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STATE BY STATE REQUIREMENT GUIDE

STATE	HOURS ALLOWED BY HOME-STUDY	TOTAL HOURS REQUIRED (NOTE: CE Rules can change. Always check your state board for the most up-to-date information.)	
Alabama	24	30	6 hrs must be live each year.
Alaska	30	30	All hours allowed by correspondence.
Arizona	30	30	3 hours opioid-related; All hours allowed by correspondence.
Arkansas	18	30	12 hrs live drug therapy/patient care; 12 hrs ACPE approved.
California	30	30	1 hour cultural competency; All hours allowed by correspondence.
Colorado	24	24	All hours allowed by correspondence.
Connecticut	10	15	1 hr of Pharmacy/Drug Law; not less than 5 hrs live presentation.
Delaware	30	30	2 hours Medication Safety/Errors; 2 hours Controlled Substances.
District of Columbia	30	40	2 hours HIV, 2 hours Medication/Dispensing Errors, 2 hours on cultural competency focused on patients or clients who identify as LGBTQ, 4 hours in designated public health priority topics.
Florida	20	30	2 hrs Prevention of Medical Errors; 2 hrs Validation of Prescriptions for Controlled Substances, 1 hr HIV first time renewal only.
Georgia	30	30	All hours allowed by correspondence.
Hawaii	30	30	All hours allowed by correspondence.
Idaho	15	15	All hours allowed by correspondence.
Illinois	30	30	1 hour sexual harassment prevention, 1 hour implicit bias awareness, All hours allowed by correspondence.
Indiana	30	30	All hours allowed by correspondence.
Iowa	30	30	15 hrs ACPE-approved activities in Drug Therapy; 2 hrs Pharmacy Law; 2 hrs Dealing with Patient/Medication Safety can be ACPE approved or not.
Kansas	30	30	1 hour Board-provided training, All hours allowed by correspondence.
Kentucky	15	15	1 hour opioid epidemic or opioid use disorder, All hours allowed by correspondence.
Louisiana	12	15	Either 15 hours each year, 3 hours must be live OR 20 hours each year if no live hours taken. All other hours may be completed by correspondence.
Maine	15	15	2 hrs ACPE/board-approved Drug Administration.
Maryland	28	30	1 hr Preventing Medication Errors; 2 hrs live.
Massachusetts	30	40	4 hrs Pharmacy Law per biennium; 15 hours live each year.
Michigan	20	30	1 hour Pain Management, 1 hour Pharmacy Ethics and Law, 1 hour Implicit Bias training each year (in addition to required 30 hours), 10 hours must be live.
Minnesota	30	30	All hours allowed by correspondence.
Mississippi	13	15	2 hours opioid abuse and prevention, 2 hours must be obtained by live seminar or webcast.
Missouri	30	30	All hours allowed by correspondence.
Montana	10	15	5 hrs in approved group setting.
Nebraska	30	30	All hours allowed by correspondence.
Nevada	29	30	1 hour Law through a Board-provided program or by attending a full day of a board meeting, All other hours allowed by correspondence.
New Hampshire	10	30	10 hours must be earned in a live setting.
New Jersey	20	30	3 hours in pharmacy law, 1 hour in opioid drug topics, 10 hours must be earned in a live setting.

NOTE: CE Rules can change. Always check your state board for the most up-to-date information.

STATE	HOURS ALLOWED BY HOME-STUDY	TOTAL HOURS REQUIRED (NOTE: CE Rules can change. Always check your state board for the most up-to-date information.)	
New Mexico	**20**	30	10 hrs live; 2 hrs Pharmacy Law; 2 hrs Patient Safety. 2 hrs Safe Use of Opioids.
New York	**23**	45	3 hour Reducing Medication & Prescription Errors, 3 hours Pharmaceutical Compounding, 23 hours must be learned in a live setting.
North Carolina	**10**	15	5 hrs must be contact activity.
North Dakota	**15**	15	All hours allowed by correspondence.
Ohio	**30**	30	2 hours Medication Errors/Patient Safety, 2 hours Jurisprudence or Law, All hours allowed by correspondence.
Oklahoma	**15**	15	All hours allowed by correspondence.
Oregon	**30**	30	2 hours Pharmacy Law, 2 hours Patient Safety/Medication Error Prevention, 2 hours Cultural Competency, 1 hour Pain Management (through Oregon Health Authority), All hours allowed by correspondence.
Pennsylvania	**30**	30	2 hours Patient Safety, 2 hours Pain Management, 2 hours Immunizations for licensees with authorization, 2 hours Child Abuse for licensees who are mandated reporters, All hours allowed by correspondence.
Rhode Island	**10**	15	1 hour Law, 5 hours must be live
South Carolina	**9**	15	1 hour Approved Procedures for Monitoring Controlled Substances, 7.5 hours must be on drug therapy or patient management, 6 hours must be live.
South Dakota	**12**	12	All hours allowed by correspondence.
Tennessee	**15**	30	15 hrs ACPE-approved live courses.
Texas	**30**	30	1 hour Texas Pharmacy Laws/Rules, 1 TX HHSC-approved course on Human trafficking, All hours allowed by correspondence.
Utah	**18**	30	12 hrs live, 15 hrs must be in Drug Therapy or Patient Management, 1 hr Pharmacy Law or Ethics.
Vermont	**20**	30	20 hours allowed by correspondence. Professionals who prescribe or dispense controlled substances must complete 2 hrs regarding controlled substances.
Virginia	**12**	15	2 hours Medications for Opioid Use Disorder (for 2023 renewals), 3 hours must be live.
Washington	**15**	15	All hours allowed by correspondence. 3 hr Suicide Prevention and Awareness Training (one time requirement at first renewal).
West Virginia	**24**	30	2 hours Drug Diversion Training, 6 hours must be live.
Wisconsin	**30**	30	All hours allowed by correspondence.
Wyoming	**12**	12	1.5 hours Responsible prescribing of controlled substances, All hours allowed by correspondence.

NOTE: CE Rules can change. Always check your state board for the most up-to-date information.

Chapter 1: Addiction Medicine Part 2: Alcohol

2 Contact Hours

By: Katie Blair, PharmD, RPh

Author Disclosure: Katie Blair and Colibri Healthcare, LLC do not have any actual or potential conflicts of interest in relation to this lesson.

Universal Activity Number (UAN): 0607-0000-22-039-H01-P
Activity Type: Knowledge-based
Initial Release Date: October 21, 2022
Expiration Date: October 21, 2025
Target Audience: Pharmacists in a community-based setting.
To Obtain Credit: A minimum test score of 75 percent is needed to obtain a credit. Please submit your answers either by mail, fax, or online at **EliteLearning.com/Book**

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Learning objectives

After reading this monograph, pharmacists should be able to:

- Summarize the complications associated with alcohol use, including inebriation, withdrawal, and long term complications.
- Describe current best practices for the treatment of alcohol withdrawal.
- Explain the screening, diagnosis and treatment of alcohol use disorder, including pharmacological and non-pharmacological treatment options.

Introduction

Alcohol is one of the most widely used intoxicants in the world. In 2020, the National Survey on Drug Use and Health found that 50 percent of adults had used alcohol in the past month, and

22.2 percent reported drinking five or more drinks on one occasion in the past month (Substance Abuse and Mental Health Services Administration, 2021). The use of alcohol occurs on a spectrum, ranging from occasional drinking to regular, heavy use. Alcohol use disorder (AUD) is a medical condition characterized by an inability to control alcohol use despite adverse consequences (National Institute on Alcohol Abuse and Alcoholism, 2021).

Alcohol use disorder is a serious national health problem in the U.S. It is estimated that more than 14 million American adults and 414,000 adolescents (ages 12 to 17 years) had an AUD in 2019 (National Institute on Alcohol Abuse and Alcoholism, 2021). There are over 95,000 deaths every year that are directly attributed to alcohol use, and the economic cost of alcohol use is astounding: Excessive alcohol use in the U.S. is said to cost nearly $250 billion annually. The majority of these costs (77 percent) are associated with binge drinking, that is drinking four or more alcoholic beverages per occasion for women, or five or more drinks for men (Centers for Disease Control and Prevention, 2019).

In the U.S., AUD has a lifetime prevalence of approximately 29 percent. Despite the high prevalence and common complications, alcohol use disorder is undertreated. Less than 10 percent of patients with a diagnosis in the past 12 months receive any treatment, and only around 6 percent of patients receive evidence-based care (Reus et al., 2018). There is a clear need for improvement in the treatment of this common condition, and this course serves to review the recognition, diagnosis, and treatment of alcohol use disorder.

SHORT- AND LONG-TERM EFFECTS OF ALCOHOL

Inebriation

Alcohol is a central nervous system (CNS) depressant, causing decreased reaction time, motor coordination, and mental performance. After ingestion, it is swiftly absorbed into the bloodstream through the stomach and small intestine. From there, it is slowly metabolized by the liver. A healthy liver typically metabolizes one standard drink per hour, which is equivalent to 12 oz of 4 percent beer, 1.5 oz of 80-proof liquor, or 5 oz of table wine. The remaining alcohol continues to flow through the bloodstream until the liver is able to process it (UC Santa Cruz, 2019).

The amount of alcohol present in the bloodstream determines the intensity of its effect on the body. Blood alcohol concentration, or the percent of alcohol in the bloodstream, increases as more drinks are consumed. Blood alcohol levels of 0.08 percent or higher are associated with mild balance, speech, and vision impairment. This concentration marks the legal threshold of driving under the influence in most states. Between 0.1 and 0.15 percent, motor coordination and balance are significantly affected, speech may be slurred, and major loss of balance can occur. Concentrations of 0.16 to 0.3 percent indicate severe intoxication, causing symptoms such as confusion, nausea, vomiting, and needing assistance walking. Blood alcohol concentrations of 0.35 to 0.4 percent are associated with a loss of consciousness, and over 0.4 percent can cause a coma and increase the likelihood of death by respiratory failure (Stanford University, 2021; UC Santa Cruz, 2019).

A number of factors can impact a person's response to alcohol consumption. The presence of food in the stomach can slow the absorption of alcohol; blood alcohol concentrations can be up to three times higher in a person with an empty stomach when compared to someone who ate a meal before drinking. In addition, up to 50 percent of people of Asian descent are less able to metabolize alcohol because of an inactive liver enzyme (alcohol dehydrogenase) needed for metabolism, resulting in more rapid intoxication, flushing, dizziness, nausea, headache, and rapid heartbeat with alcohol use. Gender can also significantly impact the effects of alcohol.

Women have less body water than men to dilute alcohol as well as lower quantities of the liver enzymes needed to metabolize alcohol, and the effects of estrogen can slow down the rate of alcohol elimination from the body (UC Santa Cruz, 2019).

Case study 1

Jane is a 21-year-old Japanese exchange student at the local university. She is brought to the emergency department by her roommate after an evening gathering of friends at their home. Her roommate states that Jane has been in and out of consciousness, and she presents with confusion, slurred speech, poor balance, and memory loss. Her blood alcohol level is tested and found to be 0.14 percent. Jane's roommate is confused because she thought Jane had fewer than two drinks that evening. The friends had a large meal together before they started drinking, and they were playing board games when Jane started to appear very intoxicated.

Jane's roommate hasn't known Jane long, since they just moved in together the previous month, and she says she had never seen Jane drink prior to this evening. Jane's roommate is concerned that maybe Jane took other drugs or was drinking more in her room where other people wouldn't see her. Jane was given a drug screen, which came back negative for the 10 most commonly abused drugs.

Self-Assessment Quiz Question #1

Which of the following factors is most likely to influence Jane's blood alcohol concentration?

a. Eating a large meal prior to drinking.
b. Jane's age.
c. Jane's ethnicity.
d. Jane's living situation.

Withdrawal

Approximately 8 to 12 hours after consuming alcohol, the body's reaction to poisoning and withdrawal from alcohol, known as a hangover, begins. This reaction varies in severity based on the amount of alcohol consumed as well as individual factors and can include headache, nausea, vomiting, fatigue, and depression. While there are a number of home remedies thought to help prevent or relieve hangovers, limiting the consumption of alcohol is the only effective remedy. Eating a full meal before drinking alcohol and alternating alcoholic drinks with nonalcoholic drinks can limit absorption (UC Santa Cruz, 2019).

Heavy drinkers who suddenly decrease or stop consuming alcohol may experience alcohol withdrawal. Alcohol withdrawal symptoms typically peak within 24 to 72 hours of the last drink and can continue for weeks. Common symptoms include irritability, anxiety, depression, mood swings, nightmares, fatigue, and confusion. Other symptoms such as rapid heart rate, sweating, tremor, insomnia, loss of appetite, nausea and vomiting can occur. Severe withdrawal can cause agitation, seizures, hallucinations, and severe confusion (Dugdale, 2021).

Patients at risk of developing complicated alcohol withdrawal should be closely monitored. Seizures can occur within 8 to 48 hours after stopping or reducing alcohol use, with risk peaking at approximately 24 hours. An impending seizure can produce signs such as high blood pressure, increased heart rate, tremors, fever, or overactive reflexes, though seizures can occur without warning. Patients who have experienced one alcohol withdrawal seizure are at a higher risk of having another seizure or progressing to alcohol withdrawal delirium (American Society of Addiction Medicine, 2020).

An acute state of confusion with impaired cognition, known as delirium, can occur during alcohol withdrawal. It is associated with increased morbidity and mortality, longer hospital stays, and increased utilization of health services. Prevention and early recognition are especially important in delirium management. Factors known to increase the risk of delirium include cognitive, visual, or hearing impairments; immobility; dehydration; and sleep deprivation (American Society of Addiction Medicine, 2020).

Complications

The unhealthy use of alcohol can cause a number of medical and psychiatric complications, with higher use resulting in more profound effects. Health conditions associated with excessive alcohol use include (Edelman & Fiellin, 2016):

- Cirrhosis
- Hypertension
- Stroke
- Cardiomyopathy
- Hypogonadism
- Gastroesophageal reflux
- Osteoporosis
- Sexual dysfunction
- Chronic pancreatitis
- Brain atrophy
- Seizures
- Arrhythmias

Malnourishment is a significant issue associated with chronic alcohol use, resulting in deficiencies in vitamins A, B, and C; magnesium; folic acid; carnitine; selenium; zinc; antioxidants; and essential fatty acids. Moderate alcohol use has been associated with a higher risk of certain types of cancer, including those of the esophagus, larynx, mouth, liver, colon, and breast. Alcohol use is also associated with a higher risk of developing diabetes and acquiring HIV, and it complicates disease state management because of the effects on medication adherence (Edelman & Fiellin, 2016).

Alcohol interacts with a number of prescription medications, including opioids, anticoagulants, anxiolytics, sedatives, and anticonvulsants. Elderly patients and patients with polypharmacy are at a particularly high risk of experiencing adverse effects from medication– alcohol interactions (Edelman & Fiellin, 2016).

Unhealthy alcohol use can also cause a number of social and mental health consequences. Depression is highly correlated with alcohol use disorders. Accidents such as falls, burns, and firearm injuries are more common among heavy drinkers, as is unsafe sex, intimate partner violence, homicide, and suicide (Edelman & Fiellin, 2016).

Alcoholic Liver Disease

Alcoholic liver disease covers a spectrum of liver disorders, beginning with steatosis, or fat accumulation in the liver; progressing to hepatitis, or inflammation of the liver cells; and ending with cirrhosis, or irreversible damage to the liver (Patel & Mueller, 2022). Signs and symptoms of liver disease include (American Society of Addiction Medicine, 2020):

- Edema
- Jaundice
- Dark-colored urine
- Itchy skin
- Pale, bloody, or tar-colored stool
- Chronic fatigue
- Confusion
- Nausea or vomiting

Heavy alcohol users can present with alcoholic liver disease between 40 and 50 years of age. Liver disease can be progressive, and between 10 to 20 percent of patients with alcoholic hepatitis progress to cirrhosis each year. The management of alcoholic liver disease can vary depending on the extent of disease. Alcohol cessation is highly recommended for patients with alcoholic liver dis-

ease. Patients may also require laboratory or diagnostic studies, nutritional support, regular screening for liver cancer, and treatment of complications or coexisting infections. A number of complications can arise from alcoholic liver disease, including variceal bleeding, ascites, peritonitis, renal failure, and encephalopathy (Patel & Mueller, 2022).

Pancreatitis

Long-term alcohol use causes between 17 and 25 percent of cases of acute pancreatitis worldwide. This inflammatory condition affecting the pancreas causes acute abdominal pain, nausea, vomiting, anorexia, and high lipase levels. Severe cases can present with sepsis, acute respiratory distress syndrome, or shock. Acute pancreatitis often requires hospitalization and management with IV fluids, electrolyte replacement, analgesics, and antiemetics (Klochkov et al., 2022).

Between 40 to 70 percent of cases of chronic pancreatitis are caused by chronic alcohol use. Patients who experience recurrent cases of acute pancreatitis are significantly more likely to progress to chronic pancreatitis, in which the inflammation of the pancreas worsens over time, leads to permanent damage, and increases the patient's risk of pancreatic cancer. Chronic pancreatitis can cause the pancreas to work less efficiently, leading to poor fat absorption, steatorrhea, and diabetes. Complications of chronic pancreatitis can be local effects on the pancreas such as necrosis and pseudocysts, as well as systemic complications such as sepsis, pleural effusion, bacteremia, and shock (Klochkov et al., 2022).

Self-Assessment Quiz Question #2

A number of complications can arise from alcoholic liver disease, including all of the following EXCEPT:

a. Variceal bleeding.
b. Ascites.
c. Heart failure.
d. Encephalopathy.

Screening/assessment

Alcohol use should be assessed in all patients routinely, especially those presenting with symptoms of alcohol abuse or any of the above comorbidities. When assessing a patient with suspected unhealthy alcohol use, ask about the following (Tetrault & O'Connor, 2021):

- Past and current use of alcohol and any prior treatment
- Family history of issues related to alcohol and treatment
- Details on the quantity and frequency of use
- Symptoms and behaviors associated with the following:
  - Alcohol use disorder criteria
  - Medical comorbidities
  - Behavioral complications
  - Psychiatric complications
  - Use of other substances

A physical examination should be conducted to assess for features of unhealthy alcohol use. Patients may come to appointments smelling of alcohol or actively under the influence of alcohol, as noted by slurred speech, incoordination, dehydration, flushing, confusion, aggression, nausea, or vomiting. Signs of alcohol withdrawal include tremor, agitation, or clouded senses. Patients with advanced liver disease may present with hepatic enlargement, splenic enlargement, or yellowing skin or eyes (Tetrault & O'Connor, 2021).

Laboratory evaluation can test for abnormalities related to heavy, repeated alcohol use or liver disease. Assessment of liver enzymes, including aspartate aminotransferase (AST), alanine aminotransferase (ALT), bilirubin, and albumin, can indicate liver damage. Hemoglobin and complete blood count can determine the presence of anemia or blood dyscrasias associated with heavy alcohol use or liver disease (Tetrault & O'Connor, 2021).

Patients with suspected alcohol withdrawal should have a similar assessment, with a focus on assessing recent or current withdrawal symptoms, history of prior withdrawal, and urine drug testing to rule out other substance use. The Clinical Institutes Withdrawal Assessment Scale for Alcohol (CIWA-Ar), developed in the 1980s, is a standardized evaluation tool that can be used to assess the severity of withdrawal symptoms. It can help clinicians determine the need for medically supervised withdrawal and is commonly used to guide the treatment of alcohol withdrawal symptoms. The severity of alcohol withdrawal symptoms assessed include the following (American Society of Addiction Medicine, 2020):

- Nausea and vomiting
- Headache
- Paroxysmal sweats
- Auditory disturbances
- Anxiety
- Visual disturbances
- Agitation
- Tactile disturbances
- Tremor
- Orientation and clouded senses

Patients are scored based on symptom severity and classified as having mild withdrawal (fewer than 10 points), moderate withdrawal (10 to 18 points), and severe withdrawal (more than 19 points) (American Society of Addiction Medicine, 2020).

Diagnosis

The *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.; DSM-5) created a new diagnosis of AUD that replaced alcohol abuse and alcohol dependence, which were described in the DSM-IV. AUD is diagnosed when patients experience a problematic pattern of alcohol use that leads to clinically significant distress or impairment, including at least two of the following characteristics within a 12-month period (American Psychiatric Association, 2013):

- Patients experience a persistent desire or unsuccessful efforts to cut down or control use.
- Alcohol is taken in larger amounts or for longer durations than intended.
- A significant amount of time is spent on activities related to obtaining, using, or recovering from alcohol.
- Patients have cravings or strong urges to use alcohol.
- Recurrent alcohol use results in a failure to fulfill significant obligations at school, work, or home.
- There is continued use of alcohol despite recurrent or persistent interpersonal or social issues caused or exacerbated by the effects of alcohol.
- Important recreational, social, or occupational activities are reduced or given up because of alcohol use.
- There is recurring alcohol use in physically hazardous situations.
- There is continued alcohol use despite knowing of persistent physical or psychological problems caused or exacerbated by alcohol.
- Tolerance develops, as defined by either a need for significantly increased amounts of alcohol to achieve intoxication or desired effects, or a decreased effect with continued use of the same amount of alcohol.
- Withdrawal occurs, as manifested by either classic withdrawal symptoms or the need to use alcohol or other depressants to relieve or avoid withdrawal symptoms.

Alcohol withdrawal can be life threatening and may require intensive or inpatient care. Diagnostic criteria for alcohol withdrawal include the following (American Psychiatric Association, 2013):

- Reduction in or cessation of alcohol use that was prolonged and heavy

- Two or more of the following symptoms that develop within a few hours to a few days after alcohol reduction or cessation:
  - Increased hand tremor
  - Nausea or vomiting
  - Autonomic hyperactivity
  - Insomnia
  - Anxiety
  - Generalized tonic-clonic seizures
  - Transient hallucinations that are visual, auditory, or tactile
  - Psychomotor agitation
- Significant distress or impairment in important areas of social or occupational functioning caused by the above symptoms
- Symptoms not attributable to another medical condition, mental disorder, intoxication, or withdrawal from another substance

Risk factors for alcohol use disorder

Risk factors for alcohol use disorder in a person's lifetime include the following (Tetrault & O'Connor, 2021):

- Age 18 to 29
- Male gender
- White and Native American ethnicities
- Significant disability
- Mood disorders, such as major depression or bipolar disorder
- Other substance use disorders
- Personality disorders such as antisocial or borderline personality disorder

TREATMENT OF WITHDRAWAL

Alcohol withdrawal treatment is typically dependent on the severity of withdrawal and should be tailored to the patient's specific needs. Patients experiencing mild alcohol withdrawal, or those with a CIWA-Ar score of less than 10, can be treated in the outpatient setting with supportive care, or with supportive care and pharmacotherapy. Appropriate medications include carbamazepine or gabapentin. Benzodiazepines may be considered if the patient is at risk of developing new or worsening symptoms while away from the treatment center (American Society of Addiction Medicine, 2020).

Patients experiencing moderate alcohol withdrawal, or those with a CIWA-Ar score between 10 and 18, can be treated in the outpatient setting and should receive pharmacotherapy.

Benzodiazepines are considered first-line treatment in these patients, though carbamazepine, gabapentin, or phenobarbital can be used as alternatives for patients with contraindications to benzodiazepines. If needed, benzodiazepines can be given with adjunctive carbamazepine, gabapentin, or valproic acid (American Society of Addiction Medicine, 2020).

Severe, uncomplicated cases of alcohol withdrawal, or those with a CIWA-Ar score greater than 19, should be treated with pharmacotherapy. These patients can be treated in a higher- level ambulatory setting, such as a treatment program, that has regular monitoring available in the event of escalation, or in higher levels of care if necessary. Benzodiazepines should be used as firs- line therapy for these patients. Phenobarbital, carbamazepine or gabapentin may be used as an alternative. Adjunctive therapy with carbamazepine, gabapentin, or valproic acid is also appropriate (American Society of Addiction Medicine, 2020).

For patients who have uncontrolled symptoms in the ambulatory setting, medication adherence should first be verified. If the patient is taking medication as prescribed, providers should consider increasing the dose. If providers are concerned about inadequate monitoring or oversedation, they can consider switching medications, adding an adjunctive medication, or reassessing the level of care (American Society of Addiction Medicine, 2020).

Providers should consider the patient's risk for severe or complicated withdrawal when determining a treatment plan, as these patients may require closer management or inpatient hospitalization. Risk factors for severe or complicated withdrawal include (American Society of Addiction Medicine, 2020):

- Prior history of alcohol withdrawal seizures or delirium
- Medical or surgical comorbidities, especially traumatic brain injury
- Numerous prior episodes of withdrawal
- Age over 65 years
- Long history of regular, heavy alcohol use
- Seizures or significant autonomic hyperactivity during the current withdrawal episode
- Dependence on medications that enhance gamma-aminobutyric acid (GABA) such as benzodiazepines or barbiturates
- Use of other addictive substances in conjunction with alcohol
- Signs and symptoms of withdrawal in conjunction with a positive blood alcohol concentration
- Moderate to severe co-occurring psychiatric disorder

The risk of severe or complicated withdrawal is higher in patients with multiple risk factors. Providers can generally use CIWA-Ar scores to assess for the risk of severe or complicated withdrawal. Patients with a CIWA-Ar score of 10 or greater or those experiencing at least moderate alcohol withdrawal on presentation are at a higher risk of severe or complicated withdrawal. Other tools such as The ASAM Criteria Risk Assessment Matrix, the Prediction of Alcohol Withdrawal Severity Scale (PAWSS), or the Luebeck Alcohol-Withdrawal Risk Scale (LARS) can help assess a patient's risk of severe or complicated alcohol withdrawal as well as potential complications of withdrawal (American Society of Addiction Medicine, 2020).

Supportive care and nutrition

Once comorbidities and alternative substance withdrawal have been excluded, the treatment of alcohol withdrawal is focused on alleviating symptoms and correcting metabolic abnormalities. Supportive care, such as IV fluids, nutritional supplementation, and frequent clinical reassessment, is a core component of withdrawal treatment. Patients should be educated on expectations over the course of withdrawal, including common symptoms and how they will be treated. In the outpatient setting, education should be provided about monitoring for more severe withdrawal. Patients should also know that safe withdrawal treatment may require transfer to a higher level of care if the ambulatory setting is not safe or effective for the patient (American Society of Addiction Medicine, 2020).

Patients experiencing withdrawal should be placed in a low-stimulation, reassuring environment that is calm and quiet. Dehydrated patients should receive IV fluids until they are euvolemic. Thiamine and glucose should be given to treat or prevent Wernicke's encephalopathy, an acute neurological condition caused by thiamine deficiency and characterized by ataxia, ocular abnormalities, and confusion. Multivitamins with folate should be initiated, and electrolyte disturbances such as magnesium, potassium, glucose, and phosphate should be corrected. Depending on the severity, nutritional supplementation may need to be intravenous for at least the first day or two for aspiration prevention, as well as impaired gastrointestinal absorption in patients who chronically abuse alcohol (American Society of Addiction Medicine, 2020; Hoffman & Weinhouse, 2021).

Self-Assessment Quiz Question #3

Which of the following should be given to patients withdrawing from alcohol to treat or prevent Wernicke's encephalopathy?

a. Lorazepam.
b. Thiamine.
c. Folate.
d. Magnesium.

Medications

Benzodiazepines

Benzodiazepines are a mainstay of alcohol withdrawal treatment. They are useful for preventing withdrawal symptoms from becoming more severe, preventing seizures and delirium, and treating psychomotor agitation. Longer-acting agents such as diazepam and chlordiazepoxide are preferable, as their longer action and less frequent need for redosing reduces the chance of seizures or recurrent withdrawal. Patients with severe liver disease are at a higher risk of benzodiazepine accumulation because of reduced metabolism. These patients should be treated with lorazepam because of its shorter half-life, or oxazepam because of the lack of active metabolites, which prevents prolonged oversedation. IV administration is often required for patients in severe withdrawal, who cannot tolerate oral administration, or who are unconscious. Doses vary greatly and should be patient-specific. Patients should be monitored for signs of oversedation and respiratory depression (American Society of Addiction Medicine, 2020).

Benzodiazepines are Schedule IV controlled substances that carry a risk of misuse or diversion. This risk can be mitigated by ordering the minimum amount needed to achieve stability and hold the patient over until their next appointment. Benzodiazepines should be discontinued once alcohol withdrawal treatment is complete. Patients and caregivers should be educated on the risks of combining alcohol with benzodiazepines, the risks of driving or using heavy machinery while taking benzodiazepines, and the interaction between benzodiazepines and other CNS depressants. Patients at a high risk of benzodiazepine abuse or diversion can be prescribed alternative medications or referred for inpatient management, depending on the severity of their case (American Society of Addiction Medicine, 2020).

For patients in hospitals or treatment centers, the preferred dosing method is symptom- triggered dosing administered by trained staff. In this method, patients are given medication only when experiencing significant symptoms of withdrawal, as noted by a symptom severity scale such as the CIWA-Ar, and doses are based on symptom severity. Withdrawal symptoms can be monitored using the CIWA-Ar scale every 1 to 4 hours initially, and can be extended to every 4 to 8 hours once the patient has been stabilized. Symptom-triggered treatment allows for individualized dosing based on real-time severity of symptoms, reducing the risk of over- or undertreatment. Patients may require large doses of benzodiazepines initially, with reduced doses over time. Studies have shown that symptom-triggered dosing reduces treatment duration and length of inpatient stay compared to fixed-dose schedules (American Society of Addiction Medicine, 2020).

Fixed dosing is commonly used in ambulatory settings. This method allows for set amounts of benzodiazepines to be administered at regular intervals, and the dose and/or frequency is gradually tapered according to a set schedule. Fixed dosing is easier for patients to self- administer, though it is also easier to over- or underestimate the dose needed, leading to oversedation or suboptimal symptom control. Patients on fixed-dose schedules still require frequent monitoring and should be reassessed regularly to determine if dosage changes are necessary (American Society of Addiction Medicine, 2020).

Front loading with benzodiazepines is recommended for patients in severe alcohol withdrawal (CIWA-Ar scores greater than 19). Front loading involves giving a moderate or high dose of a long-acting benzodiazepine to ensure withdrawal symptoms are rapidly controlled. Studies have shown that front loading reduces the risk of withdrawal seizures, shortens treatment duration, and reduces the duration of delirium. Patients receiving front-loaded doses should be closely monitored for respiratory depression and signs of oversedation, as these side effects occur more frequently with this type of dosing regimen (American Society of Addiction Medicine, 2020).

Phenobarbital

Patients who have a contraindication to benzodiazepine use and are experiencing moderate to severe withdrawal, or are at risk of developing severe or complicated withdrawal, may be treated with phenobarbital. Phenobarbital was the first medication used to successfully treat alcohol withdrawal, and its use for this indication began in the 1920s. Because of the risk of toxicity when used in high doses or in combination with alcohol, phenobarbital is best administered by providers experienced with its use who are able to closely monitor the patient. Phenobarbital has a narrow therapeutic index, which can create challenges in dosing it appropriately. It can cause respiratory depression and oversedation when used at high doses.

Its dosing can also be complicated by its long half-life of up to 7 days, and its metabolism by the liver, which can be impaired in patients who chronically abuse alcohol. Phenobarbital is associated with a number of other side effects, including hypotension, pulmonary edema, bradycardia, bradypnea, hypothermia, acute renal failure, and Steven–Johnson syndrome.

When the effective use of benzodiazepines for the treatment of alcohol withdrawal was initiated in the 1960s, the use of phenobarbital fell out of favor (American Society of Addiction Medicine, 2020).

Anticonvulsants

Anticonvulsants such as carbamazepine, gabapentin, or valproic acid can be used as adjunct therapy with benzodiazepines to improve control of withdrawal. Carbamazepine or gabapentin can also be used as monotherapy if benzodiazepines are contraindicated. Valproic acid does not have sufficient evidence to support its use as monotherapy. There is not enough evidence to support the use of anticonvulsants over benzodiazepines, particularly in patients at high risk of severe withdrawal, delirium, or seizures. Gabapentin may be an effective adjunct bridge therapy between the treatment of alcohol withdrawal and long-term management of AUD. Gabapentin has been associated with increased abstinence rates and fewer heavy drinking days compared with placebo in the management of AUD. Valproic acid should be avoided in patients with liver disease as well as in women of childbearing potential (American Society of Addiction Medicine, 2020).

Alpha-2 Adrenergic Agonists and Beta Blockers

Alpha-2 adrenergic agonists such as clonidine can be useful as adjunct therapy in patients with anxiety or autonomic hyperactivity that is not controlled by benzodiazepines. Beta-adrenergic antagonists, also known as beta blockers, can also be used to treat persistent hypertension or tachycardia. Patients with alcohol withdrawal who experience cardiac symptoms such as tachycardia or hypertension that are not alleviated by correcting electrolyte imbalances or dehydration, or through the use of benzodiazepines, can benefit from the use of alpha2 agonists or beta blockers. These agents should not be used as monotherapy in withdrawal treatment, as they can reduce the symptoms of withdrawal with-

out treating the underlying pathophysiology, thus increasing the risk of developing more severe withdrawal. They are also not effective when used alone for the treatment of withdrawal seizures or delirium (American Society of Addiction Medicine, 2020).

Managing complicated alcohol withdrawal

Seizures

Patients who have experienced a seizure during their current withdrawal episode should be admitted to a setting that has close monitoring available for frequent reassessment every 1 to 2 hours for the first 6 to 24 hours. Electrolyte levels should be monitored to determine the need for IV fluids, and patients should be closely monitored for delirium. Safety measures such as fall precautions, frequent check-ins, and assistance with activities of daily living can also be implemented to ensure patient safety (American Society of Addiction Medicine, 2020).

Treatment should be initiated immediately with a medication that is effective at seizure prevention. Parenteral administration through the intravenous route, or intramuscular if intravenous is unavailable, is preferred. Fast-acting benzodiazepines such as lorazepam or diazepam are first-line treatments. When compared to placebo in a double-blind clinical trial of emergency department patients, intravenous lorazepam significantly reduced the risk of recurrent seizures. Phenobarbital can be used in patients who are unable to use benzodiazepines, but parenteral phenobarbital should only be given in intensive or critical care units because of the risk of oversedation and respiratory depression (American Society of Addiction Medicine, 2020).

Delirium

Patients experiencing delirium because of alcohol withdrawal often need to be admitted to intensive or critical care units to receive close nursing observation and supportive care such as regular vital sign monitoring and frequent reassessment. Intravenous access should be established quickly to allow for rapid administration of fluids and medication. CIWA-Ar scores are not recommended to monitor withdrawal symptoms in patients with delirium, since they rely on patient-reported symptoms. Instead, structured assessment scales such as the Confusion Assessment Method for ICU Patients (CAM-ICU) should be utilized. One-on-one observation should be initiated in patients who are agitated and disoriented. Restraints should be avoided unless necessary to prevent injury or comply with state laws (American Society of Addiction Medicine, 2020).

Benzodiazepines are recommended as first-line treatment for alcohol withdrawal delirium. Administration of intravenous benzodiazepines to achieve a light sedation where the patient is awake but tends to fall asleep unless stimulated is recommended to help control agitation and maintain patient safety. High doses of benzodiazepines may be required to control agitation in patients with delirium as compared to other populations. Providers should not hesitate to use large doses but should monitor for oversedation and respiratory depression. Intermittent use of long- and short-acting benzodiazepines is recommended. Continuous IV infusion has not shown superiority over intermittent dosing and is typically more expensive. Patients should be monitored for signs of metabolic acidosis and hyponatremia (American Society of Addiction Medicine, 2020).

Phenobarbital can be used as an alternative to benzodiazepines but is not preferred because of the need for close monitoring. Adjunctive antipsychotic agents can be used if delirium and hallucinations are not controlled by benzodiazepines. Antipsychotics should not be used as monotherapy because of the risk of lowering the seizure threshold and increasing the risk of withdrawal seizures. Second-generation antipsychotics such as risperidone and quetiapine are preferred because they have less of an effect on the seizure threshold when compared to first-generation agents. Haloperidol has also been successfully used in the management of delirium (American Society of Addiction Medicine, 2020).

Case study 2

John is a 48-year-old combat veteran who is admitted to the hospital after a fall. He is treated for a broken leg in the emergency department, but his wife notes that her husband is a heavy drinker and that his last drink was over 36 hours ago. She says that John has withdrawn from alcohol several times in the past and experienced seizures and delirium on several occasions. John is very agitated and anxious, has a terrible headache and a tremor, and is sweating and vomiting. He also appears to be hallucinating—he is experiencing auditory and visual disturbances. The nurse administers a CIWA-Ar scale, and John scores a 23.

Self-Assessment Quiz Question #4

Which of the following is NOT a risk factor for severe or complicated withdrawal that should be considered when developing a treatment plan for John?

a. Age of 48 years.
b. Long history of regular, heavy alcohol use.
c. Numerous prior episodes of withdrawal.
d. Prior history of alcohol withdrawal seizures or delirium.

Self-Assessment Quiz Question #5

John begins to experience delirium symptoms while he is withdrawing from alcohol in the hospital and is admitted to the ICU. Which of the following is recommended as first-line therapy for the treatment of alcohol withdrawal delirium?

a. Carbamazepine
b. Phenobarbital
c. Benzodiazepines
d. Valproic acid

LONG-TERM MANAGEMENT OF ALCOHOL USE DISORDER

Treatment of alcohol use disorder should be a collaborative process between the patient and their provider. Including the patient's family or support system can also be helpful if the patient gives their permission to include them. Treatment goals should be established prior to initiating therapy, and can range from reducing alcohol use, to eliminating drinking in high-risk situations, to complete abstinence. Defining goals at the beginning of therapy is associated with improved treatment outcomes (Reus et al., 2018).

