cloth furnishings; and the handling of medical waste.

CLEANING, DISINFECTING, AND REPROCESSING EQUIPMENT

The guideline on disinfection and sterilization published by the CDC in 2008 includes updated evidence-based recommendations on preferred methods for cleaning, disinfecting, and sterilizing medical devices and for cleaning and disinfecting the healthcare environment [37]. The guideline also addresses several new topics, including inactivation of antibioticresistant bacteria, bioterrorist agents, emerging pathogens, and bloodborne pathogens; toxicologic, environmental, and occupational concerns associated with disinfection and sterilization practices; disinfection of patient-care equipment used in ambulatory settings and home care; new sterilization processes, such as hydrogen peroxide gas plasma and liquid peracetic acid; and disinfection of complex medical instruments (e.g., endoscopes) [37].

Various levels of cleaning and disinfection have been defined, and decontamination and cleaning must be carried out before any of the higher level processes (*Table 2*) [2; 37; 66]. The cleaning and disinfection of devices varies according to the Spaulding classification, which categorizes devices as critical (i.e., enters normally sterile tissue or the vascular system), semicritical (i.e., comes into contact with intact mucous membranes and does not ordinarily penetrate sterile tissue), or noncritical (i.e., does not ordinarily touch a patient or touches only intact skin) [66; 83]. Critical devices require sterilization, and semicritical devices require high-level disinfection; noncritical devices may be cleaned with low-level disinfection [2; 48; 66; 83].

DEFINITIONS OF LEVELS OF CLEANING AND DISINFECTION			
Level	Definition		
Decontamination	Use of a 0.5% chlorine solution to reduce the number of pathogenic organisms on the device		
Cleaning	Use of soap and water to remove all visible dust, soil, blood, or other body fluids		
Low-level disinfection	Use of disinfectant to destroy pathogenic organisms (may not eliminate resistant bacteria or most viruses or fungi)		
Intermediate-level disinfection	Use of disinfectant to destroy pathogenic organisms (eliminates most bacteria, viruses, and fungi)		
High-level disinfection	Use of chemical disinfectants, boiling, or steaming to destroy all micro-organisms		
Sterilization	Use of high-pressure steam (autoclave), dry heat (oven), chemical sterilants, or radiation to eliminate all forms of viable micro-organisms		
Reprocessing	A multistep procedure that consists of meticulous cleaning, high-level disinfection with a liquid chemical sterilant or disinfectant, and proper drying		
Source: [2; 37; 66]	Table	le 2	



The Association of Surgical Technologists recommends the cleaning of instruments should begin during the surgical procedure to prevent drying of blood, soil and debris on the surface and within lumens. The cleaning of instruments should continue

at the point of use post-procedure, including sorting and disassembly of instruments, containment and transportation to the decontamination room.

(http://www.ast.org/uploadedFiles/Main_Site/Content/ About_Us/Standard_Decontamination_%20Surgical_ Instruments_.pdf. Last accessed March 11, 2022.)

Strength of Recommendation: Expert Opinion/ Consensus Statement

Endoscopic instruments present a challenge to proper reprocessing because of the complex internal design and long, narrow channels [2]. Reprocessing should be carried out by trained and accredited personnel according to the manufacturer's recommendations, and the process should be monitored regularly for quality control [84]. Guidelines and recommendations for reprocessing of gastrointestinal endoscopes have been developed by several federal agencies, such as the U.S. Food and Drug Administration (FDA) and the CDC, as well as many professional organizations [2; 48; 84; 85; 86; 87]. The reprocessing procedure should begin immediately after use to prevent secretions from drying [2; 37; 86; 87].

Some inconsistencies across reprocessing guidelines and manufacturer recommendations have been found, primarily with regard to drying [86]. Also, various steps in the procedure have been emphasized as being the most critical. For example, one report notes that meticulous mechanical cleaning is the most important step because it removes the majority of the contaminating bacteria [84]. Another report emphasizes the importance of drying to avoid waterborne bacteria, such as Pseudomonas aeruginosa [86].

A report of four patients with infection with *P. aeruginosa* after transrectal ultrasound-guided prostate biopsies raised awareness about the need for thorough cleaning of equipment. Evaluation of the findings on the four patients demonstrated that the infection was caused by contamination of the needle guide as a result of inadequate cleaning (with a brush) and improper rinsing (with tap water) after reprocessing [88]. The report led to the FDA issuing a Public Health Notification on proper reprocessing of such devices [89].

Reprocessing of bronchoscopes has received less attention, perhaps because of the low risk of infection, but general recommendations, similar to those for gastrointestinal endoscopes, are available [32; 90].

CLEANING THE ENVIRONMENT

Every healthcare facility should have a written housekeeping schedule for the routine cleaning of the environment. Routine cleaning removes so-called visible dirt, which can harbor micro-organisms. Soap and water can be used to remove visible dirt from most surfaces, such as walls, doors, ceilings, and floors. A disinfectant should be used when there are signs of contamination. The level of asepsis in cleaning depends on the likelihood of contamination. WHO suggests classifying areas within a healthcare facility into four zones [2]:

- Zone A: No patient contact
- Zone B: Care of patients who are not infected and are not highly susceptible
- Zone C: Infected patients (isolation units)

• Zone D: Highly susceptible patients (protective isolation) or protected areas such as operating suites, delivery rooms, intensive care units, neonatal intensive care, transplant units, oncology units, and hemodialysis units

Cleaning according to this classification should be as follows [2]:

- Zone A: Normal cleaning
- Zone B: Cleaning procedures that do not raise dust. (Dry sweeping or vacuum cleaners are not recommended.) Use a detergent solution and disinfect any areas with visible contamination with blood or body fluids before cleaning.
- Zone C: Cleaning with a detergent/disinfectant solution, with separate cleaning equipment for each room
- Zone D: Cleaning with a detergent/disinfectant solution and separate cleaning equipment

Written policies should specify how frequently each area should be cleaned and should note the cleaning agents used for various surfaces and items such as beds, curtains, screens, fixtures, and furniture. In general, all surfaces in the environment (e.g., walls, doors, floors) must be cleaned daily to remove soil. Sinks, toilets, and baths should be scrubbed daily, or more often if needed, with a disinfectant cleaning solution using a separate mop, brush, or cloth. Patient rooms should also be cleaned daily and after each patient is discharged. Surfaces and countertops in procedure rooms, examination rooms, and the laboratory must be cleaned with a disinfectant solution after any activity.

Spills of blood or other body fluid should be removed and cleaned immediately. The area should first be cleaned with a 0.5% chlorine solution and then washed clean with a disinfectant solution. Gloves should be worn while cleaning.

MANAGING WASTE

Management of waste is a concern in healthcare facilities, but 75% to 90% of waste poses no risk of infection. The following types of waste are considered to be hazardous [2]:

- Infection-associated waste (from isolation units, laboratory cultures, tissue swabs)
- Pathologic waste (blood, body fluids, human tissue)
- Sharps (needles, scalpels, blades, knives)
- Pharmaceutical waste (expired pharmaceutical agents)
- Chemical waste (laboratory reagents, solvents)
- Heavy metal waste (broken blood pressure gauges, batteries)
- Radioactive waste

As with cleaning, written policies should document the appropriate handling, storage, and transportation of all types of waste.

SAFE INJECTION PRACTICES

Infection prevention also includes safe injection practices intended to prevent or reduce the risk of transmission of infectious diseases between one patient and another or between a patient and healthcare provider. A safe injection does not harm the recipient, does not expose the provider to any avoidable risks, and does not result in waste that is dangerous for the community [91].

Unsafe injection practices put patients and healthcare providers at unnecessary risk. A wide variety of procedures, such as the administration of anesthetics for outpatient procedures, the administration of other IV medications, flushing IV lines or catheters, and the administration of IM vaccines, have been associated with unsafe injection [91]. Outbreaks related to these practices indicate that some healthcare personnel do not adhere to basic principles of infection control and aseptic technique. A survey of U.S. healthcare professionals who provide medication through injection found that 1% to 3% reused the same needle and/or syringe on multiple patients [28].

The following guidelines should be considered with regards to injection practices [28]:

- Use aseptic technique to avoid contamination of sterile injection equipment.
- Never administer medications from a syringe to multiple patients, even if the needle or cannula on the syringe is changed. Needles, cannulae, and syringes are sterile, single-use items; they should not be reused for multiple patients.
- Use fluid infusion and administration sets (e.g., intravenous bags, tubing, connectors) for one patient only, and dispose appropriately after use.
- Use single-dose vials for parenteral medications whenever possible.
- If multidose vials must be used, both the needle or cannula and syringe used to access the multidose vial must be sterile.
- Do not keep multidose vials in the immediate patient treatment area, and store in accordance with the manufacturer's recommendations. Discard if sterility is compromised or questionable.
- Do not use bags or bottles of intravenous solution as a common source of supply for multiple patients.

SURVEILLANCE

Surveillance is an essential component of an infection control program. The infection control team has traditionally conducted surveillance through open communication with the nursing staff and physicians and meticulous review of patient records and microbiology results. The advent of electronic

health systems has enabled some infection control programs to create algorithm-driven surveillance [1]. In addition, newer technology is adding to changes in the way surveillance is conducted. An electronic, laboratory-based marker has been developed and compared with traditional medical record review and accepted surveillance methods, including hospitalwide detection by the Study on the Efficacy of Nosocomial Infection Control chart review and intensive care unit detection by National Nosocomial Infections Surveillance System techniques. Analysis with the marker was significantly better than the hospital-wide detection methods and had sensitivity comparable to medical record review [92].

The infections most commonly targeted for surveillance are those difficult to treat and those associated with substantial costs in terms of morbidity, mortality, or economics [1]. In addition, infections with a predilection for epidemics are a focus. The data gathered should be evaluated in relation to regional and national norms, and temporal trends should also be noted. Continuing analysis of the data allows the infection control team to evaluate the efficacy of programs designed to enhance compliance with hospital-wide strategies to prevent HAIs.

EXPOSURE INCIDENTS

If an occupational exposure to a bloodborne pathogen or infectious material occurs, employers should follow all federal (including the Occupational Safety and Health Administration) and state requirements for recording and reporting. The circumstances surrounding the exposure and postexposure management strategies should be recorded in the exposed person's confidential medical record and should include [93]:

- Date and time of exposure
- Details of the procedure performed
- Details of the exposure
- Details about the exposure source
- Details about the exposed person and any need for counseling, postexposure management, or follow-up

COMMUNICABLE DISEASE EXPOSURES IN HEALTHCARE PROFESSIONALS

PREPLACEMENT EVALUATIONS AND PERIODIC HEALTH ASSESSMENTS

Medical evaluations before placement may reduce the undue risk of infection to employees, patients, and visitors. Preplacement evaluations should include a review of each employee's job description for duties that may affect the risk of acquiring or transmitting infections in healthcare settings [94]. A health inventory for all new healthcare professionals who have direct patient/family contact must be documented prior to the beginning of patient/family contact. The inventory should include [26; 94; 95]:

- A history of medical conditions and other factors that may affect the risk of acquiring or transmitting infections
- A certificate of immunization against vaccine-preventable diseases (e.g., rubella, measles), as recommended for healthcare personnel by the Advisory Committee on Immunization Practices (ACIP), or professionally certified medical exemption from immunization
- A purified protein derivative (PPD) (Mantoux) skin test for tuberculosis prior to employment, and no less than every year thereafter for negative findings. Positive findings require appropriate clinical followup but no repeat test.
- An annual (or more frequent, if needed) health status assessment to ensure freedom from any health impairment that might pose a risk for other workers, patients, or visitors
- Documentation of pre-employment and annual vaccination against influenza

Screening tests are available to determine susceptibility to vaccine-preventable diseases, such as measles, mumps, rubella, and varicella. The results of these tests should be included in personnel immunization records to ensure that susceptible personnel are promptly identified and appropriately vaccinated. All healthcare settings should conduct initial and ongoing risk assessments for the transmission of tuberculosis to determine the types of administrative, environmental, and respiratoryprotection controls needed. Part of the assessment should include risk classification to determine the need for a screening program and the frequency of screening. All healthcare professionals with suspected or confirmed tuberculosis disease who have duties that involve face-to-face contact with patients should be included in a screening program [96].

All healthcare professionals experiencing fever, cough, rash, vesicular lesions, draining wounds, vomiting, or diarrhea require immediate evaluation by a licensed medical professional and possible restriction from patient care activities and return to work clearance [95]. The CDC recommends that all healthcare personnel obtain annual influenza vaccination to reduce infection of staff, patients, and family members and to decrease absenteeism [97]. Immunization against hepatitis B and pertussis (Tdap), in addition to all core vaccines, is also recommended [98]. Vaccination of healthcare personnel is considered an essential component of a patient safety program [97].

Management Strategies

Prompt diagnosis and management of job-related illnesses, appropriate postexposure prophylaxis, and implementation of measures to prevent further infection transmission are important aspects of an effective infection control program. Healthcare organization leaders and administrators are encouraged to establish a timely, confidential, and nonpunitive mechanism ers, and fact sheets on the prevention of intravascular device-

mandatory [95].

rates of HAIs, enhance knowledge about currently available guidelines, and provide instruction on carrying out guideline recommendations. Research has also suggested that education about prevention strategies may be more effective if patterns of care and levels of risk are incorporated into recommendations [99]. Numerous studies have shown that knowledge and practices related to HAIs and guidelines are improved after educational programs. The combination of a self-study module (with pretest and post-test), in-service lectures, post-

related bloodstream infections and appropriate practices led to substantial reductions in the prevalence of such infections

[100; 101]. A small study showed that intensive care nurses'

knowledge and practices were enhanced by education on

the prevention of ventilator-associated pneumonia [102]. A

Canadian study demonstrated that rates of nosocomial MRSA

infection significantly decreased after a mandatory infection

control education program on MRSA that included discussion

for healthcare personnel to report potentially infectious expo-

sures and to access exposure and illness management services

24 hours per day and seven days per week [94]. Exclusion of

personnel from work or patient contact, depending on the

mode of transmission and the pathogenesis of the disease,

may also be necessary. In these cases, personnel should avoid

contact with susceptible persons and should be encouraged to

report illnesses or exposures, including any that occur outside

the healthcare setting. Notification of emergency response

personnel possibly exposed to selected infectious diseases is

Education on best practices is a crucial aspect of preventing

HAIs and is a recommendation in all infection control guide-

lines [2; 15; 28; 36; 37; 39; 40; 42; 43; 44; 47; 49]. Education

should highlight the effect of prevention measures on the

of hospital-specific MRSA data and case-based practice [103]. It is important that all education campaigns, whether they target healthcare professionals, facility staff (e.g., janitorial staff), or the patient populations, take into consideration the special needs of the intended audience. Compounding this issue is the high rate of individuals with limited English proficiency. According to the U.S. Census Bureau data from 2019, more than 65 million Americans speak a language other than English at home, with more than 25.6 million (8.4%) of these individuals reporting that they speak English less than "very well" [104]. Even those who do speak English well may prefer to receive education in another language.

POSTEXPOSURE EVALUATION AND MANAGEMENT

When a healthcare provider has been exposed to particular infectious agents, it is important that recommended postexposure management guidelines are followed. This should reduce the risk of infection and of transmitting the infection to others [95].

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Bloodborne Pathogens

Transmission of bloodborne pathogens due to occupational exposure of healthcare professionals has occurred in needlestick accidents (0.3% risk) and blood splashes to the mucous membranes (0.09% risk) [64]. Needlestick is the most common route, but the risk of infection even through this route is low, and most exposures do not result in infection [64; 105]. The risk for transmission increases based on the source patient's viral load and the quantity of blood transferred (e.g., a needle visibly contaminated with blood; a large-gauge hollow-bore needle; a procedure that involved the needle entering directly into the patient's artery or vein; a deep puncture from a contaminated needle). In order to decrease the risks associated with bloodborne pathogen exposures, postexposure prophylaxis should be initiated as soon as possible after the incident.

Hepatitis Viruses

Recommendations for HBV postexposure management include initiation of the hepatitis B vaccine series to any susceptible, unvaccinated person who sustains an occupational blood or body fluid exposure. Postexposure prophylaxis with hepatitis B immune globulin (HBIG) and/or hepatitis B vaccine series should be considered for occupational exposures after evaluation of the hepatitis B surface antigen status of the source as well as the vaccination and vaccine-response status of the exposed person [93].

Immune globulin and antiviral agents (e.g., interferon with or without ribavirin) are not recommended for postexposure prophylaxis of HCV. In this instance, the HCV status of the source and the exposed person should be determined as soon as possible (preferably within 48 hours) after the exposure, using one of two options: test for HCV RNA (preferred), or test for anti-HCV and then if positive, test for HCV RNA [106]. If the source patient is known or suspected to have recent behavior risks for HCV acquisition (e.g., injection drug use), or if the risk cannot be reliably assessed, the initial testing should include a nucleic acid test for HCV RNA. Persons with recently acquired acute infection typically have detectable HCV RNA levels as early as one to two weeks after exposure [106]. For healthcare professionals exposed to an HCV-positive source, follow-up HCV testing should be performed to determine if infection develops [93; 106]. The timing and type of follow-up testing recommended is included in guidance from the CDC published in 2020 [106].

Healthcare professionals exposed to hepatitis viruses should refrain from donating blood, plasma, organs, tissue, or semen [93]. When based only on exposure to HBV- or HCV-positive blood, modifications to an exposed healthcare professional's patient-care responsibilities are not necessary. Acutely infected healthcare professionals should be evaluated according to current guidelines; healthcare professionals chronically infected with HBV or HCV should follow all recommended infection control practices [93].

HIV

This section is from the Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis as published by the CDC on September 25, 2013, in Infection Control and Hospital Epidemiology.

The following recommendations apply to situations where healthcare professionals have had exposure to a source person with HIV or where information suggests that there is likelihood that the source person is HIV-infected. Because most occupational HIV exposures do not result in the transmission of HIV, potential toxicity should be carefully considered when prescribing postexposure prophylaxis. The 2013 update focused on tolerability, side effects, toxicity, safety in pregnancy and lactation, pill burden, and frequency of dosing to maximize adherence to a postexposure prophylaxis (PEP) regimen [64]. When possible, these recommendations should be implemented in consultation with persons having expertise in antiretroviral therapy and HIV transmission, due to the complexity of selecting appropriate treatment.

The preferred regimen for PEP provided in the U.S. Public Health Service Guidelines for management of healthcare professionals' exposures to HIV is a basic regimen that should be appropriate for most HIV exposures: emtricitabine and tenofovir dispensed together as Truvada, a fixed-dose combination tablet, 1 mg once daily, plus raltegravir, 400 mg twice daily [64]. This preparation is available as a starter packet that should be stocked at every healthcare facility where exposure to HIV is possible. As discussed, the regimen has been selected for its tolerability and safety profile. There are several alternative regimens that may be selected due to individual patient concerns. For example, tenofovir is associated with renal toxicity, and an alternative nucleoside/nucleotide reverse-transcriptase inhibitor pair, such as zidovudine plus lamivudine (available as Combivir) would be selected for patients with renal disease [64].