When possible, treatment for alcohol use disorder should be started concurrently with withdrawal treatment if cognitive status allows (American Society of Addiction Medicine, 2020). Patient preference plays a significant role in choosing therapy. Some patients prefer nonpharmacological therapy, while others prefer the use of medications. Offering all available options to patients can help ensure treatment plans are developed based on patient preferences and potentially improve adherence (Reus et al., 2018).

Pharmacotherapy for patients with moderate to severe alcohol use disorder who have a goal of abstinence or reduced consumption of alcohol and want to initiate medication treatment should begin with naltrexone or acamprosate. These medications can also be considered in patients with mild alcohol use disorder if the patient prefers medication therapy (Reus et al., 2018).

Disulfiram can be offered to motivated patients with alcohol use disorder who have a clear goal of achieving abstinence. It is contraindicated in patients who are active alcohol users, so patients must understand the risks of consuming alcohol while taking disulfiram. Topiramate or gabapentin can also be offered as second-line agents for patients who wish to reduce or eliminate alcohol consumption, have not responded to naltrexone and acamprosate, or prefer to use these agents (Reus et al., 2018).

Psychosocial interventions are recommended for all patients with alcohol use disorder. These can include alcohol counseling, motivational interviewing, couples or family therapy, social services, or participation in a mutual help group. Psychosocial interventions can be effective to treat alcohol use disorder, but when used as monotherapy, as many as 70 percent of patients return to heavy drinking. Selection of psychosocial interventions should be made on a patient-specific basis (Hoffman & Weinhouse, 2021).

Medications

Naltrexone

Naltrexone is an opioid receptor antagonist frequently used to treat opioid and alcohol abuse. It works by blocking mu opioid receptors and preventing binding, thus reducing the pleasurable effects of opioids. It reduces alcohol consumption by modulation of opioid systems, which reduces the reinforcing effects of alcohol. Naltrexone use has been associated with a reduction in the number of drinking days and reduced likelihood of returning to drinking, and it is also thought to decrease cravings. It is the drug of choice in patients with concomitant opioid use disorder, since it is approved to treat both conditions. Patients should not be actively using opioids when naltrexone is started, since it can inhibit the effects of opioids and lead to noncompliance (Kim et al., 2018; Reus et al., 2018).

Naltrexone is available in oral tablets and an intramuscular formulation (Vivitrol), which is administered every 4 weeks. The choice between dosage forms is based on patient preference; some patients show better adherence to daily dosages, while others are more willing to attend monthly visits for injections. Typically, it is preferable to start intramuscular naltrexone to ensure adherence, though starting with oral tablets may be more appropriate in some cases, to allow monitoring of liver enzymes and side effects before committing to a longer course of treatment (Kim et al., 2018; Reus et al., 2018).

Intramuscular injections of naltrexone are given at a dose of 380 mg into the gluteal muscle every 4 weeks. Adverse reactions associated with intramuscular naltrexone include nausea, vomiting, diarrhea, fatigue, decreased appetite, and injection site reactions ranging from injection site pain to cellulitis and abscesses. Patients should be encouraged to report injection site reactions to their provider to prevent them from developing into more serious skin conditions (Kim et al., 2018; Reus et al., 2018).

Oral naltrexone is typically started at 50 mg per day, though some studies have used up to 100 mg per day or started with 25 mg per day for a few days and increased to 50 mg once the lower dose is tolerated well. Side effects with oral naltrexone are similar to those with intramuscular naltrexone and include headache, dizziness, nausea, vomiting, diarrhea, and abdominal pain. These tend to subside with regular use. Gastrointestinal side effects tend to be more common in women than in men (Kim et al., 2018; Reus et al., 2018).

Liver enzymes should be monitored within several weeks of starting either oral or injectable naltrexone, and then should be monitored every 6 months during continued treatment.

Healthcare consideration: Patients with hepatic failure or acute hepatitis should avoid using naltrexone. Naltrexone is not recommended for use in patients taking opioids, since naltrexone will decrease the effectiveness of opioids. Patients should be abstinent from opioids for 7 to 14 days prior to starting naltrexone, depending on the half-life of the opioid consumed (Kim et al., 2018; Reus et al., 2018).

Acamprosate

Acamprosate may be prescribed to help patients recovering from alcohol abuse or dependence to help decrease alcohol cravings and relieve emotional discomfort. Acamprosate's action in alcohol use disorder is through modulating excitatory glutamate neurotransmission and enhancing GABA, which may help reduce alcohol cravings. It has been shown to significantly reduce the risk of returning to alcohol use after achieving abstinence and reducing the number of drinking days. It is an effective first-line alternative to naltrexone and is often chosen for patients taking opioids and those with severe liver disease. It is also a useful second-line treatment in patients who do not experience an adequate response to naltrexone (Kim et al., 2018; Reus et al., 2018).

Dosing for acamprosate is 666-mg tablets three times daily. Patients with moderate renal dysfunction, shown by a creatinine clearance of 30 to 50 mL/min, are recommended to begin at 333 mg three times daily. Lower dosing can also be considered for patients with a body weight less than 60 kg. Acamprosate is generally well tolerated. Common side effects include nausea and diarrhea and, although rare, depression and suicidality. Renal function should be monitored. Acamprosate is contraindicated in those with creatinine clearance less than 30 mL/min. There are no known drug interactions. Health care providers should counsel patients on the importance of adherence to acamprosate to ensure its effectiveness (Kim et al., 2018; Reus et al., 2018).

Healthcare consideration: Choosing between naltrexone and acamprosate A number of factors can be considered when deciding between initiating naltrexone and acamprosate in a patient with alcohol use disorder. These include available formulations, ease of administration, side effects, and presence of renal or hepatic disease. A large meta-analysis did not show a statistically significant difference between acamprosate and naltrexone in the percent of patients with a return to drinking, percent of patients with a return to heavy drinking, or the number of drinking days. Therefore, naltrexone or acamprosate can be seen as an appropriate initial treatment for AUD, and patient-specific factors should be utilized to determine the best choice for a given patient (Reus et al., 2018).

Disulfiram

Disulfiram is prescribed to help dissuade patients from drinking. Disulfiram works by inhibiting aldehyde dehydrogenase, the enzyme involved in metabolism of the primary metabolite of alcohol, acetaldehyde. If alcohol is consumed in the presence of disulfiram, acetaldehyde levels increase to toxic levels, creating very unpleasant side effects that include nausea, vomiting, flushing, headache, dyspnea, palpitations, lowered blood pressure, and sympathetic overactivity. Symptoms typically begin within 10 minutes of consuming alcohol, and the severity of the reaction is typically related to the amount of alcohol ingested. Symptoms can last for several hours or up to a day. Some patients develop more severe reactions such as chest pain, seizures, confusion, headache, or severe vomiting. These require further evaluation to rule out alternative conditions such as myocardial infarction (Kim et al., 2018; Reus et al., 2018).

Disulfiram is typically given in doses of 125 to 500 mg per day. Disulfiram should not be administered to patients who are currently drinking or intoxicated with alcohol. Patients must be clearly informed about the effects of the drug and give permission for its use. This treatment's effectiveness depends on the patient's cooperation. Patients should be educated on hidden forms of alcohol, such as that found in mouthwash, and that the medication can continue to exert its effects for up to 14 days after discontinuation. Adherence can be a significant issue with disulfiram use. Enlisting the help of a family member, roommate, or other support person can help keep the patient accountable (Kim et al., 2018; Reus et al., 2018).

Disulfiram is often reserved for second-line therapy in patients with alcohol use disorder. Naltrexone and acamprosate appear to have more evidence of benefits with their use, and disulfiram has a number of physiological consequences if alcohol relapse occurs. However, some patients who have a clear goal of abstinence prefer the accountability that disulfiram requires. Studies have not shown robust evidence on the benefits of disulfiram, but it appears to have a clear role in motivated patients (Reus et al., 2018).

Disulfiram is contraindicated in patients with psychosis, clinically significant coronary artery disease, and known hypersensitivities to the medication. When alcohol is avoided, disulfiram is generally well-tolerated, but side effects may include drowsiness, metallic taste, and headache. Serious side effects are rare but can include psychosis and hepatitis. Patients should have a hepatic panel drawn a few weeks after initiating treatment and repeat it every 6 months with continued treatment. Patients with seizure disorders should avoid disulfiram because of the potential for seizures when alcohol is consumed while taking disulfiram (Kim et al., 2018; Reus et al., 2018).

Drug interactions with disulfiram include the following (Kim et al., 2018; Stahl, 2020):

- Isoniazid: Can increase serum concentrations of isoniazid. Avoid concurrent use.
- Metronidazole: May cause psychotic reaction because of the increased effects of both disulfiram and metronidazole. Avoid concurrent use.
- Phenytoin: May increase the toxic effect of phenytoin. Phenytoin levels must be carefully monitored, and adjust the dose as needed.
- Warfarin: Disulfiram can increase the concentration of warfarin. Therapy adjustments may be required.

An important counseling point for disulfiram is for the patient to avoid any type of alcohol- containing product, even mouthwashes and cough syrups. These products may cause adverse reactions if taken while using disulfiram. Patients should also be counseled that if they do drink alcohol, fatal hypotension can occur. Reactions with alcohol ingestion may occur up to 2 weeks after disulfiram is stopped (Kim et al., 2018; Reus et al., 2018).

Healthcare consideration: Patients should be educated on the importance of reading labels and looking for small amounts of alcohol that can be hidden in various products. Mouthwash, liquid medications, and vanilla extract are examples of daily items that contain alcohol and may cause a reaction when used with disulfiram (Holt, 2021).

Topiramate (Topamax)

Topiramate is an anticonvulsant that affects voltage-dependent sodium channels, GABA transmission, and glutamate receptors. It has been found to reduce alcohol use in patients with AUD and is the preferred second-line option in patients with seizure disorders. Some research has shown that topiramate has mild to moderate effectiveness in reducing the percent of drinking days, reducing heavy drinking days, increasing abstinence, reducing cravings, and improving quality of life, but results have not been consistent in displaying these outcomes (Kim et al., 2018; Reus et al., 2018).

Topiramate is initiated at 25 mg daily and can be titrated up slowly over 8 weeks to a maximum dose of 300 mg per day. Titration helps to minimize the risk of adverse effects. Adverse effects associated with topiramate include cognitive impairment, sedation, weight loss, gastrointestinal side effects, headache, fatigue, dizziness, depression, and paresthesias. Since weight loss occurs in 4 to 21 percent of patients, topiramate may be preferrable in patients who are obese. Some patients find the cognitive impairment associated with topiramate to be intolerable, as it affects word finding abilities and can impact psychosocial interactions. Rare but serious side effects include nephrolithiasis, acute angle-closure glaucoma, and metabolic acidosis. It may be beneficial to monitor renal function and cognitive status prior to initiation (Holt, 2021; Kim et al., 2018; Reus et al., 2018).

Gabapentin (Neurontin)

Patients who previously failed first-line treatments can consider gabapentin for alcohol use disorder. Gabapentin is an anticonvulsant that is structurally similar to GABA and may modulate excitatory neurotransmitters in the brain. It can be used off-label for AUD. Clinical trials showed that doses of 900 to 1,800 mg per day have shown efficacy in reducing the percentage of heavy drinking days; increasing abstinence rates; reducing drinking frequency and quantity; and improving mood, cravings, and sleep. Common side effects associated with gabapentin include dizziness, drowsiness, and fatigue. Gabapentin is primarily eliminated through the kidneys, and patients with renal impairment require dosage adjustments. There have been reports of addictive potential with gabapentin, so providers should be alert to potential misuse (Reus et al., 2018; U.S. Department of Veterans Affairs, 2021).

Psychosocial therapy

Along with any of these medications, one or more psychosocial interventions are recommended, including cognitive behavioral therapy, behavioral couples therapy, community reinforcement or group therapy, motivational enhancement therapy, and 12-step programs.

While the quality of evidence supporting these interventions is low, they can modestly improve adherence, reduce alcohol consumption, and assist in the recovery of patients with alcohol use disorder, particularly when used in combination with one another or with pharmacological therapy. Psychosocial therapy may be particularly beneficial in patients with co-occurring mental health conditions such as anxiety or depression (U.S. Department of Veterans Affairs, 2021).

Cognitive behavioral therapy (CBT) helps patients adjust their behavior and thinking related to alcohol use and encourages patients to change other areas of life that are related to their alcohol use. Patients are taught to track activities and thinking in order to identify the consequences, such as alcohol use episodes and cravings. Then techniques are taught to help the patient change behaviors and thoughts that contribute to alcohol use in order to improve interpersonal functioning, mood, coping skills, and social support. Treatment plans include structured practice outside of therapy sessions, such as self-monitoring, scheduled activities, thought recording, and interpersonal skill practice. Cognitive behavioral therapy has been shown to be effective in patients with alcohol use disorders compared to minimal psychosocial interventions (U.S. Department of Veterans Affairs, 2021).

The community reinforcement approach is a type of cognitive behavioral therapy that focuses on environmental factors that influence the patient's behaviors. Environmental factors can be very influential on a patient's addictive behavior, so this approach uses social, recreational, family, and occupational events to support the patient in changing their behavior. This helps the patient develop healthy behaviors that allow a sober lifestyle to become more rewarding than one that involves alcohol use. Some forms of the community reinforcement approach provide incentives for positive behaviors, such as taking medication, attending treatment sessions, or abstinence (U.S. Department of Veterans Affairs, 2021).

Behavioral couples therapy is useful for patients in relationships and focuses on reducing alcohol use and improving relationship satisfaction for both the patient and their partner.

Shared activities and behavioral assignments are given to help increase positive feelings and communication between partners.

Behavioral couples therapy has been shown to improve marital satisfaction, and improving relationship functioning is conducive to sobriety—therefore, patients with motivated partners can benefit from this intervention (U.S. Department of Veterans Affairs, 2021).

Motivational enhancement therapy is a less intensive psychosocial intervention that utilizes motivational interviewing to elicit patient reactions to feedback, help patients commit to change, and encourage collaboration on a plan to change their behavior. It helps improve the patient's awareness of their own ambivalence about changing their behavior and enhances their self-efficacy. Patients are encouraged to involve a significant other in at least one session in order to improve outcomes (U.S. Department of Veterans Affairs, 2021).

Twelve-step facilitation therapy is utilized to help the patient become more actively involved in 12-step programs. It involves 12 sessions of individual therapy that encourage the use of and help the patient understand the steps of the 12-step program. Sessions are structured and are spent reviewing events of the past week related to recovery, introducing material related to the 12 steps, and creating a homework assignment and developing a plan for the next week's recovery-related activities. Twelve-step facilitation therapy has consistently improved participation in 12-step programs and produced significant improvements in some drinking outcomes such as abstinence when compared to cognitive behavioral therapy or motivational enhancement therapy (U.S. Department of Veterans Affairs, 2021).

Conclusion

Patients who suffer from AUD have a number of hurdles to overcome in their road to recovery. AUD can be a serious, lifelong condition that affects many aspects of the patient's life.

Regardless of the severity of their condition, most patients will require customized treatment based on patient factors, preferences, and comorbid disease states. Medication options, psychosocial therapy, and nutritional support can be utilized to develop a tailored, patient- specific treatment plan. Many patients will require more than one attempt at quitting, and health care providers can offer motivation and support throughout their journey.

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ADDICTION MEDICINE PART 2: ALCOHOL

Self-Assessment Answers and Rationales

1. The correct answer is C.
Rationale: Jane is of Japanese ethnicity. Up to 50 percent of people of Asian descent are less able to metabolize alcohol because of an inactive liver enzyme needed for metabolism, resulting in more rapid intoxication, flushing, dizziness, nausea, headache, and rapid heartbeat with alcohol use.

2. The correct answer is C.
Rationale: A number of complications can arise from alcoholic liver disease, including variceal bleeding, ascites, peritonitis, renal failure, and encephalopathy.

3. The correct answer is B.
Rationale: Thiamine should be given to prevent Wernicke's encephalopathy. Folate and magnesium supplementation may be necessary in patients with these nutritional deficiencies, and lorazepam can be used in alcohol withdrawal treatment, but these are not treatments for Wernicke's encephalopathy.

4. The correct answer is A.
Rationale: Age of 48 years is not a risk factor for severe or complicated withdrawal; age over 65 years is a risk factor. Other risk factors include:

- *Prior history of alcohol withdrawal seizures or delirium*
- *Medical or surgical comorbidities, especially traumatic brain injury*
- *Numerous prior episodes of withdrawal*
- *Long history of regular, heavy alcohol use*
- *Seizures or significant autonomic hyperactivity during the current withdrawal episode*
- *Dependence on medications that enhance GABA such as benzodiazepines or barbiturates*
- *Use of other addictive substances in conjunction with alcohol*
- *Signs and symptoms of withdrawal in conjunction with a positive blood alcohol concentration*
- *Moderate to severe co-occurring psychiatric disorder*

5. The correct answer is C.
Rationale: Benzodiazepines are recommended as first-line treatment for alcohol withdrawal delirium. Administration of intravenous benzodiazepines to achieve a light sedation where the patient is awake but tends to fall asleep unless stimulated is recommended to help control agitation and maintain patient safety.

6. The correct answer is C.
Rationale: Disulfiram is prescribed to help dissuade patients from drinking, and it works by inhibiting aldehyde dehydrogenase, the enzyme involved in metabolism of the primary metabolite of alcohol, acetaldehyde. If alcohol is consumed in the presence of disulfiram, acetaldehyde levels increase to toxic levels, creating very unpleasant side effects.

ADDICTION MEDICINE PART 2: ALCOHOL

Final Examination Questions

Select the best answer for each question and complete your test online at **EliteLearning.com/Book**

1. Alcohol withdrawal symptoms typically peak within _____ of the last drink, and can continue for weeks.
   a. 30 to 60 minutes.
   b. 2 to 4 hours.
   c. 8 to 12 hours.
   d. 24 to 72 hours.

2. Alcohol interacts with a number of prescription medications, including all of the following EXCEPT:
   a. Opioids.
   b. Anxiolytics.
   c. Naltrexone.
   d. Anticonvulsants.

3. Which of the following can be used to assess the severity of alcohol withdrawal symptoms?
   a. Aspartate aminotransfera se (AST).
   b. Clinical Institutes Withdrawal Assessment Scale for Alcohol (CIWA-Ar).
   c. Diagnostic and Statistical Manual of Mental Disorders (DSM).
   d. Complete blood count (CBC).

4. Which of the following symptoms is NOT used in the diagnosis of alcohol use disorder?
   a. Alcohol is taken in smaller amounts or for shorter durations than intended.
   b. Recurrent alcohol use results in a failure to fulfill significant obligations at school, work, or home.
   c. Patients experience a persistent desire or unsuccessful efforts to cut down or control use.
   d. Important recreational, social, or occupational activities are reduced or given up because of alcohol use.

5. _____ should be used as first- line therapy in patients with moderate alcohol withdrawal, or those with a CIWA-Ar score between 10 and 18.
   a. Carbamazepine.
   b. Phenobarbital.
   c. Benzodiazepines.
   d. Gabapentin.

6. Which of the following benzodiazepines is preferred in patients experiencing alcohol withdrawal who do not have severe liver disease?
   a. Alprazolam.
   b. Lorazepam.
   c. Temazepam.
   d. Diazepam.

7. Phenobarbital dosing is complicated by all of the following factors EXCEPT:
   a. Its narrow therapeutic window.
   b. Its long half-life.
   c. Its metabolism by the liver.
   d. Its short half- life.

8. Pharmacotherapy for patients with moderate to severe alcohol use disorder who have a goal of abstinence or reduced consumption of alcohol and want to initiate medication treatment should begin with:
   a. Naltrexone.
   b. Disulfiram.
   c. Topiramate.
   d. Gabapentin.

9. Patients taking disulfiram should be counseled to avoid consuming which of the following?
   a. Alcohol-based mouthwash.
   b. High-fat meals.
   c. Grapefruit juice.
   d. More than 2,000 mg of sodium per day.

10. _____ is utilized to help the patient become more actively involved in Alcoholics Anonymous (AA) or other 12-step programs.
    a. Cognitive behavioral therapy (CBT).
    b. Group therapy.
    c. Twelve-step facilitation therapy.
    d. Couples therapy.

Course Code: RPUS03AA

Chapter 2: Educating Patients: Creating Teaching Moments in Practice

4 Contact Hours

By: Kim Maryniak, PhD, RNC-NIC, NEA-BC

Author Disclosure: Kim Maryniak and Colibri Healthcare, LLC do not have any actual or potential conflicts of interest in relation to this lesson.

Universal Activity Number (UAN): 0607-0000-23-012-H99-P
Activity Type: Knowledge-based
Initial Release Date: July 10, 2023
Expiration Date: July 10, 2026
Target Audience: Pharmacists in a community-based setting.
To Obtain Credit: A minimum test score of 75 percent is needed to obtain a credit. Please submit your answers either by mail, fax, or online at **EliteLearning.com/Book**

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Learning objectives

After reading this monograph, pharmacists should be able to:

- Appraise the significance of effective patient and family education on patient outcomes.
- Examine barriers to learning in the healthcare setting and the related effects on a person's learning capability.
- Analyze teaching strategies that deliver effective learning to the patient and/or family.
- Discuss how to create teachable moments in healthcare settings.

CHAPTER 1: THE SIGNIFICANCE OF PATIENT AND FAMILY TEACHING

Learning outcome

After completing this chapter, the learner will be able to appraise the significance of effective patient and family education on patient outcomes, including:

- Reduced readmission rates.
- Improved health outcomes.

INTRODUCTION

Patients must have a good understanding of what is needed for their health and wellness. Families and caregivers who support or assist patients also need this information. Education and teaching are essential to ensure that patients and families have a comprehension of factors that contribute to wellness and recovery from illness, such as medications, procedures, and therapies. Each person learns differently, and although there are common strategies, teaching should be individualized.

Healthcare professionals (HCPs) have many opportunities in interactions with patients, families, and caregivers to provide education. Teaching does not have to be long or complicated to be effective. Healthcare professionals should identify when there is an appropriate time for effectual teaching, and how to best educate the person they are interacting with.

Goals for patient education are to help patients and family gain, retain, and apply knowledge. Through effective education, patients should be able to manage health, actively participate in decision making, and improve compliance with their plan of care.

Depending on the setting, the "patient" may be classified as the "resident," "client," or "customer"; for the purpose of this course, the word patient will be used.

Teaching and healthcare professions

Professions have been described in many ways, although there are common themes that are included within the descriptions of a profession. These factors include that a profession is based on a higher level of knowledge and course of education, autonomy and credibility, and upholding values and ethics. An important component of a profession is to protect members of the public by using knowledge and skills (Professional Standards Councils, n.d.). For healthcare professionals, the focus is on the benefit to the patient. Teaching is an essential function of the healthcare professions, and healthcare professionals need proficiencies to successfully implement patient education. Education is concentrated on the goals, priorities, abilities, and health information needs of the patient and family, based on their existing knowledge (Health Care Education Association [HCEA], 2021).

Self-Assessment Quiz Question #1

All the following are elements of a profession EXCEPT:

a. Upholding ethics.
b. Higher level of education.
c. Credibility.
d. Need for supervision.

Patient- and family-centered care

There is much literature regarding patient- and family-centered care. The term family is defined based on what the patient wants, and who they want involved in their care. This could include significant others, immediate or extended family members, friends, colleagues, or any others the patient wishes to be involved. Each patient's definition of family is unique—and some patients may desire to have family involved in their care while others do not want them to be involved (Institute for Patient- and Family-Centered Care, n.d.).

It is essential for healthcare professionals to understand the components of patient- and family-centered care, particularly when it comes to providing teaching and education. Patients and families expect to have all relevant information communicated to them in a manner that they can understand. They also wish to collaborate with healthcare professionals in their care. Communication with patients and families should be complete, timely, courteous, valuable, and inclusive. Patients and families also expect to be listened to and validated during communication. Other considerations include transparency, respect, and adaptation to the patient's and family's needs, cultures, and beliefs (Institute for Patient- and Family-Centered Care, n.d.; Maryniak, 2019).

Self-Assessment Quiz Question #2

When preparing to provide patient education, the healthcare professional considers that:

a. The family at the bedside should be involved in every session.
b. Providing written instructions alone is effective.
c. Education should be individualized.
d. Outcomes will not be affected.

Education and patient outcomes

Patient education, when done effectively, engages patients in their healthcare management and fits in with patient- and family-centered care. Teaching involves determining patient needs by assessing and addressing them through communication, reinforcement, and confirming knowledge. Simply providing instructions, such as written material, is not effectual patient education (National Library of Medicine, 2021). Patient teaching should be done systematically by assessment, planning, implementation, and evaluation (HCEA, 2021).

Without the knowledge and understanding of steps to take for managing illness and maintaining wellness, patients may not be able to appropriately care for themselves. A lack of understanding can lead patients to noncompliance with medications or treatment, experience a difficulty or inability to manage health, and create errors at home (Mahajan et al., 2020).

Evidence-Based Practice: There is a high risk that patients and families will make medication errors. Reports show that medication errors at home occur in between 2% and 33% of cases. The most common errors include incorrect dose, missed doses, and wrong medication. Lack of understanding or ineffective teaching or communication are factors that can lead to these medication errors (Agency for Healthcare Research and Quality [AHRQ], 2021).

Self-Assessment Quiz Question #3

The first step in patient education is:

a. Asking if the patient wants teaching.
b. Assessment.
c. Printing off written material.
d. Implementation.

Even if patient teaching is performed, if it is not done effectively, there can still be negative consequences. Studies have discussed the perception of education in the hospital. One study discussed how patients over age 65 reported they had good instructions at discharge, and yet 40% did not understand the purpose of their hospitalization, and 54% did not recall follow-up instructions (Alper et al., 2022).

Healthcare Consideration: Engagement and involvement of patients in their care has been shown to produce better outcomes (AHRQ, 2022). Patient teaching has been shown to effectively lower readmission rates, particularly in specific populations.

One systematic review looked at differences in outcomes based on effective communication and education. Results showed higher satisfaction (60.9% versus 49.5%), improved compliance with treatment (86.1% versus 79%), and lower readmission rates (9.1% versus 13.5%; Becker et al., 2021).

An additional systematic review focused on education and improved outcomes with cardiac patients. Results demonstrated that there was a statistically significant difference with physical activity (mean difference 1.27), dietary habits (mean difference 0.76), and medication compliance (mean difference 0.31; Feng et al., 2021).

Another study examined the return rates of emergency department patients, based on comprehension of discharge information. The teach-back method for patient teaching was specifically tested, and results showed there was a lowered comprehension deficit (from 49% to 11.9%), and a decrease in return to the emergency department (8.1% versus 41.3%; Mahajan et al., 2020).

A research study focused on a joint education class for patients undergoing total hip or total knee replacement surgery. Results showed that total hip replacement patients were 4.45 times more likely to experience a postoperative infection if they did not have the joint education class. A total knee replacement patient who did not attend these classes was 1.3 times more likely to be readmitted and returned to the operating room with a surgical site infection after discharge (Marshall, 2020).

Studies have also shown the effectiveness of teaching with pediatric patients. One study tested the effects of an asthma education program for school-aged children. Results were statistically significant for reported symptoms, use of a peak flow meter, and daily activities. Although not statistically significant, there was also a reduction in school absences (Isik et al., 2021).

Self-Assessment Quiz Question #4

Which of the following statements is true regarding studies about patient education?

a. Patients report highly effective teaching in most studies.
b. Pediatric education is not effective.
c. Only certain forms of patient teaching work.
d. Elderly patients reported good education but had poor comprehension.

Self-Assessment Quiz Question #5

Which of these is a theme demonstrated in studies examining education and patient outcomes?

a. Education can reduce readmissions and improve outcomes.
b. Patient satisfaction is not improved with patient education.
c. Emergency department readmissions are not affected by education.
d. Education does not improve patient compliance.

Case study: Mr. Kole

Mr. Kole is a 56-year-old Caucasian male who was admitted as an inpatient at an acute care facility with a myocardial infarction. Upon arrival to the emergency department, he immediately went to the cardiac catheterization lab and had a stent placement. Following his stent, he was admitted to the intensive care unit (ICU) and will be transferred to the medical stepdown cardiac unit. Medications include metoprolol, aspirin, clopidogrel, rosuvastatin, and nitroglycerin. Mr. Kole will be following up with a cardiologist and will need cardiac rehab after discharge. His wife has been at the bedside, and she says she will be his primary caregiver at home.

- What are some educational needs that Mr. Kole will have in the hospital, at discharge, and as an outpatient?

Discussion: Mr. Kole will need education about his heart attack and his stent, even if he has already had some initial teaching. Teaching about his medications, including basics as to why he is taking them, side effects, the importance of medication compliance, and related considerations should be included. Discussion of how follow-up is essential, both with providers and cardiac rehab, is needed. Home management, lifestyle changes, and warning signs are also vital.

- What are some patient- and family-centered considerations when looking to provide education to Mr. Kole?

Discussion: In terms of patient- and family-centered care, educational topics should be discussed with Mr. Kole before involving his family, including his wife. He may not agree with having her involved in his care. After determining the wishes of Mr. Kole, if he wants his family involved, then they should participate in education as often as they are able.

Conclusion

Healthcare professionals are responsible for teaching within their scope of practice, and this is a factor in protecting the patient. Patient- and family-centered care considerations should be included with patient teaching and education. Studies have shown that appropriate, effective communication and education can significantly improve patient health outcomes and patient satisfaction, as well as reduce readmission rates.

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CHAPTER 2: BARRIERS TO TEACHING AND LEARNING

Learning outcome

After completing this chapter, the learner will be able to examine barriers to learning in the healthcare setting and the related effects on a person's learning capability, including:

- Distinguish between health literacy levels.
- Assess other factors that can create barriers to learning.

INTRODUCTION

For patient and family education to be successful, there must be knowledge given and comprehension on behalf of the learner. There are many elements that can cause barriers to effective teaching and learning. Healthcare professionals must be able to identify these obstacles and create strategies to address and overcome them.

Patients may have variations in their ability to learn medical information based on low health literacy. The individual also must be ready to learn. Individual learning styles and differences in communication must be considered. Patients may have certain limitations or cultural considerations that may also impact teaching and learning.

Literacy versus health literacy

There is a relationship between literacy, numeracy, and health literacy, although they are different concepts. Literacy and numeracy are skills that are used by individuals to complete tasks and achieve purposes (Centers for Disease Control and Prevention [CDC], 2022a). Literacy is described as comprehending, assessing, utilizing, and participating with written text to acquire one's own knowledge and potential, accomplish one's goals, and play a part in society (CDC, 2022a). Numeracy is defined as the ability to retrieve, use, decipher, and convey mathematical information and concepts as well as manage mathematical challenges in a variety of adult life situations (CDC, 2022a).

Health literacy definitions now encompass both personal health literacy and organizational health literacy, based upon the Healthy People 2030 initiative (U.S. Department of Health and Human Services, 2021). Personal health literacy is the extent to which individuals can locate, comprehend, and use information and services to make informed decisions and perform actions for their own health or that of others (CDC, 2022b). Organizational health literacy is the level at which organizations equitably support individuals to obtain, understand, and utilize material and services for informed decisions and actions for their own health or on behalf of others (CDC, 2022b).

For the purposes of this course health literacy will refer to the patient's personal health literacy.

Healthcare Consideration: Health literacy is usually referred to as "high" or "low," but there are actually four levels of health literacy: proficient, intermediate, basic, and below basic. Generally, individuals who are intermediate or proficient are considered to have high health literacy. Low health literacy usually includes the basic and below basic levels (U.S. Department of Health and Human Services, n.d.).

Health literacy is important for patients vis-à-vis not only understanding information regarding their health but also their ability to effectively use this information. Low health literacy can create misunderstandings when patient and family education is provided. Low health literacy levels are associated with poor patient outcomes, including readmissions and noncompliance due to lack of understanding of discharge information, increased development of chronic diseases, higher mortality, and increased days of poor physical or mental health (CDC, 2018; Hickey et al., 2018). Conversely, higher health literacy is related to improved patient health outcomes. When they have the highest health literacy, seniors in particular have been shown to have better health outcomes, notably fewer hospitalization, and visits to the emergency department (UnitedHealth Group, 2020).

Evidence-Based Practice: Individuals who have low health literacy compared to those with higher health literacy were shown to have 59% more days of poor physical health and 52% more days of poor mental health per month. Additionally, there were 20% more chronic disease conditions reported in individuals who had low health literacy (CDC, 2018).

Self-Assessment Quiz Question #1

"The extent to which individuals can locate, comprehend, and use information and services to make informed decisions and perform actions for their own health or those of others" is the definition of:

a. Personal health literacy.
b. Literacy.
c. Organizational health literacy.
d. Numeracy.

Studies have shown that up to 80% of medication information is immediately forgotten afterward, and about 50% of the information that is remembered is remembered incorrectly. The complexity of the information presented to the individual also impacts literacy. Eighty-four percent of people can understand medication instructions at a first-grade level, while 59% can comprehend the same information at a fourth-grade level, and only 8% of understand these instructions at a tenth-grade level (Agency for Healthcare Research and Quality [AHRQ], 2020).

Research has asked patients to describe their understanding of printed instructions on medication bottle labels. If instructions were on more than one label, 46% of patients didn't understand the complete instructions. For patients who were identified as having adequate literacy, 38% did not understand at least one label. One study examined both understanding and demonstration of taking medication. In this research, 71% of patients with low literacy showed verbal understanding of the label, and 89% of patients with adequate literacy understood it. Only 35% of patients with low literacy could demonstrate the correct way to take the medication, while 80% of those who had adequate literacy showed an ability to correctly take the medication (AHRQ, 2020).

Patients at risk

Low levels of education and/or difficulties during school have a correlation with low health literacy (CDC, 2018). Although there is a relationship between literacy, numeracy, and health literacy, it is vital that healthcare professionals do not assume that a person who is well educated has a high level of health literacy. Medical terminology, anatomy, and physiology knowledge is specialized and is not considered common knowledge. Health conditions such as confusion, fear, pain, and those requiring complex self-care can also impact health literacy (CDC, 2022b). Assessment of every individual's health literacy prior to providing patient teaching is imperative, and tools for this assessment will be discussed further in Chapter 3.

Some populations, such as those with a language barrier or the young, are at a higher risk for low health literacy. Age disparities show that those younger than age 16 and older than age 65 have the lowest health literacy. Multiple studies have examined race and health literacy. Although there are some variations, Hispanics, Asians, Pacific Islanders, and Native Hawaiians are at risk for low health literacy. Other risk factors associated with lower health literacy include inability to work, low income, visual impairment, male gender, English as a second language, chronic physical or behavioral health issues, and social isolation (CDC, 2018; Pacific University Oregon, 2022).

Red flags for low health literacy

As mentioned earlier, health literacy requires patient assessment prior to education. There are some indicators, or "red flags," related to persons with low health literacy. These factors can include repeatedly missed appointments and lack of following through with testing or referrals. Registration forms that are not complete, making excuses to avoid reading something, and an inability to provide an appropriate logical history may also be red flags. Asking very few questions or asking many questions can also be an indicator. Low health literacy may also be shown in a failure to name or explain medications, noncompliance with medications, and recognizing medications visually rather than looking at their labels (AHRQ, 2020; Pacific University Oregon, 2022).

Self-Assessment Quiz Question #2

Which of the following statements is true regarding health literacy?

a. There are no age disparities related to health literacy.
b. The use of medication labels is the solution for understanding.
c. People with high literacy can have low health literacy.
d. Health literacy is not associated with health outcomes.

Readiness to Learn

One potential barrier to effective patient education is readiness to learn. Learning readiness is described as the ability of a person to acquire and comprehend knowledge, as well as apply that knowledge successfully. For patients, readiness to learn can be affected by their physical, emotional, experiential, and knowledge states. If there are deficiencies in the patient's learning readiness, effective teaching will be highly unlikely. Physical readiness can include health status, task complexity, physical abilities, and impact of the environment. Considerations for emotional readiness are motivation, stress and anxiety, developmental level, social support, frame of mind, and risk-taking behaviors. Experiential readiness can include orientation, position of control, cultural considerations, past experiences and coping, and ambitions. Knowledge readiness involves the person's present knowledge base, learning disabilities, cognitive capability, and learning styles (Bastable, 2021).

Self-Assessment Quiz Question #3

An example of a factor that is within the state of emotional readiness to learn is:

a. Health status.
b. Past coping.
c. Learning disabilities.
d. Frame of mind.

Patient limitations

Patients may have limitations that can affect their ability to learn and retain information. Low health literacy, discussed above, is one example. Physical limitations can also exist, such as pain or fatigue from illness or procedures. Limited mobility may impact the ability for return demonstrations. Sensory impairment such as vision or hearing loss may be a limitation for following or comprehending communication. Conditions that alter cognition, recognition, focus, concentration, and/or memory will also affect teaching and learning. Emotional limitations may include resistance to change, self-confidence, unrealistic goals, lack of motivation, or procrastination. Difficulties in communication or language barriers may also limit the patient's ability to understand and learn (Bastable, 2021; Varmin et al., 2015).

Environmental considerations

The environment of the patient is another important consideration that can affect communications. A new or rapidly changing environment may be comfortable for the healthcare professional, but it is not for the patient and family. A healthcare environment can be considered scary or friendly to a patient, depending on their perception. Noise, lights, distractions, and even temperature can negatively impact communications (Maryniak, 2019).

Healthcare Consideration: Potential limitations to learning should be identified prior to teaching. Strategies that involve considerations to address these limitations must be utilized so that teaching can be as effective as possible. However, it may not be realistic to overcome all factors that can create limitations to learning.

Self-Assessment Quiz Question #4

Which of the following statements is true regarding patient limitations?

a. Pain may affect someone's ability to learn.
b. A person's self-confidence does not limit learning.
c. All factors that can limit learning can be overcome.
d. Limited mobility can affect comprehension.

Communication barriers

Multiple factors can determine whether communication is successful. The barriers and limitations discussed above affect communication, and there are other considerations as well. One of the most frequently seen communication barriers in healthcare is that of a difference in primary or native language. Many communication materials and explanations are in English. However, many patients have limited English proficiency. Even patients who understand English may learn best in another language. It is important to ask patients what their preferred language is for learning (Schouten et al., 2020; Sethi & Rani, 2017).

How the person who is teaching communicates can also create communication barriers. In addition, there are differences in linguistics within the communication itself, which can be a barrier if the learner does not understand. The style and speed in which people communicate can vary. Tone and syntax (structure and grammar) can also affect communication. Semantics (word meaning) and pragmatics (context) can impair communication. Also within healthcare communications are colloquialisms (use of jargon) and lexis (similar sounding words), which can create ineffective communication (Guttman et al., 2021). Nonverbal behaviors can negatively affect communications. An example is if a patient feels a healthcare professional is too busy, rushed, or impatient. And rapport between the healthcare professional and the patient will also determine if communication is effective (Maryniak, 2019; Sethi & Rani, 2017).

Cultural considerations

The use of the patient's preferred language for learning, as mentioned earlier, is vital to effective teaching. Even if communication is given through the language that the patient best understands, if cultural considerations are not addressed then communication may still be impaired. Understanding and respect for cultural and ethnic differences are also important, as communication can be affected by subtle dissimilarities in expression. The way the healthcare professional communicates and who the person communicates with are also important cultural considerations. The cultural competency of the healthcare professional can determine if communication is effective (Schouten et al., 2020).

For cultural considerations, ethnic background is only one factor. Religious beliefs of patients are also part of their background and culture. Patients who are members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ) community also have a culture which needs to be respected (Bass & Nagy, 2022; Schouten et al., 2020). More information on cultural competency will be discussed in Chapter 3.

Self-Assessment Quiz Question #5

Which of the following statements is true regarding communication barriers?

a. Communication is the same in every culture.
b. A patient's preferred language should be used.
c. Nonverbal behaviors do not affect communication.
d. Linguistics have a minimal impact on communication.

Learning styles

Each person learns differently, and the most successful learning occurs when the individual's learning style is taken into consideration. It is important for the healthcare professional to identify their own learning style as well, and what they will need to do to adapt to the learning styles of others. Learning styles include auditory (through listening), visual (by seeing), and tactile (through touching and doing). People may have one primary learning style or a combination that helps them learn best (Maryniak, 2019). Assessments and strategies for different learning styles will be discussed further in Chapter 3.

Developmental level

Another important consideration is the developmental level of the patient. Teaching will be provided to parents and caregivers of patients who are infants, toddlers, and preschool children under the age of six, as they are unable to fully comprehend healthcare education (Bastable, 2021; Maryniak, 2019).

School-age children are between 6 and 12 years old. They can participate in patient teaching, although it is primarily provided to parents and caregivers. Use of correct terminology is encouraged for this age group, and they should be encouraged to touch any equipment that may be used in their care. The child's attention span will be shorter than that of an adult (Bastable, 2021; Maryniak, 2019).

Adolescents are between the ages of 12 and 18 years. Teaching can be done with the adolescent separate from the parents or caregivers, but generally includes both. Medical procedures should be explained. Adolescents have the cognitive ability to understand and retain information. Respect along with encouraging questions and verbalization of fears are important (Bastable, 2021; Maryniak, 2019).

Young adults are between 18 and 44 years old, while middle adults are 45 to 64 years old. Families should be included in patient teaching based on the patient's wishes. All medical procedures should be explained (Bastable, 2021; Maryniak, 2019).

Older adults are those ages 65 and older. Families should be included if the patient desires, and any caregivers should also participate in patient education. The pace of teaching should be slower and brief, with limited distractions. Sensory considerations are also important (Bastable, 2021; Maryniak, 2019).

Developmental levels are described in relation to age groups. However, some patients may be at a developmental level that is different than their chronological age. Modifications of teaching may be needed based on those developmental levels (Maryniak, 2019).

Case study: Mrs. Thomas

Mrs. Thomas is a 67-year-old woman who was admitted to a rehabilitation facility following an acute care stay for an ischemic stroke. She has right-sided deficits and aphasia because of her stroke, as well as a medical history of hypertension, asthma, and type II diabetes. Mrs. Thomas is a pleasant retired high school-teacher who immigrated to the U.S. from the Philippines when she was a teenager. She wears glasses and has a hearing aid in her left ear. Her husband and son arrived at the facility immediately after she was admitted.

- After reviewing her history, and in preparation for communicating and possible teaching, what assumptions can be made about Mrs. Thomas regarding her health literacy?

Discussion: No assumptions can be made about Mrs. Thomas; preconceived notions may create a bias that results in ineffective teaching and communication. An assessment of health literacy should be done immediately. As a high school teacher, she may have high literacy and numeracy, but her level of health literacy is unknown.

- What potential barriers to communication and readiness to learn are there for Mrs. Thomas?

Discussion: One consideration is that this is a new environment for Mrs. Thomas, which may affect communication. There are physical concerns that may be barriers, such as the effects of her stroke, as well as visual and hearing impairment. There may also be cognitive effects from Mrs. Thomas's stroke. Language may be a barrier, so it is important to ensure information is presented in her preferred language. The healthcare professional will also need to adapt to her cultural needs. Asking about her culture and how much she would like her family involved is also needed. Her learning style should also be addressed.

Conclusion

Multiple considerations affect communication between healthcare professionals and patients, and these considerations also influence effective teaching and learning. Assumptions should never be made about patients, and assessments should be done prior to providing education. Strategies should be formulated based on these evaluations to address any barriers and provide patients opportunities to gain and retain the knowledge that they need.

Resources

Health literacy and patient safety: Help patients understand. American Medical Association video of actual patients with various levels of health literacy. https://www.youtube.com/watch?v=cGtTZ_vxjyA

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CHAPTER 3: EFFECTIVE TEACHING STRATEGIES

Learning outcome

After completing this chapter, the learner will be able to analyze teaching strategies that deliver effective learning to the patient and/or family, including:

- Demonstrate how to communicate at each literacy level
- Discuss one on one teaching techniques
- Explain strategies for educating groups

INTRODUCTION

For patient and family education to be successful, there must be knowledge given and comprehension on behalf of the learner. There are many elements that can cause barriers to effective teaching and learning. Healthcare professionals must be able to identify these obstacles and create strategies to address and overcome them.

Patients may have variations in their ability to learn medical information based on low health literacy. The individual also must be ready to learn. Individual learning styles and differences in communication must be considered. Patients may have certain limitations or cultural considerations that may also impact teaching and learning.

Strategies must be developed to address the needs of patients and effectively communicate and teach. There are standardized considerations when approaching patient education, and then individualization is needed. Assessments must be undertaken to determine which strategies are appropriate to implement. There are multiple avenues in patient teaching, which can include individual and group education.

Universal approach to patient education

Patient education should be individualized to each patient in terms of addressing health literacy, barriers to learning and communication, and content. Healthcare professionals should also use a universal approach to providing patient education for all patients, including standardized strategies.

The environment should be adapted to provide one in which effective teaching can occur. This can include lighting that is sufficient but not overstimulating and a calm, quiet atmosphere with lowered noise levels if possible. The temperature of the room is

also important, as people who are too hot or too cold may not be able to fully concentrate (Stans et al., 2017).

Studies have shown that patients and families have expectations for information sharing. Plain language should be used, and the information given should be timely, correct, complete, and applicable to the current situation (Institute for Patient- and Family-Centered Care, n.d.). It is important that the healthcare professional not overcomplicate information. Plain or common language means talking and providing information in a way that most people understand, rather than using technical jargon or other colloquialisms, abbreviations, or complex verbiage associated with higher levels of education (CDC, 2022a).

Evidence-Based Practice: Although the average person in the U.S. may read at an eighth-grade level, there are many who can only read at a fifth-grade level or below. Around 20% of people in the U.S. are considered illiterate, and 30% are marginally literate. This may also equate to the language used verbally, which is why plain language is important (CDC, 2022b).

Self-Assessment Quiz Question #1

Talking and providing information in a way that most people understand is a description of:

a. Colloquialisms.
b. Plain language.
c. The universal approach.
d. Health literacy.

First impressions and developing rapport

First impressions are important when working to develop rapport with patients and families. There are many components that are required each time healthcare professionals interact with patients. Preparation before interactions assists in recharging to focus on the patient and be present in interactions. Immediate acknowledgment of the patient and others (such as family) is essential. An approach that is warm and open, courteous, attentive, and mindful can also assist in developing trust and rapport. Introductions should be made immediately after acknowledgement. Asking how the patient would like to be addressed is also important, which aligns with respect and confidence (Maryniak, 2019; National Healthcare Communication Programme, n.d.; Wirth, 2017).

Nonverbal communications should also be considered. Maintaining eye contact and upholding focus show attentiveness and presence in the moment. Appropriate space should be given so there is comfort during the conversation. Personal space is generally two feet apart but still close enough for the healthcare professional to show caring. Healthcare professionals must have awareness of facial expressions. A warm facial expression, such as a genuine smile, can make patients feel at ease. However, facial expressions must also be appropriate. If the patient shares fear or sadness, the healthcare professional's expression must match the mood of the conversation. Open body language can influence the effectiveness of communication. It is important to also sit at the same level as the patient. Body language should be relaxed and leaning toward the person who is speaking. This demonstrates interest and that the discussion is not rushed. Linguistic cues are needed, such as a warm tone and slow pace. Therapeutic touch can demonstrate empathy and caring when used appropriately. This may include a gentle touch if a patient becomes upset, unless the patient refuses (AHRQ, 2020b; Maryniak, 2019; National Healthcare Communication Programme, n.d.; Wirth, 2017).

Involvement of the patient is crucial for developing rapport and successful teaching. Ensuring a patient is comfortable and can hear, see, and understand what the healthcare professional is saying or showing is important. Explanations are needed throughout a conversation, including the purpose of the discussion and any rationale as appropriate. Healthcare professionals should ask permission prior to doing anything with or to patients. Additionally, sharing thought processes with patients further involves them and builds confidence (Maryniak, 2019; National Healthcare Communication Programme, n.d.; Wirth, 2017).

Open-ended questions are important to use when communicating with and teaching patients. Closed-ended questions only encourage a yes or no answer. Many patients, when asked if they understand information, will answer yes. However, this doesn't confirm there is any actual comprehension, and if there is comprehension, to what degree it exists. Closed-ended questions also can have a dismissive feel, so the discussion may be cut short. Using open-ended questions invites patients to talk more, which provides a clearer picture for healthcare professionals. Using open verbiage is also vital for a question-and-answer dialogue. If the healthcare professional asks, "Do you have any questions?" the likelihood is that the patient will respond that they do not. They may not know what to ask or feel that they are wasting time. A strong question for healthcare professionals to ask is "What questions do you have for me?" This implies a continued discussion, and patients are free to ask questions (AHRQ, 2020b; Maryniak, 2019; National Healthcare Communication Programme, n.d.).

Demonstrating empathy is powerful when building strong relationships between healthcare professionals and patients. Patients associate empathy with caring, vigilance, mutuality, and healing. For empathy to be successful, recognizing the patient's emotions is important. Healthcare professionals need to identify the feeling and asking will help to clarify if the emotion is correct. Acknowledging the patient's feelings helps them feel validated. The action of empathy is not to fix a problem associated with the emotion, but rather to connect, explore the feeling, and try to understand where the patient is coming from (Maryniak, 2019; National Healthcare Communication Programme, n.d.).

Self-Assessment Quiz Question #2

Providing explanations throughout a conversation assists with:

a. Nonverbal behaviors.
b. Showing sympathy.
c. Involving the patient.
d. Self-preparation.

Health literacy assessments

Many patient assessments are needed to determine appropriate teaching strategies. Assessment of the patient's health literacy is essential for deciding the level of conversation, reference materials, and resources. The Agency for Healthcare Research and Quality (AHRQ) is one source that has developed effective health literacy assessment tools that healthcare professionals can use (AHRQ, 2019).

One tool is the Short Assessment of Health Literacy (SAHL), which is available in both English and Spanish. With this tool, the healthcare professional presents a set of words for the patient. Prior to the test, the patient is instructed that they will be shown cards with three words on each card. The patient must read the first word out loud and decide which of the words that follow is more like the top word, associating healthcare terms with one another. The patients can also respond with "I don't know." A correct answer for each test item is counted when there is both correct pronunciation and accurate association, and this is worth one point. A test item is given a zero if the patient pronounces the word correctly but cannot associate it with the appropriate healthcare term, or vice versa, or if they answer that they don't know. When the test is finished the healthcare professional sums up the total points, to a maximum of 18. A score less than 14 suggests the patient has low health literacy (AHRQ, 2019).

Stem	Key or Distracter		Don't Know
1. kidney	__ urine	__ fever	__ don't know
2. occupation	__ work	__ education	__ don't know
3. medication	__ instrument	__ treatment	__ don't know
4. nutrition	__ healthy	__ soda	__ don't know
5. miscarriage	__ loss	__ marriage	__ don't know
6. infection	__ plant	__ virus	__ don't know
7. alcoholism	__ addiction	__ recreation	__ don't know
8. pregnancy	__ birth	__ childhood	__ don't know
9. seizure	__ dizzy	__ calm	__ don't know
10. dose	__ sleep	__ amount	__ don't know
11. hormones	__ growth	__ harmony	__ don't know
12. abnormal	__ different	__ similar	__ don't know
13. directed	__ instruction	__ decision	__ don't know
14. nerves	__ bored	__ anxiety	__ don't know
15. constipation	__ blocked	__ loose	__ don't know
16. diagnosis	__ evaluation	__ recovery	__ don't know
17. hemorrhoids	__ veins	__ heart	__ don't know
18. syphilis	__ contraception	__ condom	__ don't know

Note: From Agency for Healthcare Research and Quality. (2019). *Health literacy measurement tools. https://www.ahrq.gov/health-literacy/research/tools/index.html#short*

Strategies for patients with low health literacy

Patients who are identified as having low health literacy require specific strategies to assist with learning and comprehension. It is important for healthcare professionals to focus on what information the patient wants and needs. Studies have shown that the content patients need involves briefly telling them what's wrong, telling them what they need to do and why, and emphasizing the benefits for them. With medications, there are additional requirements, such as what the medication is, exactly how the medication is taken, why the patient needs the medication, what side effects can be expected, and how the patient will benefit from the medication. Using plain language, in words the patient can understand, is vital (AHRQ, 2020a; Maryniak, 2019).

Patient understanding, especially for those with low health literacy, can be improved by a few key approaches. The focus should be on "need to know" and "need to do." Patients state in research that healthcare professionals give a lot of information, and it is difficult to determine the most important items they need to remember. Patients need to know, for example, "what comes next." In outpatient settings, this may be what the patient must know or do when they leave the room or office. Inpatients may need to know what they must do in the hospital to meet discharge criteria, or what they need to do at home after discharge. Another example is content, or what the patients need to know about. This may be information about taking medications, referrals or follow-up, or self-care (AHRQ, 2020a; Maryniak, 2019).

Healthcare Consideration: Using an effective teaching method, such as teach-back, is highly recommended when working with patients who have low health literacy. Visual materials, demonstrations, and clearly written reference materials are also needed (AHRQ, 2020a; Maryniak, 2019). These strategies will be discussed further in this chapter.

Self-Assessment Quiz Question #3

All the following are information that should be provided to a patient who has low health literacy EXCEPT:

a. What the patient needs to do before discharge.
b. How self-care should be done.
c. Why a medication is important for the patient.
d. How a medication acts in the body.

Learning style assessment

As previously discussed, learning styles include auditory, visual, and tactile. There may be some variations in descriptions of styles, including terms such as aural, read/write, and kinesthetic. Learners may prefer a specific learning style, which should be considered. Additionally, multiple tools are available for assessing the learning style of the patient and the healthcare professional. Common learning style assessments include the VARK questionnaire, Kolb's Learning Style Inventory, and the Barsch Learning Style Inventory (see the Resources section at the end of this chapter). Some tools involve longer assessments, and a few are more geared toward the learner in a school or other educational setting. The learning style assessment tools have commonalities in that they ask questions about behaviors associated with learning. After scoring, the tools can identify the style or styles with which the person most likely learns best (Holt, 2022; Maryniak, 2019).

Adapting to learning styles

Healthcare professionals can use multiple ways of presenting information while performing patient teaching. It is important to emphasize the learning style of patients to optimize learning, comprehension, and retention. A combination of strategies is useful for patients who have more than one learning style.

To learn best, patients who are visual learners need to see information, so graphics and written information can be especially helpful. Images, diagrams, pictures, shapes, forms, and even color can assist with learning. Visual aids should clearly communicate the message and present the information in a way the patient can easily interpret. Use of clear labels, captions, and headings with visual aids are recommended. Written information should be clear, it should be in plain language, and it should enhance but not replace patient teaching. If there is verbal information, the visual learner can write it down for better results. Demonstration

is also helpful for the visual learner, as they can see someone else perform the required actions (Holt, 2022; Maryniak, 2019).

Patients who relate to the auditory learning style need to hear and talk about information. The healthcare professional needs to focus on clear speech, pace, and tone, as well as use of plain language. These learners may need time to process, so time may be needed after presenting information. Auditory learners should ask questions as well as work it out aloud and answer their own questions. Discussions are helpful for this learning style and including others may be a good strategy (e.g., including family or teaching in a group setting; Holt, 2022; Maryniak, 2019).

Patients who have a tactile learning style need to feel and do for best results. Hands-on experiences, such as demonstrations and then return demonstrations, can be effective. Use of real-life examples is useful so that the learner can apply the information. Tactile learners have a need to practice (Holt, 2022; Maryniak, 2019).

Visual aids and written information

As previously discussed, the use of visual aids and written information can enhance patient teaching. There are key factors to consider when developing and using these materials.

Visual aids are recommended when they can make content more easily understood. These aids should reinforce the content being discussed but not distract from it. Visual aids need clear titles and captions and should use images that are obvious and organized. If tables are used in a visual aid, they should be short, with clear headings for rows and columns (AHRQ, 2020c).

Written information such as handouts can also reinforce patient teaching. These materials should not just be given to patients without reviewing with them. On their own, many patients do not read or completely read written information that is handed to them. Materials must include plain language and be in the language that the patient uses for learning. The healthcare professional indicates the most important points by highlighting, circling, or underlining. The material should be regularly evaluated to ensure the content is current. In addition, patient feedback is essential (AHRQ, 2020b).

Patient and family educational strategies

Most of the time, healthcare professionals perform patient education on an individual basis, or with the patient and family together. Teaching can be formalized and planned or can be spontaneous during a teaching or teachable moment (see Chapter 4 for further discussion of this point). Healthcare professionals should structure their approach to patient teaching so that it is performed in the same way each time, with individualization to the patient.

Planning for patient and family education is done by incorporating all the considerations discussed earlier, such as health literacy and learning styles. The topics and potential topics should be thought out before the discussion, visual aids should be found, and plans for any demonstrations should be considered (AHRQ, 2020b). If the patient is suspected or known to have a lower level of literacy, then factors previously discussed should be kept in mind during preparations (AHRQ, 2020a). The patient may have higher health literacy, such as those who are healthcare professionals themselves. Plain language should still be used rather than assuming those patients will comprehend all the information taught.

Teach-back is a method of patient teaching that is highly recommended, as it confirms the patient has understood the information presented by telling it back in their own words and showing it through their own actions (AHRQ, 2020b). Using teach-back doesn't test patients' knowledge, but rather how effectively the healthcare professional presented the information to them. When planning for teach-back, healthcare professionals must determine how patients will be asked to teach back the information. It is important to remember that teach-back is used for techniques as well as concepts (AHRQ, 2020b; Maryniak, 2019).

When using teach-back, it's important to perform "chunk and check," which means information should be presented in small sections and then verified with the patient. After providing some information to the patient, the healthcare professional asks the patient to repeat it back in their own words. This ensures the patient understands the information thus far and gives the healthcare professional an opportunity to clarify if needed and teach it back again. It is recommended that important information be limited to three to five points when using the teach-back method (AHQR, 2020b).

Asking patients to teach back through stating in their own words or showing how to perform a procedure may be seen as difficult. Healthcare professionals should focus on indicating they are using teach-back to meet their own needs—it is not being used to test the patient. For example, beginning the question with "I want to make sure I explained this clearly. Please tell me how . . ." or "I want to make sure I showed you correctly. Please show me how . . ." The teach-back should focus on a single topic rather than multiple concepts (AHRQ, 2020b; Maryniak, 2019).

Healthcare Consideration: Some examples of ways to ask for teach-back are:

- "I want to make sure I explained it correctly. Please tell me in your own words how you understand the plan we have to manage your pain."
- "I want to be sure that I explained your medication right. Please tell me how you are going to take this medicine at home."
- "As we discussed earlier, you will need to get up and walk so that you don't get blood clots. Please tell me how many times a day you need to do this."
- "We covered a lot of new information today, and I want to make sure that I explained things clearly. Please show me how you will use your incentive spirometer."

Teach-back should be used consistently in all settings and with every patient as appropriate. Teach-back may not be appropriate with pediatric patients, or those with developmental or cognitive challenges. Family should also be included in teach-back, particularly if they are caregivers at home (Maryniak, 2019).

Another strategy for individualized education is using a "brown bag" medication review. These sessions are generally open to any patients who would like to participate. The brown bag review is usually seen in ambulatory settings but can also occur with inpatients. Patients bring in their medications from home to review with a healthcare professional, which can assist in identifying misunderstandings and errors with medications. During the review, the healthcare professional will have the patient hold each medication bottle and answer questions. The questions to be asked should include "What do you take this medicine for?" "When do you take this medicine?" and "Show me how you take this medicine." The review can also assist with medication reconciliation, which is often incorrect. An updated medication list is to be given to patients after each brown bag review (AHRQ, 2020b).

Group Educational Strategies

Patient and family teaching can also be done in group settings. Patient classes can cover content specific to procedures, disease processes, and self-care. Opportunities for learning arise when patients ask other questions. In addition to the content presented, the group setting allows for social interaction and support. Reinforcement of key concepts may result from group classes, which are typically done with standardized didactic content. This type of learning may be especially effective for patients who are auditory learners. Group education should not replace one-on-one teaching but can enhance it. Examples of successful group educational

opportunities include content addressing diabetes, ostomies, and orthopedic procedures such as total joint replacement (Kato & Siegmund, 2022; Marshall, 2020; Merakou et al., 2015).

Self-Assessment Quiz Question #4

Which of the following statements is true regarding teach-back?

a. It is used to test the patient's knowledge before educating the patient.
b. Information is given in small sections and then verified with the patient.
c. It is a strategy that is appropriate for all patients.
d. Patients tell back the information word for word.

Use of technology

The use of technology has increased exponentially, particularly since the turn of the century. Communication through technology has grown, incorporating the use of text messaging, social media, websites, virtual meetings, and others. Technology has enabled more people to be reached virtually by breaking down barriers of distance, time, and location. This creates new avenues for presenting patient education and utilizing technology that can be advantageous. Technology has been seen in healthcare through telehealth, mobile health (including mobile apps), health information (such as electronic records), and wearable devices. Technology can help patients become empowered and more active in their health, which can improve patient outcomes (Kuwabara et al., 2020; Rozenblum & Bates, 2017).

Evidence-Based Practice: More and more people are using the Internet to find health-related information. One study showed that 71% of patients search for health information online (Stankova et al., 2020). Another study demonstrated that 69% of patients used the Internet as their first source for health information (Swoboda et al., 2018).

There are limitations to using technology for patient teaching. Technology can be used to enhance patient care and education but should not replace in-person discussions and teaching. There are concerns when people use the Internet for "researching" health information, as there are many sources that are not credible, as well as information that can be misinterpreted. Another limitation is that not all patients are willing and able to use technology, so it is important for healthcare professionals to assess a patient's willingness in advance. Barriers to using technology may include generational differences (such as elderly patients), lack of patient awareness, low health literacy, socioeconomic status, inadequate computer skills, and technical support challenges. Alternatives to technology must be available for patients who have barriers (Rozenblum & Bates, 2017).

Addressing language differences

Patients who are not primarily English speaking, including those who use sign language, may not get the information and education that they need. Language assistance is required for verbal communication. Approved language assistance services in healthcare include professionals with confirmed proficiency and trained medical interpreters, who can be involved in person or via telephone or video. Using individuals to interpret who have not been trained as medical interpreters has not been approved for language assistance, as there may be errors with accurate translations, bias, and privacy (AHRQ, 2020b).

Cultural competency

A culture incorporates many factors, including ethnicity, nationality, customs, sexual orientation and identity, socioeconomic status, religion, values, and beliefs. Culture can influence health, including self-care and decision making. There are many examples of the influence of culture on healthcare and patient education. Some cultures believe that discussing a possible poor outcome may cause it to happen. Other cultures vary in who makes decisions for health based on gender or position in the family. Dietary, interpersonal, and religious beliefs and customs can also affect actions related to health and healthcare (AHRQ, 2020b).

Cultural competence within healthcare is the ability of healthcare professionals to incorporate factors associated with culture into providing patient care. It is important for healthcare professionals to have a basic understanding of many cultures, but to also ask questions of their patients. Assuming how patients want to be communicated with or what they need for healthcare can be detrimental. Respectfully asking question ensures that the patient's wishes are clear. Examples of questions include "How would you like me to address you?" "What should I know about you and any cultural beliefs that will help me care for you?" "What do you call your illness?" and "What do you think caused your illness?" (AHRQ, 2020b; Bass & Nagy, 2022; Schouten et al., 2020).

Self-Assessment Quiz Question #5

Cultural competence is described as:

a. Incorporating culture factors into patient care.
b. Having knowledge of all cultures.
c. Using approved language services.
d. Asking patients questions about why they have beliefs.

De-escalating confrontations

There are times in healthcare when emotions run high for patients and families. Even with effective communication and education, illness and other concerns can create a personal crisis. Distress, anger, grief, confusion, and other emotions can cause escalating reactions, which may be intensified with physical and behavioral illness. De-escalation is described as a combination of communication, assessment, actions, and self-regulation to reduce agitation or aggression, while improving interpersonal relationships (Hallett & Dickens, 2017). When confrontations or behaviors become aggressive, healthcare professionals need to deescalate the situation.

Escalation of behaviors can lead to assault, so earlier interventions are more effective. It is important for healthcare professionals to recognize behaviors and then provide interventions. Violence occurs in a cycle, starting with the activation of the behavior, which may have an identifiable trigger. In the first phase, restless behaviors such as pacing can be noted. Escalation then occurs, with examples of agitation, shouting, cursing, and related behaviors. The crisis phase is when violence occurs. Following a crisis, the phases of recovery, postcrisis depression, and stabilization happen (McKnight, 2020).

There are common de-escalation techniques that can be used when someone begins to escalate. If it is safe, moving to a private area away from the public is recommended. There should be an awareness of personal space, giving around two feet distance, which may also provide some safety. Exits should not be blocked, and if the person wants to leave, they can. The healthcare professional should show empathy and not be judgmental, focusing on

trying to understand the person's emotions. Nonverbal expressions are important, such as a calming tone and relaxed body language. Healthcare professionals should avoid overreacting and remain rational. Using silence and giving time for decisions are also effective techniques. Boundaries must be respectfully set by providing clear and enforceable limits if behaviors are disruptive or belligerent, (Hallett & Dickens, 2017; McKnight, 2020).

Self-Assessment Quiz Question #6

An important consideration for de-escalation is:

a. Escalation is identified when violence occurs
b. De-escalation includes using restraints
c. Earlier interventions are more effective
d. Escalation occurs only in those with a history of violence

Case study: Mr. Frank

Mr. Frank is a 74-year-old African American male who presents to the clinic three days after discharge from the hospital following an observational stay. He was brought into the hospital with dizziness and loss of consciousness and was newly diagnosed with type II diabetes. Mr. Frank now takes metformin and says he's been taking "a water pill" for many years but doesn't know what it is or why he takes it. He is a retired contractor, and states he has avoided "anyone related to hospitals" for most of his life. At discharge, he was given multiple patient education sheets, which he has brought in with him for his appointment. Upon review, the topics he was given include a full booklet (45 pages) on diabetes, a page about type I diabetes, one on type II diabetes, one on gestational diabetes, one on testing blood glucose, and one on taking insulin.

- What are considerations for developing rapport with Mr. Frank?

Discussion: First impressions and building trust are important. This may be especially true with Mr. Frank, as it seems he may have some distrust of healthcare professionals. Acknowledgment and introductions should be done, including asking him how he would like to be addressed. Being aware of nonverbal behaviors during communication, using open-ended questions, and involving Mr. Frank in the conversation are all needed. Demonstrate empathy during the discussion.

- What assessments should be done with Mr. Frank before providing education? What other information about him should be considered?

Discussion: Mr. Frank should be assessed for his level of health literacy, as well as his learning style. He should be asked about his preferred language for learning. At this point, little is known about his personal and social background. Asking questions about his cultural beliefs will provide insight for individualizing teaching.

Initial assessment shows Mr. Frank has low health literacy. He is primarily a visual learner and secondarily a tactile learner. He speaks and learns in English, although he was born and raised in Italy. Mr. Frank is a widower whose wife passed away last year from a heart attack. He states he is Catholic but hasn't attended church for many months. Mr. Frank has a daughter who lives with her family in a different state. He plays golf weekly and considers his main support system to be his friends from his men's club, whom he socializes with frequently at the golf course. Other than those friends at the golf course, he doesn't like to go outside his house. He says he doesn't really like technology but does have a cell phone that he uses for texting.

- What are possible strategies for effective teaching with Mr. Frank? What is the important information to cover with Mr. Frank?

Discussion: Individual education with teach-back is one strategy to use with Mr. Frank. He could be asked if he would like one of his friends to participate, as a support for him. Visual aids are important to use with Mr. Frank because he is a visual learner. Written materials can also be used if they are concise, and the important points are emphasized. Demonstration and return demonstration can also assist, as they are both visual and tactile. Group education may not be effective with Mr. Frank, as he has verbalized discomfort in social situations outside of his norm. Use of technology is not appropriate for him.

Mr. Frank should understand that he has type II diabetes and be given an overview of what that is. He needs to know about his metformin—that it is for diabetes, and when and how to take it. He needs to when and how to check his blood glucose. Mr. Frank should know what high and low blood glucose readings are, how to manage his glucose level, and when to see a provider. Healthy eating should also be discussed. Teach-back should include return demonstration. Some examples of teach-back questions are "What can you tell me about diabetes?" "How often will you check your blood sugar?" "Show me how you will check your blood sugar" and "Show me how you will take your metformin." Another consideration is having Mr. Frank bring any medications, including over the counter, in for a brown bag review

Conclusion

There are many considerations when assessing patients prior to providing education, including determining health literacy, and learning styles. Teaching may be performed individually or in group settings. Teach-back is highly recommended as a strategy for effective patient education. Technology can be used with some patient populations to enhance teaching. Language and culture must be considered as they related to knowledge and retention. Healthcare professionals should also know how to deescalate behaviors as needed.

Resources

AHRQ health literacy measurement tools: https://www.ahrq.gov/health-literacy/research/tools/index.html#short

Barsch Learning Styles Inventory: https://www.honolulu.hawaii.edu/facdev/wp-content/uploads/2018/05/1-5_Barsh-Learning-Styles.pdf

Kolb Learning Styles Inventory: https://aim.stanford.edu/wp-content/uploads/2013/05/Kolb-Learning-Style-Inventory.pdf

National Library of Medicine health information in multiple languages: https://medlineplus.gov/languages/languages.html

VARK Learning Styles Questionnaire: https://vark-learn.com/wp-content/uploads/2014/08/The-VARK-Questionnaire.pdf

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CHAPTER 4: CREATING TEACHING MOMENTS

Learning outcome

After completing this chapter, the learner will be able to discuss how to create teaching moments in healthcare settings, including:

- Describe the difference between teaching moments and teachable moments.
- Examine components that create effective teaching moments.

INTRODUCTION

There is much information in healthcare related to patient health, illness, disease processes, management, and other aspects of patient care. Information is available in the community, on the Internet, through advice from lay persons, and from healthcare professionals. Patients are expected to sort through, absorb, and apply the correct information that is applicable to their individual situations. Healthcare professionals must help identify those moments of opportunity to provide patients with the knowledge they need for successful outcomes.

Teaching moments and teachable moments defined

The terms *teaching moment* and *teachable moment* have been used synonymously, but there are differences. A teachable moment is defined in a dictionary as "a time that is favorable for teaching something, such as proper behavior" (Merriam-Webster, 2022). When referring to patient teaching, for many years the "teachable moment" was considered a time when a healthcare professional identified an opportunity to provide education to a patient. Nowadays the teachable moment, in the context of patients in a healthcare setting, is focused on behavioral change, specifically creating healthy behaviors. A teachable moment is known as an opportunity to change behavior in a positive way that can be based on patient queues (Locke, 2022; Reynolds et al., 2020; Robinson et al., 2020). Teachable moments have also been associated with educating healthcare professionals through learning opportunities (Finla & Yeow, 2022; Kaban & Posnick, 2022; Keefe, 2022; Locke, 2022). Descriptions of teaching moments and teachable moments include that these times arise spontaneously rather than being planned for. The goal is to guide learning at the pace of the learner, while exploring problems and situations (Locke, 2022; Reynolds et al., 2020).

Multiple variations in definitions and descriptions of teaching moment and teachable moment can cause confusion. For the purposes of this course, the term teaching moment will be used. The description of a teaching moment for this course is an unexpected opportunity in which a healthcare professional can provide brief teaching to the patient or family. The teaching moment involves informal education at the time and can evolve into a formalized teaching process.

Components of the teaching moment

Teaching moments can be found at any time, in any situation, with any patient or family member. In addition to providing new knowledge, frequent teaching moments can enhance formal education that has been previously given. Teaching moments help develop relationships between patients and healthcare professionals, and they assist in creating empowered, involved patients and families (Marshall, 2016).

There are important factors that make up a teaching moment. Initially, healthcare professionals must identify the teaching moment itself. Teaching moments can be found within discussions between the patient and healthcare professional. Healthcare professionals can discover a lack of patient knowledge or misinformation by statements that patients make, or this information can be elicited through patient interviews (King, 2018; Robinson et al., 2020). For example, performing a baseline knowledge check or having patients perform teach-back can show if a patient has a knowledge gap that needs to be addressed. Patients can also voice concerns, ask questions, or indicate they have an interest in their health, all situations that provide other teaching moments. Nonverbal cues can also indicate whether a patient understands information. Examining patient behaviors can also indicate teaching moments (Horne, 2021; King, 2018). An example is reviewing immunizations and discovering a patient is not up to date.

The effectiveness of a teaching moment depends on the receptiveness of the patient, or their readiness to learn. Patients who are ready to learn have a higher likelihood of retaining and applying information (Bastable, 2021). Other barriers to effectual teaching moments include distractions, patient condition, the environment, and interpersonal tension (Smith & Lane, 2015).

After identifying a teaching moment, the healthcare professional must immediately act on it. Timeliness is key during a teaching moment before that time passes. This means addressing the topic through a brief, informal discussion. Because teaching moments may occur with limited time, focusing on one or two important takeaways is essential. The goals should be centered on patient needs (Marshall, 2016). Education during a teaching moment is comprised of the strategies mentioned in the individual education section above. Effective communication is the priority when acting on a teaching moment, which will be further discussed below.

Following up on a teaching moment is needed. More formal education can be done to reinforce the content of the teaching moment. If there was no provision of visual aids or written information during a teaching moment, these should be included with the follow-up. Teach-back can also confirm the level of the patient's understanding as a measure of the success of the teaching moment.

Self-Assessment Quiz Question #1

Which of the following statements is true?

a. Patient readiness to learn does not affect a teaching moment.
b. A teaching moment is planned, formal education.
c. Acting on a teaching moment must be immediate.
d. Frequent teaching moments indicate a problem with education.

Effective communication

Quick establishment of a therapeutic relationship and rapport between patients and families is vital to identifying and addressing teaching moments. Creating good first impressions, as discussed earlier, begins the relationship. Sitting with the patient gets the healthcare provider on their level, which shows respect, and that the conversation is valuable and not rushed. Communication should be respectful and courteous, responsive, and caring. Healthcare professionals need to be attentive to patients' verbal statements and nonverbal cues. There are differences between everyone that must be acknowledged and respected. The ideas, opinions, and needs of the patient are upheld, and it is important to explore underlying needs and concerns. Compassion can be demonstrated through empathy (HCEA, 2021; Maryniak, 2019; National Healthcare Communication Programme, n.d.).

Successful speaking and listening are main components of effective communication. Effectual speaking is clear, with information given in small amounts to help with understanding. Active listening includes focusing on the speaker so that not only are words heard but the whole message and meaning are communicated. The intent of active listening is to understand rather than just respond. Eye contact, attention to nonverbal behaviors, and presence are essential for active listening. Active listening uses open-ended questions, paraphrasing, clarifying, summarizing, and a nonjudgmental attitude (CDC, 2019; HCEA, 2021; Maryniak, 2019).

Personality and communication styles can also influence communication and must be taken into consideration. Indirect communication focuses on the context or meaning of the message. This type of communication may not be clear, and it can take longer to get the message from the speaker to the listener. Direct communication is based on the content of the message. Direct communication may be considered blunt by some, is shorter, and does not have implied meaning (Maryniak, 2019; Stoain, 2020).

Patients should always be encouraged to ask questions, with responses given each time. The ability to ask questions is another component of effective communication. Phrasing of questions can create a sense of trust or distrust. Questions that are used to elicit concerns involve you, for example, "What concerns you about this procedure?" Questions to test knowledge emphasize me and I so that patients don't feel pressured or tested, for example, "I want to make sure I did a good job telling you about the medicine. Tell me in your words why you are on this medicine?" Questions that include how and what help keep the focus on content. Questions with why should be used cautiously, as they may put people on the defensive, for example, "Why do you believe that?" The intent in that question may be to elicit more information, but it can be interpreted as questioning the person's belief. Open-ended questions give patients the ability to speak their thoughts how they want to, which can provide valuable insight for healthcare professionals (HCEA, 2021; Maryniak, 2019).