Healthcare professionals with occupational exposure to HIV should receive follow-up counseling, postexposure testing, and medical evaluation regardless of whether they receive PEP. The 2013 guideline highlights the importance of follow-up within 72 hours to allow the initial shock to fade and to provide greater opportunity for full understanding of the risks and benefits of PEP; confirmation testing to ensure the necessity of PEP; increase adherence to PEP; monitoring for adverse reactions and side effects; and treating comorbidities and altering the regimen [64]. This window provides an opportunity to discuss the importance of preventing secondary transmission of HIV in the 6 to 12 weeks following initial infection. HIVantibody testing should be performed for at least six months postexposure (e.g., at 6 weeks, 12 weeks, and 6 months). It is unclear whether an extended follow-up period (e.g., 12 months) is indicated for individuals not coinfected with HCV and HIV.

If PEP is used, drug-toxicity monitoring should be performed at baseline and again two weeks after starting PEP. Clinical judgment, based on medical conditions that may exist in preexposure and/or as a result of the regimen, should determine the scope of testing. If the source patient is found to be HIV negative, PEP should be discontinued immediately [64].

Airborne/Droplet Pathogens

Tuberculosis

Healthcare professionals with known or presumed exposure to Mycobacterium tuberculosis should be asked whether they have experienced any signs or symptoms of tuberculosis (i.e., coughing for more than three weeks, loss of appetite, unexplained weight loss, night sweats, bloody sputum, hoarseness, fever, fatigue, or chest pain). Because a blood assay for M. tuberculosis (BAMT) conversion likely indicates recent infection, a BAMT result should be obtained to exclude tuberculosis [107]. If either the symptom screen or the BAMT result is positive, the exposed healthcare professional should be promptly evaluated for tuberculosis. If tuberculosis is excluded, additional medical and diagnostic evaluations for latent tuberculosis infection, including an assessment of the extent of exposure, should be obtained [96; 107]. Healthcare professionals with active tuberculosis should be excluded from duty until proved noninfectious [95].

Measles

According to the CDC and Hospital Infection Control Practices Advisory Committee (HICPAC), postexposure measles vaccine should be administered to measles-susceptible personnel who have had contact with persons with measles within 72 hours postexposure [95]. People at risk for severe illness and complications from measles (e.g., infants younger than 12 months of age, pregnant women with no evidence of immunity) and people with severely compromised immune systems should receive immunoglobulin [108]. Furthermore, adherence to Airborne Precautions (for suspected and proven cases) is also necessary [108]. Healthcare professionals without evidence of immunity who are not vaccinated after exposure should be removed from all patient contact and furloughed from day 5 after first exposure through day 21 after last exposure [98; 108].

Mumps

The CDC and HICPAC have also established postexposure protocols for mumps. The mumps vaccine should be administered to all personnel without documented evidence of mumps immunity, unless otherwise contraindicated [95; 98]. Routine serologic screening is not necessary unless the healthcare professional considers screening cost-effective or requests it. Susceptible personnel who are exposed to mumps should not work from the 12th day after first exposure through the 26th day after last exposure or, if symptoms develop, until nine days after onset of parotitis [95].

Pertussis

The CDC/HICPAC guideline indicates that antimicrobial prophylaxis against pertussis should be immediately offered to personnel who have had unprotected, intensive contact with a patient who has clinical syndrome that suggests pertussis and whose cultures are pending [95; 98]. Other healthcare personnel should either receive postexposure antimicrobial prophylaxis or be monitored daily for 21 days after exposure and treated at the onset of signs and symptoms [98]. Prophylaxis may be discontinued if results of cultures or other tests are negative for pertussis and the clinical course suggests an alternate diagnosis.

Rubella

Susceptible personnel who are exposed to rubella should be excluded from duty from the 7th day after first exposure through the 21st day after last exposure [95; 98]. Those who acquire rubella should not work until seven days after the beginning of the rash.

Varicella

The Advisory Committee on Immunization Practices (ACIP) recommends postexposure prophylaxis (with vaccination or varicella-zoster immunoglobulin [VZIG], depending on immune status) of exposed healthcare personnel without evidence of immunity [98]. Healthcare professionals who have onset of varicella should be furloughed until all lesions have dried and crusted [95]. Personnel exposed to varicella who are not known to be immune (by history or serology) should be excused from work beginning on the 10th day after first exposure until the 21st day after last exposure.

Immunocompetent personnel with localized zoster should refrain from the care of high-risk patients until lesions are crusted. They may continue to care for other patients with lesions covered [95]. Susceptible personnel exposed to zoster should not engage in patient contact from the 10th day after first exposure through the 21st day after last exposure (or 28th day if VZIG was given) [95; 98].

Serologic screening is indicated for exposed personnel who have not had varicella or are unvaccinated; screening for immunity to varicella may be considered for exposed, vaccinated personnel whose antibody status is not known [95; 98]. If the initial test result is negative, retest five to six days postexposure to determine whether an immune response occurred.

All exposed susceptible personnel should receive postexposure prophylaxis [98]. If VZIG is given, exclude personnel from duty from the 8th day after first exposure through the 28th day after last exposure.

Norovirus

Although the most frequent routes of transmission of noroviruses are direct contact and food and waterborne routes, several reports suggest that noroviruses may be transmitted through infectious small-particle aerosols (e.g., vomitus, fecal

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material) over distances further than 3 feet, typically within a defined airspace (e.g., a patient's room) [109; 110; 111; 112; 113; 114]. It is hypothesized that the aerosolized particles are inhaled and subsequently swallowed. Because of its propensity for transmission within healthcare facilities, and its ability to have a disruptive impact in healthcare facilities, norovirus is an "epidemiologically important organism" [28].

The average incubation period for gastroenteritis caused by noroviruses is 12 to 48 hours, with a clinical course lasting 12 to 60 hours. There are no recommendations for postexposure prophylaxis for healthcare personnel with norovirus infection. However, recommendations for healthcare personnel who have symptoms consistent with norovirus infection include exemption from work for a minimum of 48 hours after the resolution of symptoms and exclusion of nonessential staff from areas in which outbreaks of norovirus gastroenteritis have occurred [28; 115].

Cohorting of affected patients to separate airspaces and toilet facilities may help interrupt transmission during outbreaks. Contact Precautions should be used for diapered or incontinent persons for the duration of illness or to control outbreaks. Consistent environmental cleaning and disinfection is important, with focus on restrooms even when apparently unsoiled. Persons who clean heavily contaminated areas may benefit from wearing masks, as the virus can be aerosolized [28].

HEALTHCARE PROFESSIONALS INFECTED WITH BLOODBORNE PATHOGENS

Routine voluntary, confidential testing has been recommended for all healthcare providers, particularly for those whose clinical practice places them at higher risk for exposure and transmission [116]. The New York Department of Health has developed a policy regarding HIV testing of healthcare professionals (Table 3) [38]. It is important to note that New York State Public Health Law protects the confidentiality and privacy of anyone who has been tested for, exposed to, or treated for HIV [38]. In addition, according to the Americans with Disabilities Act, an individual is considered to have a disability if he or she has a physical or mental impairment that substantially limits one or more major life activities, has a record of such impairment, or is regarded as having such impairment [117]. Persons with HIV disease, both symptomatic and asymptomatic, have physical impairments that substantially limit one or more major life activities and are, therefore, protected by the law. Persons who are discriminated against because they are regarded as being HIV-positive are also protected.

In 2010, the Society for Healthcare Epidemiology of America (SHEA) updated its guidelines for the management of healthcare professionals who are infected with bloodborne pathogens [116]. According to these guidelines, healthcare providers with HBV, HCV, and/or HIV with greater viral loads ($\geq 10^4$ genome equivalents/mL for hepatitis viruses, $\geq 5 \times 10^2$ genome equivalents/mL for HIV) should be restricted from performing activities associated with a definite risk for provider-to-patient

NEW YORK DEPARTMENT OF HEALTH POLICY FOR TESTING POSSIBLE HIV SOURCES IN THE HEALTHCARE SETTING

Postexposure prophylaxis (PEP) is recommended for healthcare professionals following exposure to blood or visibly bloody fluid or other potentially infectious material associated with potential HIV transmission.

If HIV serostatus of the source is unknown, voluntary HIV testing of the source should be sought. In New York State, specific informed consent for HIV testing is required.

Rapid testing with an approved fourth-generation antigen/antibody combination assay is strongly recommended for the source patient and for those organizations subject to OSHA regulations; rapid testing (versus standard testing) is mandated for occupational exposures. Rules regarding confidentiality and consent for testing are identical to those for other HIV tests. Plasma HIV RNA testing is recommended in certain instances.

If the rapid test result is positive, the result should be given to the source patient. To establish a diagnosis of HIV infection, the test must be confirmed by an antibody-differentiation assay, which should be performed as soon as possible.

If the result from testing the source patient is not immediately available or a complete evaluation of the exposure is unable to be made within two hours of the exposure, PEP should be initiated while source testing and further evaluation are underway.
Source: [38]
Table 3

transmission of bloodborne pathogens, such as most surgeries, organ transplantation, and interactions with patients prone to biting [116]. These providers may engage in procedures for which the risk of transmission is insignificant (e.g., history taking, regular dental preventive procedures, minor surface suturing) or unlikely (e.g., locally anesthetized ophthalmologic surgery, percutaneous cardiac procedures, breast augmentation, minor oral surgery). Routine double gloving is also recommended [116].



According to the CDC, healthcare providers with active hepatitis B infection (i.e., those who are HBsAg-positive) who do not perform exposure-prone procedures but who practice non- or minimally invasive procedures should not be subject to any

restrictions of their activities or study. They do not need to achieve low or undetectable levels of circulating HBV DNA, hepatitis e-antigen negativity, or have review and oversight by an expert review panel, as recommended for those performing exposure-prone procedures.

(https://www.cdc.gov/mmwr/PDF/rr/rr6210.pdf. Last accessed March 11, 2022.)

Strength of Recommendation: Expert Opinion/ Consensus Statement

Infected healthcare professionals with lower viral burdens (<10⁴ genome equivalents/mL of hepatitis viruses, <5 x 10² genome equivalents/mL for HIV) may engage in all clinical activities [116]. However, all healthcare providers with a bloodborne pathogen must obtain advice from an expert review panel about continued practice, undergo follow-up routinely by an appropriate public health official, receive follow-up by a personal physician who has expertise in the management of

the infection, and adhere to strict infection control procedures [116]. Those with low viral burdens should undergo testing twice per year to demonstrate maintenance of viral level.

SEPSIS

Sepsis is a systemic pathophysiologic and clinical syndrome caused by infection and manifest by signs of inflammation, host immune response, and organ dysfunction. The causes of sepsis are myriad, and the scope of illness is broad. Most cases of sepsis syndrome arise from bacterial infection, but certain viral (e.g., Ebola and other hemorrhagic fevers) and fungal (e.g., candidiasis, histoplasmosis) infections induce a sepsis syndrome as well.

In simple terms, infection is the invasion of normally sterile host tissue by a micro-organism; clinically, infection is recognized by the constellation of symptoms and signs that issue from the host response to the invading micro-organism. Bacteremia is defined as the demonstrable presence (e.g., by culture) of viable bacteria within the general circulation.

It is important that clinicians and patients alike are aware that sepsis is a life-threatening medical emergency. Most patients who develop sepsis have recently used healthcare services or have a chronic condition requiring frequent medical care. Morbidity and mortality can be decreased by early recognition and intervention.

EPIDEMIOLOGY AND BURDEN OF SEPSIS

Sepsis, septic shock, and multiple organ failure are major causes of morbidity and mortality in the United States, resulting in an estimated 1.7 million hospitalizations and 270,000 deaths annually. One in three patients who die in a hospital has sepsis [118]. In New York, sepsis and septic shock impact approximately 50,000 patients each year, almost 30% of which will die from this syndrome [119]. It is estimated that 9.3% of all deaths in the United States, and nearly half of hospital deaths, are a result of sepsis, which equals the number of deaths resulting from myocardial infarction and far exceeds the mortality rates from acquired immune deficiency syndrome (AIDS) or breast cancer. The aggregate hospital cost of care for patients with septicemia totaled nearly \$23.7 billion in 2013 [120; 121; 122; 123; 124].

A study of hospital emergency department visits between 2009 and 2011 found that of the more than 1.3 million visits, nearly 850,000 were attributed to sepsis [125]. The average length of stay in the emergency department is 4.7 hours. However, more than 20% of patients with sepsis had a length of stay that exceeded six hours, resulting in a substantial burden on facilities nationwide in providing sepsis care [126; 127].

The incidence of septicemia more than doubled between 1993 and 2009, increasing by an annual average of 6% [120]. Between 1993 and 2003, 8.4 million cases of sepsis and 2.4 million cases of severe sepsis were reported. The percentage of severe sepsis cases among all sepsis cases increased from 25.6% to 43.8% during the same time period [128]. Studies continue to report an increase in the incidence of septicemia; however, they also indicate that in-hospital mortality rates for sepsis appear to be declining. For example, according to the results of one retrospective cohort study, the incidence of septicemia as a proportion of medical and surgical admissions increased from 3.9% to 9.4% from 2010 to 2015, whereas the in-hospital mortality rate for sepsis hospitalizations declined from 24.1% to 14.8% during the same period. The percentage of patients at risk for hospital readmission after sepsis increased from 2.7% to 7.8%. Although 30-day readmission rates declined from 26.4% to 23.1% from 2010 to 2015, this was offset by an increase in emergency department visits, from 2.8% in 2010 to 5.4% in 2014 [124]. Another study that analyzed data from 2009 to 2014 also reported an increase in the incidence of sepsis but a decline in sepsis-related mortality rates [129]. The reported incidence of sepsis in the general population varies greatly and has been attributed to the data source, sepsis surveillance definition, and advances in supportive care for the critically ill [129; 130; 131; 132].

The reported incidence rates of sepsis increase with advanced age. Two-thirds of all sepsis cases occur in people 65 years of age and older, with case fatality rates as high as 40% [121]. Ageadjusted rates for sepsis hospitalization and mortality increased annually by 8.2% and 5.6%, respectively, between 1993 and 2003, whereas the fatality rate decreased by 1.4% [128]. Sepsis is more common among men than women, and the fatality rate is greater in men and nonwhite populations [133].

Mortality from sepsis of gram-negative etiology is the cause of 20% to 50% of the overall total number of septic deaths. The figures are now similar for sepsis of gram-positive etiology [134]. Mortality has been reported as high as 60% in patients with underlying medical problems. Among patients who develop the complications of shock and organ failure, mortality can reach 90% [135]. Extent of organ failure contributes to the

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prognosis, with a greater survival rate in patients with fewer than three failing organs. The risk of death increases as each organ fails [135].

Sepsis is among the leading causes of hospitalization and ranks as the most expensive inpatient condition treated in U.S. hospitals [136]. Data from the 2008 National Hospital Discharge Survey (now the National Hospital Care Survey) show that the rate of hospitalization for sepsis increased from 11.8 to 24 per 10,000 population during the period 2000 through 2008 [136]. Compared with other conditions, the hospital stay for sepsis was 75% longer and the likelihood of dying during hospitalization was eight times higher. The estimated annual cost of hospitalization for sepsis and septicemia in 2008 was \$14.6 billion and increasing at the rate of 11.9% each year [136].

One retrospective study was conducted in 2018 to characterize the burden, outcomes, and costs of managing sepsis patients in U.S. hospitals [137]. The cohort consisted of adults 18 years of age and older with a hospital discharge diagnosis code of sepsis between January 2010 and September 2016. Of the more than 2.5 million patients included in the final study cohort, the mean age was 65 years and more than one-half were female (50.8%). The overall mortality was 12.5% but varied according to severity of sepsis (i.e., 5.6% for sepsis without organ dysfunction; 14.9% for severe sepsis; and 34.2% for septic shock). Economic costs also increased according to the severity level of sepsis (\$16,324, \$24,638, and \$38,298, respectively) and varied widely by sepsis at presentation (\$18,023) and not present at admission (\$51,022) [137].

Despite immense clinical effort and high treatment expenditures, mortality rates remain high. Those who survive often sustain permanent organ damage, some degree of physical disability, and long-term cognitive impairment [138].

New York State Sepsis Improvement Initiative

In 2013, New York adopted new laws to combat sepsis, referred to as Rory's Regulations, in honor of Rory Staunton, who had died the previous year after multiple healthcare encounters failed to diagnose sepsis [139]. Specifically, amendments were made to sections 405.2 and 405.4 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York. Section 405.2 requires hospitals to have in place evidence-based protocols for the early recognition and treatment of patients with severe sepsis/septic shock that are based on generally accepted standards of care [140]. Section 405.4 further requires that these protocols include the following components [140]:

- A process for the screening and early recognition of patients with sepsis, severe sepsis, and septic shock
- A process to identify and document individuals appropriate for treatment through severe sepsis protocols, including explicit criteria defining those patients who should be excluded from the protocols, such as patients with certain clinical conditions or who have elected palliative care

- Guidelines for hemodynamic support with explicit physiologic and biomarker treatment goals, methodology for invasive or non-invasive hemodynamic monitoring, and timeframe goals
- For infants and children, guidelines for fluid resuscitation with explicit timeframes for vascular access and fluid delivery consistent with current, evidence-based guidelines for severe sepsis and septic shock with defined therapeutic goals for children
- A procedure for identification of infectious source and delivery of early antibiotics with timeframe goals
- Criteria for use, where appropriate, of an invasive protocol and for use of vasoactive agents

In addition, hospitals are required to report to the Department data that are used to calculate each hospital's performance on key measures of early treatment and protocol use.

As part of this movement, the New York State Sepsis Care Improvement Initiative was begun by the Department of Health as a resource for quality improvement in sepsis care by improving early detection and intervention, especially for patients with severe sepsis and shock [119]. The Initiative also publishes an annual public report detailing data collection, adherence to guidelines, improvements on quality measures and outcomes, and stakeholder collaborations.

RISK FACTORS AND PREVENTION

Factors considered important in the development of sepsis include: inappropriate broad-spectrum antibiotic therapy; immunosuppressive treatments, such as cancer chemotherapy; invasive procedures; transplantations; fungal organisms; burns or other trauma; anatomic obstruction; intestinal ulceration; age (the very young and the very old); and progressive clinical conditions, such as malignancy, diabetes, or AIDS [141].

Healthcare-associated infections are a major cause of sepsis among severely ill patients. Increased risk of nosocomial infection is associated with the presence of underlying chronic disease, alteration in host defenses, prolonged hospital stay, and the presence of invasive catheters or monitoring devices [142]. Pulmonary, urinary tract, gastrointestinal, and wound infections predominate [143; 144]. In hospitalized adult patients, the etiology of sepsis has shifted from being predominantly gram-negative nosocomial infections (Escherichia coli, Klebsiella spp., Enterobacter spp., and Pseudomonas aeruginosa) to grampositive infections (Staphylococcus aureus, Streptococcus pneumoniae, and Streptococcus pyogenes) [145]. The incidence of sepsis caused by gram-positive infections has increased by 26.3% per year over the last three decades [146]. Multidrug-resistant pathogens, such as S. aureus, now account for more than half of all sepsis cases. S. aureus is singly responsible for 40% of ventilator-associated pneumonia episodes and most cases of nosocomial pneumonia [146; 147]. Group B streptococcus is a leading cause of neonatal sepsis in the United States [148].