Healthcare Consideration: Open-ended questions elicit rich information from patients. There are times when closed-ended questions are appropriate. Eliciting yes and no responses during a patient history, for example, works well. Electronic health records have sections that allow for only yes, no, or N/A responses.

Here are some examples of questions healthcare professionals can use with patients:

- "What concerns you the most about your high blood pressure?"
- "What are your goals in life?"
- "What are your goals today?"
- "How do you take your medicine?"
- "How do you feel today compared to yesterday?"
- "Tell me about how you manage your pain at home."
- "Tell me what you would do if you had questions when you get home."
- "What questions do you have for me?"

There are times when patients don't provide many details, even when an open-ended question is used. Probing questions are used to gather more information and encourage further discussion. These questions can also summarize and clarify, for example, "Tell me more," "I want to make sure I understand—tell me more about that," and "How did that affect you?" (HCEA, 2021; Lapum et al., 2020).

Self-Assessment Quiz Question #2

Which of the following is an appropriate open-ended question?

a. "Tell me why you think you don't need a flu shot."
b. "Do you have pain?"
c. "Do you understand what we just talked about?"
d. "What works best to help you sleep at home?"

Incorrect information

Misinformation is described as false or inaccurate information that may be deliberately provided or manipulated (World Health Organization [WHO], 2022). Healthcare professionals must determine if patients have been misinformed or provided with incorrect healthcare information. Inaccurate information can be passed along from multiple sources and others in the community such as family and friends, traditional media, and social media. The advent of social media has increased the ease and spread of information, and studies are now examining the effects of misrepresentation of healthcare topics. Effective communication between healthcare professionals and patients can uncover misinformation or inaccurate information, which can present as a teaching moment (Khullar, 2022; Murthy, 2021).

Evidence-Based Practice: One systematic review was performed following the start of the COVID-19 pandemic to examine the level of misinformation on social media. Results showed that up to 28.8% of the content on four major social media sites involved healthcare misinformation (Borges do Nascimento et al., 2022; WHO, 2022).

Misinformation or incorrect information is an opportunity for healthcare professionals to provide correct evidence and build trust. It is important to note that some misinformation may connect to patient beliefs. Healthcare professionals should determine patients' beliefs, values, lived experiences, and knowledge while engaging and establishing relationships with them. Communication about misinformation and incorrect information requires empathy and personalization of the conversation to the patient (Khullar, 2022; Murthy, 2021).

Plain language is essential, and health literacy promotion is needed to overcome misinformation and inaccurate information. Use of resources and materials that are evidence based, at an appropriate level, can also assist with correcting misinformation. Theories of improving health literacy stress that each person has a right to health information for decision making and that healthcare should be developed in a manner that is understandable and valuable to health, long life, and quality of life. Health literacy can be improved through providing accurate healthcare (CDC, 2022).

Healthcare professionals are in positions of trust and can influence the knowledge and decisions that patients have and make about their health and healthcare. It is important that all information given to patients and families during teaching moments and while providing education be accurate and unbiased. Healthcare professionals must identify their own personal biases and provide facts to patients. An example that has been seen in recent years is related to vaccinations. Another consideration is that if patients and families ask questions to which healthcare professionals do not have immediate answers, it is vital to not use a guess or spec-

ulation in response. It is better to tell patients that an answer will be found, then come back with the correct information in a timely fashion.

Self-Assessment Quiz Question #3

All the following statements are true EXCEPT:

a. Misinformation is not related to patient beliefs.
b. Inaccurate information can come from multiple sources.
c. Providing accurate healthcare can improve health literacy.
d. A response to a question shouldn't be a speculation.

Patient and family perception

Perception in healthcare is described as thoughts, beliefs, or opinions based on how things appear (Cambridge Dictionary, 2022). An individual's perception influences experiences, relationships, and the retention and application of knowledge. In healthcare, patients' and families' perceptions are the focus. Patients' positive perceptions improve their connections with healthcare professionals, which in turn can create more teaching moments and effective education. Healthcare professionals can take steps to create positive perceptions and enhance the patient experience.

Presence is about experience and being in the moment, which is essential for teaching moments. Presence has been identified as essential to successful education and healing (American Holistic Nurses Association [AHNA] & American Nurses Association (ANA), 2019). Presence can be achieved using mindfulness and attunement. Mindfulness is associated with presence in the moment in a way that is not judgmental. Mindfulness is about observation, which includes an awareness of self and others, the environment, and the situation. Components of mindfulness include thoughts, emotions, physical sensations, communication, and dynamics. Attunement is more than just awareness and involves responding to others. Adjustments are made with attunement to better understand the needs and desires of someone else (Maryniak, 2019; Saban et al., 2021).

Self-Assessment Quiz Question #4

Presence is described as including:

a. Awareness of self and others.
b. Thoughts or opinions.
c. Being in the moment.
d. Responsiveness to others.

Reinforcement

Teaching moments should be reinforced for maximum understanding and retention of knowledge. Reinforcement can be done during the teaching moment itself, as well as through a longer educational session if needed, and by using the teach-back method. There are some strategies that can assist with reinforcement. Recognizing and encouraging patient efforts to learn is important. Acknowledgment of patient growth and learning is also essential. Using real-life examples can be useful, particularly if they are success stories of other patients (National Library of Medicine [NLM], 2021).

Providing resources can also help reinforce covered content. In addition to any written materials, resources can include community organizations, support groups, and trusted websites. After reviewing the information that was taught, it is important for healthcare professionals to check to see whether patients have other questions or concerns that need to be addressed, for example, "What other concerns do you have?" It is also essential that patients are told they can reach out if questions or concerns arise after the teaching (NLM, 2021; Maryniak, 2019).

Self-Assessment Quiz Question #5

One strategy for reinforcing a teaching moment is:

a. Having the patient memorize medication names
b. Using real-life examples
c. Providing copies of research studies
d. Keeping questions restricted to the teaching session

Case study: Miss McGill

Miss McGill is a 23-year-old Native American female who was recently diagnosed with asthma and prescribed beclomethasone dipropionate and albuterol inhalers. She was on a five-day course of oral prednisone, which was discontinued. Miss McGill has a history of smoking cigarettes daily. She meets with a healthcare professional to discuss her diagnosis and medications.

Miss McGill states that she has switched to using electronic vaping for nicotine. "That's much healthier for me than smoking." She says she doesn't really know the difference between her inhalers and asks why she is on both. She also says she ran out of her "white pills" and asks when she will be getting more.

- What teaching moments are identified?

Discussion: Miss McGill has asked questions about her medications, so that is a teaching moment. She has also made statements that have identified other teaching moments, including those about vaping and her discontinued medication.

- What are essential concepts to include with these teaching moments?

Discussion: Miss McGill needs to have her medications explained and understand the difference between them, what they are for, and how to take them. She will also need information about vaping and health effects. A discussion about discontinued medications is also needed.

- What are some important points for reinforcing these teaching moments?

Discussion: Following up with teach-back is necessary, including return demonstration. For her medications, some questions to ask are "What is this medicine?" "How will this medicine help your asthma?" and "Show me how you will take this medicine." For the topic of vaping a question may include "Tell me how vaping can affect your lungs." Further education, handouts, and resources can also reinforce concepts. The last question should be "What other concerns do you have?"

Conclusion

Teaching moments can be found by all healthcare professionals with all patients in any setting. Relationships and effective communication can assist with identifying these teaching moments. Healthcare professionals should act on teaching moments in a timely manner. Misinformation and incorrect information are other opportunities for teaching moments. Perceptions of patients and families can determine the success of teaching moments. Using strategies for reinforcement is needed.

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CHAPTER 5: PUTTING IT ALL TOGETHER

Learning outcome

Through case studies, after completing this chapter, the learner will be able to explain how the concepts included in this course can be used for effective patient education.

INTRODUCTION

Many concepts have been covered in this course. The following case studies provide thought-provoking questions and discussions to assist the healthcare professional in thinking through how to apply this information to a variety of scenarios.

Case study: Mrs. Jones

Mrs. Jones is a 48-year-old Asian American female who is a new patient at an ambulatory cancer clinic. She has stage two breast cancer, hypothyroidism, and relapsing–remitting multiple sclerosis. Mrs. Jones is at the clinic for a consult on management options, including surgery, chemotherapy, and radiation therapy. She is a homemaker with two children, ages 12 and 14, and is currently separated from her husband. Her sister has accompanied her to this appointment and has been helping her with the registration paperwork.

- What are some initial considerations going into the meeting with Mrs. Jones? What are some strategies that will promote rapport development and successful communication?

Discussion: The environment should be calm, with adequate lighting and noise levels. Mrs. Jones wants to be addressed as Cathy. The use of empathy is impactful when seeking to develop a relationship with Mrs. Jones. Open-ended questions are important and encouraging questions and dialogue will also build rapport. Plain language should be used, as should visual aids and written information. Effective communication skills such as active listening and clear speech are vital. Sitting at the same level as Mrs. Jones and being courteous and responsive while conversing will show respect.

A new diagnosis such as cancer can be frightening and emotional for anyone. Mrs. Jones already has a chronic condition (multiple sclerosis), in addition to the cancer diagnosis and changes in family dynamics. This may be a potential barrier to readiness to learn, depending on how Mrs. Jones is currently coping. This is an area to investigate further.

There is a red flag for health literacy in that Mrs. Jones had help with her paperwork. However, the help with her registration may be due to other factors, such as the familial relationship with her sister, stress and anxiety, or a language barrier. Health literacy assessment is required to determine Mrs. Jones's health literacy level.

There should also be exploration of Mrs. Jones's culture and language. Her learning style must be assessed. Discussion of who she would like to be involved in her care is required. Mrs. Jones may even want her children included in some aspects, so planning for that future education can be done.

During the initial communication with Mrs. Jones, she states that she wants her sister involved in her education and care. In the future she would like her children to have education as well as her estranged husband. Mrs. Jones says she is still processing her new diagnosis and is very afraid of dying. She states she really wants to learn but doesn't want to get overwhelmed.

Assessment shows that Mrs. Jones has a low level of health literacy and is an auditory learner. English is her primary language for learning. She also says that she wants to incorporate complementary and alternative medicine into her care plan. Mrs. Jones uses some technology, such as the Internet for searches and her smartphone for texting and video chats. She does not use any apps, and feels she has minimal computer skills.

- What are some strategies that can be used to help educate Mrs. Jones and her family?

Discussion: Mrs. Jones will initially benefit from individual education, with her sister included. Teach-back will be essential for Mrs. Jones, so information will be presented in small chunks and focused on the important pieces that she needs. Reading information out loud will benefit Mrs. Jones, who has an auditory learning style. The use of technology would not be a good fit for Mrs. Jones.

The cancer clinic also has group education for new breast cancer patients, which may benefit Mrs. Jones in addition to individual teaching. As an auditory learner, group settings can also help with learning via discussions. Group education may also provide additional resources and support for Mrs. Jones. Mrs. Jones's children and husband could participate in individual sessions or group education.

- What important content should be covered with Mrs. Jones during the initial educational sessions?

Discussion: Mrs. Jones needs to know what is wrong. In her case, she needs a brief overview of her breast cancer, what stage two means, and what treatment options are available. This requires information about what Mrs. Jones will need to do, and why she needs to do it. Mrs. Jones feels it is important to include complementary and alternative medicine in her treatment plan. She will need to know next steps for her treatments, and the benefits of management.

During teach-back, among other questions, Mrs. Jones is asked, "What does stage two breast cancer mean to you?" and "What treatment options do you have?". She responds, "I know that my cancer level means I won't die right away. I have a chance to get better." She also says, "I can have surgery, chemotherapy, or radiation. I need more tests for my cancer first." Mrs. Jones also says, "I saw a commercial for a chemotherapy drug that is a pill. I want that pill instead of an IV."

- What teaching moments are there for Mrs. Jones?

Discussion: It is important to clarify what Mrs. Jones means by "I can have surgery, chemotherapy, or radiation." The way this is stated is open to interpretation. Does she mean she will have only one of these options, or does she understand that she can have multiple treatments? The statement about a medication she saw on television is also a teaching moment. Mrs. Jones needs to have information about the fact that providers will determine the appropriate medications for her, which will likely be IV chemotherapy.

Case study: Miss Brown

Miss Brown is in the emergency department following a motor vehicle crash as a passenger not using a seatbelt. She is 17 years old, Caucasian, and registered as Robert Brown. Her history shows she was assigned male at birth and wants to transition to female. There is a suspected concussion and a left fractured clavicle noted on x-ray. Family is not at the bedside.

- What are some strategies that will promote building rapport and successful communication? What are some initial considerations when going in to meet the patient?

Discussion: It is important to ask the patient how they would like to be addressed. The emergency environment can be loud and busy at times, so any ability to decrease environmental stimulation should be done. A nonjudgmental demeanor with empathy can help create a good relationship. Respect can be shown with courtesy and responsiveness. Plain language and use of open-ended questions are essential, as is encouraging participation through dialogue and questions. Sitting at the level of the patient, showing active listening, and speaking clearly are all necessary.

An accident can be traumatic for patients and ending up in the emergency department can add to the stress and anxiety. Additionally, pain and a potential concussion may have negative effects on patient learning. Health literacy, culture, and learning style should all be assessed. Developmental level and lack of support systems present should also be explored.

The patient states she identifies as female, and would like to be addressed as Miss Rachel Brown, with the pronouns of she/her/hers. She says she is very active in the LGBTQ community, and her parents are supportive of her. She lives at home with both of her parents. Miss Brown says her mother was working and will be arriving at the emergency department soon. Miss Brown states she would like to include her mother in teaching when she arrives. She also says she has a boyfriend, who was driving when the accident occurred and who is being evaluated in the emergency department for a shoulder injury.

Miss Brown has been healthy and does not take any medications. She says she doesn't like medications, even the use of over-the-counter medicine. She does not smoke cigarettes but does smoke marijuana on a weekly basis.

Miss Brown just graduated from high school a few weeks ago and celebrated her 17th birthday two months ago. Assessment shows that Miss Brown has a basic understanding of words related to health literacy, with a score of 16 on the Short Assessment of Health Literacy tool. Her learning style is visual. She is pleasant and appropriate in her communications. Miss Brown considers herself tech savvy and uses multiple apps on her phone. In addition, she is active on many social media websites.

- What are some strategies that can be used to help educate Miss Brown and her family?

Discussion: Individual education will work best for Miss Brown in the emergency department. Using visual aids and written information is important, as she is a visual learner. Teach-back will be a good strategy to check the effectiveness of teaching, and to focus on the information she needs to know for self-care. Including Miss Brown's mother in teaching when she arrives will help enforce management at home. The use of technology can also enhance teaching with Miss Brown, such as providing trusted websites and videos. Although Miss Brown is considered a minor, she has the ability to learn and retain information. Patient teaching should be directed at her while including her mother as well.

- What important content should be covered with Miss Brown in the emergency department?

Discussion: Miss Brown needs to know what is wrong and what she will need to do. This includes what her broken collarbone means, pain management, and immobilization of the arm. Miss Brown also requires information about follow-up with an orthopedic provider after discharge. She also has a possible concussion, so will need information on what to watch for and signs that she needs to return to the emergency department. Miss Brown's mother should also be given this information, as she will be helping observe Miss Brown at home. Miss Brown will also be given a prescription for short-term use of acetaminophen and codeine for pain management of her fracture. Although Miss Brown may have a concussion, the provider has prescribed one pill of 325 mg acetaminophen with 15 mg codeine as needed every six hours for the next three days. She needs information about what the medication is, how to take it, and its benefits.

Miss Brown's mother arrives, and teaching includes both of them. Teach-back questions include "Please tell me how you will take care of your broken collarbone at home," "What will you do if you start throwing up or get headaches when you get home?" and "How will you take your medicine when you get home?" Miss Brown replies, "I will make sure I keep my arm in this sling when I get home, and I won't move it. I also need to see a specialist soon." She says, "If I start throwing up, I will come back to the emergency department. If I have a really bad headache, I will come back too." Miss Brown also states, "I will take my pain pills only if I have really bad shoulder pain."

- What teaching moments are there for Miss Brown?

Discussion: The statement Miss Brown made about "a really bad headache" should be clarified. She needs to know that a headache is a warning sign, and her perception of "really bad" may be different from the physician's meaning. Her medication should also be reviewed again, including how many pills she should take and how often she can take them. Again, her perception of "really bad" pain in her shoulder may be different from the physician's perception of what "really bad" pain is. Waiting until the pain is severe can decrease the effectiveness of pain management.

Another teaching moment is referring to Miss Brown's statement about smoking marijuana. There is an opportunity to discuss how smoking—whether it is marijuana or tobacco—affects the lungs. The use of both marijuana and opioids may also cause symptoms that could be confused with concussion.

Case study: Mr. Lopez

Mr. Lopez is a new patient admitted to a long-term care facility from an acute inpatient stay for a fractured right hip following a fall at home. He is a Hispanic 82-year-old who has been diagnosed with early-stage dementia and hypertension, and he wears hearing aids. His medications include donepezil, metoprolol, lisinopril, oxycodone, and melatonin. He has started physical therapy with a walker. Mr. Lopez has a history of falling three times at home within the previous five months. He is widowed and had been living with his 50-year-old daughter and her husband prior to being admitted to the hospital. Mr. Lopez will not be returning

home until he has stayed at the facility for at least three months. His daughter arrived at the facility shortly after Mr. Lopez did.

- What are some strategies that will promote building rapport and successful communication? What are some initial considerations when going in to meet Mr. Lopez?

Discussion: Mr. Lopez should be welcomed to the facility and asked how he would like to be addressed. Inquiring about his language preference for communication and learning is essential. There may be concerns about his ability to hear in addition to the effects of aging and his dementia. It is also important that Mr. Lopez has his hearing aids in while awake. The environment should be as quiet as possible, with effective lighting. Sitting with him at eye level, speaking clearly, and talking at a slower pace show respect and can also assist with communication. Being empathetic, courteous, and responsive is important. Active listening and paying attention to body language, including that of Mr. Lopez, are vital for communication. Plain language, open-ended questions, and dialogue are important. Participation should be encouraged to the extent that he wishes, including the involvement of his daughter.

There is stress and anxiety associated with transitioning to a new environment. Moving to a long-term care facility may also cause feelings of grief, dependency, helplessness, and hopelessness. The independence that Mr. Lopez may have had has now changed. There are safety concerns related to his falls and dementia. Pain from his hip fracture is another consideration that can affect his communication and learning. Questions are needed to find out about his cultural needs. Assessments of health literacy and learning style should also be done.

Mr. Lopez can speak English, but it is his second language. He prefers to communicate and learns best in Spanish. He moved from Mexico to the U.S. when he was in his teens and is Catholic. He is a retired laborer, and his highest education was high school and completion of a trade school. His health literacy is tested with the Short Assessment of Health Literacy tool, Spanish version, and he scored a 7. His learning style is a combination of visual and tactile. Mr. Lopez says he would like his daughter included in any teaching. He says it's important to him to regularly attend church services and keep his Bible, crucifix, and rosary near him.

- What are some strategies that can be used to help educate Mr. Lopez?

Discussion: A Spanish interpreter with formalized communications and education to help Mr. Lopez learn best is needed. Individual education will be valuable for Mr. Lopez, with visual aids and written information in Spanish for his visual and tactile learning style. He has tested as having low health literacy. Teach-back will be essential for Mr. Lopez, using brief and focused education sessions in small segments. His daughter should be included when she is at the facility. Return demonstrations can also be done. Frequent reinforcement may be needed for Mr. Lopez, and there are many potential barriers to learning

- What important content should be covered with Mr. Lopez?

Discussion: Mr. Lopez has multiple diagnoses, complications, and medications. The immediate focus is on his safety and broken hip. Too much information will not be helpful and can be overwhelming. Important information for Mr. Lopez is related to ensuring he gets help when moving, such as getting out of bed and ambulating. He also needs continued reinforcement of physical rehabilitation to help him regain his independence. Education about the long-term care setting is also important.

Teaching is done with Mr. Lopez and his daughter using a Spanish interpreter. Teach-back questions are "Tell me what you will do if you have to get up and use the bathroom," "How often can you have your pain medication?" and "Show me how you use your walker." Mr. Lopez says, "I will call for help when I have to go the bathroom" and "I can have my pain medication every time the nurse brings it in." He can show proper use of his walker when ambulating. Mr. Lopez also states, "I can't wait to get better so that I can go back home next week."

- What teaching moments are there for Mr. Lopez?

Discussion: The statement "I will call for help" needs to be clarified. Does Mr. Lopez mean use the call bell for help, or is he referring to something else, such as using the phone or yelling? His pain medication also needs to be explained again, so he knows that he can use the call bell and ask for pain medication when he needs it, every four hours. Another teaching moment is related to the anticipated length of stay at the facility. It is anticipated that Mr. Lopez will have at least a three-month stay, but he made a statement about going home next week.

Conclusion

The case studies covered in this chapter included questions and discussions related to applying the information and strategies reviewed within this course. There are many factors that must be considered in each unique patient situation.

EDUCATING PATIENTS: CREATING TEACHING MOMENTS IN PRACTICE

Self-Assessment Answers and Rationales

CHAPTER 1

1. The correct answer is D.
Rationale: The correct answer is d. Need for supervision is not a component of the description of a professional.

2. The correct answer is C.
Rationale: Education must be individualized to the patient, although there may be standard content.

3. The correct answer is B.
Rationale: Patient education should be done systematically, starting with assessment.

4. The correct answer is D.
Rationale: Patients older than age 65 reported they had good instructions at discharge, and yet 40% did not understand the purpose of their hospitalization, and 54% did not recall follow-up instructions (Alper et al., 2022).

5. The correct answer is A.
Rationale: Research shows that effective patient education can improve patient outcomes and reduce readmission rates.

CHAPTER 2

1. The correct answer is A.
Rationale: The definition is that of personal health literacy,

2. The correct answer is C.
Rationale: Although there is a relationship between literacy, numeracy, and health literacy, it is vital that healthcare professionals do not assume that a person who is well educated has a high level of health literacy.

3. The correct answer is D.
Rationale: Considerations for emotional readiness are motivation, stress and anxiety, developmental level, social support, frame of mind, and risk-taking behaviors.

4. The correct answer is A.
Rationale: Physical limitations such as pain or fatigue from illness or procedures can exist.

5. The correct answer is B.
Rationale: Even patients who understand English may learn best in another language. It is important to ask patients what their preferred language is for learning (Schouten et al., 2020; Sethi & Rani, 2017).

CHAPTER 3

1. The correct answer is B.
Rationale: Plain or common language means talking and providing information in a way that most people understand.

2. The correct answer is C.
Rationale: Involvement of the patient is crucial for developing rapport and successful teaching. Explanations are needed throughout a conversation, including the purpose of the discussion, and any rationale as appropriate.

3. The correct answer is D.
Rationale: With medications, there are requirements such as what the medication is, exactly how the medication is taken, why the patient needs the medication, what side effects can be expected, and how the patient will benefit from the medication. The mechanism of action is not necessary for the patient to know.

4. The correct answer is B.
Rationale: Information should be presented in small sections and then verified with the patient

5. The correct answer is A.
Rationale: Cultural competence within healthcare is the ability of healthcare professionals to incorporate factors associated with culture into providing patient care.

6. The correct answer is C.
Rationale: Escalation of behaviors can lead to assault, so earlier interventions are more effective. It is important for healthcare professionals to recognize behaviors and then provide interventions.

CHAPTER 4

1. The correct answer is C.
Rationale: After identifying a teaching moment, the healthcare professional must immediately act on it. Timeliness is key during a teaching moment, before that time passes.

2. The correct answer is D.
Rationale: This answer is open ended and allows the patient to provide details.

3. The correct answer is A.
Rationale: Misinformation may connect to patient beliefs.

4. The correct answer is C.
Rationale: Presence is about experience and being in the moment, which are essential for teaching moments.

5. The correct answer is B.
Rationale: Using real-life examples can be useful, particularly if they are success stories of other patients.

EDUCATING PATIENTS: CREATING TEACHING MOMENTS IN PRACTICE

Final Examination Questions

Select the best answer for each question and complete your test online at **EliteLearning.com/Book**

11. Which of the following statements regarding patient education is true?
    a. Education needs to be individualized to the patient and family.
    b. There is no association between education and outcomes.
    c. Patient education does not need to be standardized.
    d. Education is directed only at the patient.

12. Research studies have shown that:
    a. Group education classes are not effective.
    b. Elderly patients have the highest comprehension rates.
    c. Teach-back does not affect patient retention.
    d. Effective education can improve patient satisfaction.

13. Which of the following statements is accurate regarding health literacy?
    a. People with high literacy also have high health literacy.
    b. Ethnicity is not related to health literacy.
    c. Up to 80% of medication information is immediately forgotten.
    d. A red flag for low literacy is someone who frequently uses the Internet.

14. A factor that can be a barrier to teaching and learning is:
    a. An environment that is too quiet.
    b. The physical status of the patient.
    c. The age and generation of the teacher.
    d. The use of an interpreter.

15. Families should be included in teaching EXCEPT when:
    a. The family member is younger than age 18.
    b. The person is not a member of the immediate family.
    c. The patient does not wish for them to be included.
    d. The family member is not a caregiver.

16. All of the following behaviors will assist with effective communication EXCEPT:
    a. Maintaining eye contact.
    b. Using plain language.
    c. Sitting with the patient.
    d. Keeping track of the time.

17. One strategy for working with a patient with low health literacy is:
    a. Referring them to a healthcare app.
    b. Using the teach-back method.
    c. Providing detailed information.
    d. Using correct terminology.

18. A strategy that can help an auditory learner is:
    a. Discussion.
    b. Return demonstration.
    c. Visual aids.
    d. Use of technology.

19. An example of an effective teach-back question is:
    a. "How does this medication work in your body?"
    b. "Tell me what you would do if you felt chest pain."
    c. "Do you know you need to check your weight?"
    d. "Why do you think you got this disease?"

20. Which of the following is a teaching moment?
    a. A postsurgical patient is fatigued and is nodding off during teaching.
    b. A young female patient states, "I think I'm pregnant".
    c. A patient with type I diabetes says, "I will check my blood sugars every day".
    d. A cardiac patient states, "I will weigh myself every morning".

Course Code: RPUS04TP

Chapter 3: Heart Failure: Evidence Review and Management

2 Contact Hours

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Author Disclosure: Shyam Gelot and Colibri Healthcare, LLC do not have any actual or potential conflicts of interest in relation to this lesson.

Universal Activity Number (UAN): 0607-0000-22-017-H01-P
Activity Type: Knowledge-based
Initial Release Date: August 10, 2022
Expiration Date: August 10, 2025
Target Audience: Pharmacists in a community-based setting.
To Obtain Credit: A minimum test score of 75 percent is needed to obtain a credit. Please submit your answers either by mail, fax, or online at **EliteLearning.com/Book**

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Learning objectives

After reading this monograph, pharmacists should be able to:

- Understand the etiology, classification, and symptoms of heart failure.
- Describe the pathophysiology of heart failure.
- Evaluate evidence-based pharmacotherapy options for heart failure with reduced and preserved ejection fraction.

Introduction

AHeart failure is a complex clinical syndrome associated with increasingly high hospitalization, readmission, and mortality rates. After the initial hospital admission, five-year mortality rates for patients with heart failure may be as high as 75% (Shah et al., 2017). Alarmingly, 25% of patients with heart failure require readmission to the hospital within 30 days of discharge, and 25% of all these cases are preventable (Khan et al., 2021). According to the CHAMP-HF registry, of all eligible patients with heart failure, over 25% were not prescribed a guideline-based medication with proven ability to reduce mortality. Furthermore, less than 30% of these patients received the appropriate targeted doses of these core heart failure medications (Greene et al., 2018). Healthcare providers have an essential role in improving heart failure outcomes by bridging the gap between guideline-directed recommendations and actual clinical practice. A complete understanding of risk factors, comorbid conditions, pathophysiology, and current pharmacotherapeutic options can help clinicians to reduce the economic and disease burden associated with this syndrome.

BACKGROUND

Epidemiology

Heart failure (HF) is a condition that affects over 6 million adults in the United States, and approximately 960,000 new cases of HF are diagnosed each year (Benjamin et al., 2017; Virani et al., 2021). While concerning, HF's true incidence and prevalence may be even higher due to undiagnosed cases and a lag in current statistics derived from retrospective epidemiologic data. Despite advances in the medical field, the prevalence of HF is estimated to increase to more than 8 million adults in the United States by the year 2030 (Benjamin et al., 2017).

The socioeconomic burden of HF, which includes costs of medications, healthcare services, and work productivity, was estimated at $30.7 billion per year a decade ago (Benjamin et al., 2019). However, with the growing prevalence of HF, this figure increased in 2020 to $43.6 billion and may reach $69.7 billion per annum by 2030 (Urbich et al., 2020).

Certain inherent characteristics can increase the risk of HF, such as age, sex, and ethnicity. Heart failure is common with advancing age, where 80% of HF-related hospitalizations occur in those 65 years of age and older (Lesyuk et al., 2018). By the year 2030, the prevalence of HF could be as high as 8.5% amongst those 65 to70 years of age (Van Nuys et al., 2018). The lifetime risk of HF is similar regarding gender; however, the prevalence of diastolic heart failure remains two times greater in women (Lam et al., 2019; Schwinger, 2021). Furthermore, disparities in HF exist with specific ethnic groups; African Americans have a higher incidence and prevalence of HF than Caucasians, and African American females have the highest prevalence of HF of all demographics (Virani et al., 2020). Compared with Caucasians, African Americans also have a 2.5-fold higher rate of HF-related hospitalizations (Nayak et al., 2020).

In addition to the growing prevalence, HF is associated with high morbidity and mortality rates after symptom onset. In 2018, HF was listed on 13.4% (n= 379,800) of all death certificates (CDC, 2020). Given the numerous factors contributing to HF mortality, the data regarding mortality are conflicting; however, when evaluating long-term studies that use standardized criteria, the 5-year mortality rate is estimated at 50% (Roger, 2021). Additionally, uncontrolled comorbidities associated with HF can lead to mortality, hospitalization, and poor quality of life. Greater than half of all patients with HF have comorbid conditions, which may include: anemia, chronic kidney disease, diabetes, hypertension (HTN), and atrial fibrillation (Khan et al., 2020). Careful attention for treating comorbidities is imperative for clinical providers because certain medications may increase HF risk. For example, certain type 2 diabetes mellitus (T2DM) medications (e.g., pioglitazone and saxagliptin) may increase the risk of HF development and HF-related hospitalizations.

Understanding and identifying risk factors, comorbid conditions, and current pharmacotherapeutic options can help clinicians alleviate the financial burden and reduce the risk of HF.

Healthcare Professional Consideration: Certain age, gender, and ethnicities are more affected by heart failure. Implicit bias towards certain groups of patients may be one of many factors contributing to healthcare disparities. Clinicians should recognize at risk groups to promote better health outcomes. This can be achieved by engaging in clear, patient-centered conversations that promotes dialog without perceived bias. Empowering patients though discussions of all treatment options, regardless of demographics or socioeconomic status is imperative for better outcomes.

Definitions

As defined by the American College of Cardiology (ACC) and the American Heart Association (AHA), HF is a clinical syndrome resulting from a functional or structural impairment in filling of ventricles or ejection of blood (Bozkurt et al., 2021; Gibson et al., 2021). This cardiac abnormality causes a reduced cardiac output to adequately meet the body's oxygen demands during rest or physical exertion. As HF progresses, clinical signs (e.g., edema, increased jugular venous pressure, and rales) and symptoms (e.g., dyspnea, fatigue, fluid retention, and orthopnea) may manifest (Bozkurt et al., 2021). The two main subtypes classify heart failure: heart failure with reduced ejection fraction (HFrEF) and heart failure with preserved ejection fraction (HFpEF). Also referred to as systolic HF, HFrEF is the inability of the left ventricle to contract sufficiently and is defined by having a left ventricular ejection fraction (LVEF) of 40% or less (Bozkurt et al., 2021). Conversely, HFpEF, or diastolic HF, is the inability of the left ventricle to relax and fill with blood adequately. Representing half of all HF-related hospitalizations, HFpEF is defined as an LVEF of 50% or more and still having signs and symptoms similar to HFrEF. Within the next decade, HFpEF is projected to be the leading subtype of HF (Sharma et al., 2020). Approximately, 13 to 24% of patients with HF have heart failure with mid-range ejection fraction (HFmrEF), defined as an LVEF 41 to 49%, that could progress into either HFpEF or HFrEF (Baliga, 2017).

Classification of heart failure

Two different scales exist to help clinicians classify the presence and severity of HF: the ACC/AHA Staging System and the New York Heart Association (NYHA) functional scale (See Table 1). Although complementary, the two scales provide different functionality. The ACC/AHA Staging System describes the progression of patients in a unidirectional manner based on the presence of symptoms and cardiac structure abnormalities. This stepped approach means that patients with HF may progress from Stage A (at risk of HF development) to Stage D (end-stage HF) but cannot return to a previous stage. Therefore, clinicians should focus on preventive strategies to reduce risk factors at Stage A and implement pharmacotherapy treatment strategies that reduce morbidity and mortality beginning at stage C. Meanwhile, the NYHA functional scale subjectively designates limitations in physical activity as HF progresses. Unique to the NYHA scale is the ability to independently predict mortality with each worsening class (Briongos-Figuero et al., 2019).

Table 1: ACC/AHA Staging System and NYHA Functional Classification

ACC/AHA Stage	Recommendation*(COR/LOE)	NYHA Functional Class
Stage A: Patients at risk of HF (e.g., metabolic syndrome, HTN, or T2DM) with no HF symptoms nor cardiac structural abnormalities.	Implement lifestyle modifications Control Risk factors: HTN, T2DM, HLD (I/A) Use natriuretic peptide biomarkers for HF diagnosis, prognosis, and disease severity (I/A)	No corresponding functional class
Stage B: Patients with cardiac structural abnormalities but no HF symptoms (e.g., valvular disease).	Prevent symptomatic HF with ACEI/ARB if a recent history of ACS or MI (I/A), statin (I/A), BB (I/B) Control Blood pressure to prevent HF (I/A)	**Class I:** No limitations or symptoms of HF in physical activity.
Stage C: Patients with cardiac structural abnormalities and previous or present HF symptoms.	HFpEF: Add ACEI/ARB (I/A) or ARNI (1/B) with a BB for treatment to reduce morbidity and mortality HFpEF: Control comorbidities (HTN I/B) and symptom management (diuretics (I/C)	**Class II:** Marginal limitation of physical activity **Class III:** Severe limitation of physical activity **Class IV:** Unable to perform any physical activity. Symptoms at rest.
Stage D: Patients from Stage C, but no relief from treatment interventions	Receive inotropic support until definitive therapy is available (I/C) Cardiac transplantation evaluation (I/C)	

Note. Stage, recommendation, and NYHA functional class from: 2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure, by C.W. Yancy, M Jessup, B Bozkurt, et al. JACC, 70(6), 776-803.

Note. ACEI= Angiotensin Converting Enzyme; ACS=Acute Coronary Syndrome; ARB= Angiotensin Receptor Blocker; BB= Beta-Blocker; HLD=Hyperlipidemia; HTN=Hypertension; MI= Myocardial Infarction; T2DM= Type 2 Diabetes Mellitus

*Not a complete list of recommendations. Please refer to guidelines for further information

Etiology

Historically, coronary artery disease has been the primary cause of HF. According to data from an analysis of the PARADIGM-HF trial, non-ischemic cardiomyopathy (e.g., valvular heart disease, hypertension, dilated cardiomyopathy, or arrhythmias) represents approximately 40% of the cases of HF (Balmforth et al., 2019). Other less common non-ischemic causes of HF may include iat-

rogenic causes (e.g., anthracycline agents, alcohol, and cocaine) viral, familial, congenital, and metabolic disorders. The evolving shift from ischemic etiology to non-ischemic causes suggests concern and the need to control comorbid conditions better. The lifetime risk of HF at age 50 has increased from 20 to 30% in the last 25 years, and those with obesity, hypertension, and diabetes incur a higher relative risk (Vasan et al., 2022). Some risk factors are shared between HFrEF and HFpEF; however, HFpEF is linked to chronic conditions, such as T2DM, obesity, arterial hypertension, sleep apnea, and aortic valve disease, while coronary artery disease predominantly leads to HFrEF (Libby et al., 2021; Schwinger, 2021). Understanding the etiology and treatment targeting those specific origins of HF may help to improve outcomes.

Pathophysiology

Heart failure may result from previously described conditions that damage or weaken the heart, and the ventricles become too weak to supply oxygenated blood to the body sufficiently.