Vascular and monitoring catheters and infusion sets may become contaminated and lead to the development of nosocomial infections and sepsis. The risk of catheter-related sepsis is increased when the IV catheter is placed in a central vein, particularly if the catheter remains in place longer than three to five days or if the catheter is used for blood sampling [149]. The results of a Cochrane review originally revised in 2013 found evidence indicating that administration sets that do not contain lipids, blood, or blood products may be left in place for intervals of up to 96 hours without increasing the risk of infection [150; 151]. Generally, consideration should be given to changing the catheter and possibly the insertion site after 72 hours [152]. The risk of contamination of arterial catheters is higher than that observed with venous catheters. Contamination can occur if the system is entered frequently for blood sampling, if the infusate remains in place for more than 48 hours, or if inflammation develops near the catheterized artery [152]. Urinary catheters left in the bladder longer than two weeks often cause infection. Therefore, increased surveillance for signs of urinary tract infections when catheters remain in place beyond a few days is necessary [153].

Central venous catheters (CVCs) are increasingly used in the pediatric population, leading to an increase in CVC-related complications. Implanted ports may be the device of choice when long indwelling times are expected, with consideration given to the patient's age and need for sedation and analgesia during the insertion procedure. Radiograph following the insertion procedure is recommended to ensure correct catheter positioning. Full sterile barrier precautions, strict protocols for catheter care, and prompt removal of the catheter when it is no longer needed are recommended to prevent infectious complications [154]. A study conducted by the American Pediatric Surgical Association found that chlorhexidine skin prep and chlorhexidine-impregnated dressing and heparin and antibiotic-impregnated CVCs can decrease CVC colonization and bloodstream infection and that ethanol and vancomycin lock therapy can reduce the incidence of catheter-associated bloodstream infections [155].

Bacterial contamination of platelet units (estimated at 1 in 1,000–3,000) results in many occurrences of transfusionassociated sepsis in the United States each year. In 2017, two separate clusters of platelet transfusion-associated bacterial sepsis were reported in Utah and California, resulting in three deaths [156]. The AABB (formerly the American Association of Blood Banks) adopted a new standard in 2004 requiring member blood banks and transfusion services to implement detection measures and limit bacterial contamination in all platelet components [157]. The 33rd edition of the standard is available as of April 2022 [158; 159].

DIAGNOSIS AND MANAGEMENT

Methods to identify critically ill patients who are likely to die as a result of sepsis have become clearer, and increased awareness that sepsis is more common and lethal than previously understood has helped to promote the development of an organized approach to care. While the early diagnosis of sepsis continues to be a challenge (primarily because a rapid, sensitive, and specific diagnostic test is lacking), research indicates that improvements in outcomes are possible when treatment protocols are applied in a timely manner [160; 161].

An international consortium of critical care specialty societies has worked to standardize the definition and clinical parameters of sepsis and to develop evidence-based guidelines for optimal management of sepsis and septic shock. This is an ongoing effort, the goal of which is to improve care and reduce mortality worldwide. Clinical care guidelines have been developed by the Surviving Sepsis Campaign and published by the Society of Critical Care Medicine (SCCM) in 2008, 2013, and 2016. Detailed management strategies are provided for rapid diagnostic evaluation and antimicrobial treatment, fluid resuscitation, and the use of vasopressors in septic shock [162; 163; 164].

Initial funding of the Surviving Sepsis Campaign was provided by the SCCM. The ongoing work and the campaign's guidelines have no direct or indirect connection to industry support. The 2021 international guideline for the management of sepsis and septic shock are available online at https://www.sccm.org/ Clinical-Resources/Guidelines/Guidelines/Surviving-Sepsis-Guidelines-2021 [165].

The 2021 guideline recommendations use the "Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach to identify outcomes that the authors considered important from a patient's perspective [165; 166].

Management of Sepsis

Fluid Resuscitation and Diagnosis

The SCCM guideline emphasizes that sepsis and septic shock are medical emergencies; treatment and resuscitation should begin immediately upon recognition [165]. Intravenous fluid resuscitation of a patient with sepsis-induced shock (defined as tissue hypoperfusion) should be initiated as soon as the hypoperfusion is recognized (i.e., not delayed pending admission to an ICU).

The principal recommendations for fluid resuscitation are [165]:

- Intravenous fluid resuscitation should be started immediately, beginning with crystalloids (grade weak [downgraded from strong], suggested).
- In the setting of sepsis-induced hypoperfusion, at least 30 mL/kg of intravenous crystalloid fluid should be given within the first three hours (grade weak [downgraded from strong], suggested).

- It is suggested that albumin be added when patients require substantial amounts of crystalloids (grade weak, suggested).
- Fluid resuscitation should initially target a mean arterial pressure (MAP) of 65 mm Hg in patients with septic shock requiring vasopressors (grade strong, recommended).

It is recommended that, following initial fluid resuscitation, additional fluid administration be guided by frequent reassessment of hemodynamic status. A reasonable set of treatment goals suggested for the first six hours of resuscitation are [163; 164; 165]:

- Central venous pressure of at least 8 mm Hg (12 mm Hg in mechanically ventilated patients)
- MAP of 65 mm Hg or greater
- Urine output of 0.5 mL/kg/hour or greater
- Central venous or mixed venous oxygen saturation of at least 70% or 65%, respectively

Antibiotic Therapy and Source Control

The SCCM recommends obtaining appropriate cultures before beginning antimicrobial therapy, but the process of doing so should not delay antibiotic administration. Whenever possible, this should be completed within three hours of presentation [165]. At least two sets (aerobic and anaerobic) of blood cultures should be obtained, including one drawn through any indwelling vascular catheter or device in place prior to onset of infection. Cultures from other suspected sites should be obtained as well. The guideline committee also recommends that imaging studies be performed to confirm the source of infection, assuming the patient's condition allows it [162; 163; 164; 165].

Intravenous antimicrobial therapy should be started as early as possible, ideally within the first hour of recognition of sepsis or septic shock (grade strong). Early administration of appropriate antimicrobials is one of the most effective interventions to reduce mortality in patients with sepsis. However, this must be balanced against the potential harms (e.g., allergic or hypersensitivity reactions, kidney injury, C. difficile infection, antimicrobial resistance) associated with administering unnecessary antimicrobial agents. The mortality reduction associated with early antimicrobial therapy appears strongest in patients with septic shock versus those without septic shock [165]. Clinical studies have shown that delay in antimicrobial therapy for serious infection and sepsis prolongs morbidity, lengthens hospital stay, and increases mortality [167]. A retrospective cohort study involving 2,731 patients with sepsis showed that initiation of antimicrobial therapy within the first hour of documented hypotension was associated with increased survival to discharge. Moreover, each hour of delay conferred an approximately 12% decreased probability of survival [168].

The initial choice of antibiotics will depend on the most likely pathogens associated with the source of infection as well as the prevalent micro-organisms in the local community and hospitals. The clinician should assess risk factors for multidrugresistant pathogens, including prior hospitalization, health facility residence, recent antimicrobial use, and evidence of prior infection with resistant organism. The anticipated susceptibility profile of prevalent local pathogens and the ability of the antibiotic to penetrate to the source of the infection must also be considered. A combination of drugs with activity against all likely pathogens should be administered initially, but the regimen should be reassessed in light of culture results, the goal being to identify a single, narrow-spectrum antibiotic that will best control the infection [169; 170]. It has been found that combining an extended-spectrum beta-lactam antibiotic (e.g., penicillins, cephalosporins) with an aminoglycoside (e.g., gentamicin) was no more effective in reducing mortality than using the beta-lactam agent alone. In addition, the combination carries an increased risk of renal damage [169; 170]. A common approach is to initiate empiric therapy with a carbapenem or extended-spectrum penicillin/beta-lactamase inhibitor (e.g., ticarcillin/tazobactam) to cover gram-negative enteric bacilli and Pseudomonas, often in combination with vancomycin to cover S. aureus pending culture results.

The empirical antimicrobial regimen should be narrowed as soon as the pathogen has been identified and sensitivities are known. The duration of therapy will depend on the nature of the infection and other considerations specific to a given case. As a general rule, a 7- to 10-day course of bactericidal antimicrobial therapy is considered adequate for most serious infections associated with sepsis [164; 165]. For adults with an initial diagnosis of sepsis or septic shock and adequate source control where optimal duration of therapy is unclear, the SCCM suggests using procalcitonin in conjunction with clinical evaluation to decide when to discontinue antimicrobials over clinical evaluation alone [165]. In the event that the syndrome is due to something other than an infectious cause, such as trauma, antibiotics should be discontinued as soon as possible.

Source control requires that a specific anatomic diagnosis of infection (e.g., skin/soft tissue infection, pyelonephritis, cholangitis, peritonitis) be identified, or excluded, as soon as possible and preferably within the first six hours after presentation [165]. Small studies suggest that source control within 6 to 12 hours is advantageous [166; 171; 172]. Studies generally show reduced survival beyond that point [165]. Radiographic imaging is often necessary and should be undertaken promptly as soon as the patient's condition permits and antimicrobial therapy has been administered. Source control may be achieved by percutaneous drainage of an infected cyst or abscess, debridement of infected tissue, or removal of an infected device or catheter (removal should be prompt after other vascular access has been established) [164; 165; 169]. Surgical exploration also may be indicated when diagnostic uncertainty persists despite radiologic evaluation, when the probability of success with a percutaneous procedure is uncertain, or when the desirable effects of a failed procedure are high [165].

Vasopressors and Inotropic Therapy

If hypotension persists after intravascular volume repletion, then vasopressors may be required to restore and maintain adequate blood pressure and tissue perfusion (goal MAP 65 mg Hg) [165]. Such patients are considered to have the combination of vasodilation and reduced cardiac contractility, a condition best managed with a combined inotrope-vasopressor agent. In order to monitor arterial pressure accurately, it is suggested that all patients requiring vasopressors have an arterial catheter placed as soon as practical, if resources are available [164].

Historically, norepinephrine, dopamine, and epinephrine were three inotrope-vasopressors used to correct hypotension in septic shock [169]. Based on comparison studies and a metaanalysis of six randomized trials, norepinephrine is considered superior to dopamine and is now the recommended first choice for vasopressor therapy in septic shock (grade strong) [163; 164; 165; 173]. If a second agent is needed to maintain blood pressure, consider adding vasopressin (grade weak). If cardiac dysfunction with persistent hypoperfusion is present, despite adequate volume status and blood pressure, consider adding dobutamine or switching to epinephrine (grade weak) [165]. If dopamine is used, special attention should be given to patients at risk for arrhythmias [165]. For patient safety and effectiveness, intravenous vasopressor therapy should be administered via a central venous catheter.

As an alternative second drug, or to decrease the required effective dose of norepinephrine, vasopressin (up to 0.03 units/minute) may be added to norepinephrine. Vasopressin is usually started when the dose of norepinephrine is in the range of 0.25 - 0.5 mcg/kg/min [165]. Vasopressin should not be administered as the initial agent in septic shock.

Phenylephrine is a pure vasopressor that may be used in very select cases of septic shock [162; 163]. It reduces cardiac stroke volume, which can have deleterious effects in the patient with low cardiac output, and thus is not recommended as initial or additive therapy. Phenylephrine is reserved for the unusual case in which tachyarrhythmia limits norepinephrine use or the patient has known high cardiac output. Intravenous phenylephrine should be administered only by properly trained individuals familiar with its use [169; 174; 175].

Inotropic therapy may involve the use of dobutamine if the cardiac output remains low. If dobutamine is used, it should be combined with the vasopressors. All patients requiring vasopressors should have an arterial line placed for monitoring blood pressure [169; 174].

Monitoring Serum Lactate

If elevated, serum lactate provides a marker of tissue hypoperfusion, and serial measurements (of lactate clearance) can be used to monitor progress in resuscitation of the patient with sepsis or early septic shock. In cases in which elevated lactate levels are used as a marker of tissue hypoperfusion, it is recommended that resuscitation efforts target serum lactate with the goal to achieve normalization as rapidly as possible (grade weak) [162; 163; 164; 165].

Corticosteroids

Prior to the 1990s, there was evidence that the overall 28-day mortality was not impacted by the use of corticosteroids; consequently, their use was not advised. A review of studies conducted between 1992 and 2003 concluded that corticosteroids did not change the 28-day mortality in patients with sepsis and septic shock, but that the use of low-dose corticosteroids did reduce the all-cause mortality [176]. An update to this review found moderate-certainty evidence that corticosteroids reduce 28-day and hospital mortality in children and adults with sepsis and that the agents result in large reductions in ICU and hospital length of stay [177]. Corticosteroids are not recommended in adult patients with sepsis if hemodynamic stability has been achieved with fluid resuscitation and vaso-pressor therapy [164].

The patient with persistent hypotension despite fluids and vasopressors should be assessed for adrenal responsiveness and may benefit from corticosteroid therapy [165]. If corticosteroids are to be given, the 2021 SCCM guideline suggests IV hydrocortisone at a dose of 200 mg per day, in divided doses or by continuous infusion (grade weak, D) [165]. In 2017, a multispecialty task force of 16 international experts in critical care medicine, endocrinology, and guideline methods, all members of the SCCM and/or the European Society of Intensive Care Medicine, published a guideline for the management of corticosteroid insufficiency in critically ill patients. This group suggests using IV hydrocortisone <400 mg/day for three or more days at full dose in patients with septic shock that is not responsive to fluid and moderate- to high-dose vasopressor therapy. They suggest not using corticosteroids in adult patients with sepsis without shock [178].

Recombinant Human Activated Protein C

Drotrecogin alpha (activated), or recombinant human activated protein C (rhAPC), has been studied in patients with sepsis due to its antithrombotic, anti-inflammatory, and profibrinolytic properties. It was voluntarily withdrawn from the market in 2011 due to studies showing no improvement in mortality with treatment [179].

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Blood Product Administration

In some cases, blood product administration may be required. The 2021 guideline recommends using a restrictive (over liberal) transfusion strategy (grade strong). A restrictive transfusion strategy typically includes a hemoglobin concentrations transfusion trigger of 70 g/L; however, RBC transfusion should not be guided by hemoglobin concentration alone. Assessment of the patient's overall clinical status and consideration of extenuating circumstances (e.g., acute myocardial ischemia) is required [165]. The routine use of erythropoietin is not recommended for treatment of anemia in patients with sepsis unless other conditions are present, such as the compromise of red blood cell production induced by renal failure. Prophylactic platelet transfusion is suggested when the platelet count is $<10,000/\text{mm}^3$ (10 \times 10⁹/L) in the absence of apparent bleeding and when counts are $<20,000/\text{mm}^3$ (20 × 10⁹/L) if the patient has a significant risk of bleeding [164].

Patients who require invasive procedures or surgery typically require a platelet count that is in excess of 50,000/mm³[169]. The routine use of fresh frozen plasma is not recommended unless there is active bleeding or planned surgery. Direct administration of antithrombin agents for the treatment of sepsis or septic shock is not advised [164; 169].

Supportive Therapy for Sepsis and Septic Shock

Mechanical Ventilation

Patients who develop sepsis-induced acute lung injury (ALI) or acute respiratory distress syndrome (ARDS) may require assisted ventilation. The routine use of pulmonary artery catheters for patients with ALI/ARDS is not recommended, and it is important to remember to avoid high pressures and volumes.

The SCCM guideline committee recommends a target goal for maximum end-inspiratory plateau pressures of 30 cm H_2O and a target tidal volume of 6 mL/kg predicted body weight in adult patients with sepsis-induced ARDS (grade strong, A). In addition, the use of lower tidal volumes over higher tidal volumes is suggested for adult patients with sepsis-induced respiratory failure without ARDS [165].

Unless contraindicated, it is recommended that mechanically ventilated patients be kept with the head of the bed elevated (30–45 degrees is suggested) to limit aspiration and prevent the development of ventilator-associated pneumonia. In hospitals with advanced experience and equipment, it may be advantageous to treat patients with ARDS in a prone position if higher pressures are required and the patient's condition allows for the positional change [164; 169]. For adults with sepsis-induced moderate-to-severe ARDS, the SCCM recommends using prone ventilation for more than 12 hours daily [165].

A protocol for weaning patients from the ventilator should be developed for use following a successful spontaneous breathing trial. Extubation should be considered if the breathing trial is successful. A successful breathing trial is characterized by the following criteria [169]:

- Patient is arousable.
- Patient is hemodynamically stable (without vasopressor agents).
- Patient has developed no new potentially serious conditions.
- Ventilatory and end-expiratory pressure requirements are low.
- Fraction of inspired oxygen requirements are able to be safely delivered with a face mask or nasal cannula.

The SCCM recommends a conservative fluid strategy for patients with established ARDS and no evidence of tissue hypoperfusion in order to minimize fluid retention and weight gain (which have been shown to prolong mechanical ventilation and lengthen ICU stay) [164].

Sedation, Analgesia, and Neuromuscular Blockade

Sedation, whether intermittent or by continuous infusion, may be required for patients who are mechanically ventilated. In such cases, the practice of daily interruption or lightening of the sedation, preferably by established protocol, will serve to maintain the minimum degree of necessary sedation.

Neuromuscular blockade agents (NMBA) are sometimes used in the ICU to improve chest compliance, reduce airway pressures, and facilitate mechanical ventilation. Neuromuscular blockade agents should be used with caution in the patient with sepsis and only for brief periods, so as to avoid the risk of prolonged blockade when the drug is discontinued. The SCCM 2016 guideline issued a weak recommendation for using NMBA for 48 hours or less in adult patients with sepsis-induced ARDS and a PaO₂/FiO₂ ratio <150 mm Hg (grade weak, B) [164]. A review of randomized controlled trials published since 2016 produced conflicting results about important outcomes (e.g., mortality). This uncertainty about the outcomes and the balance between the benefits and potential harms of using NMBA led the 2021 guideline panel to issue a weak recommendation favoring intermittent NMBA boluses over a continuous infusion. Clinicians are reminded to ensure adequate patient sedation and analgesia if NMBA are used [165].

Glucose Control

Glucose control includes a regimen of appropriate nutrition, beginning with IV glucose and enteral feeding within 72 hours (grade weak, suggested) in critically ill patients with sepsis [165]. Following initial stabilization, patients with hyperglycemia should receive IV insulin therapy to reduce blood glucose levels. The 2016 version of the SCCM guideline recommended that blood glucose management be done by protocol: insulin dosing to commence when two consecutive blood glucose levels are greater than 180 mg/dL, and targeting an upper blood glucose of ≤180 mg/dL rather than an upper blood glucose ≤110 mg/dL [164]. In the 2021 guideline, the panel sought to identify what level of glucose (>180 mg/dL or >150 mg/dL) should trigger commencement of IV insulin [165]. After reviewing a network meta-analysis of 35 randomized controlled trials, the panel concluded that the balance of effects (e.g., hospital mortality, hypoglycemia) favored initiation of insulin therapy at a glucose level of >180 mg/dL and provided a strong recommendation to that effect [165]. Following initiation, a typical target blood glucose range is 144-180 mg/dL [165]. Note: The meta-analysis that the 2021 guideline panel reviewed compared four different blood glucose targets: <110 mg/dL; 110-144 mg/dL; 144-180 mg/dL; and >180 mg/ dL. No significant difference in risk of hospital mortality was observed among the four targets. Concentrations of <110 mg/ dL and 110-144 mg/dL were associated with a four- to ninefold increase in the risk of hypoglycemia compared with the 144-180 mg/dL and the >180 mg/dL ranges. No significant difference in the risk of hypoglycemia was observed when the target range of 144–180 mg/dL was compared with the target range of >180 mg/dL [165].