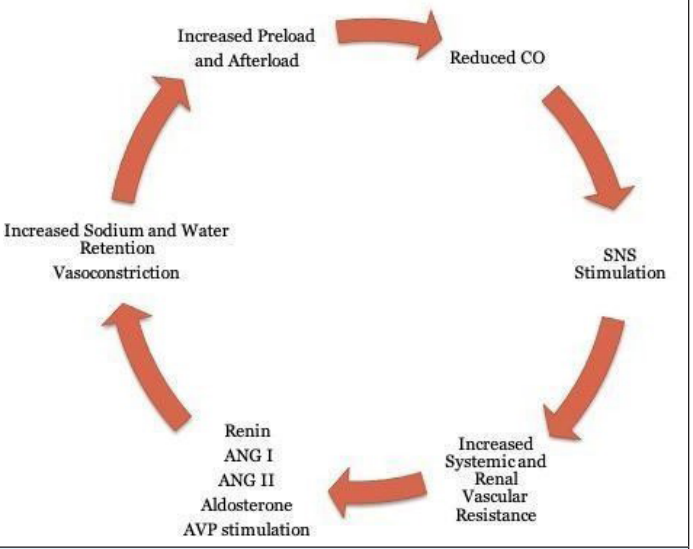
In response, the body activates two main neurohormonal compensatory mechanisms to maintain an adequate cardiac output: the renin-angiotensin-aldosterone-system (RAAS) and sympathoadrenergic systems (see Figure 1). As the sympathetic nervous system releases catecholamines (e.g., norepinephrine) to increase inotropy and chronotropy, this process contributes to renal hypoperfusion and ultimately the release of renin by the juxtaglomerular cells in the kidney. This process initiates the RAAS system (a neurohormonal cascade) that, through downstream signaling, ultimately produces aldosterone ((Libby et al., 2021). The final result is an increase in salt and water retention. Aldosterone and other vasoconstrictors of the RAAS system, coupled with catecholamines, increases systemic and renal vascular resistance. Influenced by vascular resistance, cardiac afterload is the pressure against which the heart has to pump. Furthermore, the volume overload associated with the RAAS system activation leads to increased left ventricular volume and pressure that causes cardiac myocytes to stretch. The stretching prior to contraction is called preload.

In a normal heart, increasing preload and decreasing afterload will increase cardiac output; however, in a weakened heart, the increase in preload via compensation will only maintain stroke volume to a certain extent before a plateau effect is observed (the Frank-Starling principle). These adaptive mechanisms, while initially helpful, lead to a perpetual vicious cycle that causes cardiac remodeling and further symptoms of HF.

With HFpEF accounting for half of HF cases, understanding the pathological differences between the two main HF subtypes is paramount for treatment strategies. Events or conditions causing cardiac myocyte destruction resulting in contractility issues are characteristic of HFrEF. Meanwhile, the exact underlying mechanisms of HFpEF are complex and not fully understood. Proposed theories involve pathways relating to inflammation and dysfunction of endothelial cells, which lead to impaired relaxation and filling of the ventricles (Rech et al., 2018; Schwinger, 2021).

The type of symptom manifestation of HF depends on whether the dysfunction is predominantly located within the left or right ventricle (or both). For example, with left ventricular dysfunction, retained blood in the left ventricle increases pulmonary pressure that manifests in symptoms, such as dyspnea, tachypnea, and crackles. Meanwhile, right-sided HF occurs when blood backflows into the periphery, producing edema, weight gain, and additional volume overload that affects various organs (e.g., increased pressure in the liver leading to ascites) (Schwinger, 2021).

Figure 1: Pathophysiology: Vicious Cycle of Heart Failure.



(Original figure by author, information sourced from: Libby, P., et al. (2021). Braunwald's Heart Disease, 2 Vol Set, 12th Edition (12th ed., Vol. 1–2). Elsevier.)

Note. ANG I= angiotensin I; ANG II= angiotensin II; AVP= arginine vasopressin; CO= Cardiac Output; SNS=Sympathetic Nervous System

Diagnosis

No single test exists to diagnose HF definitively. Instead, clinicians should evaluate the patient using physical examination, medical history, various diagnostic tests (e.g., echocardiogram), and laboratory values. The 2017 ACC/AHA focused update guidelines for HF management gives a 1/A class of recommendation/ level of evidence (COR/LOE) (see Appendix B for recommendation class and level of evidence definitions) for the use of clinical biomarkers to determine the presence and severity of HF (Yancy et al., 2017). The B-type natriuretic peptide (BNP) and N-terminal-proBNP (NT-proBNP) are two biomarkers released endogenously due to elevated ventricular pressures that provide a diuretic and natriuretic response while additionally antagonizing the RAAS system. Guidelines recommend using biomarkers early in screening for at-risk patients as a HF preventive tool (IIa/B). The B-type natriuretic peptide helps exclude a HF diagnosis because of the high sensitivity when used as a diagnostic tool (Yancy et al., 2017). For example, a BNP level greater than 100 pg/mL may support a diagnosis; however, concentrations less than 100 pg/mL reduce the likelihood of a diagnosis of HF, and a differential diagnosis should be evaluated. Healthcare institutions may use either of the two biomarkers for evaluation; however, the laboratory values may not be interchanged.

PHARMACOLOGY OF HEART FAILURE

The following sections will focus on evidence-based recommendations at stage C of the ACC/AHA guidelines for the treatment of HFrEF and HFpEF. While important, the pharmacologic options at stage D are beyond the scope of this activity. Additionally, guidelines from large international societies (e.g., European Society of Cardiology) highlight the differences in clinical practice with other countries; however, this activity will focus on recommendations exclusively from the ACC/AHA guidelines.

Heart failure with reduced ejection fraction

The goal of pharmacotherapy intervention is to reduce morbidity (e.g., decrease hospitalization and HF symptoms) and mortality; this may be achieved by decreasing cardiac preload and afterload by blunting the effects of the RAAS and sympathoadrenergic systems.

ACE Inhibitors/ ARB Therapy

Several drug categories are considered pillars of therapy management to reduce mortality in patients with HFrEF—Angiotensin Converting Enzyme (ACE) Inhibitor and Angiotensin Receptor Blocker (ARB) therapy are two of those classes.

The ACC/AHA HF guidelines recommend ACE Inhibitors as a class I/A agent. The evidence is based on clinical trials (e.g., AIRE, ATLAS, CONSENSUS, SOLVD, and SAVE) from various ACE inhibitors that reduce morbidity and mortality. Although data from landmark trials included captopril, enalapril, lisinopril, and ramipril, the benefit of ACE Inhibitors is considered a class effect. Table 2 lists the ACE inhibitors in the trials mentioned above for simplicity. Please refer to guidelines for a complete list of all drugs and targeted doses.

Angiotensin Converting Enzyme Inhibitors work by blocking the conversion of angiotensin I to angiotensin II (a potent vasoconstrictor) in the RAAS system to prevent the downstream formation of aldosterone. As a result of direct and indirect effects of reduced aldosterone levels, hypotension, hyperkalemia, and elevated serum creatinine are apparent. Additionally, ACE inhibitors block the breakdown of bradykinin, which can produce a dry cough in patients. The incidence of cough ranges in literature, with some reports of up to 37% (mean of 10%) (Shim et al., 2020). Additionally, an uncommon (0.1-0.7%) but serious adverse effect of ACE Inhibitors is angioedema. This adverse effect manifests more frequently in African Americans, women, the elderly, smokers, and those with a history of drug allergies (Kostis et al., 2018). Due to the severity of this adverse event, reintroduction or use of another ACE Inhibitor is not recommended.

An ARB can be used for patients who cannot tolerate an ACE Inhibitor. The ACC/AHA guidelines classify angiotensin Receptor Blockers as a class I/A agent per guidelines; however, only candesartan, losartan, and valsartan have this recommendation. Evidence supporting the use of these particular ARBs comes from the CHARM (candesartan), HEAAL (losartan), ValHeFT (valsartan), where a reduction in morbidity and mortality was observed (Yancy et al., 2017).

Angiotensin Receptor Blockers inhibit angiotensin II by blocking the angiotensin II type-1 receptor to prevent vasoconstrictive effects of this enzyme. The rates of angioedema with ARB are difficult to determine in literature but appear to be half of that of ACE Inhibitors (Brown et al., 2017). Because ARBs do not inhibit the enzyme kininase, angioedema is less frequent. For patients intolerant to ACE Inhibitors due to angioedema, the guidelines recommend initiating an ARB (I/A) (Yancy et al., 2017). Furthermore, the incidence of cough is less with ARB therapy than ACE inhibitors due to less interference of bradykinin metabolism (Chen et al., 2021).

As with ACE Inhibitors, clinicians need to monitor blood pressure, renal function, and potassium levels with ARBs.

Angiotensin Receptor-Neprilysin Inhibitors

Endogenous neuropeptides, such as natriuretic peptides, bradykinin, and substance P, have beneficial properties in alleviating symptoms, including decreases in: sodium retention, vascular tone, and RAAS activation. Neprilysin is an enzyme that degrades these advantageous neuropeptides; understanding this process led to the development of sacubitril to block neprilysin. Unfortunately, neprilysin also degrades angiotensin II; therefore, blocking neprilysin leads to an increase in vasoconstriction. Adding valsartan to sacubitril allows for the blockade of both angiotensin II and neprilysin, resulting in an increase in natriuretic peptides without the unwanted effects of angiotensin II. This combination drug of sacubitril and valsartan is a novel agent in treating HFrEF and the first agent in the Angiotensin Receptor-Neprilysin Inhibitors (ARNIs) class.

The ACC/AHA HF guidelines recommend sacubitril/valsartan as a I/B agent. Evidence for the use of this agent is based on the PARADIGM-HF trial. In this trial, sacubitril/valsartan was compared to enalapril in 8,442 patients with NYHA class II-IV HF and an LVEF of 40% or less. Sacubitril/valsartan, compared with enalapril, significantly reduced the risk of the composite outcome of cardiovascular mortality or HF-related hospitalizations by 20% ($p < .001$) (Yancy et al., 2017). Due to this trial, the ACC/AHA guidelines recommend, for those patients currently tolerating an ACE inhibitor or an ARB, changing to sacubitril/valsartan for further morbidity/mortality benefits (I/B)(Yancy et al., 2017). The recommended dose of sacubitril/valsartan is 24/26 mg twice daily for patients on low-dose ACE inhibitors/ARB therapy (enalapril equivalent of 10 mg/day or less or valsartan equivalent of 160 mg/day or less).

Additionally, patients with an eGFR <30ml/min/1.732, Child-Pugh Class B, and individuals 75 years or older require a lower initial dose of 24/26 mg twice daily. The recommended sacubitril/valsartan dose is 49/51 mg twice daily for patients currently taking moderate to high ACE inhibitor/ARB doses. A 36-hour washout period is necessary when converting from an ACE Inhibitor to an ARNI to help prevent the development of angioedema. If angioedema previously occurred with an ACE inhibitor, sacubitril/valsartan is contraindicated. Furthermore, a monitoring period of two to four weeks is necessary to observe patients for hyperkalemia, hypotension, and decreased renal function before doubling to the next dose (target goal of 97/103 mg)(Maddox et al., 2021).

Patients in the PARADIGM-HF experienced significantly more symptomatic hypotensive events with sacubitril/valsartan than enalapril, but this did not affect discontinuation rates. Because of clinical trial exclusion criteria, initial concerns existed for using sacubitril/valsartan in de novo HFrEF (new-onset acute HF) or in patients not previously taking an ACE inhibitor or ARB; however, in light of new data, the 2021 ACC Expert Consensus document now recommends a direct-to-ARNI approach using 24/26 mg twice daily with monitoring for blood pressure, renal function, and electrolytes for individuals naïve to ARNI therapy (Maddox et al., 2021).

Beta-Blockers

Beta-blockers are considered a cornerstone of HFrEF management; ACC/AHA guidelines recommend using an evidence-based beta-blocker in conjunction with an ACE Inhibitor, ARB, or ARNI (I/A) (Yancy et al., 2017). Because of mortality-reducing evidence from CIBIS-II (bisoprolol), COMET (Carvedilol), and MERIT (metoprolol succinate), only these three cardioselective agents are recommended per guidelines (Yancy et al., 2017). Little evidence exists regarding the efficacy between these agents, and the choice may depend on compliance and the cost of the medication.

By negating the effects of the compensatory sympathoadrenergic system in HF, beta-blockers improve systolic and diastolic dysfunction, reverse cardiac remodeling, and prevent or control arrhythmias. To negate some of the adverse effects of beta-blockers, clinicians should initiate at the lowest dose when patients are volume stable due to the possibility of initial fluid retention with these agents. Additionally, titrating to the recommended goal should be done every two weeks to assess worsening HF symptoms. Clinicians should not suddenly discontinue beta-blockers because of withdrawal effects, such as tachycardia and rebound hypertension.

Other adverse effects to monitor with beta-blockers include bradycardia, fatigue, dizziness, and hypotension.

Mineralocorticoid Receptor Antagonists

Spironolactone and eplerenone are mineralocorticoid (aldosterone) receptor antagonists (MRAs) with a I/A recommendation per ACC/AHA HF guidelines for specific individuals.

Evidence supporting these agents is based on the RALES (spironolactone) and EMPHASIS-HF (eplerenone) trials. According to the RALES trial, spironolactone, compared with placebo, decreased mortality by 30%, hospitalization by 35%, and significantly improved HF symptoms in patients with an NYHA class III and above. In the EMPHASIS trial, eplerenone also reduced the risk of the composite outcome of mortality and HF-related hospitalizations by 37% in patients with NYHA class II-IV (Ferreira et al., 2019). Both the RALES and EMPHASIS-HF trials were prematurely

stopped due to the overwhelming benefit. Guidelines recommend the use of these agents in patients with an NYHA class II-IV, a potassium level of less than 5.0mEQ/L, a eGFR greater than 30 mL/min/1.73 m2, or creatinine less than 2.5 mg/dL in men and less than 2.0 mg/dL in women (Maddox et al., 2021).

Both spironolactone and eplerenone curb the effects of the RAAS system by antagonizing aldosterone-specific mineralocorticoid receptors in the distal convoluted tubule. This process results in a decrease in sodium reabsorption and potassium retention. Due to the mechanism, clinicians should carefully monitor for hyperkalemia. Additionally, gynecomastia occurs more frequently with spironolactone than with eplerenone. This is due to eplerenone's higher binding affinity for mineralocorticoid receptors rather than androgen receptors. Furthermore, hypotension is not problematic with these agents in the HFrEF setting. In an analysis of the RALES and EMPHASIS-HF trial, the use of MRA for HFrEF treatment did not result in systolic blood pressure changes (Serenelli et al., 2020).

According to the CHAMP-HF registry, of all eligible patients, 67% were not prescribed an MRA (Greene et al., 2018). Often underutilized for concern of adverse events with MRAs, clinicians can play an essential role in ensuring these agents are added on and monitored in patients meeting criteria (Serenelli et al., 2020).

Isosorbide Dinitrate/Hydralazine Combination

The ACC/AHA HF guidelines recommend the combination of isosorbide dinitrate and hydralazine for patients who are intolerant to ACE Inhibitors, ARBs, or ARNIs (II/A COR/LOE). Additionally, guidelines recommend using the combination agent in African Americans still experiencing NYHA class III-IV symptoms despite receiving guideline-directed management and therapy (I/A). Evidence for use in patients of African American descent comes from the 2004 African-American Heart Failure Trial, where a significant improvement in mortality ($p = .02$) was observed amongst black patients with NYHA class III-IV receiving a fixed dose of isosorbide dinitrate and hydralazine plus standard therapy compared with standard therapy alone (Maddox et al., 2021; Yancy et al., 2017). As with MRAs, isosorbide dinitrate/hydralazine is underutilized in practice and represents a practice gap that clinicians should be aware of (Brewster, 2019).

Isosorbide dinitrate stimulates cyclic GMP production, resulting in decreased vascular smooth muscle tone, while hydralazine is a peripheral vasodilator that decreases arterial resistance.

The combination of the agents contributes to both a preload and afterload reduction. Due to the vasodilatory properties of this combination agent, headache, dizziness, and hypotension are common. Clinicians should be aware of rare adverse events with hydralazine, such as lupus erythematosus, nephritis, vasculitis, and hemolytic anemia (Herman et al., 2021).

The fixed-dose combination is dosed three times daily, posing a problem to non-compliant patients. Additionally, the cost of the fixed-dose can prompt clinicians to order the medications separately, which can contribute to pill burden.

Ivabradine

The latest drug included in the 2017 ACC/AHA HF guidelines is ivabradine. Unlike beta-blockers, this novel therapeutic agent reduces heart rate without compromising blood pressure. It achieves this mechanism by inhibiting the If channel (sodium channel) in the sinoatrial node to slow depolarization and ultimately reduce heart rate. The guidelines give ivabradine a IIa/B recommendation for the reduction of HF-related hospitalization in individuals with: symptomatic HF (NYHA class II-III), an LVEF 35% or less, normal sinus rhythm with a heart rate of 70 bpm or greater, and receiving guideline-directed therapy including a beta-blocker at the maximally tolerated dose (Yancy et al., 2017). The recommendation comes from the SHIFT trial, where 6,558 patients were randomly assigned to ivabradine or placebo. According to this trial, compared with placebo, ivabradine significantly reduced the composite outcome of cardiovascular mortality or HF-related hospitalization ($p < .0001$). However, when analyzing outcomes separately, ivabradine had little impact on all-cause mortality or cardiovascular mortality; the composite outcome was primarily driven by a significant reduction in HF-related hospitalizations (Yancy et al., 2017).

In the SHIFT trial, symptomatic bradycardia and transient vision changes were reported more commonly in the ivabradine group than in the placebo group. Real-world data began to surface with an increased risk of atrial fibrillation after initiating ivabradine. According to a recent meta-analysis consisting of thirteen trials and 37,533 patients, a significantly higher incidence of atrial fibrillation was associated with ivabradine than with placebo (OR 1.23; 95% CI, 1.08-1.41) (Wang et al., 2021). Therefore, ivabradine is contraindicated in patients with atrial fibrillation.

The initial dose of ivabradine is 5 mg twice daily; however, a lower dose of 2.5 mg twice daily is recommended for individuals with a history of conduction defects or those at risk of hemodynamic compromise. Titration is based on the patient's heart rate. If the heart rate remains above 60 bpm and the patient is asymptomatic, the dose can be increased to the goal of 7.5 mg twice daily. If not already at the target dose and the patient's heart rate is between 50 to 60 bpm, a dose increase is not warranted, and the patient should remain on the current dose. Lastly, if the patient's heart rate falls below 50 bpm or experiences bradycardia symptoms, the dose should be reduced to 2.5 mg twice daily unless the patient is already at the lowest dose, which would require discontinuation.

Sodium-Glucose Cotransporter-2 Inhibitors

Patients with HF have a four-fold higher prevalence of T2DM than those without HF (Maack et al., 2018). Until recently, limited pharmacological options existed to treat both highly correlated conditions. Furthermore, some T2DM agents, such as pioglitazone and saxagliptin, increase the risk of HF development and hospitalization. Sodium-glucose cotransporter-2 (SGLT2) inhibitors are a novel class of antidiabetic agents that reduce both cardiovascular- related events and diabetic outcomes.

Clinical trials of SGLT2 inhibitors have shown a class effect in reducing HF-related hospitalization in patients with and without T2DM. This serendipitous finding led researchers to look for plausible mechanisms. Unfortunately, the mechanism of action for benefit in HF is complex and elusive. A leading theory is that SGLT2 inhibitors potentially cause a preload and afterload reduction. Sodium-glucose cotransporter 2 is a protein found mainly in the proximal convoluted tubule and is responsible for reabsorbing glucose via an electrochemical gradient with sodium. Sodium-glucose cotransporter-2 inhibitors work by blocking the endogenous protein and allowing for sodium and glucose to be excreted. An osmotic diuretic effect occurs by eliminating sodium (natriuresis), which contributes to a preload reduction (Verma & McMurray, 2018). An afterload reduction might be plausible by regulating the renal afferent nerve activity, which blunts the central reflex mechanism to activate the sympathetic nervous system. The result is a decrease in catecholamines that would otherwise increase vascular resistance (Sano, 2018).

Data from large randomized controlled trials involving SGLT2 inhibitors were published after the 2017 ACC/AHA HF guidelines. However, the 2021 ACC Expert Consensus Pathway for Optimization of HF document recommends empagliflozin or dapagliflozin for patients with NYHA class II-IV and adequate renal function (Maddox et al., 2021). In addition, the American Diabetes Association Standards of Medical Care do not specify a specific SGLT2 inhibitor but recommend the use in patients with T2DM when HFrEF predominates (American Diabetes Association, 2021).

Evidence supporting the empagliflozin recommendation comes from the EMPEROR-REDUCED trial (Packer et al., 2020). This trial included 3,730 adult patients with or without T2DM, an LVEF of 40% or less, and an NYHA class II-IV that were randomly assigned to empagliflozin 10 mg or placebo. The empagliflozin group, compared with placebo, had a 25% risk reduction in the composite outcome of cardiovascular death or first hospitalization for decompensated HF (HR 0.75; 95% CI 0.65 to 0.86; $p <$

.001). The primary composite outcome benefit was mainly from a 31% reduction in HF hospitalization. When analyzed separately, empagliflozin, compared to placebo, did not significantly reduce cardiovascular mortality (HR, 0.92; 95% CI, 0.75 to 1.12).

The HFrEF dosing of empagliflozin is 10 mg by mouth every morning. While this agent is contraindicated with an eGFR less than 30 ml/min/1.732 for a T2DM indication, empagliflozin can be initiated in adults with HFrEF at an eGFR as low as 20 ml/min/1.732. From clinical trials, genital infections were a statistically significant adverse event; this adverse event can be treated with antifungal agents and does not warrant discontinuation of the SGLT2 inhibitor. Other adverse effects are urinary tract infections, diabetic ketoacidosis, volume depletion, and hypotension.

The ACC Expert Consensus Pathway for HF also supports dapagliflozin in the HFrEF. The evidence for this decision comes from the DAPA-HF Trial (McMurray et al., 2019). This trial consisted of 4,744 adult patients with HFrEF (regardless of T2DM status) with an LVEF of 40% or less, NYHA II-IV symptoms, and elevated NT-proBNP levels. Like empagliflozin in the EMPEROR- REDUCED trial, dapagliflozin reduced the risk of the composite outcome of cardiovascular death and the initial episode of worsening heart failure by 26% (HR, 0.74; 95% CI, 0.65 to 0.85%; $p < .001$). This significant outcome was also driven primarily by a risk reduction in HF-related hospitalizations (30%).

Currently, dapagliflozin has the FDA approvals for glycemic control in T2DM patients; HF risk reduction in patients with or without T2DM; and risk reduction for renal decline, end-stage kidney disease, cardiovascular death, and hospitalization in patients with HFrEF and chronic kidney disease. The current dose for HFrEF patients is 10 mg daily in patients with an eGFR greater than 30 ml/min/1.73m2. Genital infections and diabetic ketoacidosis were significantly greater in patients taking dapagliflozin compared with placebo in clinical trials. Patients can also experience urinary tract infections, volume depletion, and hypotension while taking this medication.

To date, dedicated HF trials involving other SGLT2 inhibitors (canagliflozin and ertugliflozin) are not available. Unfortunately, clinical trials that brought these agents to market had a low percentage of patients with a history of heart failure. For that reason, these two SGLT2 inhibitors do not have an FDA indication for HFrEF.

Digoxin

Atrial fibrillation is a concomitant condition associated with HF, where the prevalence reaches nearly 25% (Carlisle et al., 2019). Controversy exists with the role of digoxin therapy in the HFrEF setting to treat both conditions despite this agent being nearly a century old. Conflicting data exist regarding whether digoxin increases mortality risk due to older clinical trials having inconsistent baseline criteria and definitions. According to the DIG trial, patients with an LVEF of 45% or less had no improvement in mortality but had decreased symptoms and a reduction in hospitalization. The trial is from 1997, and guideline-directed therapy has since evolved, which questions the efficacy of digoxin today. Meta-analyses that try to reconcile data over the years have led to mixed results on mortality. The 2021 ACC/AHA consensus update states digoxin lacks any new compelling data to change the IIa/B recommendation from the previous guidelines (Maddox et al., 2021). Currently, digoxin may be used to reduce hospitalizations in patients with HFrEF. Alternatively, guidelines suggest the consideration of digoxin in patients with atrial fibrillation for heart rate reduction when other agents are not appropriate. The starting dose of digoxin is 0.125 to 0.25 mg daily with dose adjustments for renal insufficiency, drug interactions (e.g., amiodarone and macrolide antibiotics), and drug levels.

The mortality risk is independently associated with a digoxin level of 1.2ng/mL or greater in patients with atrial fibrillation; therefore, a lower target of 0.5-0.9 ng/mL is recommended in the HFrEF setting (Lopes et al., 2018). Drug toxicity leads to conduction abnormalities, hallucinations, intestinal ischemia, and potentially death. Common reactions of the drug may include dizziness, headache, nausea, anorexia, and abdominal pain.

Diuretics

Diuretics will be discussed in a subsequent section.

Other Therapeutic Options: Vericiguat

The latest HF medication to receive FDA approval for HFrEF is vericiguat, based on the results from the VICTORIA trial.

Vericiguat is an agent classified as an oral guanylate cyclase stimulator. Guanylate cyclase is an enzyme that works in tandem with nitric oxide to stimulate cyclic guanosine monophosphate. Intracellularly, cyclic guanosine monophosphate facilitates systemic and pulmonary vasodilation, prevents cardiac hypertrophy, and reduces the harmful effects of catecholamines.

Vericiguat, compared to placebo, reduced the risk of the primary composite outcome of cardiovascular mortality and HF-related hospitalizations by 10% (HR, 0.90; 95% CI, 0.82 to 0.98; $p = .02$) according to results from the VICTORIA trial (Armstrong et al., 2020). In a secondary analysis that separated the primary outcome components, HF-related hospitalizations were statistically significant; however, CV mortality was not. The authors of this study stated that the risk reduction of vericiguat, compared to other novel HFrEF agents, was not as substantial-potentially due to a more advanced HF population (41% with NYHA class III-IV) included within the VICTORIA trial. Vericiguat is FDA approved for HFrEF with an LVEF of 45% or less and for patients recently hospitalized or receiving outpatient intravenous diuretics. This agent should be dosed at 2.5 mg by mouth daily with food and titrated as tolerated to 10 mg by mouth daily. The adverse effects of vericiguat were not statistically different from placebo in the VICTORIA trial. However, vericiguat had a numerically higher number of symptomatic hypotensive cases. Additionally, this drug has a contraindication for use in pregnancy due to associated fetal toxicity.

Since the FDA approved vericiguat in early 2021, the 2017 ACC/AHA HF guidelines do not mention this agent. Given the novelty of this agent, the place in HFrEF therapy is unknown at this time. However, it can be considered an add-on agent for those already taking guideline- directed therapy. In addition, the daily cost of vericiguat is $14.57, which may affect clinical decisions (Alsumali et al., 2021).

Healthcare Professional Consideration: With newer agents available for the treatment of HFrEF and HFpEF, affordability may be a factor for many patients. However, socioeconomic status should not preclude patients from receiving beneficial treatment. Clinicians should be aware if a drug manufacturer has a savings card that can be used together with health insurance to reduce the monthly cost of the medication. Additionally, drug manufactures may have a patient assistance program for uninsured or underinsured individuals to receive the medication at no additional cost.

Table 2: Recommended HFrEF Treatment and Dosing Guideline

Class	Drug	COR/LOE	Initial Dosing	Maximum Dose
ACEI	Captopril	I/A	6.25 mg TID	50 mg TID
ACEI	Enalapril	I/A	2.5 mg BID	10-20 mg BID
ACEI	Lisinopril	I/A	2.5-5 mg daily	20-40 mg daily
ACEI	Ramipril	I/A	1.25-2.5 mg daily	10 mg daily

Table 2: Recommended HFrEF Treatment and Dosing Guideline				
ARB	Candesartan	I/A	4-8 mg daily	32 mg daily
ARB	Losartan	I/A	25-50 mg daily	50-150 mg daily
ARB	Valsartan	I/A	20-40 mg BID	160 mg BID
ARNI	Sacubitril/valsartan	I/B	24/26 mg BIDa 49/51 mg BID	97/103 mg BID
β-Blocker	Bisoprolol	I/A	1.25 mg daily	10 mg daily
β-Blocker	Carvedilol	I/A	3.125 mg BID	25 mg BID or 50 mg BID (for ≥ 85 kg)
β-Blocker	Metoprolol succinate	I/A	12.5-25 mg daily	200 mg daily
I_f Channel inhibitor	Ivabradine	IIa/B	5 mg BID	7.5 mg BID
MRA	Eplerenone	I/A	25 mg daily	50 mg daily
MRA	Spironolactone	I/A	12.5-25 mg daily	25 mg daily or BID
NA	Isosorbide dinitrate/ hydralazine (Fixed- dose combination)	I/A	20 mg isosorbide dinitrate/ 37.5 mg hydralazine TID	40 mg isosorbide dinitrate/ 75 mg hydralazine TID
NA	Isosorbide dinitrate/hydralazine	I/A[b]	20–30 mg isosorbide dinitrate/ 25–50 mg hydralazine TID or QD	40 mg isosorbide dinitrate TID with 100 mg hydralazine TID
SGLT2 Inhibitor	Empagliflozin	Not evaluated	10 mg every morning	NA
SGLT2 Inhibitor	Dapagliflozin	Not evaluated	10 mg daily	NA

Note. Drug Information and COR/LOE from: 2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure, by C.W. Yancy, M Jessup, B Bozkurt, et al. JACC, 70(6), 776-803.

Note. ACEI= Angiotensin Converting Enzyme Inhibitor; ARB= Angiotensin Receptor Blocker; BID= Twice a day; ARNI= Angiotensin Receptor-Neprilysin Inhibitors; COR/LOE= Class of Recommendation/Level of Evidence; NA= Not applicable; TID= Three times a day.

a= de novo initiation; age ≥75, severe renal impairment, Child-Pugh class B, low dose ACE/ARB.
b=Recommendation for African American patients on guideline-based therapy

Self-Assessment Quiz Question #1

Which of the following agents does NOT have evidence supporting a mortality benefit for patients with HFrEF?
a. Carvedilol.
b. Lisinopril.
c. Spironolactone.
d. Digoxin.

Heart failure with preserved ejection fraction

Unlike HFrEF with evidence-based treatment options, agents used to manage HFpEF have had limited success. While several trials have demonstrated HF-related hospitalization reduction, trials evaluating various agents have either unclear or no impact on mortality reduction. Due to the lack of successful pharmacological options in this setting, the ACC/AHA HF guidelines recommend initially treating comorbid conditions and managing symptoms.

The latest guidelines give a 1/B recommendation to control systolic and diastolic blood pressure to prevent morbidity in patients with HFpEF (Yancy et al., 2017). Additionally, the guidelines give a 1/C recommendation for the use of diuretics to reduce symptoms caused by volume overload. The discussion below describes the various agents investigated for managing hypertension and relieving symptoms in patients with HFpEF.

Mineralocorticoid Receptor Antagonists

Evidence for using a mineralocorticoid receptor antagonist comes from the large international TOPCAT trial using spironolactone. This trial included patients with HF symptoms and an LVEF greater than 45%. Patients were randomly selected to receive either spironolactone or placebo and evaluated for the composite primary endpoint of CV mortality, HF-related hospitalization, or aborted cardiac arrest. Despite the primary composite outcome not reaching statistical significance (p = .14), HF-related hospitalizations were significantly reduced with spironolactone compared with placebo (12% vs 14.2%, p= .04) (Kumbhani, 2021). A post hoc analysis revealed variations in event rates between testing centers in Russia and the Americas; treatment with spironolactone in the Americas improved efficacy, while efficacy rates did not improve in some Russian testing facilities. Furthermore, active metabolites for spironolactone were undetectable at some Russian sites, suggesting possible non-adherence to trial protocols and, therefore, skewing the primary outcome results in the TOPCAT trial (Yancy et al., 2017).

Because of affordability and the ability to reduce HF-related hospitalizations, spironolactone remains a potential option in the treatment of HFpEF. The ACC/AHA guidelines recommend mineralocorticoid receptor antagonists for HF-related hospitalizations in patients with: an LVEF of 45% or greater, elevated BNP levels, hospitalizations within one year, GFR above 30 ml/min, serum creatinine less than 2.5 mg/dL, and potassium levels less than 5mEQ/L (IIb, LOE B-R) (Yancy et al., 2017).

ACE Inhibitors/ ARB Therapy

In the last two decades, only a select few ACEI/ ARB agents have been studied in the HFpEF setting: candesartan (CHARMED-Preserved), irbesartan (I-Preserve), and perindopril (PEP-CHF). The data from these trials have been less than robust, with no impact on HF-related hospitalization. A secondary analysis from the CHARM-PRESERVED trial provides the best evidence supporting the use of an ARB (candesartan) in patients with an LVEF greater than 40%. Initially, the primary composite outcome for HF-related hospitalizations and CV mortality did not reach statistical significance in the main CHARMED-PRESERVED trial (HR, 0.89 (95% CI, 0.77–1.03); P = 0.12). However, after adjusting for baseline characteristics in the secondary analysis, compared with

placebo, candesartan had a significant decrease in the composite of HF-related hospitalizations and cardiovascular death (p = .051) (Kjeldsen et al., 2020). Based on this trial, current guidelines give a IIb/B recommendation for using ARBs to decrease HF hospitalization (Yancy et al., 2017). Unfortunately, efficacy for the use of irbesartan could not be duplicated in the I-PRESERVE trial. In this trial, no significant difference was observed in patients with an LVEF 45% or greater taking irbesartan 300 mg daily or placebo in terms of all- cause mortality or cardiovascular-related hospitalization after a 50 month mean follow-up (Kjeldsen et al., 2020). In the PEP-HF trial, perindopril (4 mg/day), compared with placebo, failed to show a difference in the composite outcome of all-cause mortality or HF-related hospitalization (Kjeldsen et al., 2020).

Angiotensin Receptor-Neprilysin Inhibitors

In early 2021, the FDA approved sacubitril/valsartan for the treatment of HFpEF based on the results of the PARAGON-HF trial; this marks the first time a medication received approval, specifically the treatment of HFpEF. This study included 4,822 patients older than 50 years, with NYHA class II-IV symptoms, an LVEF of 45% or greater, structural heart disease, and elevated NT-proBNP. Patients were randomly assigned to receive sacubitril/valsartan (dose targeted to 97 mg/103 mg twice daily) or valsartan alone (dose targeted to 160 mg twice daily). The combination of sacubitril/valsartan, compared with valsartan alone, clinically reduced the risk of the composite of HF-related hospitalizations and cardiovascular death by 13% (RR, 0.87; 95% CI, 0.75 to 1.01; p = .06), but failed to achieve statistical significance (Solomon et al., 2019). Despite sacubitril/valsartan narrowly not meeting the statistical significance for the primary outcome, the FDA advisory committee discussed a favorable safety profile and positive evidence in the PARADIGM-HF in the decision for drug approval (FDA Advisory Committee, 2020).

Beta-Blockers

The ACC/AHA HF guidelines mention beta-blockers in conjunction with an ACE inhibitor/ARB therapy as a class IIa/C recommendation in patients with HFpEF. Like evidence with ACE inhibitors/ARBs, data are sparse regarding beta-blockers in the HFpEF setting. According to a meta-analysis of eleven trials, no morbidity or mortality benefit existed using various beta- blockers in a small group of patients with an EF of 50% or greater (N=73) (Cleland et al., 2018). More recently, according to a secondary analysis of the TOPCAT Trial, beta-blockers were associated with an increased risk of HF-related hospitalization in 1,567 patients with an EF greater than 50%; however, there was not a significant associated risk of CV mortality in this population (Silverman et al., 2019). While evidence supports a mortality benefit in patients with HFrEF, the use of beta-blockers in HFpEF may be better used as an agent for rate control for atrial fibrillation management.

Diuretics

Current ACC/AHA HF guidelines recommend diuretics to provide symptom relief in patients with volume overload in HFrEF and the HFpEF setting (class IC). In combination with sodium and fluid restriction, loop diuretics (e.g., bumetanide, furosemide, torsemide) are typically used for diuresis, where dose and route are based on the severity of volume overload. The pharmacokinetics of loop diuretics may influence clinical decisions. For example, furosemide has a variable bioavailability (10-90%) that is influenced by food, which affects drug absorption. Meanwhile, the bioavailability of torsemide and bumetanide is larger, less variable (80-90%), and has a longer half-life (3-4 hours) than furosemide (1-1.5 hours) (Gupta et al., 2019; Oh & Han, 2015). Therefore, patients refractory to furosemide may have more success with a different loop diuretic. Adverse effects of loop diuretics may include but are not limited to electrolyte imbalances, hypovolemia, and ototoxicity; therefore, clinicians need to be cautious in aggressive diuresis.

In patients that are refractory to loop diuretics, thiazide or thiazide-like diuretics (e.g., metolazone) can be used to augment management. Thiazide and thiazide-like diuretics work to prevent the reabsorption of sodium in the distal convoluted tubule, as well as potassium. As such, adverse events of electrolyte imbalances, hyperuricemia, and orthostatic hypotension may occur.

When managing fluid status, clinicians should carefully examine changes in electrolyte levels, renal function, daily weight (reduction of 1 kg/day), and blood pressure.

Sodium-Glucose Cotransporter-2 Inhibitors

As previously mentioned, SGLT2 inhibitors reduce the risk of HF hospitalizations; however, data from these landmark trials enrolled a small number of patients with HF or did not stratify patients according to HF subtype. As a result, these trials had mixed results with the use of SGLT2 inhibitors for patients with HFpEF (Cosentino et al., 2020; Januzzi, 2019; Kato et al., 2019).

The EMPEROR-PRESERVED trial was the first clinical trial dedicated to investigating patients with HFpEF, which used the SGLT2 inhibitor empagliflozin (Anker et al., 2021). In this study, 5,988 patients (with or without T2DM), having an LVEF above 40% and classified as an NYHA class II to IV, were randomly assigned to receive empagliflozin 10 mg daily or placebo. The primary outcome of the composite of hospitalization for heart failure or cardiovascular death occurred in 13.8% (n = 415) of patients receiving empagliflozin and 17.1% (n = 511) of patients receiving placebo (6.9 vs. 8.7 events per 100 patient-years, respectively; HR 0.79; 95% CI, 0.69 to 0.90; p < .001). Separating the components of the primary outcome, a reduction in cardiovascular mortality rates was not statistically significant. Nevertheless, based on the results from this trial, the FDA granted empagliflozin breakthrough therapy designation status as an investigational treatment option for HFpEF. Breakthrough designation status signifies that a drug improves outcomes over other therapeutic agents on at least one clinical endpoint. Additionally, FDA expedites the review and drug development process for this agent.

The DELIVER trial (NCT03619213) is another dedicated HFpEF trial with SGLT2 inhibitors that is currently underway. This trial is currently evaluating dapagliflozin 10 mg compared to placebo for the primary composite outcome of HF events and cardiovascular death (Solomon et al., 2021). Included in the trial were patients with an LVEF greater than 40%, elevated natriuretic peptides, and HF signs and symptoms. Results from the DELIVER Trial are expected in 2022.

Trials evaluating sotagliflozin, an investigational SGLT2 inhibitor, provide further information with SGLT2 inhibitors' use in patients with HFpEF. According to the SOLOIST WHF and SCORED Trials, the primary outcome of the composite of cardiovascular mortality and hospitalizations or urgent outpatient care visits related to HF was reduced by 33% with sotagliflozin when compared with placebo. Unfortunately, these trials ended prematurely due to a loss of funding, and this trial included a small sample of patients with HFpEF (N = 1,931) (Bhatt, 2021).

Because data from trials evaluating patients with HFpEF dedicated trials are still pending or resulted after the 2017 ACC/AHA HF guidelines, no recommendation exists for the use of SGLT2 inhibitors in this setting. The Paragon-HF study and the dedicated HFpEF trials with SGLT2 inhibitors included patients with an LVEF less than 50%; this may have confounded results by including HFmrEF patients by definition. The next update to the HF guidelines should address this and make recommendations on these two novel drug classes for HFpEF

Other Therapeutic Options

The 2017 ACC/AHA guidelines do not recommend other agents at this time, such as nitrates, phosphodiesterase-5 inhibitors (e.g., sildenafil), or nutritional supplements due to insufficient evidence (Yancy et al., 2017).

Self-Assessment Quiz Question #2

Which of the following therapeutic agents has both FDA approval AND is recommended per HF guidelines for the treatment of HFpEF?

a. Sacubitril/valsartan.
b. Empagliflozin.
c. Dapagliflozin.
d. None of the above.

Conclusion

Heart Failure is a clinical syndrome associated with significant morbidity and mortality that varies with age, gender, and ethnicity. The current understanding of HF pathophysiology allows for medications that reduce preload and afterload by curbing the compensatory response of the sympathoadrenergic and RAAS systems. Multiple agents in the treatment of HFrEF significantly reduce mortality. In the next decade, the percent of cases of HFpEF will likely surpass those of HFrEF; unfortunately, treatment options to date are limited. More research on the pathophysiology of this condition and drugs with beneficial outcomes in this setting is imperative. For the time being, clinicians can help curb the prevalence of HFpEF by preventing and controlling comorbid conditions. An update to the 2017 ACC/AHA guidelines is warranted, with newer pharmacotherapeutic options available for HF treatment. According to the ACC, the estimated release of new guidelines will occur by mid-2022. Until then, clinicians need to work together to close the gap between guideline recommendations and actual clinical practice to provide the best outcomes for patients with heart failure.

Case study

CW is a 68-year-old African American female with a history of HFrEF, hypertension, T2DM, obesity, and seasonal allergies. She presents to the emergency room after Christmas dinner at her sister's house. CW complains of increased symptoms of "difficulty in breathing, unable to walk to the mailbox without having to rest, and needing to sleep on two big pillows to get any rest." Her current laboratory values are within normal limits, except her BNP is 1,200 pg/mL, prompting the ER provider to put in for a cardiology consult and admit the patient. Upon reviewing her home medications with the busy ER provider, she states she does not have insurance but lists the following home medications: carvedilol 25 mg twice a day, metformin 500 mg twice a day, and loratadine 10 mg daily. She states she was prescribed captopril but is not taking it anymore because her sister "had her mouth swell up, and taking all of these medications are expensive." The provider told her, "Isosorbide dinitrate/hydralazine is better in the black population, and we may need to consider that since you cannot afford to take your captopril." The provider quickly leaves the room to attend to a stroke alert next door. After hearing this, CW becomes irate and does not want to be admitted to the hospital. You come in to finish her medication reconciliation prior to hospital admission, only to find her visibly upset.

Question 1:
What are some examples of implicit bias that the initial provider may have had upon evaluating CW?

Discussion:
According to recent studies, African Americans are associated with a higher incidence and prevalence of HF than Caucasians (Chandra et al., 2022; Virani et al., 2020). African American women also have a 2.5-fold higher rate of HF hospitalizations than Caucasians (Nayak et al., 2020). Furthermore, the majority (80%) of HF-related hospitalizations occur in individuals 65 years and above (Lesyuk et al., 2018). Because of these variances in demographics, discussions and further studies are needed to better understand factors contributing to this gap.

Factors such as implicit bias towards race, age, and socioeconomic background lead to worse healthcare outcomes. In this case, an implicit bias towards the patient may be evident in the provider's comments, such as a quick recommendation on isosorbide dinitrate/hydralazine without examining and explaining other options for CW. Additionally, we see that the provider states, "…since you cannot afford to take your captopril". We do not know if the provider is referring to her socioeconomic status or the inability of CW to take an ACE inhibitor due to what seems to be a family history of angioedema. Having a conversation with the patient with clear word choices will alleviate perceived bias.

Question 2:
What is an evidence-based recommendation that is a better option for CW?

Discussion:
According to the African-American Heart Failure Trial, isosorbide dinitrate/hydralazine significantly reduced mortality in African American patients. This agent may not be the best choice for CW, however. The provider needs to investigate the history of "mouth swelling" and if CW has ever used an ACE inhibitor in the past and for how long. Furthermore, if a valid contraindication exists because of angioedema, it does not preclude using an ARB per guidelines. Using an ARB versus an isosorbide dinitrate/hydralazine combination can reduce pill burden and improve compliance.

Appendix:

Appendix A: Abbreviations in This Activity	
ACC	American College of Cardiology
ACE	Angiotensin Converting Enzyme
AHA	American Heart Association
ARB	Angiotensin Receptor Blocker
BNP	B-type natriuretic peptide
HF	Heart Failure
HTN	Hypertension
LVEF	Left Ventricular Ejection Fraction
LOE	Level of Evidence
MRA	Mineralocorticoid Receptor Antagonist
NT-proBNP	N-terminal-proBNP
NYHA	New York Heart Association
RAAS	Renin-angiotensin-aldosterone-system
SGLT2	Sodium-glucose cotransporter-2 inhibitors
T2DM	Type 2 diabetes mellitus

Appendix B: ACC Classification and Level of Evidence	
Class of Recommendation	**Level of Evidence**
I: Clear benefit that exceeds risk and treatment or procedure should be done	**Level A**: Data from several randomized controlled trials or meta-analyses with multiple patient populations studied
IIa: Benefit is in favor, but additional studies are needed for treatment or procedure	**Level B**: Data from single randomized controlled trials or non-randomized studies with limited patient populations studied. **B-R-** denotes level B from randomized controlled trials
IIb: Unclear benefit, but treatment or procedure may be considered	**Level C**: Cases studies or consensus opinion with minimal patient populations studied.
III: No benefit or harm with treatment or procedure	
Note. Class of Recommendation and Level of Evidence from: 2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure, by C.W. Yancy, M Jessup, B Bozkurt, et al. JACC, 70(6), 776-803.	

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HEART FAILURE: EVIDENCE REVIEW AND MANAGEMENT

Self-Assessment Answers and Rationales

1. The correct answer is D.
Rationale: Carvedilol and lisinopril are considered core medications that patients with HFrEF must be on due to mortality benefits. Spironolactone decreased mortality in the RALES trial. Therapy can be implemented in patients with an NYHA class II-IV provided potassium levels are less than 5mEq/L and have acceptable renal function. According to the DIG trial, digoxin improved symptoms and reduction in hospitalization, but not mortality.

2. The correct answer is D.
Rationale: Currently, sacubitril/valsartan has the only FDA approval for the treatment of HFpEF. Evidence in favor of this agent came after the ACC/AHA guidelines were published. Of the SGLT2 inhibitors, only empagliflozin currently has FDA breakthrough designation status but not FDA approval. Additionally, information on these agents was also made available after the HF guidelines were published.

HEART FAILURE: EVIDENCE REVIEW AND MANAGEMENT

Final Examination Questions

Select the best answer for each question and complete your test online at **EliteLearning.com/Book**

21. Which of the following definitions best describes heart failure with preserved ejection fraction?
    a. An ejection fraction of ≤ 40%.
    b. An ejection fraction of ≥ 50%.
    c. An ejection fraction between 41-49%.
    d. None of the above.

22. Which demographic has the highest prevalence of heart failure with preserved ejection fraction?
    a. Age greater than 65 years.
    b. African American males.
    c. Female gender.
    d. None of the above.

23. Which statement best describes the difference between the ACC/AHA staging system and the NYHA functional class system?
    a. The ACC/AHA scale is based on the presence of symptoms and cardiac structure abnormalities, while the NYHA is based on limitations in physical activity with severity progression.
    b. The ACC/AHA is based on limitations in physical activity with severity progression, while the NYHA class is based on the presence of symptoms and cardiac structure abnormalities.
    c. The ACC/AHA scale allows for bidirectional movement with patient improvement and worsening, while the NYHA class is unilateral only.
    d. There is no difference between the two systems, and they can be used interchangeabl y.

24. Which of the following statements accurately describe the pathophysiology of heart failure?
    a. The compensatory mechanism of heart failure enables the RAAS system to ultimately produce norepinephrine.
    b. Preload is the pressure at which the heart has to pump against.
    c. Afterload is referred to as the myocardial stretching prior to ventricular contraction.
    d. Increasing preload and afterload in patients with heart failure boosts stroke volume initially before reaching a plateau.

25. Which of the following statements is most accurate in diagnosing heart failure?
    a. Heart failure can be diagnosed exclusively on BNP.
    b. BNP helps to rule in a diagnosis because of the high sensitivity associated with the test.
    c. BNP and N- terminal- proBNP levels can be used interchangeabl y.
    d. A BNP level greater than 100 pg/mL may support a diagnosis of heart failure.

26. Based on ACC/AHA guidelines, which of the following agents should be used initially in patients with HFrEF unless contraindications exist?
    a. Carvedilol.
    b. Digoxin.
    c. Hydralazine/ Isosorbide dinitrate.
    d. Ivabradine

27. Which of the following statements is most accurate regarding SGLT2 inhibitors in the HFrEF setting?
    a. All SGLT2 inhibitors are created equal, and any should be used in the initial management of HFrEF.
    b. Robust data exists for SGLT2 inhibitors to significantly reduce cardiac mortality.
    c. Empagliflozin and dapagliflozin have the most evidence supporting the use in HFrEF.
    d. The ACC/AHA gives an 1/B recommendation to empagliflozin due to lack of improvement in HF-related hospitalization.

28. Which of the following recommendations is most accurate for the management of HFpEF?
    a. Robust data exists regarding mortality benefits with many drug classes.
    b. Guidelines recommend focusing on treating comorbid conditions and symptom management.
    c. Sildenafil is an I/A recommendatio n due to improvement in morbidity.
    d. Currently, dapagliflozin has FDA approval for the treatment of HFpEF.

29. Which of the following statements is true about digoxin?
    a. Robust data exists regarding mortality benefit for its use in heart failure.
    b. Drug concentration levels >1.2 ng/mL are associated with an increase in survival.
    c. Clinicians should target drug concentrations between 0.5-0.9 ng/mL in the HFrEF setting.
    d. It is considered a first-line agent for heart rate management due to the lack of significant drug interactions.

30. What is the best recommendation for a patient who experienced angioedema with lisinopril?
    a. The patient can try sacubitril/valsar tan after a 36- hour washout period.
    b. The patient can retry a different ACE inhibitor due to a lack of cross-sensitivity.
    c. The patient can try an angiotensin receptor blocker.
    d. The patient should immediately be changed to ivabradine.

Course Code: RPUS02HM

Chapter 4: Mental Health Concerns and the Older Adult

6 Contact Hours

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Author Disclosure: Mary Perry and Colibri Healthcare, LLC do not have any actual or potential conflicts of interest in relation to this lesson.

Universal Activity Number (UAN): 0607-0000-23-013-H99-P
Activity Type: Knowledge-based
Initial Release Date: October 12, 2022
Expiration Date: October 12, 2025
Target Audience: Pharmacists in a community-based setting.
To Obtain Credit: A minimum test score of 75 percent is needed to obtain a credit. Please submit your answers either by mail, fax, or online at **EliteLearning.com/Book**

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Learning objectives

Upon completion of this course, the learner will be able to do the following:

- Examine the most common theories on aging, developmental tasks, and reflection from the older adult perspective.
- Evaluate essential components of the therapeutic alliance with the older adult.
- Demonstrate verbal communication styles that enhance the interpersonal connection with the older adult.
- Differentiate the social determinants of health and the barriers to care for the older adult.
- Select recommended assessment considerations for the older adult.
- Appraise biopsychosocial considerations for the assessment for the older adult.
- Analyze crisis, loss, grief, and bereavement for the older adult.
- Distinguish risk factors, treatment, and recovery for the older adult with a mental health diagnosis.

INTRODUCTION

Aging is a normal biological process. It is a distinctive, often progressive, natural decline in functioning that includes all body systems— cardiovascular, endocrine, immune, and neurological, to note a few. *Elderly* is a term often used interchangeably with *older adult*, which the American Association of Geriatric Psychiatry (Lundebjerg et al., 2017) defines as those age 65 years and older, which qualifies them for Medicare eligibility. This patient population is projected to double from 2015 to 2050 worldwide (World Health Organization, 2017). As the world population rapidly increases, so too do mental health needs. Everyone will experience aging on some level, but differing populations will advance at different rates. However, increasing age is not proportionally associated with declining intellectual and physical capacity. Older adults with mental health needs are a population subset with specific characteristics for the healthcare worker. The ability to thoroughly assess and diagnose, individualize care (whether lifestyle related or pharmacologic), and tailor mental health interventions for the older adult can improve quality care and safety. The unique presentation of the older adult can provide a better understanding for assessment, intervention, and treatment considerations for the healthcare worker addressing the mental health needs of the older adult.

THEORIES ON AGING

The inevitability of aging and its developmental stages in association with human health have been studied and debated over the years. What follows is a summarization of the most common theories on older adulthood, from Sigmund Freud, Heinz Kohut, Bernice Neugarten, Daniel Levinson, and Erik Erikson. Healthcare workers see aspects of each of these while assessing and caring for the older adult's mental health needs. Sigmund Freud was focused on the need to control the ego (part of the human psyche that operates in the real world) and id (part of the human psyche that strives to fulfill primal needs) with the superego (internalized values and morals that push the ego to act in a more virtuous way). Regression may induce rudimentary methods of coping to resurface in the older adult (Sadock et al., 2015). Heinz Kohut stated that the elderly are constantly faced with narcissistic injury as they cope and adapt to the biological, psychological, and social losses associated with the aging process. The central task of aging is preservation of self-esteem (Sadock et al., 2015). Bernice Neugarten theorized the major conflict of old age to lie in the release of autonomy and authority; the focus is on accomplishments and previous victory. This time is for reconciliation with others and processing grief related to the death of others and the inevitability of death of self (Sadock et al., 2015). Daniel Levinson found that age 60 to 65 is a transition period. Older people, "late adults," become consumed by the thought of their death and are often narcissistic and heavily engrossed in their body appearance. He found that creative mental activity is recommended and is a healthy substitute for decreased physical activity (Sadock et al., 2015). All the above theorists have aspects of interest for the healthcare worker to note; however, Erik Erickson's eight psychosocial stages of development are especially worthwhile to consume prior to working with an older adult.

Erik Erikson created a framework that highlights tasks to be accomplished, virtues to be gained, or—conversely—a crisis can occur throughout the life span. He expanded on Freud's theory by recognizing the relationship between the individual and their environment to include a client's customs and traditions (Sadock et al., 2015). The healthcare worker should approach each client's meaning, acceptance, or toil with life and death with cultural awareness. Erikson's stages from birth to older adult are a trajectory of development, an amalgamation of physical, cognitive, instinctual, and sexual realms (Sadock et al., 2015). An interruption or inability to accomplish the tasks in each stage may lead the client to undergo a decision point in their life. The older adult is influenced by each stage along the continuum. The healthcare worker can gain much by capturing the perspective of the older

adult client through the lens of the stages of Erik Erikson's psychosocial stages of development. Stage 1 is trust versus mistrust (usually met in infancy and has an associated virtue of hope); stage 2 is autonomy versus shame (usually met in the toddler timeframe with an associated virtue of will); stage 3 is initiative versus guilt (usually met in the preschool age and the associated virtue is purpose); stage 4 is industry versus inferiority (usually met during the school age and the associated virtue is competence); stage 5 is identity versus confusion (usually met in adolescence and the associated virtue is fidelity); stage 6 is intimacy versus isolation (usually met in early adulthood and the associated virtue is love); stage 7 is generativity versus stagnation (usually met in adulthood and has the associated virtue of care); and stage 8 is integrity versus despair (usually met in older adulthood and has the associated vesture of wisdom) (Boyd, 2017).

The older adult grew an appreciation of interdependence from stage 1. Acceptance of the life cycle and self-control were gained in stage 2. In stage 3, the older adult gains humor, empathy, resilience, and life direction. The older adult developed humility and acceptance of the course of their life to include unfulfilled hopes in stage 4. Stage 5 brings a sense of complexity to life and helps merge perception and devotion to life for the older adult. The older adult gathers a sense of relationships and comes to value tenderness and love during stage 6. In stage 7, the older adult has learned empathy and how to care for others with concern. The eighth and final stage, integrity versus despair, refers to the time period between being an older adult and death. An older adult client in this stage of life is juggling the purpose versus the finality of their life. This concept can be deep and meaningful, and it can drive the decisions a client makes toward their own health and the care they want/expect at the end of their life. An older adult client struggling with the fulfillment of this stage can experience high levels of despair and detachment (Sadock et al., 2015). These can be barriers the healthcare worker must consider when planning care and offering mental health interventions and treatments to the older adult. With an awareness of the theories on aging, the healthcare worker can more accurately conceptualize the client in their current presentation and use this information in the administration of mental healthcare.

Self-Assessment Quiz Question #1

The healthcare provider identifies the sense of satisfaction the older adult feels reflecting on a life lived productively as which task from the final stage of Erik Erikson's psychosocial stage of development?

a. Integrity.
b. Despair.
c. Generativity.
d. Stagnation.

INTERPERSONAL CONNECTION WITH THE OLDER ADULT

An essential component of mental healthcare is the therapeutic relationship between the healthcare worker(s) and the older adult client. A healthcare worker who builds and maintains a therapeutic relationship will be connected to the older adult client, enhancing their ability to meet their mental healthcare needs. The older adult views connection as vital to their identity, autonomy, and self-esteem (Jack et al., 2019). Key elements in the healthcare worker forming a therapeutic relationship are rapport, empathy, and professional boundaries—all within the bounds of cultural consideration for the older adult. These elements will aid communication between the healthcare worker and the older adult, which in turn strengthens the therapeutic relationship, a paramount component of mental healthcare.

Rapport—trust

Rapport is "interpersonal harmony" rooted in mutual understanding and respect for another (Boyd, 2017, p. 93). This concept of rapport is critical for the healthcare worker to develop a therapeutic relationship with the older adult in order to address their mental health needs. Trust is the foundation of the therapeutic alliance (Carlat, 2017). How a healthcare worker establishes rapport and builds trust depends on their individual capabilities and the current presentation of the client.

Connecting with the older adult can be challenging if the healthcare worker harbors conscious or unconscious bias or stereotypes. Ageism is a healthcare worker's perception and outlook based on their assumptions, perceptions, expectations, and beliefs that they form about older people, aging, and old age (Ayalon & Tesch-Romer, 2018). Ageism can negatively drive a healthcare worker's interaction with the older adult client. The World Health Organization (WHO) has identified ageism as one of the key targets for improving health (WHO, 2021). Awareness of ageism by the healthcare worker when meeting and building rapport with an older adult mental health client is imperative.

An example of ageism is a healthcare worker undervaluing depressive symptoms reported by the older adult and failing to address them in a timely manner or adequately because the healthcare worker assumes depression is common in all older adults. Ageism in this context could lead to a reduced calculation of risk, leaving the older adult client in an unsafe situation to self or others. Caution is warranted to avoid discriminating against the older adult client.

The healthcare worker can decrease common pitfalls of ageism through the practice of self-examination. The principle of self-awareness is defined as a healthcare worker's personal beliefs, thoughts, motivations, biases, and limitations (Boyd, 2017). By evaluating one's self, often through directed questions/thoughts, the healthcare worker can break internal or external barriers that inhibit personal connection with the older adult client. Self-concept awareness can be explored with a series of methodical questions related to what, when, and how a person has come to define themselves. The questions can be thought of as being in three major categories: body image, self-esteem, and personal identity (Boyd, 2017). Body image refers to the physical attributes that make up the outside of one's appearance and includes beliefs and attitudes about one's body (Boyd, 2017). An example of how this idea can be self-searched is to ask questions such as "How do I see myself when I look in the mirror?" and "What do I like about my body and/or dislike about my body?" How comfortable a person feels within their own skin can positively or negatively affect the way they interact with others. Self-esteem, another category, is one's perception of worth or importance, and it is a deeper view than body image (Boyd, 2017). It encompasses a person's confidence, which can be molded throughout time. An example of how to review self-esteem is to ask questions such as "How do I feel about myself and my worth?" and "How do I talk to myself in my own head (positive or negative self-talk)?" The third category of self-concept awareness is personal identity.

Personal identity is how a person sees themselves in relation to others (Boyd, 2017). An example of how to search this concept further is to ask questions such as "What words describe who I am?" and "What groups do I identify with?" and "How does my cultural or spirituality play into who I am?" By knowing more about body image, self-esteem, and personal identity, a healthcare worker can have a better understanding of their own roots, which provides insight into relationships. Self-assessment takes time and humility but will benefit the healthcare worker in all client interactions. Self-awareness leads a healthcare worker closer to objective empathy, thus allowing for connection with the older adult shaped through their individualism. Spend time getting to know yourself and re-evaluate regularly. There is value in understanding yourself and how you have changed over time, and this understanding can enhance interpersonal relationships with the older adult.

Rapport and trust are assembled or hindered from the initial client meeting and transform/shift at every subsequent interaction. Other ways to increase rapport and trust are with the use of interpersonal warmth and a nonjudgmental attitude (Boyd, 2017). The healthcare worker should prepare for positive interactions prior to the first interaction with the client and work at strengthening

the bond whenever possible. Healthcare organizations can also strive to decrease ageism by offering educational activities that dispel misconceptions and prejudices while addressing intergenerational concerns of the older adult (WHO, 2021). Ultimately, the healthcare worker must foster a therapeutic relationship nurtured in rapport and trust in order to meet the mental health needs of the older adult.

Cultural care

To understand the older adult more completely, the healthcare provider must enter the therapeutic relationship with the understanding that cultural beliefs and practices impact care. The older adult client may identify with a particular culture, and the healthcare provider needs to assess that identification in order to provide quality mental health services. The healthcare worker needs to understand the definition of culture, its application, and how to extend cultural acceptance.

Definition of culture (American Psychiatric Association, 2022c):

1. The distinctive customs, values, beliefs, knowledge, art, and language of a society or a community. These values and concepts are passed on from generation to generation, and they are the basis for everyday behaviors and practices.
2. The characteristic attitudes and behaviors of a particular group within society, such as a profession, social class, or age group.

The healthcare provider must assess each older adult client with openness using cultural competence and cultural humility. Cultural competence is the knowledge, skill, and awareness the healthcare provider possesses (Boyd, 2017). Cultural humility is the healthcare provider's ability to self-reflect on potential bias and possible factors that could interfere with providing mental healthcare (Stubbe, 2020). It places emphasis on a continuous learning process for the healthcare worker. Both concepts are defined and designed to aid the healthcare worker in their interactions with older adult clients and provide cultural acceptance.

Techniques for the healthcare worker to extend cultural acceptance (Stubbe, 2020) include:

- Review your agency's policies and practices toward culture.
- Find out if your agency provides accommodations for language.
- Simply ask the client how they identify their culture.
- Take notes on specific practices, customs, and beliefs the client discusses.
- Avoid assumptions.
- Ask about discrimination, bullying, or possible harassment related to culture.
- For validation, reword and repeat what is being shared.
- Give the client permission to speak up when they are feeling misunderstood.

Empathy

In the healthcare profession, empathy has nineteenth-century historical beginnings. Florence Nightingale is the most notable advocate as a result of her role in bringing compassion and empathy to patients. She is credited with unifying science and skill with compassion and empathy (Magpantay-Monroe, 2015). Exhibiting empathy can be thought of as an individualistic portion of healthcare with artistic freedom. There is more than one correct and therapeutic way to connect with older adult clients when assessing, intervening, and delivering treatment—especially when meeting mental health needs. The healthcare worker addressing mental health concerns can utilize and modify various approaches to communication to elicit trust and rapport that enrich the environment for information exchange, often of a sensitive nature. The healthcare worker can use originality with the empathetic approach, with the goal of maximizing the dialogue with the older adult client. This is important for the older adult client because the WHO (2021) notes empathy as a method for combatting ageism. With trust and empathy, the healthcare worker can increase interpersonal connection enveloped in empathy with the older adult client, making it easier to assess, intervene, and treat mental healthcare needs.

Professional boundaries for the mental healthcare worker

While meeting the needs of the older adult mental health client, the healthcare worker is cautioned to maintain professional boundaries. Ethical topics such as abuse can be of concern with older adult mental healthcare, and they warrant a review of appropriate interaction. The National Council of State Boards of Nursing (2018) defines professional boundaries as the area between the healthcare worker's "power and the client's vulnerability." Mental healthcare assessments and interactions depend on the healthcare worker's aptness within this delicate scope. The focus during the interview should always be the client. Keeping the perspective of the client's recovery goals can guide the healthcare worker to maintain appropriate balance. The healthcare worker should avoid self-disclosure whenever possible. Self-disclosure is defined as personal information a healthcare worker shares with a client (Boyd, 2017). Using honesty and redirection can give the healthcare worker the ability to shift questions or comments about themselves back in line with the therapeutic relationship. Remember, the goal is to help the older adult client through professional interactions and work to improve their quality of life.

Transference and countertransference are two sides of the same coin. The healthcare worker meeting mental healthcare needs for the older adult should use acute recognition/awareness for the hindrance of either element. Transference is a client placing the thoughts, feelings, or behaviors they associate with someone else onto the healthcare worker (Boyd, 2017). This can be heard when a client says things such as "You remind me so much of my son/daughter" or "You look like a girl/boy a grew up with." While these comments are not infallible indicators, they should prompt the healthcare worker to follow up on the association the client is making. The association can be favorable—or an obstacle to overcome. Countertransference is when a healthcare worker knowingly or unknowingly places their own feelings or attitudes onto the client (Boyd, 2017). This term can present in a positive or negative connotation. If the elderly client reminds you of your loving grandparent, then you might take great care in meeting needs or risk breeching professional boundaries. If the older adult client reminds you of your abusive grandparent, then the client is at risk for decreased objectivity in assessment and possible degradation of care rendered. Both transference and countertransference can be combatted with awareness. The practice of self-awareness and the review of extenuating factors that contribute to ageism, as discussed above, can also be applied to transference and countertransference. Trust, empathy, and a focus on professionalism place the healthcare worker in the appropriate space for communicating and enhancing mental healthcare needs of the older adult.

Theory of interpersonal relationship

In 1952, Hildegarde Peplau created the first psychiatric framework for the nurse–patient relationship (Boyd, 2017). The systematic organization of the professional relationship she created can be generalized to a wider spectrum for healthcare workers meeting mental health needs. The framework consists of three phases of the professional relationship. The first phase is the orientation phase: the introduction and initial exchange of acquaintance and building of trust that can happen in minutes or may take months (Boyd, 2017). The older adult is seeking help and has identified unmet mental health needs. The therapeutic relationship begins with the first interaction and changes with every subsequent interaction. The healthcare worker uses the orientation phase to listen, establish boundaries, manage expectations, and use self-awareness to check for countertransference (Boyd,

2017). The second phase is the working phase: the space for examining existing problems and finding acceptable solutions to overcome them (Boyd, 2017). This phase is where the majority of the interpersonal relationship for assessing, implementing, and evaluating take place. It typically happens over time. A sense of comfort is felt in this phase for the older adult and the healthcare worker. The older adult has emotional safety in this phase and is able to address mental health struggles. The healthcare worker is cautioned that transference is common in this phase (Boyd, 2017). Goals toward recovery should be reached during this phase. The final stage of the framework is the resolution phase: the termination of the services and relationship take place in this stage (Boyd, 2017). Not all relationships will follow through to the resolution phase. But if they do, the healthcare worker can say "good-bye" and reflect on the progress made by the older adult as well as the social support put into place for continued success (Boyd, 2017).

The components of trust that build rapport, culture consideration, empathy, and professional boundaries can be applied throughout Hildegarde Peplau's framework. The healthcare worker can visualize the potential psychiatric therapeutic relationship with the older adult client prior to initiation with the goal of improved interactions. The healthcare worker can also have an awareness for the progression and evolution of the therapeutic relationship, including its termination.

COMMUNICATION AND LIMITATIONS WITH OLDER ADULTS

Communication is a vital key for the healthcare worker to properly meet mental health needs of older adult clients. A healthcare worker can provide dignity and respect when the older adult client feels heard (Jack et al., 2019). The National Institute on Aging (NIA) has recommendations for improving communication with the older adult. Communication with older adults is often hindered by declining sensory, cognitive, and physical abilities (NIA, 2021a). Therefore, a healthcare worker must utilize a variation in communication techniques—tailored to suit the needs/abilities of the client. These can aid the healthcare worker's ability to elicit information for proper assessment and intervention. They also have recommendations for communicating with the older adult who has hearing, visual, or cognitive deficiencies. Hearing and vision are both normal biological processes that decline with age and need to be accommodated when assessing and intervening with the older adult to ease the information exchange.

Recommendations for improving communication with the older adult include the following (NIA, 2017):

- Use an older client's preference for being addressed and include their proper titles such as Mr., Mrs., Ms., Dr.
- Avoid endearing terms such as *honey* and *dear*.
- Ensure comfort for them and provide adequate chairs or adjust the setting as needed.
- Choose your words wisely and clarify when confusion seems apparent; some words are used flippantly, such as *depression* and *crazy*.
- Proceed with cultural competence.
- Encourage the client to write or take notes if desired.
- Suggest that a family member or caregiver be present during interactions and be involved in tasks to provide support.
- Include reassurance of understanding and use the teach-back method when applicable to the older adult and the family members or caregivers.

Recommendations for accommodating hearing impairments include the following (NIA, 2017):

- Assess that the client can clearly hear you. If they cannot, ask if they use a hearing aid and make sure it is being used properly if needed.
- Use a regular pitch and volume. Raising your voice actually decreases understanding for those with hearing difficulties.
- Posture yourself directly in front of the client for face-to-face contact, which enhances their ability to read your lips if needed.
- Decrease background noise and close doors if they're comfortable with it.
- Spell words out if confusion is present nonverbally.
- Have a piece of paper ready if you need to write or they want to write to you.
- When transitioning is going to take place in the interview, tell them verbally that you are changing the subject, for example, "I'm going to move on to the next part of this interview."

Recommendations for accommodating visual impairments include the following (NIA, 2017):

- Assess whether the client can clearly see. If they need eyeglasses, ask if they brought them.
- Proper lighting is necessary for the older adult. Reduce glare for screens.
- Ask for their preferred method of learning when providing instructions (verbal, written, visual, pictures, etc.)
- If writing, make sure they can read it.
- If using printed materials, 14-point font is suggested.

Recommendations for accommodating cognitive impairments include the following (NIA, 2017):

- Be patient and allow for ample time to reduce feeling rushed.
- Ensure you have the client's attention prior to starting.
- Orient and reorient the client as needed throughout the interaction.
- Use a familiar setting for the interview if possible.
- Include family, friends, or caregivers with client consent.
- Avoid medical jargon and rephrase to understandable wording.
- Present one question or direction at a time.
- Choose open-ended (e.g., "How does that make you feel?" or "What do you think might have contributed to this feeling?") or closed-ended questions (e.g., "Did you get any sleep last night?" or "Have you been feeling sad and down lately?") based on the client's ability to answer (closed-ended questions are often easier if cognitive deficits are present).
- Consider following up with the client within the week to assess for understanding and allow for questions.
- Encourage cognitively stimulating activities, exercise, and a healthy diet.

Hearing, visual, or cognitive impairments that are clinically prohibitive to communication will require the healthcare worker to utilize more extensive variations in technique, and possibly require professional assistance or assistive devices. If professional assistance and assistive devices are required, the healthcare worker can collaborate with experts, such as case management, to mitigate communication barriers for the older adult client.

A brief review of verbal and nonverbal communication with older adult considerations can benefit the healthcare worker. Nonverbal communication is gestures, expressions, and body language (Boyd, 2017). It encompasses more of the interaction than verbal communication. The psychiatric older adult client can be difficult to interpret if disabilities or cultural differences are present. Using understandable language to verbally validate nonverbal observations can help clear any perceived deficiency in the information exchange.

Ten techniques can be used to improve the psychiatric interview with the older adult: acceptance, confrontation, doubt, interpretation, observation, open-ended statements, reflection, silence, and validation (Boyd, 2017). Acceptance is a therapeutic way to encourage information exchange in an open manner and is useful for establishing trust and building rapport (Boyd, 2017). The healthcare worker can practice this by saying things such as "It is ok to tell me about it—I would like to hear how it made you feel." Confrontation is used with discretion when trying to confront reality for the older adult (Boyd, 2017). The healthcare worker can use confrontation gently to address inconsistencies; however, it has the potential to divide the therapeutic relationship and cause discourse in communication. Doubt is also used cautiously when a healthcare worker is certain the older adult is incorrect about factual information. The healthcare worker should assess for the

presence of cognitive deficiencies if misinformation in the older adult's communication is apparent.

Interpretation is a technique that the healthcare worker can embrace when trying to help the older adult identify their thoughts and feelings. For example, if the older adult is adamant that they cannot attend appointments anymore after dark because they might wreck their car, the healthcare worker could state, "It sounds like you are scared to drive after dark. Let us chat about driving safety." The older adult may respond to the interpretation, and the healthcare worker can work from the given response. Observation is the healthcare worker noticing and remarking on the older adult's verbal and/or nonverbal behaviors (Boyd, 2017). It can be used by noting body language and remarking on it by saying, "I can see that you are reluctant to discuss this topic." Open-ended statements are a method for getting the older adult to speak freely on topics to aid with insight (Boyd, 2017). The healthcare worker can start a statement with something like "Happiness means . . ." and have the older adult finish the sentence/thought. Reflection is a technique that gives the older adult permission to have uncomfortable feelings (Boyd, 2017). If the older adult asks a pointed question to the healthcare worker such as, "Should I stop drinking alcohol?" The healthcare worker can use reflection to answer back with, "Do you think you should stop drinking alcohol?" The use of reflection can keep the focus on the patient instead of the healthcare worker. Restatement is a therapeutic way of validating what the older adult is saying (Boyd, 2017). For example, if the older adult says, "I hate coming here," the healthcare worker can restate the expression and say, "It sounds like you do not want to be here." A similar technique is validation. It is used when the healthcare worker is searching for understanding (Boyd, 2017).

When the healthcare worker uses it, it can sound like "I want to make sure I understood you"—and then describe what you think you heard. If restated or validated correctly, they both can reassure the older adult that you are listening and open to discussion. Silence is a communication tool that needs proper utilization with the older adult. With therapeutic silence, the healthcare worker remains silent but uses nonverbal facial expressions to show interest so that the older adult can have time to put their thoughts together (Boyd, 2017). The healthcare worker can try therapeutic silence early in the assessment and ask if the extra time is helpful. Extra silence during communication may indicate the need for intervention for the older adult or the need to change selected communication techniques. All communication techniques are useful for various situations. The healthcare worker will choose which technique(s) work best for each individual communication exchange.

The healthcare worker can also have difficulties with communication if the older adult client is reluctant to talk or, inversely, is overly talkative. These challenges can be due to poor cognition or resistance to change in the older adult (Jack et al., 2019). The healthcare worker needs a specific approach to address these situations.

Recommendations for the reluctant patient include the following (Carlat, 2017):

- Use open-ended questions, allowing for an opportunity for free dialogue such as "What things make you feel sad?"
- Use continuation prompts such as "Go on" and "Tell me more."
- Search for a neutral ground when the interview is going awry; talking on neutral ground can provide an easier and subtle way into difficult thoughts, feelings, or emotions.
- Remember that rapport and trust take time.
- Triage the information you need at each visit, and prioritize safety.

Recommendations for the overly talkative patient include the following (Carlat, 2017):

- Use close-ended questions and multiple-choice questions to keep the patient's answers brief (an interview needs open-ended questions as well, but closed questions and multiple choice can speed the interview along to maximize the information shared).
- Learn to politely interrupt. This requires empathy. If it was not covered prior to starting the assessment, a reminder of the allotted time of the interview helps reign in an overly talkative client.

The older adult who is unable to communicate may experience high rates of loneliness and depression (Palmer et al., 2016). Depression in older adulthood is often accompanied by tears. This can make interviewing difficult for the healthcare worker. Traversing tears and sad emotions can be heavy and uncomfortable for the healthcare worker.

Recommendations for the tearful patient include the following (Carlat, 2017):

- Refrain from self-disclosure.
- Provide tissues.
- Embrace any lengthy silences and lean into empathy.
- Try to understand the meaning behind the tears.
- Assess the frequency of tearful episodes.
- Validate that crying is acceptable if needed.
- Be aware that crying is also a sign of intense emotion and warrants further investigation; assess for safety.