Bicarbonate Therapy and Deep Vein Thrombosis Prophylaxis

Bicarbonate therapy to improve hemodynamics or reduce vasopressor requirements in patients with sepsis-induced lactic acidemia is not recommended for those patients with a pH equal to or greater than 7.15 [165]. While the 2016 recommendation is essentially unchanged, for patients with severe metabolic acidemia (pH \leq 7.2 and acute kidney injury (AKI) [AKIN score 2 or 3]), the 2021 panel suggests (weak recommendation) using sodium bicarbonate therapy [165].

The use of anticoagulants to prevent deep vein thrombosis (DVT) has been well studied. For patients with sepsis, the SCCM guideline committee recommends the administration of low-dose unfractionated heparin (UFH), two to three times per day, or low-molecular-weight heparin (LMWH), once daily, unless there are contraindications, such as active bleeding, thrombocytopenia, or severe coagulopathy. LMWH has been found to be superior to UFH and is preferred in high-risk patients if there are no contraindications [165; 169].

When contraindications exist, other preventive measures, such as graduated compression stockings or an intermittent compression device, are recommended. In very high-risk patients, such as those who have sepsis and a history of DVT, trauma, or orthopedic surgery, a combination of both therapies is suggested [169; 174].

Stress Ulcer Prophylaxis

The SCCM guideline recommends stress ulcer prophylaxis for patients with sepsis who have risk factors for gastrointestinal bleeding, using either a proton pump inhibitor or a histamine-2 antagonist. It is recommended that stress ulcer prophylaxis not be used for patients without risk factors for gastrointestinal bleeding [165].

Patient Education

History-taking and examination are important aspects in the assessment of patients with suspected sepsis. All patients should be told of the importance of providing accurate and relevant information.

Also included in the supportive therapy points of care is the SCCM recommendation that advance care planning, including the communication of likely outcomes and realistic goals of treatment, be discussed with patients and families [165; 169]. 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 communication with patients and families is considered an essential aspect of care, it is each practitioner's responsibility to ensure that information regarding goals and potential outcomes 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.

All patients should be given comprehensive education on their condition and instructions regarding when to seek help. Infection prevention strategies (e.g., appropriate handwashing, wound care, vaccination) are essential. Patients at high risk for sepsis should be informed of risk factors and warning signs/symptoms of the disease. These patients should be told to seek immediate care for worsening infections and sign/ symptoms of sepsis.

Sepsis Bundle

Reducing mortality due to sepsis requires an organized process that guarantees early recognition and consistent application of evidence-based practice. To this end, carefully designed protocols and measurable quality indicators should be incorporated into hospital practice. Beginning in 2005 the Surviving Sepsis Campaign converted its guideline into protocols, with sets of quality indicators that could be implemented by hospitals working to improve outcomes. The Sepsis Bundles are a series of therapies that, when implemented together, have been proven to achieve better outcomes than when implemented individually [162]. In conjunction with the 2013 guideline, two bundles (resuscitation and management) were released.

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In order to reflect the changes in the 2016 guideline, in 2018 the Surviving Sepsis Campaign published the Hour-1 Bundle, taking the place of the previously separate resuscitation and management bundles [162]. This new bundle emphasizes the importance of beginning resuscitation and management immediately, then escalating care seamlessly (e.g., by adding vasopressor therapy) on the basis of ongoing clinical parameters rather than waiting or extending resuscitation measures over a longer period. The Hour-1 Bundle consists of five elements that are intended to be initiated within the first hour after the time of triage in the emergency department or, if referred from another care location, from the earliest chart annotation consistent with all elements of sepsis or septic shock. The five elements are [162]:

- Measure lactate level. Re-measure if initial lactate is >2 mmol/L.
- Obtain blood cultures prior to administration of antibiotics.
- Administer broad-spectrum antibiotics.
- Rapidly administer 30 mL/kg crystalloid for hypotension or lactate ≥4 mmol/L.
- Apply vasopressors if patient is hypotensive during or after fluid resuscitation to maintain MAP ≥65 mm Hg.

More than one hour may be required for resuscitation to be completed, but initiation of resuscitation and treatment should begin immediately [162]. The Hour-1 Bundle, based on the 2018 guideline, is evidence-based and intended for use by emergency department, hospital, and ICU staff as a tool for improving the care of patients with sepsis and septic shock. The Bundle is supported in the 2021 guidelines [165].

CONCLUSION

An effective infection control team is critical to reducing the incidence of HAIs in a healthcare facility. All departments within a healthcare facility should be represented on this team to ensure widespread adherence to prevention measures. The responsibilities of an infection control team are to conduct surveillance of infections; ensure compliance with infection control guidelines, including those for management of drug-resistant organisms; and establish response and control plans for outbreaks and epidemics. Most important is the development of an organizational culture that fosters a focus on patient safety and that emphasizes education on HAIs and infection control for healthcare professionals and patients and their families.

COURSE TEST - #58643 INFECTION CONTROL: THE NEW YORK REQUIREMENT

This is an open book test. A passing grade of at least 70% must be achieved in order to receive credit for this course.

This 5 CE Credit Hour activity must be completed by March 31, 2025.

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1. Which of the following categories of healthcareassociated infections (HAIs) does the Centers for Medicare & Medicaid Services consider to be reasonably preventable?

- A) HIV infection
- B) Ventilator-associated pneumonia
- C) Catheter-related urinary tract infection
- D) Methicillin-resistant Staphylococcus aureus (MRSA) infection

2. Which of the following statements regarding prevention of HAIs is TRUE?

- A) An estimated 70% of HAIs are preventable.
- B) Adherence to prevention guidelines is generally low.
- C) Most professionals comply with hand hygiene guidelines.
- D) There are few evidence-based guidelines for the prevention of infection in healthcare facilities.
- 3. For which of the following pathogens is the skin not an effective barrier?
 - A) Candida spp.
 - B) Human papillomavirus
 - C) Haemophilus influenzae
 - D) Mycobacterium tuberculosis

- 4. Which of the following statements about the pathogenesis of infection is TRUE?
 - A) Commensal bacteria are always a source of infection.
 - B) Infection with parasites is as common as infection with bacteria.
 - C) Viral nosocomial infections are more common in adults than in children.
 - D) Fungal infections frequently occur during prolonged treatment with antibiotics.
- 5. The greatest risk of morbidity and mortality is associated with infection with
 - A) fungi.
 - B) viruses.
 - C) bacteria.
 - D) parasites.

6. Percutaneous exposure to a bloodborne pathogen may occur during

- A) blood splashes.
- B) handling contaminated needles.
- C) infusion of contaminated fluids.
- D) sharing of blood monitoring devices.
7. Airborne Precautions should be used for a patient with

- A) pertussis.
- B) diphtheria.
- C) meningitis.
- D) tuberculosis.

8. When adhering to Droplet Precautions, healthcare professionals should

- A) wear a mask when working within 3 feet of the patient.
- B) wear an N95 respirator when entering the room of the patient.
- C) ensure that the patient's room has 6 to 12 air changes per hour.
- D) not enter the room of the patient if they are susceptible to the disease.

9. Hands should be washed after

- A) removing gloves
- B) contact with a patient's skin.
- C) contact with body fluids or excretions, nonintact skin, or wound dressings.
- D) All of the above

10. With regard to hand hygiene,

- A) compliance is usually more than 80%.
- B) antibacterial soap is more effective than alcohol-based handrub solutions.
- C) reasons given for noncompliance include inconveniences, understaffing, and skin damage.
- D) the impact as an individual strategy in reducing healthcare-associated infections is well documented.

11. Intermediate-level disinfection is defined as

- A) use of a 0.5% chlorine solution to reduce the number of pathogenic organisms on the device.
- B) use of disinfectant to destroy pathogenic organisms (eliminates most bacteria, viruses, and fungi).
- C) use of high-pressure steam (autoclave), dry heat (oven), chemical sterilants, or radiation to eliminate all forms of viable micro-organisms.
- D) a multistep procedure that consists of meticulous cleaning, high-level disinfection with a liquid chemical sterilant or disinfectant, and proper drying.

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- 12. According to Spaulding classification, a device that enters the vascular system is
 - A) critical.
 - B) noncritical.
 - C) less critical.
 - D) semicritical.
- 13. According to World Health Organization classification, an isolation unit in a healthcare facility should be cleaned
 - A) using normal cleaning procedures.
 - B) using procedures that do not raise dust.
 - C) after disinfection of any areas with visible contamination with blood or body fluids.
 - D) using a detergent/disinfectant solution, with separate cleaning equipment for each room.
- 14. Which of the following is NOT an aspect of safe injection practices?
 - A) Using aseptic technique
 - B) Keeping multidose vials in the immediate patient treatment area
 - C) Using a sterile needle and syringe when a multidose vial is used
 - D) Using single-dose vials for parenteral medications whenever possible
- 15. After an occupational exposure to an infectious agent, which of the following should be recorded in the exposed person's confidential medical record?
 - A) Date and time of exposure
 - B) Details about the exposure source
 - C) Details about necessary follow-up
 - D) All of the above
- 16. Healthcare professionals experiencing all of the following symptoms require immediate evaluation by a licensed medical professional, EXCEPT:
 - A) Rash
 - B) Vomiting
 - C) Vesicular lesions
 - D) Nasal congestion

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17. Healthcare professionals exposed to hepatitis viruses

- A) may safely donate semen.
- B) should be administered ribavirin and interferon.
- C) should refrain from patient-care responsibilities.
- D) should consider receiving hepatitis B immune globulin (HBIG).

Susceptible personnel who are exposed to mumps should not work

- A) until proven noninfectious.
- B) until 3 days after parotitis develops.
- C) from the 12th day through the 26th day after last exposure or, if symptoms develop, until nine days after onset of parotitis.
- from the 4th day through the 28th day after last exposure, unless symptoms develop.

19. According to the New York Department of Health policy regarding HIV testing,

- A) rapid testing is not mandated for occupational exposures.
- B) specific informed consent for HIV testing is not required.
- C) if a rapid test result is positive, the test must be confirmed by an ELISA test.
- D) rules regarding confidentiality and consent for testing in the occupational setting are identical to those for other HIV tests.
- 20. In hospitalized adult patients, sepsis is primarily the result of infection with $(A) = (A + A)^2$
 - A) fungal organisms.
 - B) gram-positive bacteria.
 - C) gram-negative bacteria.
 - D) group B streptococcus.

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Audience

This course is designed for all dental professionals.

Course Objective

Problematic oral changes can affect more than oral health, and healthcare professionals should consider individuals' oral health in their overall patient care plans. The purpose of this course is to define oral cancer and briefly explain its diagnostic criteria as well as discuss the changes experienced within the oral environment after the treatments for oral and systemic cancers are initiated.

Learning Objectives

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

- 1. Identify the most common etiologies of oral cancer and its incidence within the population.
- 2. Review the basic histology of the oral mucosa and the changes that occur with premalignant and malignant lesions and their patterns of occurrence.
- 3. Compare and contrast erythroplakic lesions and leukoplakic lesions.
- 4. Distinguish among the varied diagnostic procedures for suspicious oral lesions and the classification and staging of those that are found to be malignant.
- 5. Review the principles of and the complications from radiotherapy utilized postsurgically for patients with oral cancer.
- 6. List dental procedures that should be completed before surgery and radiotherapy that can minimize oral complications after the completion of these treatment modalities.
- 7. Explain the basic principles by which chemotherapeutic agents exert their cytotoxic effect.
- 8. Discuss the serious chemotherapy-induced infections of oral origin that can be disseminated systemically.
- 9. List other common oral effects of chemotherapy.

Faculty

Mark J. Szarejko, DDS, FAGD, received his dental degree from the State University of New York at Buffalo in 1985. He received fellowship from the Academy of General Dentistry in 1994.

Faculty Disclosure

Contributing faculty, Mark J. Szarejko, DDS, FAGD, has disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

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INTRODUCTION

Few diagnosed medical conditions evoke as much fear and emotion as cancer. The incidence of cancer increases with age, and given the demographics of an aging population, more patients will be diagnosed with cancer annually [1]. The type of malignancy, its location, and the presence or absence of metastasis will dictate the options for medical intervention. In the last several decades, tremendous strides have been made in the prevention, diagnosis, and treatment of this group of diseases.

When chemotherapy is used to treat organic and systemic malignancies, alterations are commonplace in the cells of the oral epithelium, in those that form the cells necessary for immunocompetence, and in those that produce the formed elements of blood. The tissues within the oral cavity can undergo changes of such a deleterious nature that patients may require temporary respites from chemotherapy. Fortunately, these negative effects usually subside after chemotherapy ends.

In the United States in 2023, there will be approximately 54,540 new diagnoses of oral cancer and approximately 11,580 deaths; however, the number of deaths increases when complications of oncologic treatment are taken into consideration—nearly one death per hour [2; 3]. This high mortality rate relates to the advanced metastatic stages at which these lesions are usually diagnosed. A challenge should be issued to healthcare professionals to reverse this trend with clinical procedures facilitating early detection. Surgical removal may be an option based on the extent of lesion size, its invasive-ness into the proximate soft and hard tissues, and presence of metastasis into the regional lymph nodes. A postoperative course of radiotherapy may also have deleterious effects. As opposed to chemotherapy, the negative oral effects induced by radiotherapy are usually long-term or permanent.

The progression of cancer and the ensuing treatment will compromise the immune systems of most patients. Therefore, problematic oral changes can affect more than oral health. Debilitated and ulcerated oral mucous membranes can be a portal of entry for resident organisms of the oral microflora, with systemic dissemination and sepsis possible. A high degree of morbidity with potentially fatal consequences may ensue. It is imperative that all members of the allied healthcare team who treat these patients are aware of the etiology of these oral problems, available treatment modalities, and the consequences of delayed or inappropriate treatment.

ORAL CANCER

Oral cancer, in which the primary malignancy arises within the oral cavity, is the eighth most common cancer in men, with incidence rates more than three times as high in men as in women [3]. Incidence has been declining since the 1970s, though it appears to be stable now in men, with women continuing to experience a 0.9% decline per year. The exception is of cases associated with human papillomavirus (HPV) infection, which are increasing in the white population.

Oral malignancies diagnosed in their initial stages can be treated more conservatively than their larger, metastatic counterparts. Unfortunately, the most common oral malignancy, squamous cell carcinoma, usually remains undetected until it is in its advanced stages. Pain, numbness, swelling, loss of function, and difficulty swallowing, which may appear later in disease progression, often do not accompany the beginnings of oral malignancies. The five-year survival rate of only 68% reflects the trend of late diagnosis [3].

The rich vascular and lymphatic network of the oral cavity, which extends beneath the tongue and into the floor of the mouth, facilitates local, regional, and distant metastasis. Early lesions may be difficult for the clinician to visualize and are often asymptomatic for the patient. Therefore, it is important for healthcare professionals to be familiar with the etiologies and risk factors associated with oral cancers.

ETIOLOGIES AND RISK FACTORS

Most patients with oral cancer have used tobacco products for prolonged periods of time [4]. Cigarettes, with their multitude of carcinogens, are the most frequent form of tobacco used. However, cigars, pipes, and smokeless tobacco also contain carcinogens; these should not be considered safe alternatives to cigarettes.

Although many more people smoke than develop oral cancer, the majority of oral cancers may be attributed to tobacco and/ or alcohol use, either individually or together [4; 5]. The use of alcoholic beverages by those who use tobacco products may enhance the negative effect upon the oral tissues [4]. The desiccating effects of alcohol provide a prolonged exposure of the carcinogens within tobacco on these tissues. This additional contact time increases the risk of the development of an oral malignancy, such as squamous cell carcinoma, 100 fold [4]. Factors such as immunosuppression and immunocompromise, a family history of cancer, nutritional considerations, alcohol abuse, systemic disease, and the duration and amount of tobacco used are possible reasons some tobacco users develop oral cancer and others do not. Because the majority of patients with oral cancer have a history of tobacco use, the implication of this product's carcinogens as agents that can cause malignant transformation in the oral tissues is strongly correlated.

ORAL CANCER RISK FACTORS	
Tobacco use	
Alcohol use	
Cannabis use	
Family history	
Advanced age	
Male gender	
Poor oral hygiene	
Poor nutrition	
HPV infection	
Human herpesvirus infection	
Immunosuppression (including HIV infection)	
Source: [2; 4; 5; 7; 8; 9]	Table 1

Increasing age is another risk factor in the development of oral cancer, with a peak incidence in individuals 63 years of age; however, it is now occurring more frequently in younger individuals [2; 6]. The exact causes for this are not yet clear, but there appear to be associations between young men and women who use conventional "smokeless" chewing or spit tobacco [2]. Historically, the incidence of oral cancer in the African American population has been twice that of the white population, but 2020 data from the National Cancer Institute indicates that the incidence in the white population has surpassed that of the African American population for both men and women [2; 3]. A strong gender differentiation has also been noted historically, as men developed oral cancer with a frequency that was more than six times that of women. The ratio is now one woman to every three men, likely due to the increase in women who smoke since the 1950s [2]. It is thought that lifestyle choices (e.g., tobacco use, particularly in combination with the consumption of alcohol), rather than genetics, are responsible for these various disparities.

Chronic tissue trauma from ill-fitting prostheses, such as dentures or partial dentures, may predispose tissues to malignant change, though as a whole, there is no heightened risk for those with dentures [4]. However, patients who utilize these devices should be educated that any area of irritation should be examined and the corresponding adjustment should be made by a dentist. Sore spots that cannot be eliminated after adjustments, relines of the existing prosthesis, or the fabrication of a completely new prosthesis should be monitored very closely. If the prosthesis is not worn and the sore spot remains, a biopsy of the area is indicated.

In one study, HPV type 16 (HPV16) was found to account for approximately 55% of oral cancer cases in the absence of any other risk factors [7]. While HPV16 and HPV18 infections are widely recognized as a main cause of cervical cancers in women, they are also increasingly linked to oral cancer in those younger than 40 years of age [3; 4]. The increase of oral cancer cases in this population is associated with the spread of HPV

and is strongly correlated to having multiple oral sex partners [2; 3; 7]. Autoimmune factors, complex genetic mechanisms (individually or collectively), and other viral agents, such as herpes simplex virus, may also be etiologic risk factors in this group (*Table 1*).

Excessive, chronic ultraviolet light exposure has been linked to cancers of the lip, particularly in individuals who work outdoors [4]. Other documented or researched causes include poor nutrition (i.e., lack of fruits/vegetables), lichen planus, and graft-versus-host disease. Oral cancer may also develop in the absence of known risk factors. Approximately 25% of patients with oral cancer have no identified risk factors for the disease [10]. Most of these patients are younger than 40 years of age, well below the age distribution for this disease [2; 11].

THE DEVELOPMENT OF ORAL CANCER

A discussion of the histologic basis for normal, healthy oral mucosa is required before an understanding of the stages that lead to the development of an oral malignancy can be appreciated. Also, some of the problems that develop after radiotherapy and chemotherapy have a cellular basis in these tissues.

The oral mucous membrane does not have the same surface consistency throughout the oral cavity. The oral mucosa is classified into three types:

- Masticatory mucosa: It has a firm texture that comprises the hard palate and the gingiva. This tissue is bound to the bone and has a minimal capacity to stretch.
- Specialized (sensory) mucosa: Located on the dorsum of the tongue, it contains the taste buds.
- Lining (reflecting) mucosa: The vast majority of the oral mucosa is lining (reflecting) mucosa. It is easily flexible and distensible.

Common to all three mucosal types is an outermost cellular layer composed of stratified squamous epithelium. Some of the stratified squamous epithelium, specifically the masticatory mucosa, may be keratinized. All of these surface cells are produced from a deeper layer of cells called basal cells. This cellular layer consists of cells that are active in deoxyribonucleic acid (DNA) synthesis and undergo mitosis. The cells that replace the outer squamous layer every three to four days originate here. When radiotherapy or chemotherapy causes ulcerations anywhere in the oral mucosa, it is because the mitotic sequence of the basal cells has been interrupted. A small membrane beneath the basal cells, called the basement membrane, is what malignant cells perforate to invade the underlying tissue and begin the growth of a malignant lesion [12].

Premalignant Lesions

The earliest deviation from normal cellular arrangement is dysplasia. Dysplasia is characterized by atypical cellular formation and arrangement without any malignant transformation. Dysplastic cells can progress to carcinoma in situ, in which actual malignant transformation has occurred to one layer of cells. At this point, there is no invasion into the underlying tissue. The potential for continued growth and metastasis continues to be very high [13]. Both dysplasia and carcinoma in situ can only be diagnosed by histologic analysis. Lesions of varying sizes, shapes, colors, and surface textures cannot be discerned by visual means to possess any of these cellular alterations. Patients with premalignant lesions do not experience symptoms that would prompt them to seek medical or dental care.

There is no universal appearance of malignant lesions. It is recommended that an oral lesion of unknown origin that does not heal within two weeks should be submitted for an expedited referral [2]. Patients should be advised that lesions that appear harmless may be malignant, while those that appear aggressive may be benign. Whether benign or malignant, oral lesions span a remarkable array of clinical presentations.



The National Guideline Alliance recommends considering an urgent referral (for an appointment within two weeks) for assessment for possible oral cancer by a dentist in people who have either a lump on the lip or in the oral cavity or a red or

red and white patch in the oral cavity on a red of erythroplakia or erythroleukoplakia.

(https://www.nice.org.uk/guidance/ng12. Last accessed February 1, 2023.)

Level of Evidence: Expert Opinion/Consensus Statement

Leukoplakic and Erythroplakic Lesions

The surface appearance of oral lesions may be flat, raised, smooth, ulcerated, invasive, pedunculated, or velvety, among many other descriptions. Some lesions may share two or more of these characteristics and may occur anywhere in the mouth.

Leukoplakic (white) lesions are much more common than their erythroplakic (red) counterparts. Clinically, the latter group of lesions is more difficult to see amidst oral mucous membranes of a similar color, especially in areas of tissue inflammation or hypertrophy. A prominent vascular supply causes erythroplakic lesions to appear red and to bleed easily upon palpation. These lesions occur with less frequency than leukoplakic lesions but have a 91% probability of being dysplastic or malignant [14]. Therefore, it is essential that any

HISTOPATHOLOGY OF CANCER					
Classification	Cellular Activity	Malignancy	Status	Indication	
Hyperplasia	Accelerated cell proliferation Cell structure is normal	Noncancerous	Potentially reversible	Cause must be investigated	
Dysplasia	Accelerated cell proliferation Cell structure is changing	Noncancerous	Potentially reversible, but may progress to cancer	Close monitoring is indicated	
Carcinoma in situ	Accelerated cell proliferation Cell structure is changing	Cancerous (very early)	Noninvasive; does not extend beyond the epithelial membrane Likely to progress to invasive and metastasize	Removal is indicated	
Invasive	Cell structure is completely aberrant	Cancerous	Invasive; extends beyond epithelial membranes May have metastasized	Immediate therapy is indicated	
Source: [16; 17; 18; 19] Table 2					

erythroplakic lesion is biopsied. Among leukoplakic lesions that have undergone histologic examination, 20% are found to be malignant or premalignant [14]. However, this rate is more than doubled for leukoplakic lesions that are found in the floor of the mouth [14]. Healthcare professionals should perform thorough oral soft tissue exams as these lesions may be difficult to detect and patients are usually asymptomatic. It is also important to remember that lesion color cannot be used as a feature to distinguish a malignant lesion from one that is innocuous.

DIAGNOSTIC PROCEDURES FOR ORAL CANCER

BIOPSIES

Ultimately, histologic analysis is the only standard by which an oral lesion can be classified (*Table 2*) [8]. However, only 25% of intraoral leukoplakic lesions are submitted for histopathic examination via traditional biopsy procedures [15].

Traditional biopsy techniques are either incisional or excisional in nature. Larger lesions that cannot be removed completely usually undergo an incisional biopsy. This procedure features the removal of a small portion of the lesion along with a continuous band of healthy tissue. If a lesion plus some adjacent healthy tissue is small enough to be removed in its entirety, this process is essentially an excisional biopsy. If a general dentist does not provide this service, the patient should be referred to an oral or maxillofacial surgeon or an otolaryngologist. Lesions located on the soft palate or the tonsillar pillar area may be difficult to biopsy due to a strong gag reflex. These patients may need sedation to accomplish the procedure.

Correspondence from any specialist to which the patient has been referred should be monitored closely for the diagnosis and the treatment plan. It should not be assumed that the patient will go to the specialist or follow his or her recommendations; a follow-up with the patient is necessary. In the event a malignancy is detected, the patient should be made aware of his or her treatment options, and those options should be pursued. Similarly, a patient's refusal to seek specialty care when it is recommended should be documented in the chart for medicolegal reasons. The patient should clearly be informed that the risks of refusing a biopsy procedure may allow for the formation of a malignant lesion that is capable of metastasizing with possible fatal consequences. Ideally, the patient should sign this informed refusal with at least two staff members witnessing it. Legal counsel may be necessary to prepare the appropriate forms.

Diagnostic tools that precede traditional biopsy procedures have been developed. Toluidine blue, ViziLite, and computerassisted brush biopsy analysis are such adjunctive techniques. These screening tools do not replace the traditional biopsy procedures but provide an initial assessment of a questionable lesion [8].



The American Dental Association does not recommend autofluorescence, tissue reflectance, or vital staining adjuncts for the evaluation of potentially malignant disorders among adult patients with clinically evident, seemingly innocuous,

or suspicious lesions.

(https://jada.ada.org/article/S0002-8177(17)30701-8/ fulltext. Last accessed February 1, 2023.)

Level of Evidence: Low or very low

VIZILITE

The principle upon which ViziLite works is based on the cell physiology of abnormal cells. These cells have a nuclear content and mitochondrial matrix that is denser than normal cells. The patient rinses with a special ViziLite solution for 60 seconds and expectorates the excess. This acetic acid rinse removes the adherent mucosal glycoprotein layer and increases the nuclear/cytoplasmic ratio via osmosis. A disposable handheld ViziLite is then passed over the oral tissues. Normal cells will absorb the light and appear dark. Abnormal cells, given the increased density of the nucleus and the mitochondrial matrix, will reflect the light and appear bright [20]. This reflection pattern from ViziLite provides for the detection beneath the epithelial surface. If a suspicious lesion is detected at or below the epithelial surface, the clinician should perform a biopsy or refer the patient to a specialist who is able to perform this procedure. Further study is needed to determine what role, if any, this test should play in oral cancer screening [8]. The ultimate diagnosis of the lesion is still dependent on a biopsy procedure.

TOLUIDINE BLUE

Toluidine blue is a metachromatic dye that stains abnormal DNA, thereby identifying appropriate tissue for biopsy. Studies have proven its efficacy as a diagnostic adjunct in detecting the presence of potential malignant lesions, particularly in the early stages [8; 21; 22]. A Taiwanese study found a 79% increase in the detection of oral submucous fibrosis when using the dye compared to standard visual screening [23].

Sections suspected of being malignant lesions should be deparaffinized and hydrated with distilled water. Then, the sections may be stained with toluidine blue solution for two to three minutes, after which the section should be thoroughly rinsed and dehydrated. Malignant cells will appear as violet or red purple against a blue background.

THE ORAL CDX BRUSH BIOPSY SYSTEM

The Oral CDx brush biopsy system is another means of attaining an initial assessment for suspect oral lesions [8]. The Oral CDx kit contains a sterile brush biopsy instrument, a precoded glass slide, a tissue fixative pouch, a requisition form, and a preaddressed container into which the slide and requisition form are placed [24]. The brush biopsy instrument is a small, circular wire brush that is rotated several times over the lesion surface until the tissue is slightly pink or is just beginning to bleed. This slight degree of lesion penetration is usually done without topical or local anesthesia. The tissue sample on the brush biopsy instrument is then applied to the precoded glass slide, which is bathed in the tissue fixative. This sample undergoes analysis by the Oral CDx computer.

One of four classifications is possible for all submitted samples. An inadequate category indicates that not enough of a tissue sample for a meaningful classification has been obtained. A negative classification means that no epithelial abnormality has been detected. An atypical sample is one that has some epithelial abnormalities whose diagnostic meaning is unclear. A positive classification indicates positive evidence of epithelial dysplasia or carcinoma [25]. Treatment from this point depends on the lesion classification. This is an expedient addition to the armamentarium of oral cancer screening devices. Of note, screening should be done by the clinician who has adequate illumination, visualization, and knowledge of how the tissues of the oral and maxillofacial complex appear in a healthy state.

LESION DIAGNOSIS

The most common sites of oral cancers are the tongue, lip, and floor of the mouth [3]. However, oral cancers associated with HPV16 and HPV18 may appear at less common sites, such as the tonsils, tonsil pillar and crypt, base of the tongue, and the oropharynx [3]. Given the pleomorphic nature of oral cancers, clinicians should not ignore a lesion because it does not appear malignant or because it is on a site less frequently targeted by squamous cell lesions.

SQUAMOUS CELL CARCINOMA

The oral malignancy responsible for more than 90% of the total cases of oral cancer is squamous cell carcinoma [26]. Squamous cell carcinoma is the result of uncontrolled differentiation of surface squamous cells of the oral mucosa into malignant cells. This is an aggressive lesion whose nests of malignant cells penetrate the basement membrane and the underlying connective tissue. Infiltration into the vascular and lymphatic circulation may occur early and facilitate metastasis. Continued proliferation can extend into the musculature and the supporting bone, with the capacity to destroy both. Upon histologic confirmation of a squamous cell carcinoma, surgery and radiotherapy should be scheduled as quickly as possible, because growth of the primary lesion and metastasis both occur rapidly; combined therapy may also include chemotherapy in later stages [26].

Squamous cell carcinoma can occur anywhere in the oral cavity. However, there are some areas of the mouth where these lesions occur more frequently than others. As noted, the most common sites of involvement are the tongue, lip, and floor of



the mouth [21]. Many squamous cell carcinomas are located in areas that preclude visualization by the patient and can grow to larger sizes asymptomatically (*Image 1*).

KAPOSI SARCOMA

The remaining types of oral malignancies affect tissues within the oral cavity or the adjacent salivary glands. Kaposi sarcoma, mainly associated with late-stage human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS), is one such malignancy. A rarity in the United States until the AIDS epidemic, Kaposi sarcoma has been identified as an AIDS-defining illness.

The initial presentation of these lesions is usually on the skin, but oral manifestations occur frequently. The palate, gingiva, and tongue are the primary sites of the appearance of these lesions; however, they may occur anywhere in the mouth. The human herpesvirus-8 (HHV-8) is considered to be the etiologic agent of this malignancy [9]. The lesions of Kaposi sarcoma may be red, violet, dark blue, or black-blue and usually begin asymptomatically. This vascular malignancy is typically flat at its onset but progresses to form nodules that develop a spongy consistency. Their growth can interfere with swallowing and eating, and larger lesions bleed easily. Treatment is usually a combination of surgery and radiation therapy, which is taxing for patients with an advanced stage of immunosuppression (**Image 2**).

Other types of cancers that may occur in the oral cavity include lymphomas, melanomas, and cancer of the minor salivary glands. These cancers are rare; nonetheless, they should be considered as a part of differential diagnosis when a patient presents with oral lesions of unknown etiology.



CLASSIFICATION AND STAGING OF ORAL MALIGNANCIES

Before surgery and radiation therapy can begin, classifying and staging of the lesion must be completed. The internationally recognized system is the TNM classification (*Table 3*), which is based on assessment of primary tumor size (T), metastasis into regional lymph nodes (N), and the presence of distant metastasis (M) [27].

Primary tumor size ranges from TX, at which the tumor cannot be assessed, to a T4 level. The latter assessment indicates that the primary tumor size exceeds 4 cm and has extensive infiltration of the muscle, bone, cartilage, sinus, and/or skin. Lymph node metastasis features more complicated divisions and subdivisions. When the lymph nodes cannot be assessed, an NX designation is given, while N0 indicates a lack of lymph node involvement. The first designation of nodal involvement is N1, which indicates involvement of only one lymph node less than 3 cm in greatest dimension. Progressive nodal involvement in terms of number of lymph nodes, their distance from the primary tumor, and the nodal involvement of the same and/or opposite side, continues in this spectrum to a N3 level. Metastatic disease has only three levels of assessment. When distant metastasis cannot be assessed, an MX designation is assigned. No distant metastasis is an M0, while M1 indicates distant metastasis [30]. A chest radiograph is the current method by which metastasis is measured. With this system, lower numbers are equated with a better prognosis.

Staging is a system by which the individual components of the classification results are compiled together in stages (*Table 4*). Due to the asymptomatic nature of the lesions, diagnosis is often delayed [31; 32; 33].

OVERVIEW OF TNM CLASSIFICATION OF ORAL CANCER					
Classification	Assessment				
Primary Tumor (T)	Primary Tumor (T)				
TX	Primary tumor unassessable				
ТО	Primary tumor is not evident				
Tis	Carcinoma in situ				
T1, T2, T3	Size of primary tumor may range from less than 2 cm to greater than 4 cm				
T4a (lip or oral cavity) T4b (lip and oral cavity)	Primary tumor has invaded deeper and/or surrounding tissue, including nerve, cartilage, muscle, skin, sinus, bone, and skull				
Regional Lymph Node (N)					
NX	Regional lymph node metastasis cannot be assessed				
NO	No metastasis to the regional lymph node(s)				
N1	Metastasis to only one lymph node 3 cm or less in greatest dimension				
N2a	Metastasis of one ipsilateral lymph node greater than 3 cm but less than 6 cm				
N2b	Metastasis to multiple ipsilateral lymph nodes less than 6 cm				
N2c	Metastasis to bilateral lymph nodes less than 6 cm				
N3	Lymph node metastasis is greater than 6 cm				
Distant Metastasis (M)					
MX	Distant metastasis unassessable				
M0	Distant metastasis is not evident				
M1	Distant metastasis is evident				
Source: [27; 28; 29]	Table 3				

CANCER STAGING CRITERIA				
Stage	General Description	Associated Classifications		
0	Carcinoma in situ; lesion affects only the epithelial tissue	TONOMO TisNOMO		
Ι	Tumor size is small; there is no metastasis to the regional lymph nodes or other organs	Т1N0М0		
II	Tumor size is larger; no metastasis to regional lymph nodes or other organs	T2N0M0		
III	Any tumor concomitant with lymph node metastasis; there is no distant metastasis	T1N1M0 T2N1M0 T3N0M0 T3N1M0		
IV(A, B, C)	Invasive tumor without metastasis to lymph nodes or other organs Any tumor concomitant with considerable lymph node metastasis Any tumor with any lymph node metastasis concomitant with distant metastasis	T(1-3)N2M0 T4aN(any)M0 T(any)N3M0 T4bN(any)M0 T(any)N(any)M1		
Source: [28; 29; 30]				

TREATMENT FOR ORAL CANCER

SURGERY

When the diagnosis of oral squamous cell carcinoma is confirmed, plans for surgery and radiotherapy are initiated. Surgery includes the removal of the lesion and its extension into the neighboring hard and soft tissue. Surgical extension into the neck (neck dissection) is usually required to evaluate the extent of the tumor and its spread into local and regional lymph nodes. Areas where surgical deficits are created should be stabilized prior to surgical closure. Muscle from sites such as the pectoralis major muscle may be grafted to repair the surgical wound. Vascular grafts may also be needed to provide adequate circulation for the new muscle grafts. Larger lesions can intertwine around nerves of varying sizes. The removal of these lesions may cause permanent loss of sensation and loss of motor function for many structures in the oral cavity. The loss of hard and soft tissue is commensurate with the size of the lesion. Many patients require the use of maxillofacial prostheses to restore form, function, cosmetics, and self-esteem after these extensive surgical procedures. If a large portion of the tongue is removed, speaking, swallowing, eating, and drinking become arduous functions.

RADIOTHERAPY

Surgery may not eliminate all squamous cell carcinoma cells. Radiotherapy is utilized to eliminate the cancer cells that may have persisted beyond surgical measures. A common modality used postsurgically, radiotherapy may be rarely used presurgically to decrease the size of larger lesions [34].

The current unit of absorbed radiation is the gray (Gy) or the centigray (cGy). Tumor size, location, and metastasis will determine the required cumulative dosage of radiation.

Radiation in adequate doses is cytotoxic to malignant cells because it causes free radical damage to the cellular components that are required for cell division and replication. Unfortunately, healthy tissues in the area of the radiation beam will undergo the same cellular damage. So, the goal is to destroy the malignant cells with as little damage to healthy cells as possible.

The amount of radiation required to destroy all affected cells is too large to be administered in only one dose. Modified fractionation is used to make doses smaller and more tolerable. Most patients receive the same dose of radiation five days a week, over a five- to seven-week period [35; 36]. Because salivary glands are particularly radiosensitive, relatively small doses or irradiation may result in damage [37]. Most radiotherapy is given in fractionated doses of 150 – 200 cGy per day [35]. Once a cumulative dose of 4,500 cGy has been absorbed, long-term deleterious side effects are encountered. Because most radiotherapy regimens for squamous cell carcinoma patients range between 5,000 and 7,000 cGy, most patients will encounter undesirable side effects [38]. The area at which the radiation is targeted will influence the types of side effects experienced by the patient.

Concurrent antibody therapy with cetuximab, an epidermal growth factor receptor (EGFR) inhibitor, may be considered for patients in whom chemotherapy is contraindicated, as many oral squamous cell carcinomas show moderate to high levels of EGFR expression [39; 40]. It has been suggested that side effects may be minimized if the agent is administered between the hours of 11 a.m. and 3 p.m., due to the circadian rhythm of the oral mucosa [41; 42]. This timeframe is hypothesized as being ideal for maximum therapeutic effect and reduced toxicity of both cetuximab and radiotherapy treatments.