The healthcare worker should view each older adult client as an individualized opportunity. Being able to effectively communicate is crucial for the healthcare worker to assess and build trust with the older adult. Understanding the problems and difficulties the client is facing will not be possible if a mutual understanding is not present. There are a multitude of variations in communication styles and techniques the healthcare worker can utilize to nurture rapport, build trust, and foster a therapeutic alliance with the older adult. If more assistance is needed to connect and communicate with the older adult client, ask for help from family, caregivers, and/or your employer. An inability to communicate is determinantal to successfully meeting the mental health needs of the older adult.

Self-Assessment Quiz Question #2

The healthcare worker initiates a therapeutic conversation with an older adult and is focused on improving communication techniques to enhance the relationship and elicit information for assessment. The healthcare worker will use all of the following EXCEPT:

a. Cultural competence.
b. Inclusion of family or caregivers.
c. Teach-back method.
d. Terms such as honey and dear.

Older adults seek mental healthcare 40% less than younger populations (Substance Abuse and Mental Health Services Administration [SAMHSA], 2019). Mental health treatment for instability or illness for the older adult is multifaceted. How the older adult views their collective health can determine the level at which they will seek care to maintain or restore their mental imbalance or illness. The U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion (ODPHP) in Healthy People 2030 names five areas related to social determinants of health: education access and quality, healthcare access and quality, neighborhood and built environment, social and community context, and economic stability (ODPHP, 2022). Each will be expanded upon for potential barriers and benefits of care.

Determinant 1: Education access and quality

On average, people who have greater levels of education live longer and healthier lives (ODPHP, 2022). Educational opportunities are often focused on younger populations, and older adults might be beyond the point of increasing their educational status level. However, the healthcare worker can identify and help them overcome this deficit. The healthcare worker should assess health literacy in the older adult client and plan written materials accordingly. Further assistance might be necessary for people with disabilities that severely impair cognition, hearing, or vision.

The Centers for Disease Control and Prevention (CDC) states that 71% of adults over the age of 60 struggle to read printed materials (CDC, 2021a). This is often due to naturally declining vision. With recommendations to help older adults who struggle with poor vision, the healthcare worker can help mitigate hindrances related to vision.

Ensuring health literacy in the older adult with visual challenges includes the following practices (CDC, 2021a):

- Ensure the written material can be read by the client (have them read it to you).
- Use high contrast (black words on a white background are best).
- Use an average font size of 16 to 18 (increase if needed).
- Use extra white space between lines of information (make the space of the lines at least 25% of the point size).
- Do not use glossy paper (it creates glare).
- Use the least amount of text necessary.
- Use audio instruction in addition or as a substitute (see NIA recommendations listed prior for best outcomes).
- Adjust needs accordingly and reduce screen glare if electronic materials are used.

Determinant 2: Healthcare access and quality

Older adults often delay addressing mental health needs until the problems become chronic or severe. While access to mental health services is problematic for many people across the mental health spectrum, it is critically important for those that suffer with severe mental illness (SMI) (Sadock et al., 2015). To address the healthcare access and quality social determinant for the older adult, the healthcare worker can review the frequency, ease, or difficulty of accessing mental health services. Available options for care, transportation, technology, and stigma will be discussed related to the role they play in the older adult client accessing or being prohibited from accessing mental healthcare.

If access to healthcare or decreased quality of current care is an issue for the older adult, the healthcare worker can propose federally qualified and/or local community-based options. The following recommendations are from the U.S. Department of Health and Human Services (HHS) and provide recommendations and tools to increase healthcare access and quality of care for the older adult. The older adult client, family, or caregiver can search for local options using the official benefits website of the U.S. government. One website to explore is Medicare. The older adult client can sign up for benefits that include preventative screenings and services; check what services are covered; submit claims; compare providers; find physicians, group practices, hospitals, home health agencies, and facilities based on star ratings, services offered, and quality of care; and get a replacement card if needed (United States Department of Health and Human Services [HHS], 2022). Another website to search is Medicaid. The older adult client can access information about state programs (HHS, 2022). The website Eldercare can connect the older adult to local and community-based care. The older adult, family, or caregiver can use their ZIP code or city and state to find resources in the local community that provide information and assistance for older adults and caregivers (HHS, 2022). Sometimes access to care is hindered by awareness, and the healthcare worker can increase awareness by providing federal and local sources for care.

Transportation

A crucial component of face-to-face access and quality of healthcare is transportation. The older adult may access public, community-based transportation options or a privately owned vehicle. If options are lacking, the deficit can be noted and further assistance sought. The need to assess an older adult's ability to safely operate a vehicle will be addressed in depth in the psychosocial assessment section.

Technology

The use of technology for healthcare dramatically increased with the COVID-19 pandemic. Telemedicine decreases direct contact and limits disease transmission while providing access to care. The WHO (2021) classifies its use as advantageous for vulnerable populations such as older adults. Telemental health has been found to reduce the number of emergency department visits for older adults with comorbid depression and chronic obstructive pulmonary disease or congestive heart failure (Tusaie & Fitzpatrick, 2017). It has also been effective for psychotherapy interventions. One study found that older adults who suffer from depression and insomnia had positive outcomes from cognitive-behavioral therapy administered via telemental health (Tusaie & Fitzpatrick, 2017). Telemental health can benefit the older adult in many ways.

The American Psychiatric Association (APA) collaborated with the American Telehealth Association (ATA) to address telepsychiatry. The healthcare worker is encouraged to reference the APA and ATA for clinical tips, tools, guidelines, and more, while continuing to follow all policies at their place of employment. The APA (2018) has specific recommendations for the healthcare worker caring for the older adult population: include family members on video calls when clinically necessary (with patient permission); adapt technology and assessment for cognitively, visually, or audio impaired patients; modify cognitive testing carried out via videoconferencing.

Although telemedicine ensures access to care, it is not always available for the older adult client. It is estimated that 40% of older adults on Medicare are unable to receive video care and 20% are unable to receive phone care (Chu et al., 2022). This can place an older adult needing virtual mental healthcare in a difficult position. The healthcare worker must perform a baseline assessment of the infrastructure required for and attainability of this option for the older adult.

Deficits in cognition, hearing, or vision may present greater challenges for the older adult client using telemedicine. The ATA has created guidelines for telemedicine. However, the guideline only addresses live video conferencing for mental health services (Tusaie & Fitzpatrick, 2017). Other forms of communication such as phone text messaging, social media, apps, and emails are not covered by the ATA. The healthcare worker is encouraged to refer all questions to their place of employment. The same considerations the healthcare worker would utilize for in- person visits for securing protected information exist for telemedicine. The older adult client would need access to stable Internet as well as reliable video and audio services on a Health Insurance Portability and Accountability Act (HIPAA)–compliant site prior to medical use (Johnson et al., 2021). Barriers to utilizing telemedicine must be weighed when considering this approach for mental healthcare for the older adult.

To increase the potential benefits of telemedicine, the healthcare worker can interview the older adult as well as their family, friends, or caregivers when assessing the inclusion of telemedicine for mental healthcare. There are other technological gains for a willing and able client. Apps related to, for example, healthy coping techniques, exercise logs, medication reminders, and communication can enhance the quality of life and safety of the older adult. Technology can strengthen mental healthcare for the older adult; however, the healthcare worker must prudently examine the initial and continued feasibility of its use.

Stigma

Mental healthcare access and quality can also be affected by stigma. Racial inequalities have been found in this social determinant of health. Research has found that African Americans experience greater amounts of stigma surrounding mental health treatment than other Americans (Conner et al., 2010). The basis and continued existence of mental health stigma for African Americans is unclear; however, the rates of access to mental healthcare are undeniable. Stigma is a mental healthcare barrier that the healthcare worker should not ignore. More than half of people suffering with mental illnesses do not get help (APA, 2020). Older adults can be unwilling to seek mental healthcare due to feelings of shame and guilt; these same patients, who are willing to receive treatment from their primary care provider, are often reluctant to seek mental health specialty care until their symptoms are severe (SAMHSA, 2021). Stigma can trap the older adult and cause them to suffer silently. It can drive an older adult to feel the loss of dignity and reinforce isolation, which perpetuates loneliness (APA, 2020). The healthcare worker should be equipped to help reduce the feelings around stigmas.

Suggestions to help reduce the stigma of mental illness include the following (APA, 2020):

- Encourage the client to talk openly about mental health (share with others).
- Empower the client to stand up to misconceptions (give them facts and data).
- Be aware of the language used (this goes for words you say or they say; humor is acceptable but in the proper context).
- Educate the client about the importance of mental illness (draw comparisons to how they would treat someone with a physical illness).
- Show empathy for those with mental illness.
- Be honest about treatment (normalize mental health treatment).

The healthcare worker can educate family, friends, and caregivers about participating in normalizing mental healthcare for the older adult. Table 1 presents communication suggestions the healthcare worker can pass on to family, friends, or caregivers of the older adult suffering from mental illness. Words are powerful, so encourage others to choose them wisely.

Table 1: Anyone Can say This and Not That to Reduce Stigma

Say This	Not That
"Thanks for sharing with me."	"That's not that bad."
"Can I help you in any way?"	"You can do it."
"That sounds really difficult."	"Life moves on."
"I'm here for you."	"That happens to everyone."
"That sounds heavy and sad."	"Everything happens for a reason."
"I can't imagine. Tell me more."	"I know all about that."
"How are you feeling?"	"You've got to think happy thoughts."

Determinant 3: Neighborhood and built environment

The physical place where someone resides contributes to their overall health and safety. Those at highest risk for unsafe or unhealthy environments in the U.S. are ethnic and racial minorities (CDC, 2022b). Examples of negative impacts on health and safety are neighborhoods with high crime rates or environments close to pollution sources. A client's physical environment falls into the social and developmental history of the mental health assessment. Homelessness falls into this social determinant and would require additional assessment and coordination of care. The depth a healthcare provider should reach will depend on the client and their individual living situation. Clarity of a client's physical health and safety can also be obtained with client consent by interviewing and family, friends, or caregivers.

Determinant 4: Social and community context

Relationships and social support play crucial roles for the older adult. Lack of social support and decreased or absent significant relationships negatively impact mental health in the older adult (Harandi et al., 2017). A healthcare worker can assess this social determinant in the social and developmental history of the mental health assessment. Older adults are at significant risk of experiencing isolation and loneliness (CDC, 2021c). This can be due to the death of a spouse/significant other, estrangement from family, worsening disabilities, or perceived feelings of burden to others. Groups most at risk within the older adult population are immigrants; those who are lesbian, gay, bisexual, and transgender; and those suffering abuse (CDC, 2021c). While there is not a clear measure for loneliness, there is evidence of related health risks that accompany it.

Health risks of loneliness include the following (CDC, 2021c):

- Higher risk for premature death from disease, especially related to smoking, obesity, and sedentary lifestyle.
- Dementia risk increases by 50%.
- Heart disease risk increases by 32%, leading to higher rates of stroke.
- Coincides with higher rates of depression, anxiety, and suicide.
- Specific to heart failure: risk of death increases four times, risk of hospitalization increases by 68%, and emergency visits increase by 57%.

Determinant 5: Economic stability

Poverty contributes to clients not being able to meet their basic needs. Approximately 9.3% of the older adult population in the U.S. lives below the poverty line (SAMHSA, 2019). Housing, healthcare, and nutritious food and drink are major concerns for older adults that could contribute to mental health conditions. Case managers are a prudent referral for the older adult lacking the financial means to meet their needs.

The five *Healthy People 2030* social determinants from the U.S. Department of Health and Human Services {ODPHP, 2022 #17}—education access and quality, healthcare access and quality, neighborhood and built environment, social and community context, and economic stability—can be used as a circular framework for the healthcare worker assessing older adult mental health needs (ODPHP, 2022). A deficiency in any of the determinants for the older adult can be a barrier to accessing mental health services and treatment. More than one social determinant can be missing for a client. Assessing social determinants can lead to better understanding of the obstacles an older adult must overcome to seek mental healthcare. Insufficient coverage in social determinants might require additional assistance from case management, family, or peer interventions. Stigma can stand in the way of access to care and treatment. Breaking stigma is everyone's job, but

it can start with one healthcare worker. The healthcare worker capable of fostering a therapeutic alliance built on trust and rooted in empathy will enhance the possibility for healthy communication and connection, naturally decreasing stigma. Friends, family, and caregivers can also be educated in empathetic communication with the older adult to normalize mental illness and treatment.

Self-Assessment Quiz Question #3

Social determinants of health can enhance or inhibit care for the older adult. When the healthcare worker assesses Internet access and connectivity along with the technological capabilities of the older adult for telemental health follow-ups, the healthcare worker is exploring which social determinant of health?

a. Healthcare access and quality.
b. Education access and quality.
c. Social and community context.
d. Stigma.

ASSESSMENT CONSIDERATIONS FOR THE OLDER ADULT

Addressing mental health needs in the older adult will depend on the assessment recorded or provided to the healthcare worker. Assessment is not a single interaction; rather, it is a calculated and continuous process that evolves throughout the care for the older adult client (Boyd, 2017). The first interview can set the tone. Preparation prior to meeting the client is encouraged.

The healthcare worker can review common developmental tasks of the older adult at any point while providing mental healthcare. Developmental tasks of the older adult are to maintain body image and physical integrity, to conduct a life review, to maintain sexual interests and activities, to deal with the death of significant loved ones, to accept the implications of retirement, to accept the genetically programmed failure of organ systems, to divest oneself of the attachment to possessions, and to accept changes in relationships with grandchildren (Sadock et al., 2015). Any of these tasks can be explored in more depth to establish known protective factors or barriers to the mental health of the older adult.

An assessment is a deliberate and systematic gathering of information with the goal of formulating a plan. A mental health assessment includes biopsychosocial data to show current and previous health, functional ability, and problems/diseases/illnesses both present and future (Boyd, 2017). The mental health assessment includes the biological domain, that is, the physical status of the client. This assessment is often carried out in conjunction with the client's primary care provider. Biological data is important to the mental healthcare worker; however, a team approach to the older adult can serve the client best by allowing multiple disciplines to focus on their specialty area of practice. The medical record for the older adult can be quite involved. However, a records review and collaboration with the older adult client's primary care provider can benefit the holistic picture of the mental health needs to be addressed. Physical problems or disorders can be exacerbated or accounted for by addressing the underlying psychiatric disturbance. The overlap of biological problems and psychosocial problems can be complicated. The American Geriatric Society (AGS) organizes geriatric health via alliteration for ease of remembrance. The five M's of older age are multicomplexity, mind, mobility, medication, and what matters most (AGS, 2020). Multicomplexity is the description of the older adult as a client with comorbid biopsychosocial needs that can challenge the healthcare worker. Mobility refers to the level of autonomous or diminished functionality of the older adult, especially the ability to ambulate and care for themselves. Medication is typically remarkable for the older adult; polypharmacy can be common and problematic and often results in undesirable side effects that signal a strict need for regular consolidation evaluation. The final ideal, mattering most, encompasses the notion of aging and decision making to include the older adult as an advocate for health decisions and goals. This depiction can aid the mental healthcare worker to conceptualize the older adult's biopsychosocial needs.

Assessing the older adult as they present in their current level of functioning is paramount and requires establishing trust and building rapport. The psychiatric interview is the most important part of the mental health assessment. It provides an opportunity to positively impact older adults suffering from mental health issues and illnesses.

Approaches that can enhance the therapeutic alliance include the following aspects (Boyd, 2017):

- Establishing a relationship rooted in cultural competence and cultural humility.
- Availability to assist in times of crisis.
- Awareness of acute safety issues related to the patient.
- Ability to provide education and manage expectations.
- Review and modification of treatment to individual preferences.
- Realistic intervention and goal setting.
- Support for patient to maintain safe autonomy.

Every interaction provides the opportunity to strengthen or weaken this bond and to obtain facts, feelings, and thoughts that can be targeted for treatment. The psychiatric interview can be administered in any setting (e.g., hospital, clinic, nursing home, residential facility). The length of time allotted or needed will vary by client and setting. Consult your facility for the proper organization of psychiatric assessment documentation.

Healthcare directives

Advanced care planning can be completed for clients of any age; however, it is responsible to offer the option to all older adults prior to medical crises or the end of life. The mental healthcare provider can support the older adult in these legal and ethical plans according to policy. Advanced care planning decisions include measures that can be taken in an emergency: cardiopulmonary resuscitation, use of a ventilator, artificial nutrition such as tube feedings or intravenous fluids, and comfort care measures (NIA, 2018). Older adults need to be aware of the risks and benefits of these differing emergency measures. Older adults with multiple comorbidities are less likely to recover from cardiopulmonary resuscitation and might need extended ventilator care (NIA, 2018). The healthcare provider seeing the older adult for mental health needs can prompt the discussion with the inclusion of quality of life. Several options exist for an older adult in terms of an advanced directive: living will, durable power of attorney, and other specific medical measures such as a do not resuscitate order or a tissue or organ donation request (NIA, 2018). The mental healthcare worker can assist the older adult and family with advance care planning needs to increase the likelihood of receiving desired treatment during crises or the end of life.

Healthcare provider exceptions to confidentiality

There are notable exceptions to confidentiality for the healthcare worker meeting the mental health needs of the older adult. The healthcare provider should refer all scope of practice questions to their state regulatory agency. State laws define the scope of practice. Understanding confidentiality, and when to breach it, is a necessary discussion when caring for older adults. Confidentiality is a client's right for restricted information (Boyd, 2017). All healthcare workers play a role in maintaining client confidentiality. The HIPAA of 1996 is a federal guarantee of legal protection for privacy and confidentiality.

Exceptions to confidentiality (when the need to inform outweighs confidentiality) include the following (Boyd, 2017):

- Client has an intent to harm self or others.
- Litigation if an attorney is involved.

- Insurance company need to know for coverage and billing purposes.
- Sending information to answer a court order, subpoena, or summons.
- State requirement to report.
- Tarasoff principle—warn victim of imminent homicidal danger.
- Elder abuse suspected or involved (refer to state laws for proper channels).

Knowing when and how to provide notification when exceptions of confidentiality are in question varies per state. The healthcare provider will need to follow policies subject to their practice and should take steps to familiarize themselves with the relevant policies and regulations.

Informed consent and diminished capacity

The American Bar Association (ABA) and APA created a working group to address the diminished capacity of the older adult in 2008. The framework is aimed at the psychologist who could be called to determine capacity in a legal, a medical, an ethical, or a civil situation for the older adult in medical, long-term care, or private practice settings. The healthcare provider should consult their scope of practice for their role in determining capacity. The ABA and APA outline six domains for capacity: medical consent, sexual consent, financial, testamentary, driving, and independent living capacities (American Bar Association & American Psychological Association, 2008). The ABA and APA working group highlights the importance of cultural and age considerations. Cultural intricacies such as immigration status, language, health perceptions, family member roles, and economics must be considered. The ABA and APA caution against ageism and the surrounding negative consequences. Clinical assessment and evaluation of older adult capacity is complex. Older adults have the right to informed consent for treatment. The healthcare provider must be aware of the importance of providing informed consent in conjunction with the client's voluntary competency.

> The APA (2022f) defines informed consent as a person's voluntary agreement to participate in a procedure on the basis of his or her understanding of its nature, its potential benefits and possible risks, and available alternatives. Informed consent is a fundamental requirement of research with humans and typically involves having participants sign documents, prior to the start of a study, that describes specifically what their involvement would entail and noting that they are free to decline participation or to withdraw from the research at any time. In therapeutic contexts, the principle of informed consent has provided a foundation for do not resuscitate (DNR) orders and other advance directives and for the natural-death acts that have been passed into law throughout the United States.

Along the lines of DNR and advanced directives for the older adult is the legal concept of undue influence:

> Undue influence is defined as a dynamic between an individual and another person. It describes the intentional use of social influence, deception, and/or manipulation to gain control of the decision making of another. For the healthcare worker, undue influence can be understood as a dynamic of a relationship when a person uses a role and power to exploit the trust, dependency, and/or fear of another. The role and power permit the person to gain control over the decision making of the victim. In cases of undue influence, a person may have full capacity. Alternatively, there may be a cognitive impairment that increases susceptibility and dependence. (ABA & APA, 2008, p. 14)

Mental capacity can be questioned for the older adult. The healthcare provider must differentiate between capacity and competency. Competency is a legal (not a medical) concept.

The APA (2022b) defines capacity as:

- The maximum ability of an individual to receive or retain information and knowledge or to function in mental or physical tasks.,
- The potential of an individual for intellectual or creative development or accomplishment.
- Inborn potential, as contrasted with developed potential

Collateral reports

Family, friends, and caregivers often play an important role in the mental healthcare of an older adult. The healthcare provider must obtain permission from the older adult client prior to discussing any medical or mental health information. Family, friends, and caregivers can help corroborate information (objective and subjective) gathered in the psychiatric interview of the older adult. Legal and ethical matters must be considered at all times. While caregivers can be beneficial to older adults and healthcare workers, they can also be sources of abuse and negative interactions in private for the older adult. Caregivers can experience overextension of self and inflict harm on older adults knowingly or unknowingly (NIA, 2017). The healthcare provider is cautioned to consult all places of practice and state boards of practice for scope of practice questions or concerns.

The healthcare worker has much to incorporate for the older adult assessment. Common developmental tasks can focus the healthcare worker's assessment and note strengths and deficits. Legal documentation or intervention for healthcare directives, confidentiality, informed consent, and diminished capacity considerations should be included in older adult mental healthcare. If assistance is needed, consult your place of employment. Assessment considerations specific to the older adult are integral to addressing mental health concerns.

ASSESSMENT OF THE OLDER ADULT: BIOLOGICAL AND PSYCHOSOCIAL

Assessment is a prerequisite for intervention and treatment. The healthcare worker needs to tailor the styles and techniques for obtaining the information needed to fully assess the older adult based on abilities and disabilities. The healthcare worker must enter each interaction with the older adult client with a willingness to embrace an objective perspective, the uniqueness of the encounter, and individualization of the assessment to maximize the quality of mental healthcare.

The assessment of the older adult will include biological and psychosocial elements. The current presentation and history of the older adult will help define the assessment depth, highlight symptoms of diagnostic criteria, as well as maneuver toward or eliminate treatment options and interventions for stabilization and recovery. The biological considerations of the older adult can impact the psychiatric treatment options and necessitate the need to collaborate with primary care or initiate coordinated care efforts. The most troubling mental health symptoms or concerns that interfere with daily functioning or relationships are often at the surface. The healthcare provider must verify nonverbal cues with verbal inquiry. The variation in communication and information exchange will be individualized, and the review of records will be taken into consideration, preferably before the initial interview. The psychiatric history will provide the healthcare provider with a detailed, longitudinal picture of effective and ineffective treatments. A discussion of biological and psychosocial considerations for the older adult is imperative for the healthcare provider prior to diagnosing and recommending mental health treatment. Biological components coupled with psychosocial components provide the mental healthcare provider with a more comprehensive assessment of the older adult presenting with mental health concerns. The older adult assessment can be extensive and take multiple visits. The complexity level does not negate the need to assess in its entirety.

Biological considerations

The APA lists medical components for psychiatric evaluation. The healthcare worker can gather the data for the older adult directly from the client, family, friends, or caregivers (with consent), as well as historical medical charts. The information can be accumulated over time and prioritized during each interview. For example, the healthcare provider needs a complete medication history that includes all interventional trials (successes and failures), and most notably any side effects, prior to beginning or restarting psychiatric medication. The APA recommends that the following biological considerations be obtained by the healthcare worker: primary care involvement; allergies or drug sensitives; an exhaustive medication review of past and current prescription drugs as well as over-the-counter nutrients, supplements, and vitamins; current or historical medical illnesses, including hospitalizations, past or present medical treatments, surgeries, procedures, and alternative treatments; past or present neurological or neurocognitive disorders; physical trauma, especially head injuries and any sequela; sexual and reproductive history; cardiopulmonary issues; endocrinology involvement; past or current infectious disease; and current or past pain levels and treatments (Sadock et al., 2015).

There are a few notable biological considerations in neuropsychiatry for the healthcare worker to include when planning mental healthcare for the older adult. The healthcare worker understands the older adult can learn new information; however, the rate at which an older adult solidifies the material can take longer than for other age populations (Sadock et al., 2015). In addition, psychomotor speech and memorization are slower in older age, especially simple recall and encoding ability, but they are considered normal for the older adult. In addition, the intelligence quotient (IQ) typically holds steady until age 80 (Sadock et al., 2015). These biological considerations can drive the approach and length of time the healthcare worker might allot for assessment, intervention, or treatment. The healthcare worker might also include the older adult's family, friends, or caregiver(s) when new information is presented to the older adult. A historical baseline is an important piece of the assessment for the healthcare worker. The healthcare worker needs to know basic objective measures for physiological functioning such as vital signs (blood pressure, pulse rate, temperature, respiratory rate, and pain level) and nutritional status for older adult clients if psychopharmacology is involved. The healthcare worker adult can increase their understanding and provide a more thorough plan of care by coupling with the older adult's primary care provider.

Psychosocial considerations

There are psychosocial considerations related to an older adult's mental healthcare. Some overlap with biological considerations and can be assessed and targeted for treatment. For example, driving is a psychosocial aspect that can be affected by biology.

Activities of daily living (ADLS)

The healthcare worker needs to assess the older adult's ability to be autonomous. The inability to perform ADLs may indicate an unsafe or poor quality of life (Edemekong et al., 2022). The healthcare worker can utilize standardized measurement tools for assessing ADLs (basic and instrumental) of the older adult and intervene with other services when safety or quality of life is at stake. The AGS defines basic and instrumental ADLs.

Basic ADL are (AGS, 2022):

- Ambulating (ability to move and transfer independently, walking).
- Feeding (ability to feed self independently).
- Dressing (ability to cover self with clothing).
- Grooming (ability to care for personal hygiene, bathing, hair and nail care).
- Continence (ability to maintain bowel and bladder function).
- Toileting (ability to make it to the toilet and clean self).

Instrumental ADL are (AGS, 2022):

- Transportation and shopping (ability to buy groceries and necessities).
- Financial management (ability to pay bills and manage finances).
- Cooking (ability to prepare meals and serve them).
- Household maintenance (ability to clean and live in a home).
- Communicate (ability to get in touch with others via phone or electronic means).
- Medicate (ability to manage medications as prescribed).

Increasing age and health problems can cause increased difficulty with ADLs. Decreased physical functioning can be caused by biological deficiencies in the musculoskeletal, neurological, circulatory, or sensory systems. Cognitive, auditory, or visual impairments can increase difficulty with ADLs (Edemekong, 2022). Dementia can limit the older adult's capable and safe performance of ADLs like cooking and self-medicating. The healthcare provider can assess the strengths and weaknesses verbalized by the older adult as well as gather information from collateral sources. Interventions might include caregivers, family, other healthcare providers, or case management.

Employment status

The healthcare worker needs to assess the employment status and working habits of the older adult. Retirement is common in the older adult and can be a turbulent period of transition. The healthcare worker should attempt to assess whether retirement was voluntary or involuntary. Involuntary retirement is associated with negative mental health effects and decreased self-image (Rhee et al., 2016). However, the Age Discrimination Employment Act (ADEA) of 1967 protects older adults in the workforce from forced retirement by making it unlawful (Sadock et al., 2015). If the older adult is retired, follow-up questioning about how the older adult feels about the loss of occupation can open an opportunity for exploration of other topics like finance and relationships. The healthcare provider can assess beyond formal employment for responsibilities and time commitments acquired by the older adult.

Housing

The healthcare worker should assess the housing situation of the older adult. Housing is a basic need and typically must be met prior to the administration of interventions. It is estimated that about 5% of Americans live in nursing homes; however, approximately 35% of older adults will reside in a long-term care facility at some point during their lifetime (Sadock et al., 2015). The living situation of an older adult can affect treatment options. For example, an older adult that lives near a bus stop has the necessary financial resources, and is capable of navigating will have greater options for meeting their needs like attending mental health treatment. Where an older adult resides must be assessed to understand available mental health intervention and treatment.

Transportation—Driving safety

One of the most difficult subjects for the healthcare worker to discuss with the older adult, yet an impactful topic for self and others is autonomous driving. Driving is the leading cause of injury-related deaths in the 65- to 74-year-old population and is the second leading cause (behind falls) in the 75- to 84-year-old population (Promidor, 2019). The cessation of driving privileges is inevitable for everyone. Each older adult interaction is an opportunity for the healthcare worker to assess for prevention. Knowing when and how to approach the older adult about driving safety is imperative. Preventing driving disability with properly timed interventions can impact lives.

There are acute and chronic medical conditions that should be strong indicators of safety for the older adult client. Cessation of driving privileges should be reviewed when the conditions in Tables 2 and 3 manifest or the medications in Table 4 are prescribed in the older adult and until they are medically evaluated by their primary care provider. The healthcare worker meeting mental health needs of the older adult will need to be in contact with the primary care provider about medical conditions and medications outside of their scope of practice.

Table 2. Acute Medical Conditions That Require Immediate Driving Cessation

- Acute myocardial infarction.
- Acute stroke or other traumatic brain injury.
- Arrhythmia (e.g., atrial fibrillation, bradycardia).
- Lightheadedness, dizziness.
- Orthostatic hypotension.
- Syncope or presyncope.
- Vertigo.
- Seizure.
- Surgery.
- Delirium from any cause.
- Newly prescribed sedating medications or those that can cause confusion or dizziness.
- Acute psychiatric diseases impairing cognitive function or decision making.

Note. Reproduced with permission (Promidor, 2019).

Table 3. Chronic Medical Conditions That Require Investigation for Driving Safety

Medical Condition	Examples
Disease/conditions affecting vision	• Cataracts • Diabetic retinopathy. • Macular degeneration. • Glaucoma. • Retinitis pigmentosa. • Field cuts. • Low visual acuity even after correction.
Cardiovascular disease, especially when associated with presyncope, syncope, or cognitive deficits	• Unstable coronary syndrome. • Arrhythmias. • Palpitations. • Congestive heart failure. • Hypertrophic obstructive cardiomyopathy. • Valvular disease.
Neurologic disease	• Dementia. • Multiple sclerosis. • Parkinson's disease. • Peripheral neuropathy. • Brain injury. • Spinal cord injury.
Psychiatric disease	• Mood disorders. • Depression. • Anxiety disorders. • Psychotic illness. • Personality disorders. • Alcohol or other substance abuse.
Metabolic disease	• Type 1 and type 2 diabetes mellitus (especially with hypoglycemic attacks or severe swings in blood glucose).
Musculoskeletal disabilities	• Arthritis and foot abnormalities. • Contractures and decreased range of motion. • Inflammation. • Pain.
Respiratory disease	• Chronic obstructive pulmonary disease. • Obstructive sleep apnea.
Chronic renal failure	• End-stage renal disease. • Hemodialysis.
Cancer and chemotherapy	• Weakness and extreme fatigue. Medication side effects.

Table 3. Chronic Medical Conditions That Require Investigation for Driving Safety

Medical Condition	Examples
Insomnia	• Sleep apnea. • Restless leg syndrome. • Anxiety/depression/pain contributing to insomnia.

Note: Reproduced with permission (Promidor, 2019).

Table 4. Medications that can Impair Older Adults and Increase Driving Risk

- Anticholinergics.
- Anticonvulsants.
- Antidepressants.
- Antiemetics.
- Antihypertensives.
- Antiparkinsonian agents.
- Antipsychotics.
- Benzodiazepines and other sedatives/anxiolytics.
- Hypoglycemic agents.
- Muscle relaxants.
- Narcotic analgesics.
- Stimulants.
- Hypnotics.
- Marijuana.
- Alcohol.
- Over-the-counter agents with anticholinergic adverse effects such as sleeping agents or allergy/cold medications, which are often first-generation antihistamines.

Note. Reproduced with permission (Promidor, 2019).

The healthcare worker should check for routine driving safety of the older adult and can refer to the CDC when planning interventions that maximize safe independence. Interventions should be individualized and performed in collaboration when necessary. The healthcare worker can help the older adult maintain their autonomous driving with proper identification of and interventions addressing clinical deficits. The most common disturbances are vision, cognitive, and motor/sensory (CDC, 2022a). The healthcare worker can evaluate the older adult or refer the older adult for prompt assessment of any notable organ systems, acute or chronic conditions, and medication(s) that interfere with safe driving. Intervention and rehabilitation can keep the older adult safely behind the wheel. The healthcare worker can utilize referrals and other resources to help the older adult client maximize restoration of functioning, leading to safer driving. The healthcare worker can contact case management and other specialty areas to collaboratively form a holistic care plan that meets all the needs of the driving older adult.

The healthcare worker is faced with a complicated decision matrix when it comes to addressing the older adult's driving privilege; there are personal, clinical, ethical, and legal ramifications. The healthcare worker is often consulted about the safety of the older adult who drives and is faced with the weight of the older adult's needs and safety versus the safety of society. The healthcare worker is encouraged to refer to state laws associated with reporting of unsafe driving and prescribed revocation of driving privileges in addition to the information provided.

Social support system (Isolation)

An important part of the social history is the social connectedness of the older adult. The older adult is capable of being physically and mentally healthy and maintaining autonomy. However, the inescapability of mortality often pushes the older adult living away from friends, family, and possibly their partner. An increased sense of isolation can cause symptoms of depression (Sadock et al., 2015). The healthcare worker can assess the social support system the older adult utilizes on a daily/weekly/as needed basis to better understand any deficits of care in the social history section of the psychiatric interview. Where the older adult resides is an important consideration for social support. The healthcare worker might work along with the long-term care facility team in coordinating the social needs of the older adult. Social isolation and loneliness have negative effects on the mental health for the older adult. They increase the risk for negative health consequences such as obesity and smoking as well as shorten life span

(Czaja et al., 2021). The members of an older adult's social cohort and family structure will vary. There are objective and subjective measurements for social isolation and loneliness. The number of contacts and size of a social support network can be quantified, whereas loneliness is subjective. Loneliness is verbalized by the client and assessed qualitatively. Older adults who live alone are not always lonely. Loneliness is multifaceted and often intertwined with social interactions, which are unique to each client. Assessing limitations such as revoked driving privileges that can alter social interactions requires the healthcare provider to assess the social domain. Social engagement (personal, community, society connection) and individual productivity are major keys of successful aging (Czaja et al., 2021). This requires the healthcare provider to assess the quality of interactions and feelings of belonging when evaluating quality of life of the older adult.

Faamily history

The family history of an older adult can provide a genetic understanding and hint at vulnerabilities. Formal diagnosis can be lacking in older generations; however, subjective data on family members is a worthwhile investigation for the healthcare provider. Some mental health diagnoses are more likely than others to run in families. Obtaining historical family mental health diagnoses and medical diagnoses can focus risks as well as treatment options for the healthcare provider to consider. The healthcare worker can obtain the family history from the older adult, the family of the older adult (with consent), or caregiver(s).

Sexual orientation, function, and dysfunction

Sexual identification and function are assessed regardless of age. Older adults who identify as part of a sexual or gender minority (lesbian, gay, bisexual, transgender, etc.) are more prone to sexual difficulties and psychological distress later in life (NIA, 2022a). The healthcare provider is cautioned to assess with open empathy. Older adults often redefine the meaning of sexuality and intimacy in their life, and the healthcare provider must approach sexuality professionally and at the comfort level of the older adult. The healthcare provider needs to assess for the importance of sexual performance in the older adult's life. For example, sexual dysfunctions that can include decreased desire, delayed or absent orgasm and ejaculation are known side effects of antidepressant medications (Sadock et al., 2015). The healthcare provider must know the expected physical changes that occur in the older adult female, shortening and narrowing of the vaginal walls and decreased lubrication, which can decrease enjoyment of sexual activity (NIA, 2022a). The healthcare provider must also know the age-related physical changes that occur in the older adult male, erectile dysfunction (impotence) and decreased firmness with erection, which can cause stress in the older adult (NIA, 2022a). The healthcare provider can assess for sexual dysfunction distress. There are other common causes of sexual dysfunction: alcohol in excess, arthritis, chronic pain causing exhaustion and decreased energy, dementia, depression, diabetes, heart disease, incontinence, obesity, and stroke (NIA, 2022a). The healthcare provider can prescribe or refer the older adult for evaluation and treatment if desired.

Substance use, abuse, and treatment history

Substance use and abuse are a crucial part of the psychiatric assessment for the older adult. The Substance Abuse and Mental Health Services Administration (SAMHSA) states that substance use and abuse in older adults is often "overlooked and undertreated" (SAMHSA, 2022d, p. xi). The healthcare provider is reminded to self-assess for ageism, conscious bias, and unconscious bias that might inhibit the ability to evaluate substance disorders in the older adult.

Substance use disorder (SUD) guidance for the older adult population includes the following (SAMHSA, 2022d):

- Substance misuse disorders occur more in younger populations than elderly populations; however, this does not void the importance for assessment.
- Substance misuse in older adults increases physical injury and mortality.
- Illicit drug use in the older adult population is currently on the rise, as is dual diagnosis (co-occurring mental health and substance use disorders).
- Alcohol is the most abused substance by older adults.
- Caution is warranted for the older adult due to the commonality of multiple prescriptions and possible detrimental interactions with substances.
- Substance abuse symptoms can mimic cognitive deficits (normal or clinical).
- Avoid assumptions that older adults are unwilling to change or seek treatment.
- Multiple approaches have been found to be effective in the older adult population (screening, brief intervention, and referral to treatment; brief structured treatment; patient education; relapse prevention techniques; formal SUD treatment programs; and pharmacotherapy).

With alcohol being the most commonly misused substance by older adults, the healthcare worker must understand the risk factors contributing to increased alcohol consumption by the older adult. Older adults will experience numerous life stressors such as financial hardship, retirement or involuntary loss of job, living rearrangement, loss/grief/bereavement, trauma, or social isolation (SAMHSA, 2022d). Increased alcohol use and misuse can be detrimental to the older adult. Due to aging factors such as decreased metabolism and body fat storage, the older adult is more at risk for confusion, falls, injury, and exacerbated chronic conditions (SAMHSA, 2022d). The healthcare provider should assess tobacco product use presently or historically. Older adults who are lonely are at greater risk for smoking (Czaja et al., 2021). Smoking, vaping, or oral tobacco habits can be noted and assessed for intervention. Assessment of substance (legal or illegal), quantity, and frequency of use is critical for accurate assessment.