CHEMOTHERAPY

For patients with oral cancer, chemotherapy is recommended only as an adjunct to radiation and/or surgical therapy [2]. Chemotherapy alone has not been shown to have the same efficacy against oral cancer as with other cancers. Chemotherapy is recommended as an adjunct in the treatment of oral cancer in order to [2; 14]:

- Reduce and/or inhibit distant metastasis
- Reduce tumor size prior to surgery
- Sensitize malignant tissue to radiotherapy

Additional research to determine the most effective use of chemotherapy as part of the overall treatment plan for oral cancer is necessary.

ORAL COMPLICATIONS FROM RADIOTHERAPY

The earliest complication seen after radiotherapy is damage to the skin and hair follicles that lie in the direct path of radiation, known as the treatment portal. Hair follicles are highly radiosensitive, and hair will cease to grow and may fall out. This is a temporary loss that may take weeks or months to reverse. The skin in the portal area may become cracked, reddened, and ulcerated to the extent that radiation therapy should be postponed. This problem is also reversible upon cessation of radiotherapy. In addition, radiotherapy can result in negative effects on oral health.

MUCOSITIS

Normal oral epithelium regenerates every three to four days. The outer squamous cells are replenished by cells made anew at the basal layer. The cellular regeneration corresponds with a high level of mitotic activity. Radiotherapy cannot distinguish the mitotic activity between malignant cells and those needed to replenish the oral epithelium; it is cytotoxic to both groups of cells, resulting in mucositis.

Oral mucositis is the most common intraoral side effect of radiotherapy and usually has an onset in the second week of therapy [43; 44]. Mucositis affects nearly 80% of all patients who undergo head and neck radiotherapy and occurs in four phases [43]. The inflammatory phase is begun as ionizing radiation causes the generation of free radicals. The disruption of the normal sequence of turnover and stratification from the basal cell layer is a continuum into the epithelial phase. The ulcerative phase features ulcerations of varied dimensions on any mucosal surface. The consequent pain can be so intense that patients may have difficulty eating at a time when adequate nutrition is life sustaining. Patients with removable complete or partial dentures may be unable to wear them, further complicating their ability to masticate and swallow. The denuded mucosal surfaces also are a portal of entry for organisms of an altered oral microflora. This, coupled with a host whose immunocompetence is challenged, can lead to systemic bacterial or fungal infections that may be fatal. Severe mucositis mandates that radiotherapy be postponed until adequate healing of the epithelium occurs. The healing phase may take several weeks after the last radiotherapy treatment [45].



A Cochrane Review found that oral cryotherapy leads to large reductions in oral mucositis of all severities in adults receiving 5FU for solid cancers.

(https://www.cochranelibrary.com/cdsr/ doi/10.1002/14651858.CD011552.pub2/

full. Last accessed February 1, 2023.) Level of Evidence: Meta-Analysis

The National Cancer Institute has developed a Mucositis Scale to allow for the basic categorization of the mucositis lesions according to severity [46]. Grade 1 is defined as the absence of symptomatic mucositis or mild symptoms. Minimal mucositis, grade 2, involves moderate pain that does not greatly interfere with food intake but may necessitate a slightly altered diet. A grade 3 (severe) reaction is present when extreme pain causes feeding to become difficult. At this grade, the patient can only tolerate a liquid diet. When the mucosal ulcerations are deep or necrotic and bleed spontaneously, a grade 4 level has been attained. This level of mucositis is considered life-threatening. Patients with grade 4 mucositis may require intravenous fluids, analgesics, and antibiotics in a hospital setting until they are medically stabilized. Even if radiotherapy has been completed, the patient should still be followed closely to assure complete healing of all lesions. If radiotherapy has been interrupted because of the severity of mucositis, the cumulative dose of radiation that remains may be fractionated into smaller daily doses. Grade 5 is death [46].

Management of less severe grades of mucositis consist of palliative relief of pain, the monitoring and treatment of localized infections that may develop, and monitoring the patient's ability to maintain an oral care regimen and an adequate nutrition level. Liquid forms of systemic analgesics and antibiotics may be easier for the patient to swallow. Topical liquid anesthetics such as 2% viscous lidocaine may provide temporary analgesia. Because these patients may be taking medications for other conditions, care should be taken to avoid any adverse drug interactions. Prednisone, 40 mg to 80 mg per day prescribed for one week or less, may help to resolve some of the inflammation [47]. Varied rinses of sodium chloride and sodium bicarbonate may allow for tissue cleansing, moistening, and lubricating and are well tolerated. These rinses, along with proper oral hygiene and hydration, are mainstays of prevention and treatment. Chlorhexidine 0.12% rinses are useful but have a tendency to cause discomfort and nausea. Evidence supporting their use is generally inadequate and/or conflicting [48].

There is increasing evidence that severe oral mucositis due to radiotherapy may be pre-empted with palifermin, a recombinant human keratinocyte growth factor, though this use is an off-label use [49]. Palifermin is approved by the U.S. Food and Drug Administration for the treatment of severe oral mucositis in patients with hematologic malignancies undergoing total body irradiation, stem-cell transplantation, and chemotherapy [50]. Though the agent is expensive, oral mucositis is often reported to be the most torturous side effect of cancer treatment and may necessitate the cessation of radiotherapy even with advanced-stage malignancies. Evidence supporting the use of palifermin is conflicting [48].

The prophylactic palifermin regimen begins with one 60 mcg/kg IV dose three days prior to treatment and three days following treatment up to a maximum of six doses [51]. The most common side effect is skin rash/erythema [51; 52]. A 2011 study examined its use in patients with head and neck cancer undergoing postoperative radiochemotherapy and found a modest reduction in the incidence of severe mucositis in those given palifermin (51%) versus placebo (67%), but the primary outcome was the reduction in duration of severe mucositis (4.5 days versus 22 days, respectively) [53]. A phase 3 clinical trial to determine safety and efficacy as an adjuvant treatment for those with head and neck cancers undergoing radiochemotherapy was completed in 2016, but the results of the study have not been published [54].

Palifermin use should be carefully considered for patients at increased risk of developing severe mucositis [51; 52]. Pediatric patients and the elderly are at an increased risk; other risk factors include existing periodontal disease, poor diet, alcohol use, tobacco use, certain medications, oxygen therapy, and changes in breathing [55].

	0	RAL ASSESSMENT GUIDE (OAG)	
Category	Assessment	Finding	Score
	Listen to the patient's	Normal	1
	voice	Deep or raspy	2
		Unable to speak	3
Swallow	Ask the patient to swallow	Swallowing normally	1
	and test gag reflex with tongue	Some pain while swallowing	2
	depressor	Too painful to swallow	3
Lips	Observe and palpate	Smooth, pink, and moist	1
		Cracked and/or dry	2
		Ulcerated or bleeding	3
Tongue O	Observe and palpate	Pink and moist, papillae present	1
		Coated or papillae loss, shiny appearance with or without redness	2
		Blistered or cracked	3
Saliva	Use depressor to assess	Watery	1
the tong for saliv	the tongue and mucosa	Excessive amount of saliva, drooling	2
	for saliva	Thick, ropey, or absent	3
Mucous O	Observe	Pink and moist	1
membranes		Reddened or coated without ulcerations	2
		Ulcerations with or without bleeding	3
Gingiva	Observe and gently scrape gingival tissue	Pink and firm	1
		Oedematous	2
	with depressor	Spontaneous bleeding	3
Teeth or	Observe and scrape teeth with depressor	Clean, no debris or plaque	1
dentures		Plaque or debris in some areas	2
		Generalized plaque or debris along gum line	3
Source: [56]			Table 5

The Oral Assessment Guide (OAG), developed by Eilers, may be used in the staging of mucositis and when creating a management plan (Table 5) [56]. Using the OAG, the patient is assigned a number of points, from 1 to 3, in each of eight categories, with a total score of 8 indicating no change and a total score of 24 indicating severe mucositis. The OAG has been shown to be effective and reasonably easy to use in several studies [57; 58]. It provides for objective assessment (as it omits pain as a measure of severity) and is able to identify subtle changes in status when used daily, thus ensuring rapid intervention. Another assessment tool is the World Health Organization scale, which despite its simplicity, is regarded as the most effective instrument used worldwide (followed by the OAG) [56; 58]. Whichever tool is implemented, daily evaluation using a standardized assessment instrument is considered to be an integral part of oral mucositis management and should also be used at every patient contact [55; 56; 57; 58]. Self-assessment using the OAG can also be taught for closer observations.

While mucositis usually resolves after radiotherapy is completed, other radiotherapy-induced problems may be long-term or permanent. These include changes in the salivary glands, caries due to radiation, and osteoradionecrosis.

SALIVARY GLAND CHANGES

Saliva has several critical functions in the oral environment. Its chemical composition allows it to function as a lubricant, a buffer in the modulation of acidity (pH) levels, an initiator in the enzymatic process of digestion, and as part of the immune system. The immune function is not readily apparent but is critical in maintaining the delicate balance of the oral microflora. Certain salivary proteins inhibit microbial growth. Lysozyme, a salivary enzyme, can hydrolyze and thus destroy certain components of the bacterial cell wall. Immunoglobulin (Ig) is also secreted into saliva, with IgA being the predominant secretion. Small amounts of IgG and IgM are also secreted. These substances may exert their action by decreasing bacterial adherence to hard and soft tissue. The pH of saliva ranges from 6.7 (a weak acid) to 7.4 (a weak base) [59]. Alteration of this range toward either spectrum promotes certain forms of microbial growth over others. *Lactobacillus* and *Streptococcus mutans*, two cariogenic resident bacterial species, favor a more acidic environment. This situation occurs when salivary output decreases secondary to radiation therapy [60].

The parotid, submandibular, and sublingual glands compromise the major salivary glands. Scattered throughout the remainder of the oral mucosa are minor salivary glands. Location of the radiation portal will determine which gland or glands will be susceptible to damage. Because the secretory product of each gland varies, postradiation salivary composition will be determined by which gland or glands are damaged and which are spared.

The parotid gland is a purely serous gland (i.e., it releases a watery secretion without a mucous component). The submandibular gland has both a serous and a thicker mucus secretion, with the serous component being predominant. The sublingual salivary gland features secretions that are more mucus than serous. The minor salivary glands have secretions that are nearly all mucus in origin. Damage to one or both parotid glands will increase the viscosity of the saliva as the watery component of the saliva decreases. The saliva develops a thick, ropy consistency that decreases its function as a lubricating medium. The location of some malignant lesions is such that all of the major salivary glands are damaged. The cells that produce the serous secretions are extremely sensitive to ionizing radiation and can undergo a 50% decrease in output with a cumulative radiotherapy dose of only 1,000 cGy [61]. Salivary glands that are irradiated with a cumulative dose of 4,000 cGy usually have a permanent decrease in output [62].

The resultant condition of xerostomia will usually remain with patients for the remainder of their life. It is the most common persistent radiotherapy side effect [63]. Saliva substitutes and certain cholinergic drugs, such as pilocarpine, may decrease the severity of the xerostomia, but no treatment regimen will return salivary output to the levels prior to radiotherapy [64]. However, a 2011 multicenter randomized controlled trial found that intensity-modulated radiotherapy that spares the parotid glands is significantly less likely to cause severe xerostomia [63].

Xerostomia presents patients with a host of problems that they must confront on a daily basis. Patients who wear complete or partial dentures may have chronic sore spots because the lubrication that saliva produces to lessen the friction against the mucosal tissues is significantly decreased. These prostheses may be difficult to use for mastication and thus complicate the ability to eat. Because the perception of taste is partially dependent on food particles dissolved in a salivary medium, taste perception is altered. Patients often attempt to compensate for this by selecting foods that are very spicy or very sweet, which further compromises their medical and dental health. Swallowing food becomes more difficult as the bolus of food is less lubricated. Patients may need frequent sips of water during meals to alleviate this problem. The oral tissues can become subject to frequent irritation, tissue trauma, and opportunistic infection. The cleansing action that saliva provides for the teeth can be severely compromised. This can lead to a form of multiple caries that occurs after radiotherapy has damaged the salivary glands.

RADIATION CARIES

The changes that occur in the oral environment after radiotherapy portals have damaged the salivary glands may cause rapid and widespread destruction of teeth that previously had no dental pathology [65]. It is postulated that radiation alters the organic and inorganic matrix of enamel and the remaining tooth structure [47]. Decalcification may be favored over remineralization as an initiator of the carious process. The decrease in pH levels, which is commensurate with the amount of damage to the salivary glands, begins the creation of a caries-prone oral environment. When the serous component of saliva decreases and the viscosity increases, adherence of cariogenic bacteria to tooth structure increases. These organisms thrive in the more acidic oral environment that develops after radiotherapy.

These factors, coupled with the difficulty patients have with their oral hygiene maintenance amidst sensitive teeth and soft tissues, create a problem known as "radiation caries." This is an aggressive and rapid form of dental decay, targeting parts of the tooth that are usually not prone to decay. The smooth buccal (outer) and lingual (inner) walls of the tooth become involved with rapidly advancing carious lesions. The area of the tooth that is closest to the gingival tissues, the cervical area, is a frequent point of origin. The process can also affect the incisal edges of anterior teeth and the cusp tips of posterior teeth. Within weeks or months, the process renders teeth that were previously devoid of any dental pathology completely destroyed.

Extractions of the teeth should only be done after a consultation with the patient's primary care physician. Oral surgery procedures can produce extensive postsurgical complications, with significant morbidity and even death in patients who have undergone a full course of radiotherapy.

OSTEORADIONECROSIS

The most serious of the complications postradiotherapy is osteoradionecrosis (ORN), occurring in 3% to 10% of patients [66]. This is defined as necrosis of the bone in areas that have received radiotherapy. Patients who have received doses of radiation for head and neck malignancies in excess of 6,000 cGy have the highest risk of this pathologic entity [66; 67]. The blood vessels that supply the bones with oxygen and nutrients become hyalinized, with a subsequent decrease in the ability to perfuse the tissue with enough oxygen-rich blood. Areas of bone supplied by these damaged vessels lack the oxygen and nutrients necessary to sustain the appropriate levels of metabolism. These areas of bone become ischemic and ultimately necrotic. The mandible is affected more frequently because it has less of a blood supply than the maxillary arch [66]. Necrotic pieces of bone may be small fragments or large sections whose loss undermines support for either arch. A pathologic fracture of the affected arch is a possible complication. Three grades of ORN have been categorized [67; 68]. Grade I occurs in close proximity to the completion of surgery and radiotherapy. Exposed alveolar bone is observed [67]. Grade II designates ORN that does not respond to hyperbaric oxygen therapy and requires sequestrectomy/saucerization [67]. Grade III is demonstrated by full-thickness involvement and/ or pathologic fracture. Patients may demonstrate grade I or III ORN at initial presentation [67].

Given the tumoricidal doses of radiation used, the 6,000 cGy threshold is easily reached for most patients with head and neck malignancies. Changes within the bone marrow include fibrous and fatty degeneration. The cells responsible for the production of bone, the osteocytes, are greatly diminished in number secondary to radiotherapy. The cells whose function is the resorption of bone, the osteoclasts, have fewer losses after radiotherapy. Thus, the dynamics of bone metabolism now favor bone resorption rather than bone apposition [60]. When this is combined with the damage to the blood vessels, the risk of ORN will be present for the remainder of the patient's life. Unfortunately, the passage of time does little to reverse the damage and the subsequent risk of ORN.

Treatment for ORN is variable. Small pieces of necrotic bone may migrate through the tissue and can be removed under local anesthesia. Larger segments of bone may require hospitalization for their removal. The risk of osteomyelitis, an infection of the bone, is increased in the patient who has undergone radiotherapy. The bony segments that perforate the mucosal tissues create a portal of entry for microbial organisms of the oral flora. Aggressive surgical and antibiotic treatment is needed to debride the area and resolve the infection. Hyperbaric oxygen treatments may help in the regeneration of new blood vessels with a resultant increase in the oxygen supply to the affected bone [69]. There is also evidence to suggest that hyperbaric oxygen treatments may be helpful as a therapy for soft tissue injury caused by radiation, as well as restoring tissues and cells damaged by chemotherapy and radiation treatments [66]. However, routine use is not recommended, and clinicians should assess any potential benefit to the patient on a case-bycase basis [67; 70]. Any oral surgery procedure increases the risk of the development of spontaneous ORN, even if it is performed years after the last radiotherapy treatment. Trauma to the soft tissue by any means also causes a localized area of inflammation and infection that can extend to the bone and cause ORN. Bone that has been irradiated can undergo dire consequences from seemingly minor events.

OTHER ORAL COMPLICATIONS OF RADIOTHERAPY

Patients can experience a wide range of undesirable effects from any treatment modality, and radiotherapy is no exception. One such experience common to many patients undergoing radiotherapy is hypogeusia, the partial loss of the sensation of taste, or ageusia, the complete loss of this sensory function. Taste buds are very sensitive to ionizing radiation and begin to experience damage when a cumulative dosage of 1,000 cGy has been given. When the cumulative dose of 6,000 cGy has been reached, damage to the taste buds is usually permanent with the sensation of taste being lost [71]. Thus, if the oral malignancy being irradiated is in the area of the taste buds, the extent of damage and the ability to regain the sensation of taste will depend on the cumulative dose of radiation and the number of taste buds involved. The lower the dose and exposure, the better the chance that the sensation of taste will be restored. Patients should be counseled about the problems associated with the overcompensation of this loss by eating foods that are high in sugar content or excessively spicy.

A resident oral fungal organism with pathogenic capabilities, *Candida albicans*, causes a common opportunistic infection in the oral tissues of patients receiving radiotherapy. The normal competitive mechanisms among the microbial species of the oral environment and the immunocompetence of the host are usually sufficient to prevent infection of the mucosal tissues by this fungal organism. After radiotherapy, both of these protective mechanisms are altered, which can result in candidiasis in the oral tissues. This may be especially painful and even difficult to diagnose if it is superimposed on areas of mucositis.

The most significant concern is that a Candida infection superimposed over an area of mucositis could be a source of a regional or systemic fungal infection, which could have fatal consequences in a patient already weakened by illness, surgery, radiotherapy, and/or chemotherapy. Treatments for these infections consist of antifungal oral suspensions, such as nystatin, that follow a swish-and-swallow protocol (used with varying degrees of efficacy), or systemic fluconazole (highly effective for prophylaxis and treatment) [72]. Antifungal lozenges are difficult to use in patients whose salivary flow has diminished. Patients who wear complete or partial dentures, orthodontic retainers, or night guards should disinfect these appliances in accordance with the manufacturers' directions (e.g., soaking in antifungal solutions). The acrylic portions of these appliances have microscopic porosities in which C. albicans organisms thrive and re-infect oral tissues that have been cleared of the infection. Systemic fungal infections in these patients have a high mortality rate and should be treated with intravenous antifungal agents in a hospital setting.

Trismus, a condition in which the muscles that coordinate the functional range of jaw movements become spasmodic and contracted, can affect patients weeks or months after radio-therapy has been initiated [72]. Irradiation causes a thickening and scarring of the blood vessels that supply these muscles.

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The decreased oxygen and nutrient supply cause scars to form among the muscle fibers. This results in a state of relative contraction and a loss of range of motion. The onset of this problem is more gradual than that of mucositis because the muscle cells have a slower rate of mitosis. The prevalence of trismus increases with greater doses of radiation, and levels in excess of 60 Gy are more likely to cause the condition. Patients who have been previously irradiated and who are being treated for a recurrence appear to be at higher risk of trismus than those who are receiving their first treatment [72]. A physical therapist can recommend exercises for the facial musculature that minimize this problem. Preventive exercises should be employed before trismus becomes established, as it is difficult to regain muscle function and elasticity after this problem is firmly developed.

SURGERY AND RADIOTHERAPY: DENTAL CONSIDERATIONS

PRETREATMENT CONSIDERATIONS

Oral complications secondary to surgery and radiotherapy for the treatment of malignancies may occur in patients with optimal oral health. These problems are exacerbated for those patients who have carious lesions, periodontal disease, problematic wisdom teeth, fractured teeth with sharp exposed edges, and prosthetic appliances that fit poorly and persistently traumatize the tissues.

A complete clinical and radiographic examination of the teeth and soft tissues should be completed as far in advance as possible from the surgical phase of oral cancer therapy. This will allow sufficient healing time for the extractions of teeth with unrestorable decay and advanced periodontal disease. Partially erupted wisdom teeth should be removed if they are in an area to be irradiated. Teeth with dental caries should be restored to optimal clinical condition. Teeth in which the carious process has extended into the pulp and has caused irreversible inflammation or necrosis should undergo root canal therapy or be extracted. Those teeth that cannot have deep periodontal pockets reduced to levels that will facilitate oral hygiene should be extracted. Prosthetic appliances should be adjusted so that their use will not promote tissue trauma. The goal is definitive treatment, avoiding a "watch and wait" approach. Patients should be informed that dental problems may exist without any symptoms and that lack of treatment will contribute to infections and even ORN after the completion of oral cancer therapy.

All patients should receive oral hygiene instruction and nutritional counseling. Manufacturers offer special spongelike toothbrushes with toothpaste impregnated into the foamy material that may provide for an adequate means of cleansing the teeth without causing soft tissue trauma. The use of dental floss or dentotape for the interproximal areas should only be done if it can be accomplished atraumatically. Patients should demonstrate that proper flossing technique is within their capability.

Mouth rinses that contain alcohol may irritate the mucosal tissues and increase the dryness within the mouth. If an alcohol-based mouth rinse can be tolerated, 0.12% chlorhexidine gluconate is an excellent adjunct to the oral hygiene regimen [73]. This mouth rinse has substantivity, the ability to adhere to the tissues within the oral environment for several hours. This bactericidal formulation diminishes the number of bacteria associated with dental caries and periodontal disease. However, as discussed, chlorhexidine may cause additional discomfort for many patients [48].

All patients who will retain some or all of their natural teeth should have custom fluoride trays made before oral cancer treatment. These trays serve as reservoirs for a neutral formulation of 1.1% sodium fluoride or 0.4% stannous fluoride gels, depending on the composition of the patient's dental restorations [74]. These trays should be worn about 10 minutes daily, and patients should refrain from eating or drinking for 30 minutes after the fluoride treatment. Patients who do not want to use trays may brush the gels onto their teeth. Patients should also brush their teeth twice daily using 1.1% fluoride toothpaste [75]. This regimen should be a lifelong commitment for these patients in an attempt to minimize the risk of dental caries in a postsurgical oral environment that poses a high risk of dental caries.

POST-TREATMENT CONSIDERATIONS

Before surgery and radiotherapy for oral cancer is begun, patients should have an appointment for an oral assessment. The status of the teeth and the soft tissue should be scrutinized to minimize the chance of any condition that would lead to an infection necessitating oral surgery procedures, especially after radiotherapy. If a dental emergency develops that requires an extraction of a tooth, a 14- to 21-day window of healing should be allowed prior to radiotherapy to minimize the risk of ORN. Recall appointments should be frequent to allow for the examination of the oral tissues, as there is always a chance that an oral malignancy can recur at the original site or a new lesion can arise. These appointments also allow for an opportunity to evaluate oral hygiene status, presence of carious lesions, periodontal condition, and overall condition of the oral mucosa.

Rehabilitation of the patient with oral cancer is a challenging experience. The extent of necessary rehabilitation is proportionate to lesion size and the presence of metastasis. Larger squamous cell carcinoma lesions can engulf nerves, muscle, and bone. As noted, the removal of larger lesions adversely affects the ability to eat, speak, swallow, and enjoy the previous quality of life. Cosmetic disfigurement may not always be correctable to the patient's satisfaction. The team approach, involving the surgical and radiotherapy team, dentists, oral surgeons, oral and maxillofacial prosthodontists, nurses, nutritionists, occupational therapists, speech therapists, physical therapists, pharmacists, and plastic surgeons, may be needed. Counseling may be necessary to assist these patients as they face life from an entirely new perspective. Because most patients with oral cancer have a history of tobacco use, tobacco cessation education is an important aspect of patient recovery.

ORAL COMPLICATIONS FROM CHEMOTHERAPY

According to the Centers for Disease Control and Prevention, the death rate caused by cancers of all types is second only to heart disease [76]. During the 1990s, the incidence of cancer and death rates from this group of diseases actually declined. However, due to an increasing population, the actual number of deaths from cancer has increased [76].

Malignancies that involve individual organs, organ systems, or the bone marrow are usually treated by surgery, chemotherapy, and localized radiotherapy. When the primary lesion of squamous cell carcinoma arises within the oral cavity, chemotherapy is not typically a part of treatment. When chemotherapy is used postsurgically for organic or systemic malignancies, severe oral complications may also occur. When radiotherapy involves treatment of a malignant neoplasm that is distant from the oral and maxillofacial complex, oral complications rarely develop.

Because chemotherapy regimens are introduced intravenously, these drugs can interact with cells anywhere in the body. Chemotherapeutic agents exert their effects by interaction with the nuclei of malignant cells. Interference with DNA production, separation of the DNA helix, and disruption of protein synthesis are mechanisms by which the rapidly dividing and highly mitotic malignant cells are destroyed [77]. Normal cells, which undergo frequent turnover, can only be replaced if their successors also undergo frequent mitosis and cell division. Many chemotherapeutic agents exert their deleterious effect on normal cells as a result of the mitotic similarities between rapidly dividing malignant cells and those of normal cells. Because the cells of the oral mucosa undergo frequent turnover, they are subject to the nonspecific detrimental effects of chemotherapy.

The oral tissues are also subject to other problems, such as bleeding and infection, caused by the effects of chemotherapy on the cells from which the formed elements of human blood are produced. A review of these cells and their functions in the clotting mechanism and in appropriate immune function is necessary before the effects that chemotherapy has on these cellular elements, and ultimately the host, can be understood. All blood cells are formed through the process of hematopoiesis, beginning with an undifferentiated cell, the hemocytoblast. Erythrocytes, platelets (thrombocytes), and the spectrum of the granular leukocytes (neutrophils, basophils, and eosinophils) are produced in the red bone marrow. This productive tissue is located in several bones, including the sternum, ribs, pelvis, and vertebrae. The agranular leukocytes are produced both in the red bone marrow and lymphoid tissue, such as the tonsils, spleen, and lymph nodes. Erythrocytes, containing their large hemoglobin molecules, are essential for carrying oxygen to the tissue. Platelets are a critical component of the blood clotting mechanism. The granular and agranular leukocytes serve different functions within the immune system. Any procedure or medication that interferes with the production of any of these components can cause systemic problems. Chemotherapy is a significant source of these problems.

HEMORRHAGE

When the number of platelets produced or the quality of those in existence are diminished, oral bleeding can occur. The normal range of platelets is 150,000 – 450,000 per mm³ of blood. Spontaneous bleeding occurs when the platelet count decreases to 20,000 – 50,000 per mm³ of blood [78]. When platelets contact a damaged blood vessel, they increase in size and adhesiveness and form a plug upon the damaged vessel. Some chemotherapeutic agents alter the ability of platelets to adhere to each other in the formation of a fibrous plug, which is required for hemostasis. Others may interfere with actual platelet production and decrease the number of platelets available. Regimens that use more than one chemotherapeutic agent may affect both platelet quality and production.

Interference with coagulation causes oral manifestations, including petechiae, ecchymoses, or oozing of blood [79]. The most common areas in which petechiae are found intraorally include the palate, gingiva, lips, and tongue. Petechiae are small areas of bleeding within the tissue that occur because of a decreased platelet count. Similarly, bleeding submucosally or subcutaneously due to platelet deficiencies in quality or quantity may produce ecchymoses. These lesions can occur anywhere within the oral tissues and appear as a dark red or reddish-blue area submucosally. They are exacerbated by accidental trauma or by prostheses that irritate the tissues. The most disconcerting problem for the patient is hemorrhage, which occurs spontaneously or with actions such as eating, brushing, or flossing. This problem is exacerbated in patients who have chronically inflamed gingival tissues characteristic of gingivitis and periodontal disease. Ideal depth of the gingival sulcus in health is 3 mm or less. As gingivitis and periodontal disease progress, destruction of the epithelial attachment causes this sulcus to become deeper. Cleansing the pocket depth becomes increasingly difficult, with a resultant state of chronic inflammation. As alveolar bone is lost during the progression of periodontal disease, the gingival tissues become poorly attached to the tooth and bone.

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An environment of continually deepening periodontal pockets causes severe soft tissue inflammation. Despite this, tissues in this pathologic state often do not bleed spontaneously. Patients receiving chemotherapy, however, may have spontaneous gingival bleeding even if the depth of the gingival sulcus is not excessive. The clots usually appear as dark red and are friable, with slight bleeding evident when they are removed. Patients may experience this at any time, but it is most noticeable upon awakening in the morning. Dried blood from nocturnal bleeding can be encrusted on the lips, tongue, or anywhere in the oral mucosa. Sharp edges of fractured teeth or broken fillings, dental restorations that extend below the gingival crest, prostheses that cause tissue irritation, and partially erupted wisdom teeth are all potential sources that compromise tissue integrity and allow easy bleeding during chemotherapy. When bleeding is seen within the oral cavity, the patient should be referred to their physician, as internal bleeding in other areas of the body is possible.

The effect of chemotherapy on hemostasis subsides for most patients after the completion of the regimen. Even basic dental treatment, including prophylaxis, should not be performed until laboratory values ascertain that the platelet levels have returned to a range that is acceptable for hemostasis. Further diagnostic tests, such as a prothrombin time, may need to be done. The oncologist should be consulted before any invasive treatment is planned, as patients can have a wide interval of recovery times after chemotherapy ends. Emergency dental treatment that cannot be postponed, such as oral and maxillofacial trauma or painful exacerbations of dental problems, may need to be performed in a hospital setting.

INFECTIONS

Oral infections that are usually treated successfully with standard antibiotics can become a life-threatening problem for patients receiving chemotherapy. Oral infections may be bacterial, fungal, or viral in origin. Chemotherapy interferes with the production of the granular and agranular leukocytes, which are important components of the defense mechanism of the immune system. Oral infections in the aftermath of chemotherapy are common and may manifest into systemic conditions [80].

Bacterial Infections

As mentioned, the normal host defense mechanisms and competitive inhibition among the oral microflora organisms are altered in many patients after chemotherapy. Any bacterial species have the potential to become a local or systemic pathogen. Pathologic dental conditions that preclude adequate cleansing, such as periodontal disease, necrotic pulps that have caused periapical infections, or partially erupted wisdom teeth, are potential sources of acute infections in patients receiving chemotherapy. The denuded, ulcerated areas of mucositis also facilitate a means of systemic bacterial dissemination. Antibacterials are indicated either as prophylaxis or as treatment if patients present with clinical signs of infection [81].

Fungal Infections

Oral infections of fungal origin (with the potential to spread systemically) occur in as many as 38% of patients receiving chemotherapy [80]. As mentioned, *C. albicans* is a resident fungal organism in the oral microflora. This opportunistic pathogen thrives in the oral environment of a host who is immunologically compromised. Oral candidiasis has different manifestations and degrees of severity. Angular cheilitis occurs when these organisms infect the commissures of the lips and the surrounding skin. The affected areas are sore and can crack and bleed easily. Treatment with a topical antifungal (such as miconazole) that is usually successful in the immunocompetent patient may not be successful in patients with cancer.

Pseudomembranous candidiasis features white to yellow-white raised plaques that may occur on any oral surface. These plaques may be wiped away from the underlying mucosal surface and an erythematous base will be revealed. This fungal infection can spread to the pharynx and esophagus by direct extension. Organisms that infect an area of mucositis have a portal for hematogenous dissemination and cause invasive candidiasis. Treatment with the swish-and-swallow regimen of nystatin may not work as well, or as quickly, in the immunocompromised patient [72]. Systemic antifungals, such as fluconazole, caspofungin, micafungin, anidulafungin, or lipid formulation of amphotericin B, may be necessary [82]. Another antifungal medication, voriconazole, is also available, but the side effects associated with its use are more severe and it offers little advantage over fluconazole as initial therapy [82]. The resistance of fungal organisms to these medications is becoming an increasing problem. Systemic antifungal medications should be prescribed with care, as they can interact with many other medications to produce serious side effects. Patients with impaired liver function may be unable to take these medications due to the risk for potentially fatal hepatotoxicity [51]. Prosthetic appliances that are made of acrylic should also be treated to destroy any inhabitant fungal organisms [82]. Some patients (e.g., neutropenic patients) benefit from a course of prophylactic antifungal medication (in recommended order: fluconazole, posaconazole, caspofungin) during chemotherapy [82]. Itraconazole is available for prophylaxis but is not recommended, except in the instance of fluconazole-refractory disease [82]. Isavuconazole, an expanded-spectrum antifungal approved in 2015, has excellent in vitro activity against Candida species [82; 83].

Viral Infections

The activation of herpes simplex virus or varicella zoster virus (shingles) is a common occurrence in immunocompromised patients [84]. These viruses reside and lie dormant in the ganglia of neurons until a triggering event or stressor stimulates their activation. In immunocompromised patients, these viral infections are more susceptible to systemic or organ dissemination [85]. Because they reside in the actual nerve, these viruses cannot be destroyed by any medical procedure.

Intraoral herpetic lesions may appear as large ulcerative areas and can resemble mucositis. Only a culture for this virus distinguishes between the two. When varicella zoster manifests facially, it follows the sensory distribution of either the right or left trigeminal nerve. The affected areas are much larger than those infected with the herpes simplex virus, and there is a commensurate increase in pain. The skin is most commonly involved, although the mandibular division of the trigeminal nerve may allow for an intraoral manifestation.

Analgesic and antiviral medications will decrease the symptoms associated with the outbreak. The ultimate goal of therapy in cases of postchemotherapy varicella zoster is to prevent or control systemic and/or organ dissemination, as the majority of mortalities related to varicella zoster are attributable to these complications [85]. Acyclovir is recommended, especially for immunosuppressed patients [85; 86; 87; 88]. Valacyclovir or famciclovir may also be used [86; 87; 88]. Brivudin is contraindicated for patients receiving chemotherapy as the risk of fatal interaction with certain chemotherapeutic agents has been established [85; 86; 88]. Brivudin is not currently available in the United States [51]. Unlike the healing pattern for the herpes simplex virus, varicella zoster may leave scars upon healing and may have painful exacerbations of posthealing neuralgia. If the ophthalmic branch of the trigeminal nerve is involved, an ophthalmologist should be consulted as involvement of the cornea may lead to corneal scarring and blindness [85].

MEDICATION-RELATED OSTEONECROSIS OF THE JAW

The use of large doses of IV bisphosphonates, as is common among patients with multiple myeloma or metastatic breast cancer, has been linked to the development of jaw osteonecrosis [89]. This phenomenon was previously referred to as bisphosphonate-related osteonecrosis of the jaw. However, the preferred term is now medication-related osteonecrosis of the jaw (MRONJ), which is favored due to the rise in osteonecrosis cases associated with other antiresorptive (denosumab) and antiangiogenic therapies [90; 91]. MRONJ is diagnosed by the presence of three characteristics [90]:

- Current or previous treatment with antiresorptive or antiangiogenic agents
- Exposed bone or bone that can be probed through an intraoral or extraoral fistula(e) in the maxillofacial region that has persisted for more than eight weeks

 No history of radiation to the jaws or obvious metastatic disease to the jaws

The risk of developing MRONJ increases with extended use of the medications. According to one meta-analysis, the majority of cases (60%) were precipitated by tooth extraction or oral surgery, which may involve trauma to the alveolar bone during the procedure as well as complications arising during recovery [89; 92; 93]. Among patients with jaw osteonecrosis who have not had oral surgery or tooth extraction, the use of dental prostheses or other oral problems are often present [94]. The results of one study suggest that the accurate diagnosis of MRONJ at the time of extraction is critical, and that an additional category of MRONJ that encompasses cases of bony necrosis found in the extraction socket during tooth extraction procedures may be needed. The study results also suggest that the routine discontinuation of bisphosphonates several months prior to the extraction procedure should be considered carefully [95]. All patients who are being treated with bisphosphonates or denosumab should be counseled regarding the possibility of MRONJ developing, including early signs, and the importance of good oral hygiene [90].

When MRONJ does develop, the stage of the disease should be determined, which will in turn guide the treatment plan. MRONJ is categorized as [90]:

- Stage 0: No exposed/necrotic bone with non-specific symptoms or clinical and radiographic findings
- Stage 1: Exposed/necrotic bone with no symptoms and no evidence of infection
- Stage 2: Exposed/necrotic bone with pain and clinical evidence of infection
- Stage 3: Exposed/necrotic bone with pain, infection, and one or more of the following:
 - Exposed necrotic bone extending beyond the alveolar region
 - Oral antral/oral nasal communication
 - Pathologic fracture
 - Extra-oral fistula
 - Osteolysis extending to the inferior border of the mandible or sinus floor

Patients with stage 1 MRONJ are usually treated conservatively, with oral antimicrobial rinses (e.g., chlorhexidine 0.12%) and no surgical intervention. Stage 2 MRONJ is treated with the use of antibiotic therapy in addition to oral antimicrobial rinses; certain cases may require surgical intervention to reduce the volume of colonized, necrotic bone. Stage 3 disease often impacts quality of life and requires more intensive intervention. These patients usually require surgical debridement/ resection in combination with antibiotic therapy [90].

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OTHER ORAL COMPLICATIONS OF CHEMOTHERAPY

Systemic chemotherapy can have oral manifestations that are dependent on the agent(s) used, their dosage, and the duration of therapy. As with any medication, there is a considerable variability in the tolerance for a given pharmacotherapeutic regimen as well as any side effects. As noted, one such effect may be xerostomia. This problem is associated with some chemotherapeutic agents more than others. The parotid glands, with their serous secretions, are the glands most frequently affected. Because chemotherapeutic agents are administered as a systemic therapy, these substances course through all salivary glands. With the serous component reduced, the saliva develops a mucus-laden, ropey consistency. The decreased lubrication exacerbates the pain associated with concurrent areas of mucositis and makes it difficult to wear any dental prostheses. Eating, speaking, and swallowing may become difficult, and the taste of foods may be altered.

While radiotherapy-induced xerostomia and all of the problems associated with it are long-term or permanent, those associated with chemotherapy dissipate after the completion of the regimen. Chemotherapy is usually given in an incremental fashion, with several days or weeks separating the appointments. Xerostomia may be a continuous problem until enough time has elapsed after the last session. A 2015 Cochrane Review concluded that cryotherapy (i.e., holding ice chips or ice water in the mouth from 5 minutes prior to 30 minutes after treatment) is effective in reducing mucotoxicity [96]. A simple act to palliate the symptoms associated with this xerostomia and mucositis is to frequently suck on ice chips. Being that the cost and risks of this preventative measure are virtually nonexistent, cryotherapy should always be considered.

Neurologic effects may be seen in some patients on chemotherapy. Vincristine sulfate is the chemotherapeutic agent most commonly associated with this problem [51; 97]. Chemotherapeutic agents exert varied effects on any nerve. The most commonly affected nerves that serve the oral and maxillofacial complex are the facial and trigeminal nerves. The facial nerve is the major source of motor innervation for the muscles of facial expression. Transient neural toxicity manifests as weakness of these muscles and decreased facial muscular coordination. The trigeminal nerve is another cranial nerve that provides sensory innervation to many portions of the face and for those structures within the oral cavity. Symptoms of neural toxicity present in a variety of ways. Pain that mimics that of dental origin may affect both the maxillary and the mandibular arches. There may be temporary paresthesia in the soft tissues or in the teeth. Pain in the temporomandibular joint (TMJ) may mimic TMJ problems. Patients should be reassured that these problems will regress after chemotherapy is completed.

Special Considerations

Special considerations for the oral complications of chemotherapy include the pediatric population and those patients who receive bone marrow transplants. Unfortunately, many children must undergo the rigors of chemotherapy. This often affects tooth development and craniofacial growth in children younger than 12 years of age [98]. Effects are even more severe in children younger than 5 years of age [98]. Additionally, children are subject to all of the other chemotherapy-induced problems. Their immature immune systems are less capable of the provision of defense against oral infections. Any anticipated dental treatment should be cleared through the oncologist.

Patients who have received bone marrow transplants are particularly prone to infections [81]. Chemotherapy and radiation therapy are used to eliminate the normal and malignant cells within the bone marrow in anticipation of replacement marrow from a donor. As a result, the patient has virtually no immunocompetence. Patients are usually required to take immunosuppressive drugs for life and may be subject to life-threatening sepsis from dental infections that would be self-limiting in immunocompetent individuals. Any dental problem that has the potential to cause an infection should be eliminated before the patient begins therapy for the bone marrow transplant.

CHEMOTHERAPY: DENTAL CONSIDERATIONS

PRETREATMENT CONSIDERATIONS

The guidelines established for dental pretreatment of patients who will receive radiotherapy should also be followed by those receiving chemotherapy. The major additional caveat is that these patients may have decreased defense mechanisms against oral infections for an extended period of time. Like bone marrow transplant patients, some patients receiving chemotherapy may be so immunocompromised that the cardinal signs of warmth, redness, and swelling may be completely lacking as a warning sign of an infection. It is imperative that within this patient population, any dental pathology related to the teeth, the periodontium, or the soft tissue is eliminated well in advance of chemotherapy [99].

POST-TREATMENT CONSIDERATIONS

Postchemotherapy dental treatment should include frequent recall appointments to examine the oral cavity and reinforce the need for meticulous oral hygiene. Antimicrobial prophylaxis may be required for any procedure in which bleeding is anticipated due to the increased risk for infection. Laboratory values for the formed elements of human blood may be necessary. The healthcare team, including dentists and oncologists, should be in communication regarding patient dental pretreatment and post-treatment [99; 100].

CONSIDERATIONS FOR NON-ENGLISH-PROFICIENT PATIENTS

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 history and education are such vital aspects of the diagnosis of oral lesions and the prevention and treatment oral complications of systemic cancer therapies, 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 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.

CONCLUSION

It has been suggested that most people know someone who has been afflicted with cancer. Whether it is a family member, friend, or relative, this group of diseases has been associated with high morbidity and high mortality rates. Medical science has made considerable breakthroughs in the prevention, diagnosis, and treatment of cancer. Prevention of any form of cancer remains the ideal. If this cannot be realized, then early diagnosis and prompt treatment are possibly life-saving measures. Patients should be educated about the warning signs of cancer and encouraged to maintain yearly check-ups with their primary care physician. If treatment for cancer ensues, patients should be informed that the potential oral complications of cancer treatment may result in fatal consequences. Continued improvement of medical technology will be a medium through which patients can be treated more effectively when cancer strikes. All members of the healthcare team must commit to providing the highest level of care and compassion for these patients. Perhaps one day cancer will be spoken of in the past tense.

RESOURCES

American Cancer Society 1-800-227-2345 https://www.cancer.org

Cancer Treatment Centers of America 1-844-244-4326 https://www.cancercenter.com

National Cancer Institute 1-800-4-CANCER https://www.cancer.gov

The Oral Cancer Foundation 1-949-723-4400 https://oralcancerfoundation.org

COURSE TEST - #50683 ORAL CANCER AND COMPLICATIONS OF CANCER THERAPIES

This is an open book test. A passing grade of at least 70% must be achieved in order to receive credit for this course.

This 5 CE Credit Hour activity must be completed by November 30, 2024.

Accreditations & Approvals: NetCE is an ADA CERP Recognized Provider.

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Designations of Credit: NetCE designates this activity for 5 continuing education credits.

AGD Subject Code: 730.

- 1. The five-year survival rate for oral squamous cell carcinoma is approximately
 - A) 25%.
 - B) 33%.
 - C) 68%.
 - D) 80%.

2. Which of the following statements is TRUE regarding risk factors for oral cancer?

- A) It usually occurs in the second and third decades of life.
- B) Smokeless tobacco products are a safe alternative to cigarettes.
- C) The frequency of oral cancer is equal between men and women.
- D) Approximately 25% of afflicted patients have no known risk factors.

3. The oral mucosa

- A) lacks specialized (sensory) mucosa.
- B) is lined primarily by masticatory mucosa.
- C) has a surface layer of stratified squamous epithelium.
- D) has the same surface consistency throughout the oral cavity.

4. An expeditious referral should be sought for a lesion of unknown origin if it has not healed in

- A) two weeks.
- B) four weeks.
- C) six weeks.
- D) eight weeks.

5. Leukoplakic lesions

- A) are red in color.
- B) are more common than erythroplakic lesions.
- C) usually have pain as the presenting symptom.
- D) have a 91% probability of being premalignant or malignant.

6. Which of the following statements about erythroplakic lesions is FALSE?

- A) There is a tendency to bleed easily upon palpation.
- B) They are usually asymptomatic in their earlier stages.
- C) They can be difficult to detect amidst the oral mucosa.
- D) They have a 20% chance of being malignant or premalignant.
- 7. Oral squamous cell carcinoma comprises approximately what percentage of all oral malignancies?
 - A) 30%
 - B) 50%
 - C) 70%
 - D) 90%
- 8. Which of the following areas of the oral cavity is among the most common sites involved in oral cancer?
 - A) The palate
 - B) The tongue
 - C) The gingiva
 - D) The buccal mucosa

9. The oral manifestations of Kaposi sarcoma

- A) are usually white to yellow-white in color.
- B) are believed to be caused by human papillomavirus.
- C) are associated with the early stages of HIV infection.
- D) may occur anywhere in the mouth, but are usually seen on the palate, gingiva, or tongue.

10. In the TNM International Classification System, which of the following designates a malignant oral lesion that exceeds 4 cm and has extensive infiltration of the muscle?

- A) N1
- B) T4
- C) N4
- D) M4

11. Radiotherapy is cytotoxic to malignant cells because it causes

- A) hypoxia.
- B) dysplasia.
- C) hyalinization.
- D) free radical damage.

12. The most common intraoral side effect of radiotherapy is

- A) trismus.
- B) mucositis.
- C) hemorrhage.
- D) osteoradionecrosis.

13. Radiation caries, which occur after radiotherapy,

- A) are a rapidly progressing pathologic state.
- B) are caused by increased salivary pH levels.
- C) are due to a less viscous salivary consistency.
- D) only occur on teeth with existing dental pathology.

14. Which of the following should be avoided prior to oral cancer treatment?

- A) Extractions of teeth that cannot be restored
- B) Reduction of the depths of periodontal pockets
- C) Complete clinical and radiographic examination of teeth
- D) A "watch and wait" approach for existing dental problems

15. Chemotherapy can interfere with the coagulation process because it

- A) increases the number of circulating platelets.
- B) decreases the number of granular leukocytes.
- C) increases the number of agranular leukocytes.
- D) decreases platelet production and their ability to adhere to each other.

16. Oral hemorrhaging during chemotherapy regimens

- A) occurs only spontaneously.
- B) may be brought on by eating or brushing.
- C) is never heralded by the presence of petechiae.
- D) is not exacerbated by gingivitis or periodontal disease.

17. Angular cheilitis is an oral fungal infection that affects the

- A) hard palate.
- B) floor of the mouth.
- C) dorsum of the tongue.
- D) commissures of the lips and the surrounding skin.

Decreased immunocompetence due to chemotherapy can cause the reactivation of the varicella zoster virus, which is the etiologic agent of

- A) shingles.
- B) mucositis.
- C) candidiasis.
- D) Kaposi sarcoma.

19. When chemotherapy is administered, xerostomia

- A) is usually permanent.
- B) does not affect speech or taste.
- C) alters saliva to have a ropey consistency.
- D) cannot be alleviated until after the completion of regimen.

20. The neurologic effects caused by chemotherapy

- A) are usually permanent.
- B) are seen in the facial nerve only.
- C) will usually regress after chemotherapy.
- D) is most closely associated with the use of nystatin.

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Course Availability List

These courses are available online at **www.NetCE.com**. Additional titles are also available.

ORAL AND MAXILLOFACIAL TRAUMA

#50002 • 5 Hours • \$45

Purpose: The purpose of this course is to provide dental professionals with a deeper understanding of and appreciation for oral and maxillofacial trauma.

Faculty: Mark J. Szarejko, DDS, FAGD

Audience: This course is designed for all dental professionals, especially those who work in emergency and trauma care.

AGD Subject Code: 070

AIRWAY MANAGEMENT: BASICS FOR HEALTHCARE PROVIDERS #50010 • 5 Hours • \$45



Purpose: Gaining control of the airway in a

compromised patient is absolutely crucial. The purpose of this course is to provide dental professionals with the clinical knowledge needed to rapidly and effectively assess the patient's airway and intervene efficiently to begin to ventilate the patient in distress. **Faculty**: Richard E. Haas, PhD, CRNA (Retired), LTC US Army Nurse Corps (Retired)

Audience: This course is designed for dental professionals involved in monitoring and maintaining patients' airways. **AGD Subject Code**: 142

AGD Subject Code: 142

HIPAA PRIVACY AND SECURITY #51140 • 5 Hours • \$45

Purpose: The purpose of this course is to provide information that will allow dental professionals to more easily comply with

the Privacy and Security Rules defined by HIPAA.

Faculty: Carol Shenold, RN, ICP

Audience: This course is designed for all dental professionals. AGD Subject Code: 566

SMOKING AND SECONDHAND SMOKE #51784 • 10 Hours • \$90



Purpose: The purpose of this course is to provide dental professionals with a formal educational opportunity that will address the impact of tobacco smoking and secondhand exposure in public health and disease as well as interventions to promote smoking cessation among their patients.

Faculty: Mark S. Gold, MD, DFASAM, DLFAPA

Audience: This course is designed for dental professionals who may intervene to stop patients from smoking.

AGD Subject Code: 158

DENTAL CARE FOR SPECIAL NEEDS PATIENTS #51913 • 5 Hours • \$45

Purpose: The purpose of this course is to focus awareness upon the difficult oral health issues that special needs patients face on a daily basis and to provide dental professionals with the necessary information to improve patients' oral and systemic health. **Faculty**: Mark J. Szarejko, DDS, FAGD

Audience: This course is designed for dental professionals involved in assessing and promoting optimum oral care for special needs patients.

AGD Subject Code: 750

ORAL HEALTH ISSUES DURING PREGNANCY #53073 • 2 Hours • \$18



Purpose: The purpose of this course is to provide

dental professionals with the information necessary to appropriately intervene to promote good oral health in pregnant patients, with lasting positive effects to the patient and fetus.

Faculty: Mark J. Szarejko, DDS, FAGD

Audience: This course is designed for all dental professionals involved in the care of pregnant patients.

AGD Subject Code: 750

Prices are subject to change. Visit www.NetCE.com for a list of current prices.

Course Availability List (Cont'd)

ORAL AND MAXILLOFACIAL INFECTIONS

#54032 • 5 Hours • \$45

Purpose: The purpose of this course is to emphasize to dental professionals the importance of quickly identifying and treating oral and maxillofacial infections.

Faculty: Mark J. Szarejko, DDS, FAGD

Audience: This course is designed for all dental professionals involved in the identification and treatment of oral and maxillofacial infections.

AGD Subject Code: 310

ORAL MANIFESTATIONS OF SEXUALLY TRANSMITTED INFECTIONS #54072 • 5 Hours • \$45

Purpose: The purpose of this course is to introduce dental professionals to the pathophysiology of STIs, their oral manifestations, systemic complications, available treatment options, and any modifications required for dental treatment. Faculty: Mark J. Szarejko, DDS, FAGD Audience: This course is designed for all dental professionals. AGD Subject Code: 148

NUTRITION AND ORAL HEALTH

#54120 • 6 Hours • \$54

Purpose: The purpose of this course is to provide clinicians with a better understanding of the impact of nutrition on dental health and care.

Faculty: Mark J. Szarejko, DDS, FAGD

Audience: This course is designed for all dental professionals. AGD Subject Code: 150

THE CORONAVIRUS DISEASE (COVID-19) PANDEMIC #54151 • 2 Hours • \$18



Purpose: This course is designed for dental

professionals who may identify or educate patients regarding coronavirus infection.

Faculty: John M. Leonard, MD

Audience: This course is designed for dental professionals who may identify or educate patients regarding coronavirus infection. AGD Subject Code: 148

MULTIDRUG-RESISTANT **MICROBIAL INFECTIONS** #54214 • 5 Hours • \$45



Purpose: The purpose of this course is to provide an overview of the basics of antimicrobial resistance mechanisms and to review the classes of multidrug-resistant pathogens currently prevalent in dental facilities and the community, including guidelines for prevention and options for therapy. Faculty: Carol Shenold, RN, ICP; John M. Leonard, MD Audience: This course is designed for dental professionals involved in the treatment and care of patients with infections. AGD Subject Code: 148

ANALGESICS IN DENTISTRY #55044 • 5 Hours • \$45

Purpose: The purpose of this course is to describe new reports and new information on analgesics for the dental professional to use in determining the best pharmacotherapeutic approach in those situations requiring oral analgesics.

Faculty: Richard L. Wynn, BSPharm, PhD

Audience: This course is designed for all dental professionals. AGD Subject Code: 200

ANTIBIOTICS REVIEW #55073 • 5 Hours • \$45



Purpose: The purpose of this course is to provide a review of the major classes of antibiotics and their

characteristics as well as an overview of selected individual agents within each class that are most useful for today's clinical practitioner.

Faculty: Donna Coffman, MD

Audience: This course is designed for dental professionals who prescribe or administer antibiotics to patients.

AGD Subject Code: 148

MEDICAL MARIJUANA AND OTHER CANNABINOIDS #55172 • 5 Hours • \$45

Purpose: The purpose of this course is to provide dental 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 dental professionals involved in the care of patients who use or who are candidates for the therapeutic use of marijuana and other cannabinoids. AGD Subject Code: 149

Prices are subject to change. Visit www.NetCE.com for a list of current prices.

Course Availability List (Cont'd)

LOCAL ANESTHETICS IN DENTISTRY

#55182 • 5 Hours • \$45

Purpose: The purpose of this course is to provide dental professionals with a comparative perspective on the use of local anesthetics.

Faculty: Mark J. Szarejko, DDS, FAGD

Audience: This course is designed for all dental professionals whose patients may be administered local anesthetics. AGD Subject Code: 340

MEDICATION USE IN DENTISTRY

#55253 • 5 Hours • \$45

Purpose: As the number of medications and range of uses grow, dental prescribing has become increasingly complex. The purpose of this course is to provide dental professionals with the knowledge necessary to effectively prescribe and to monitor the effects of commonly used drugs.

Faculty: Mark J. Szarejko, DDS, FAGD

Audience: This course is designed for all dental professionals. AGD Subject Code: 010

COCAINE USE DISORDER

#56944 • 5 Hours • \$45

Purpose: The purpose of this course is to provide a current, evidence-based overview of cocaine abuse and dependence and its treatment, in order to allow dental professionals to more effectively identify, treat or refer cocaine-abusing patients. **Faculty**: Mark Rose, BS, MA

Audience: This course is designed for dental professionals who are involved in the evaluation or treatment of persons who use cocaine. **AGD Subject Code**: 157

DENTAL ETHICS: A BRIEF REVIEW #57423 • 2 Hours • \$18

Purpose: The purpose of this course is to provide dental professionals with a review of ethics and ethical theoretical systems that pertain to their profession. The content of this course is not intended as legal advice for patients or practitioners. **Faculty**: William E. Frey, DDS, MS, FICD; Michelle Nichols, RN, BSN,

Faculty: William E. Frey, DDS, MS, FICD; Michelle Nichols, KN, BSN, MA

Audience: This course is designed for all dental professionals. AGD Subject Code: 555

HERBAL MEDICATIONS: AN EVIDENCE-BASED REVIEW #58394 • 10 Hours • \$90

Purpose: Considering the pharmacological interactions between herbal medications (HMs) and conventional medications, it is paramount to increase the awareness and knowledge of dental professionals about HMs. The purpose of this course is to increase dental professionals' awareness of the potential risks and benefits of HMs from an evidence-based perspective and promote the planned inclusion of HM use in patients' medical history. This course should allow dental professionals to discuss HMs in a knowledgeable and succinct manner with patients and colleagues.

Faculty: A. José Lança, MD, PhD

Audience: Considering the widespread availability and increased use of herbal medications, this course is designed for dental professionals who will benefit from the course. **AGD Subject Code**: 010

SLEEP DISORDERS

#58883 • 10 Hours • \$90

Purpose: Many of the complications associated with sleep disorders are preventable, making early diagnosis and appropriate treatment vital. The purpose of this course is to provide dental professionals with the information necessary to identify and contribute to the treatment of sleep disorders, thereby improving patients' quality of life and preventing possible complications.

Faculty: Teisha Phillips, RN, BSN

Audience: This course is designed for all dental professionals who are involved in the care of patients experiencing a sleep-related disorder.

AGD Subject Code: 730

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#54032 ORAL AND MAXILLOFACIAL INFECTIONS 5 CE Credit Hours — \$35

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#58394 HERBAL MEDICATIONS: AN EVIDENCE-BASED REVIEW 10 CE Credit Hours - \$70

#58612 ALLERGIC REACTIONS IN DENTAL PATIENTS 2 CE Credit Hours - \$15

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