Barriers to older adults seeking treatment for substance misuse include the following (SAMHSA, 2022d):

- Negative beliefs and attitudes.
- Denial.
- Justification (caregivers accepting misuse due to the end of life).
- Decreased information on dangerous effects of substances and older age.
- False information about older adult treatment.

Protective factors for the older adult against substance misuse include the following (SAMHSA, 2022d):

- Healthy coping skills.
- Marriage or committed relationships.
- Social and family support.
- Autonomy and independent living.
- Accountable basic needs covered (food, shelter, safety).
- Positive self-esteem and self-image.
- Access to medical care and medications.
- Sense of purpose and belonging.

Person-centered care accounts for older age and lifestyle modifications, access to care, and quality of life considerations (SAMHSA, 2022d). The healthcare provider needs to consider the following for the older adult seeking treatment: physical disabilities to accommodate (mobility, hearing, vision), cognitive deficits that interfere (memory and attention), learning needs and preferences (slower pace and repeated information if needed), and respect for age and gender preferences for provider and group therapies.

Spirituality

The spiritual assessment of the older adult is documented in the social history section of the psychiatric evaluation. The healthcare worker is reminded that it is critical to maintain neutrality of stance while assessing the older adult's spiritual beliefs. Spirituality is a broader topic than religion. It is estimated that 80% of Americans practice some type of religion (APA, 2013). All healthcare workers will interact with the spiritual aspects of an older adult's beliefs, religion, or purpose of life while meeting their mental health needs. The inability to address spiritual involvement in an older adult's life can limit a client's recovery (Neathery et al., 2020). If the healthcare worker is reluctant or uncomfortable assessing an older adult's spirituality, a self-assessment to identify the barriers can be beneficial. Cultural awareness and acceptance are key for impartiality of assessment. Spirituality is a component of mental healthcare that is often woven into an older adult's lifestyle, guid-

ing their adherence to medications and therapies (Rodgers et al., 2018). Proper understanding of an older adult's belief system, spirituality, and feeling of belonging is essential during assessment for relevant intervention and treatment.

Legal involvement

Legal history can be notable for the older adult client. The mental healthcare worker will assess for legal involvement or ramifications that could hinder treatment. A history of problematic behavior related to disregard for rules and remorse can be diagnostic for antisocial personality disorder (ASPD). ASPD is associated with younger populations; however, the presence of it historically must be taken into consideration, as it carries high rates of comorbidities, most commonly substance use disorders (Holzer et al., 2022). The healthcare worker can also assess for caregivers, friends, or family members who have any legal stake in the older adult's decision making.

Elder abuse (physical/emotional/sexual/financial)

According to statistics, abuse is reported for around 10% of those age 65 years and older (Sadock et al., 2015). The healthcare worker must understand definitions and classifications of abuse and assess for mistreatment in all older adults. The American Medical Association has three general definitions for elderly mistreatment: abuse (something that causes harm or the withholding of something to cause harm to the health and well-being of an elderly person), neglect (the inability to do good or provide needed services or basic needs [food, shelter, medical care] to an older adult), and exploitation (using an older adult's money for self-purposes) (National Research Council, 2003) The older adult is vulnerable to all generalized types of abuse: physical, emotional, sexual, and financial. Physical abuse is defined as "bodily harm by hitting, pushing, or slapping. This may also include restraining an older adult against his/her will, such as locking them in a room or tying them to furniture" (NIA, 2020). Emotional abuse, also called psychological abuse, includes "a caregiver saying hurtful words, yelling, threatening, or repeatedly ignoring the older adult. Keeping that person from seeing close friends and relatives is another form of emotional abuse" (NIA, 2020). Sexual abuse involves unwanted sexual acts or being forced to watch sexual acts (NIA, 2020).

Financial abuse happens when money or belongings are stolen from an older adult. It can include forging checks, taking someone else's retirement or Social Security benefits, or using a person's credit cards and bank accounts without their permission. It also includes changing names on a will, bank account, life insurance policy, or title to a house without permission (NIA, 2020).

Older adults most at risk for abuse are female, those without support systems, those with disabilities, and those who are cognitively inhibited or have dementia (NIA, 2020). The healthcare provider must assess for physical and verbal signs of abuse when interacting with the older adult.

Signs of abuse in the older adult include the following (NIA, 2020):

- Cessation of enjoyed activity.
- Unkempt appearance.
- Difficulty sleeping.
- Unexplained weight loss.
- Easily agitated or violent outbursts.
- Outward signs of trauma and regression (e.g., rocking back and forth).
- Unexplained bruises, burns, cuts, scars.
- Signs of physical altercation (such as broken eyeglasses).
- Bed sores or other preventable disorder or disease.
- Lack of medical aids needed for functioning (glasses, hearing aids, dentures, medications, etc.).
- Financial warnings (eviction notices, unpaid bills despite financial means).
- Report of unsafe living conditions (hazardous, unsanitary, or unsafe).

Long-term effects of elder abuse can lead to declining physical and psychological health, severed social support, financial loss, and early death (NIA, 2020). Elder abuse requires intervention. The healthcare worker must comply with state laws and authorized means of reporting elder abuse according to facility policy. Local, state, and national resources exist to report and/or stop elder abuse.

Self-Assessment Quiz Question #4

Abuse, a biopsychosocial consideration, in the older adult can lead to negative long-term effects; therefore, the healthcare worker recognizes the signs of elder abuse as all of the following EXCEPT:

a. Disheveled appearance.
b. Severed family ties.
c. Difficulty sleeping and easily agitated.
d. Unexplained bruises and bed sores.

CRISIS, LOSS, GRIEF, AND BEREAVEMENT IN THE OLDER ADULT

Older adults have lived through a multitude of challenges by the time the healthcare worker is assessing for intervention. Adaptation and change are inevitable. How the older adult has coped in the past is salient for how they will cope with present and future difficulties. The healthcare worker will see the older adult experience crisis, loss, grief, or bereavement; therefore, it is imperative to know the difference in presentation as well as the course of typical action and line of intervention.

Crisis

Prior to discussing loss, grief, and bereavement, it is prudent for the healthcare worker to understand crisis and its presentation to differentiate the state of being and possible intervention needed for the older adult. The definition of crisis is:

> A time-limited event that triggers adaptive or non-adaptive responses to maturational, situational, or traumatic experiences. A crisis results from stressful events for which coping mechanisms fail to provide adequate adaptive skills to address the perceived challenge or threat. (Boyd, 2017, p. 211)

Crisis is a crossroad. The direction taken in the context of crisis determines the positive or negative consequences of the outcome. If the older adult chooses to grow and strengthen from the crisis, positive outcomes are expected. However, if the reverse is apparent or the client is incapable of coping, a negative and possible destructive outcome can occur such as self-harm or suicide. If an older adult in crisis has historically had difficulty coping, caution should be taken when assessing their safety. Depression and suicide are risks for clients who are unable to overcome a crisis (Boyd, 2017). Assessment for self-harm is paramount for the older adult in a crisis, regardless of past psychiatric history. A crisis should mitigate within four to six weeks (Boyd, 2017). When chronic crisis is not acknowledged, however, constant unrest is classified as chaos. The healthcare worker can note varying types of and reasons a client might be experiencing a crisis.

The healthcare worker assessing the older adult for mental health needs must be able to define crisis and understand the circumstances around the situations causing disequilibrium to psychological well-being. A crisis can cause feelings of being out of control, desperation, and/or fear (Boyd, 2017). There are three types of crises that an older adult can experience: developmental (a remarkable maturational event in life), situational (a specific event in a person's life that upsets the biopsychosocial equilibrium), and traumatic (due to an unknown incident) (Boyd, 2017). The older adult might experience a developmental crisis when their living situation changes dramatically, such as moving into a long-term care facility. A situational crisis can be an internal or external event for an older adult, such as disease progression or a new diagnosis. A natural disaster or a pandemic could affect the older adult and cause a traumatic crisis.

Differentiating a temporary crisis from acute stress disorder depends on the severity of distress and how it impairs social functioning. It will also depend on diagnostic criteria in the *Diagnostic*

and Statistical Manual of Mental Disorder (*DSM-5*). Diagnostic inclusion for acute stress disorder requires "exposure to actual or threatened death, serious injury, or sexual violation" (not experienced through electronic media unless work related) (APA, 2013, p. 280). The healthcare worker must gather sufficient detail about the stressors and their causes in the older adult's life to offer appropriate intervention.

A healthcare worker often intercedes in times of crisis. Assessment for self-harm or harm to others is needed when an older adult is in crisis and will drive the immediate interventions. If harm is not a factor, the healthcare worker should focus their initial intervention on active listening (Corey & California State University, 2013). Allow the older adult the space to verbalize their feelings and experiences. The healthcare worker can meet these expressions with openness driving for acceptance. Feeling heard can help an older adult in crisis feel grounded (Corey & California State University, 2013). Stability in the midst of a crisis can help deescalate the extremes of emotions such as anger or sadness. Positive mental health support during a crisis opens the door for future intervention. Not all older adults who experience a crisis need mental healthcare. The necessity of crisis intervention will be determined by the ability or inability of the older adult to self-soothe and cope. It is worth understanding that the older adult may value feeling understood and supported during a crisis more than a healthcare worker's ability to solve the problem (Corey & California State University, 2013). Assessment of coping skills and previous crisis coping will provide the healthcare worker with a plan for present needs and intervention.

Loss, grief, and bereavement

Loss, grief, and bereavement are an expected part of life and will be seen in various presentations by the healthcare worker assessing the older adult. Statistical analysis suggests that 51% of women and 14% of men older than age 65 years will be widowed at least once in their lifetime (Sadock et al., 2015). The healthcare worker will assess the older adult suffering from loss, grief, and bereavement. Knowing the differences in terminology, the cycle of grief, and the risks to older adults unable to cope are crucial for the healthcare worker. The definition of loss according to the Merriam-Webster dictionary (2022) is "the act or fact of being unable to keep or maintain something or someone." Loss is synonymous with more than death. For example, the older adult can feel the loss of identity, loss of autonomy, or loss of functioning. The definition of bereavement is "the process of mourning and coping with the loss of a loved one" (Boyd, 2017, p. 213) This is synonymous with death. The definition of grief is:

> The anguish experienced after significant loss, usually the death of a beloved person. Grief is often distinguished from bereavement and mourning. Not all bereavements result in a strong grief response, and not all grief is given public expression. Grief often includes physiological distress, separation anxiety, confusion, yearning, obsessive dwelling on the past, and apprehension about the future. Intense grief can become life-threatening through disruption of the immune system, self-neglect, and suicidal thoughts. Grief may also take the form of regret for something lost, remorse for something done, or sorrow for a mishap to oneself. (APA, 2022e).

For the older adult, loss, grief, and bereavement are topics that are encountered over a lifetime. Loss can be felt over animate and inanimate objects. Older adults can experience loss over loved ones, driving privileges, jobs, and autonomy on many levels of health, home, and happiness. Cultures and societies have determined an acceptable amount of time to grieve loss. Typical American culture expects people to return to work or school after a few weeks of loss, find a new balance in a few months, and be adept in their coping to establish new relationships 6 to 12 months after the loss of a loved one (Sadock et al., 2015). The healthcare worker should assess and recognize that grief is an individual process each time it occurs. One notable framework for understanding grief in marked stages is by Kübler-Ross. However, the stages are not meant to be linear as they are written (Kübler-Ross & Kessler, 2005). Grief is felt uniquely by everyone but is often encountered with proportionally greater impact by the older adult than younger generations.

The Kübler-Ross and Kessler (2005) framework allows common terminology and an expression of information with the hopes of a better understanding of the psychological process occurring individually over loss. The stages are written sequentially but are not always experienced linearly. The stages can last minutes or hours, weeks or months. The stages are a response to loss that is seen and felt by many. There is no normal response to loss; all loss is different. Kübler-Ross and Kessler (2005) hoped by creating the stages it would create a space for grief to resolve, enabling a person to cope with the loss and carry on with their life.

Another view of grief comes from the dual process model. It provides the healthcare worker with a way of conceptualizing how an older adult can cope with loss over time. The exploration of this model can enable a healthcare worker to identify the coping mechanisms the older adult is utilizing in their journey of healing. The model has two processes working, sometimes simultaneously and other times not, and it focuses on the switch between loss-oriented coping and restoration-oriented coping as oscillation (Boyd, 2017). Both processes may take large amounts of time and effort, or one may take more or less. They are not mutually exclusive, but awareness of both is necessary for processing grief and loss. Loss-oriented coping is focused on the loss itself—the relationship—and restoration-oriented coping is focused on the burden felt from the responsibility from the loss (Boyd, 2017). The older adult might be consumed with thoughts of the loved one who has passed away and consumed with sadness by the void created in their life, thus exhibiting loss-oriented coping. Restoration-orientated coping can be scary and difficult for the older adult if the loss is accompanied with lifestyle changes, for example, related to finances.

Table 5. Five Stages of Grief: Denial Anger, Bargaining, Depression, and Acceptance	
Stage	**Characteristics**
Denial	• Frozen with shock or overcome with numbness. • Unconscious ability to manage strong emotions and feelings by slowly feeling them (this is a survival technique). • Feelings of grief varied to prevent mental overload (protection). • Nature's way of letting in only as much as we can handle.
Anger	• Does not have to make sense or be rooted in reality (also has no limits). • Anger surfaces once you are feeling safe enough to know you will probably survive what comes. • Needed for healing to process. • May be reoccurring visits with this emotion. • Can lead to an uneasy or hateful feeling toward spirituality/religion. • Contrary to its negative connotations is the strength it contains to solidify the idea of void and loss. • Difficulty in feeling it without causing damage to self or someone else. • Finding avenues of release such as exercise can help externalize and explore anger (decreases the chance of bottling it all up for a explosion). • Is an indication of the intensity of love. • Is a normal response to the unfairness of life and death. • Anger towards self is guilt; however, it is undeserved blame. • "Anger affirms that you can feel, that you did love, and that you have lost." (Kübler-Ross & Kessler, 2005, p. 16)
Bargaining	• Agreeing to anything to avoid loss prior to loss. • Agreement to anything after a loss can look like a temporary truce. • Understand if lost in the darkness of "what if." • Like anger, this stage can present guilt. • After a death, focus can futuristic.
Depression	This is a *DSM-5* clinical diagnosis as well as a Kubler-Ross and Kessler stage. It will be talked about with DSM-5 criteria later. Clinic depression can lead to worsening mental health if left untreated: • Feelings of nothing and emptiness take over. • A normal response to major loss. • Can feel heavy (like hitting the bottom) and lonely. • A natural way to protect the body's nervous system from overload by slowing it down or turning it off for processing. • A way toward healing. • Seeking a way out of depression can feel like being lost in a storm with no seeable way to escape (loss of hope). • Shift the view of depression from unwanted to invited (like a guest). • Allow the encounter with it even though it feels hard. • Use the opportunity to explore and renew self. • Society often seeks to rid someone of depression as quickly as possible. • Depression intervention can be necessary, but time can also heal if allowed an acceptable space. • Treating depression is seeking equilibrium. • View and feel sadness as an appropriate part of grief (balanced with quality of life and meeting needs). "Depression makes us rebuild ourselves from the ground up because it takes us to a deeper place in our soul that we normally would explore" (Kübler-Ross & Kessler, 2005, p. 24)
Acceptance	• Is not the notion of being all right or fine with what has happened (is about acknowledging all that has been lost and learning to that loss). • Healing looks like remembering–recollecting–reorganizing (RRR). • Not in a linear sequence; goal is not to arrive at acceptance (it is not a destination) rather, is a journey of healing to take, not a point. • Past cannot be altered; has been forever changed; therefore, readjust. • Slowly withdraw energy from the loss and begin to invest it in life. • Put loss into perspective. • What is lost cannot be replaced, but new connections, relationships, and interdependencies can be made. • Living begins again (but only if grief is given its time).
Note: From Kübler-Ross & Kessler (2005, pp. 7–28)	

Different types of grief can be experienced. The type of grief being felt can drive the responses and state of being for the older adult presenting to the healthcare worker. Uncomplicated grief is considered the normal and expected course of grief after major loss triggered by events other than death (Boyd, 2017). When initial news of loss is presented, physical symptoms are often felt such as shortness of breath, a feeling of choking, rapid heart rate, sickness in the stomach, and body weakness (Boyd, 2017). The healthcare worker can help assess and prompt the older adult to assemble their social support system. Although yearning over the loss can occur for two years, most people do not need clinical treatment (Boyd, 2017). Complicated grief can happen when a person cannot move beyond the loss and a degradation of functioning occurs; however, it is only experienced by about 10% to 20% of people (Boyd, 2017). If the older adult cannot move past the loss and is overwhelmed by the change, the healthcare worker needs to intervene.

Complicated grief occurs after six months of intense mourning; there is a feeling of being "stuck," deep yearning is expressed, trust toward other people is apparent, and life become meaning-

less (Boyd, 2017). The healthcare worker will assess safety and the social support network to help the older adult overcome complicated grief. Grief that does not follow a normal response in the timing of symptoms can be documented as delayed grief. In delayed grief, there is a lack of initial symptoms of grief but they surface later (Sadock et al., 2015). The healthcare worker can explore the Kübler-Ross cycle of grief to assess for extended denial when the older adult appears stoic in presentation to acute loss. Cultural norms and awareness are cautioned as the healthcare provider works with the client to determine their definition of normal and what an appropriate response to loss and death are.

Another form of grief is prolonged grief, which is sometimes called traumatic grief because the loss was unforeseen. It is similar to persistent complex bereavement disorder. Persistent complex bereavement disorder is a clinical diagnosis that requires the deceased to have a significant connection to the mourner. In addition, there are intense feelings of yearning/sorrow/constant thoughts of the deceased/constant thoughts of the nature of death (one of those), and these difficulties interfere with functioning for more than a year after the death (APA, 2013). Traumatic grief is more difficult to cope with, thus leading to a longer recovery time. It often includes external circumstances such as violence, abruptness, and unanticipated or preventable death (Boyd, 2017). Traumatic grief is often termed prolonged grief due to extenuating forces and an anticipated loss. Therefore, the person experiencing the loss faces a longer period of change and adaptation.

Symptoms of traumatic grief/prolonged grief include the following (APA, 2013):

- Last all day (nearly every day) for at least one month.
- Disruption of self (feeling loss of self).
- Extended denial about the death.
- Inability to confront reminders of the deceased person (avoidance).
- Intense outward feelings (emotions such as anger).
- Constant struggle with moving forward with daily activities and social engagements.
- Empty feelings about life.
- Loneliness (feeling isolated and distant from others).

While considering the cycle of grief and the various types of grief an older adult may experience, the healthcare worker should consider the symptoms of grief and their interference with functioning and relationships, the risk of self-harm or harm to others, and the symptoms of clinical depression when presenting appropriate intervention. Most grief will resolve on its own accord without psychiatric intervention; however, a healthcare provider might be consulted for acute medical intervention. Sleep deficits can be addressed with short-term psychopharmacological agents; however, anxiolytics, antidepressants, and narcotics are not recommended for normal grief (Sadock et al., 2015). If therapy is warranted, the healthcare worker can provide options for treatment. Grief therapy (one-on-one or group sessions) and self-help groups have been found to be most beneficial for those mourning and unable to overcome grief, loss, or bereavement (Sadock et al., 2015). The healthcare worker can work with the client, family, and community to assess the availability of resources to support the older adult.

Case study: Ms. P

Ms. P. is a 68-year-old Caucasian female being seen by you in the mental health clinic. She recently lost her husband of 48 years. She barely talked at her appointment last week and has mostly been looking down at the floor avoiding eye contact. She reluctantly tells you that she overheard her children talking about housing options for her. She does not want to leave her home. Her husband drove her to all of her appointments and took care of all of her needs (groceries, medications, etc.). She has two married children who both live out of state. Her oldest daughter brought her to the visit today and is sitting in the lobby. Ms. P has a history of colon cancer (currently in remission), diabetes, hypertension, and depression. She takes oral medication for her elevated blood pressure, diabetes, and depression. Today she tells you that she feels empty, alone, and hopeless.

Question:
What stage of grief is Ms. P in and what assessment criteria supports this?

Discussion:
Ms. P is displaying signs that support the depression stage (Kübler-Ross & Kessler, 2005). She is stating that she feels empty, alone, and hopeless after the loss of her husband and loss of access to groceries, medications, and medical appointments. She is expressing concern that she might even be moved from her home. Depression is also a clinical diagnosis. Further assessment would be warranted to determine her safety risk and the need to intervene or treat. Ms. P's daughter is in the waiting area and can possibly provide clarity and insight into Ms. P's current and future mental health needs.

MENTAL HEALTH DIAGNOSES FOR THE OLDER ADULT

Neurocognitive disorders
Changes in cognition are statistically significant for the older adult population (Boyd, 2017). The healthcare worker must understand the differences in neurocognitive disorders for assessment, intervention, treatment, and when to refer to other disciplines and community resources. According to the APA (2013), the DSM-5 diagnosis of a neurocognitive disorder is a deficiency in the following: attention (distractibility with multiple stimuli), executive functioning (decision making, planning, and working memory), learning and memory (recollection and recognition), language (expressive, fluency, grammar, receptive), perceptual-motor (visual and motor perception), and social cognition deficits (emotion recognition, ability to relate to another). Differentiating cognitive regression and disruption can be difficult, especially when a baseline of functioning or collateral information is not available. The healthcare worker who assesses and/or treats older adults will encounter older adults with neurocognitive disorders.

Delirium

Delirium is a neurocognitive disorder that a healthcare worker will come across in the older adult population. Delirium is an acute cognitive impairment caused by an underlying medical culprit (Boyd, 2017). The healthcare worker needs sharp attention of its presence; however, treatment is often administered in the acute care setting by medical professionals. There are a multitude of risk factors and known causes for delirium in the older adult population.

Delirium risk factors for the older adult include the following (Boyd, 2017):

- Advanced age (65 years and older).
- Male.
- History of falls.
- Preexisting dementia.
- Functional dependence (long-term care facility residents).
- Endocrine and metabolic disorders.
- Fractures in bones.
- Medications (consider AGS 2019 BEERS criteria for potentially inappropriate medications in older adults).
- Vital sign changes (hypotension, hypo- or hyperthermic).
- Imbalances in intake (dehydration, renal failure, hyponatremia).
- Long-term care admission.
- Pain (acute or chronic).
- Stress (acute or chronic, notable risk during loss or bereavement).
- Substance use and alcohol withdrawal (alcohol is greatest offense).

Known causes that induce acute delirium include the following (Sadock et al., 2015):

- Seizures.
- Trauma (especially head trauma after a fall).
- Diabetes.
- Infection.
- Insufficient nutritional status.
- Uncontrolled pain.
- Medications (e.g., pain medication, antibiotics, antivirals, antifungals, steroids, anesthesia, cardiac medications, anticholinergics).
- Serotonin syndrome.
- Over-the-counter substances (e.g., herbs, teas, supplements).
- Cardiac disturbances (failure, arrhythmias, myocardial infarction).
- Disease (abnormality or failure in pulmonary, endocrine, renal, and hepatic systems).

Delirium can be life threatening but is usually reversible with treatment. The healthcare worker must be able to identify the signs of delirium. Key features of delirium include rapid and abrupt onset, decreased level of consciousness, altered attention, impaired cognitive functioning (can look like disorientation), and diminished memory (Sadock et al., 2015). It can present like other mental health disorders. A psychotic episode of schizophrenia, mania, or a factitious disorder can look like delirium upon the first encounter. Generally speaking, schizophrenia presents with better organization and a more stable level of consciousness; mania will be explained historically with a bipolar diagnosis or become apparent over time; and in a factitious disorder, inconsistencies will surface during examination or be easily revealed after an electroencephalography (Sadock et al., 2015). The healthcare worker can provide or request further examination of the older adult. Cognitive testing can be administered and compared to a baseline examination if available, along with laboratory studies looking for underlying causes of delirium. The treatment will often be dependent on the underlying cause of the delirium. Caution is needed for the older adult receiving treatment for psychosis. The AGS (2019) highly recommends avoidance of antipsychotic medications such as haloperidol (Haldol), risperidone (Risperdal), and quetiapine (Seroquel) due to their increased affiliation with tremors, fall risk, stroke, and death in patients with dementias. A refined assessment and understanding of underlying sequalae of psychosis are needed for treatment of delirium long term.

Mild cognitive impairment (MCI)

MCI lives in the space between normal age-related cognitive changes and dementia. Older adults with MCI are at greater risk for developing dementia or Alzheimer's disease (NIA, 2022f). The mental healthcare provider can note subjective data from the older adult or from caregivers, family, or friends (with consent). Data to note for older adults with suspicion of MCI: increased frequency of losing items; forgetting important dates, events, or appointments; and difficulty with word selection (NIA, 2022f). These symptoms can be concerning to the older adult. The NIA recommends tips to improve MCI. These suggestions can empower the older adult who feels embarrassed or saddened by their cognitive state. Recommendations for improving memory include the following (NIA, 2022f):

- Stick to a daily routine—predictability is key.
- Utilize tools such as calendars, to-do lists, notes, and reminders.
- Place daily objects in the same place in your house.
- Consider learning a new skill (check community resources).
- Volunteer time (give back to the local community).
- Increase time spent with friends and family.
- Ensure adequate sleep at night.
- Prioritize exercise and nutrition.
- Avoid alcohol (receive help if needed).

The older adult with MCI needs to be assessed regularly to recognize increased symptoms that would warrant intervention. The findings of MCI do not predict further impairment, do not necessitate treatment, and can cease without medical intervention (NIA, 2022f). Further evaluation by a neurologist or neuropsychologist can be provided if desired.

Dementia (vascular, lewy body, frontotemporal, Alzheimer's disease)

Dementia is a major neurocognitive disorder classified in the DSM-5 by severe impairment of memory, judgment, orientation, and cognition (APA, 2013). It is not part of normal aging and is common in older adults. Half of older adults age 85 years or older have a diagnosis of dementia (NIA, 2022c). Not all causes of dementia are known, and differentiating them can be challenging to the healthcare worker. If a specific dementia cannot be categorized but symptoms meet criteria, the diagnosis of general dementia will stand. Delirium and dementia are often confused, but they can be contrasted by several clinical features. The most distinguishable characteristic of delirium is the rapid onset of presentation and attention level. Delirium has an abrupt beginning and inconsistent level of attention, while most dementias occur over the course of time and maintain a consistent level of attention (Sadock et al., 2015).

Although vascular dementia, which is caused by a stroke, presents very similarly to delirium, it can be separated by clinical evaluation. Vascular dementia is one of the several subcategories of dementia. It is the second most common type behind Alzheimer's disease (NIA, 2022g). Those most at risk for developing vascular dementia are men, people with hypertension (especially uncontrolled), people with high cholesterol, and those who have other cardiovascular diseases (Sadock et al., 2015). The cognitive invasion of this type of dementia is a result of an infarcted plaque or emboli traveling to the brain. A diagnosis can be made after cognitive testing is performed, a medical history is taken, and brain imaging is completed (NIA, 2022g). One unfortunate truth about vascular dementia is the irreversibility of its damage. Treatment can include preventing further strokes by thinning the blood and lowering risk factors with lifestyle changes and medications (NIA, 2022g).

Another subtype of dementia is Lewy body disease (LBD). It presents similarly to Alzheimer's but it is distinguished by areas in the brain lumped with proteins known as alpha-synuclein and called Lewy bodies after the physician who discovered them (NIA, 2022e). The accumulation of Lewy bodies causes destruction and death of neurons and results in gradually decreasing brain activity (NIA, 2022e). There are two types of Lewy body dementia—dementia with Lewy bodies and Parkinson's disease dementia. The biggest difference between Lewy body and Parkinson's dementia is the timing and disruption in thought and movement.

Classification of dementia with Lewy bodies (NIA, 2022e):

> Problems with thinking, unpredictable change in attention and alertness, and visual hallucinations develop early in relation to movement symptoms, such as slow movement, difficulty walking, and muscle stiffness.

Classification of Parkinson's dementia (NIA, 2022e):

> Movement symptoms start first and are consistent with a diagnosis of Parkinson's disease. Later, problems with thinking and changes in mood and behavior develop.

Not everyone with Parkinson's disease will develop dementia. The evaluation of a person with either Lewy body or Parkinson's dementia will entail a physical exam, mental status examination, cognitive functioning evaluation, and brain imaging. LBD is neither preventable nor curable, and treatments focus on the patient's safety and quality of life (NIA, 2022e). Interventions can include many disciplines, especially case management. The mental healthcare worker can also offer community resources and nonprofit organizations as care options, dependent on their accessibility to the older adult.

Frontotemporal dementia (FTD), also known as Pick's disease, is named after a physician who described it and the "Pick bodies" seen in the brain postmortem (Sadock et al., 2015). FTD is a rare, progressive disease with an unknown etiology. It carries a

life expectancy of 2 to 10 years after diagnosis and often requires full-time care (NIA, 2022d). It can present with notable personality and behavioral changes. Frontal lobe involvement can cause changes to behavior and movement; temporal lobe changes feature language and emotional changes (NIA, 2022d). FTD can have distinguishable symptoms. It can present with Klüver-Bucy syndrome: hypersexuality, placidity or complacency, and hyperorality or oral compulsions (Sadock et al., 2015). There is no cure and no way to prevent disease progression. Treatment focuses on symptom control (sometimes using antidepressants or antipsychotics) and quality of life. This disease can be distressing for family members and caregivers. The mental healthcare provider can refer all involved to resources and support groups.

The most common form of dementia is Alzheimer's disease. The mental healthcare worker will treat older adults with it or will see a family member affected by it. The NIA (2022b) states that over six million Americans, most 65 years and older, are diagnosed with Alzheimer's disease. It often presents as dementia. The causes of Alzheimer's disease remain unclear, but what has been discovered is brain atrophy and inflammation, genetic predispositions on chromosome 17, and environmental exposures such as aluminum toxicity (Sadock et al., 2015). Older adults or caregivers usually note the first symptoms as forgetfulness. The NIA (2022b) notes symptoms of Alzheimer's disease as difficulty finding words, struggles with vision and spatial perception, reduced reasoning and poor judgement, length of time it takes to complete ADLs, repetition of stories or questions, danger due to wandering and getting lost, losing common items, and change in mood and personality (usually more irritable).

There are three stages of Alzheimer's defined by the NIA (2022b):

- **Early-stage Alzheimer's**: When a person begins to experience memory loss and other cognitive difficulties, though the symptoms appear gradual to the person and their family. Alzheimer's disease is often diagnosed at this stage.
- **Middle-stage Alzheimer's**: Damage occurs in areas of the brain that control language, reasoning, sensory processing, and conscious thought. People at this stage may have more confusion and trouble recognizing family and friends.
- **Late-stage Alzheimer's**: A person cannot communicate, is completely dependent on others for care, and may be in bed most or all the time as the body shuts down.

Cognitive testing can be performed, as can brain scans. The mental healthcare worker can refer to neurology if needed. There is no cure, but the U.S. Food and Drug Administration (FDA) has approved medication to treat symptoms and slow the progression of invasion. The life expectancy with a diagnosis of Alzheimer's disease varies from 3 to 10 years (NIA, 2022b). The mental healthcare provider can prepare the older adult and family members for the future and focus treatment options on quality of care that is uniquely important to the older adult.

Sleep difficulties

Sleep is a crucial component of physical and mental health and warrants an assessment during every psychiatric mental health examination. Dementias, most notably Alzheimer's disease, can be a perpetuating cycle of negative sleep and interference with cognition (Boyd, 2017). Sleep changes are a natural part of advancing age but can contribute to worsening states of mental health if natural adaptations are not rendered or medications are improperly prescribed. With advancing age, restful sleep decreases and interruptions in the sleep pattern shorten, both of which contribute to a decreased quality of sleep. Rapid eye movement (REM) during sleep (the deepest and most restful part of sleep) becomes less frequent, as do circadian rhythms (Sadock et al., 2015). Falling asleep, staying asleep, and feeling rested become more difficult with advancing age. Sleep deficiencies can worsen cognitive functioning and can be magnified if the older adult has cognitive disorders. It's necessary to routinely assess the older adult's quality and quantity of sleep. Interventions for sleep difficulties will vary for the older adult. The safest sleep intervention is nonpharmacological. The healthcare worker can encourage and educate the older adult on healthy sleeping habits.

Nonpharmacological sleep interventions for the older adult include the following (Boyd, 2017):

- Use awareness for when to go to bed and go to bed when feeling tired.
- Create a routine and stick to it (it can take time).
- Use your bed only for intimacy or sleep.
- Decrease or eliminate stimulating foods after lunch (caffeine).
- Avoid naps.
- Add or increase physical exercise.
- Include relaxation techniques (simple relaxation, guided imagery, or distraction).

The use of pharmacological interventions needs further assessment and possible referral. The AGS (2019) notes possible dangers in prescribing medications that are potentially inappropriate for older adults: zolpidem (Ambien), zalepon (Sonata), eszopiclone (Lunesta), alprazolam (Xanax), lorazepam (Ativan), and diazepam (Valium). Sleep hygiene is the primary recommendation from the AGS (2019) for older adults. If the older adult is technologically savvy, the healthcare worker can suggest apps for healthy sleep regimen reminders, sleep logs, relaxation techniques, or medication reminders. Getting restful sleep is important for the health and well-being of the older adult.

Depression

The healthcare worker is likely to interact with an older adult experiencing depressive symptoms or suffering from a diagnostic depressive disorder. Depression is more common in people who suffer from illness or decreased functioning; 80% of older adults have at least one chronic health condition, and 50% have two or more (CDC, 2021b). Remembering ageism and bias is important as the healthcare worker assesses for depression. Depression is not part of the aging process, and not all older adults experience depression (CDC, 2021b). The healthcare worker must be able to identify risks for the older adult. The NIA (2021b) lists the risk factors for older adults as physical conditions (most notably stroke and cancer), genetics (familial history increases risk), stress (being a caregiver can cause greater stress), sleep difficulties (falling asleep or staying asleep), isolation and loneliness (assess the root cause of it if found and the subjective impact), sedentary lifestyle, limited physical functioning (struggling with ADLs), and alcohol addiction. Older adults can find themselves alone and socially disconnected. Loneliness can contribute to depression and heightens the risk of suicide for the older adult population (NIA, 2021b). Loneliness is a common feeling experienced by older adults and is an indication for further assessment to determine the level of distress.

The healthcare worker needs an understanding of the signs and symptoms of depression and can teach them to the older adult to empower them to speak up. Caregivers should also receive this intervention so that they can request early intervention when possible. Symptoms of depression include sad mood, persistent feelings of hopeless/worthless/helplessness, an inability to find pleasure in regular activities (including sex), a low energy level, markedly slow speech (noticed by others), cognitive struggles (difficulty concentrating/remembering/making decisions), problems sleeping (more or less than usual), changes in appetite (increased or decreased), and thoughts of death or suicide (NIA, 2021b). If multiple symptoms are found and last more than two weeks, the healthcare worker (if allowed within scope of practice) can consider a clinical diagnosis of major depressive disorder (MDD) in line with the DSM-5 (APA, 2013). Recent loss, grief, bereavement, and culture must be taken into consideration prior to diagnosing. Untreated depression can lead to physical detriment for the older adult. Coping inappropriately with food can lead to obesity or geriatric anorexia (APA, 2022f). Depression can also alter

cognitive clarity. Depressed older adults have a slower reaction time to stimuli, increasing the risk and dangers of driving, cooking, and self-care activities such as medicating (APA, 2022f). The healthcare worker can use a self-reporting scale when assessing. Geriatric-specific depression scales are available, but documentation and scope of practice should be discussed with your place of employment. A strength assessment can help the healthcare worker find the older adult's historical methods of coping and resilience. It can also highlight unhealthy coping mechanisms that can be discussed.

Questions for assessing an older adult's strength include the following (Boyd, 2017):

- How have you coped with depression or depressive symptoms in the past?
- What do you find relaxing?
- What brings you joy?

Treatments and recommendations for depression depend on the health status of the older adult and their living situation. Treatment may be necessary for older adults experiencing symptoms of depression that have a sustained impact on positive mental health: physical exertion, proper nutritional intake, regular restful sleep, social connection, and engagement in activities that bring satisfaction (NIA, 2021b). These recommendations can be individualized to fit the needs of the older adult and their circumstances. Case management and community engagement can be useful additions for support.

The APA has published treatment recommendations specific to age ranges. For initial treatment of the older adult with MDD, the APA (2019) recommends group-based cognitive-behavioral therapy (CBT) or interpersonal psychotherapy (IPT) in combination with pharmacotherapy. The APA recognizes that treatment options are dependent on social determinants. The following are recommended treatments for MDD if group CBT or IPT are unavailable for initial treatment: individual CBT with or without pharmacotherapy and problem-solving group therapy (APA, 2019). If the healthcare provider is considering psychopharmacological interventions, a review of the AGS list of potentially unsafe medications for the older adults is needed. The AGS (2019) lists two tricyclic antidepressants, amitriptyline (Elavil) and imipramine (Tofranil), as potentially inappropriate and encourages considering prescribing selective serotonin reuptake inhibitors (SSRIs) citalopram (Celexa) and sertraline (Zoloft) as well as bupropion (Wellbutrin) if possible. Treating depressive symptoms of MDD with medication can be accomplished but must be reviewed for the safest option that meets the needs of the older adult.

Suicidal risk

The older adult population has a particularly high rate of suicide. White men over the age of 65 have a risk that is five times higher than the general population, and older adult men account for 60% of all completed suicides (Sadock et al., 2015). The safety of the older adult is paramount for all healthcare workers in all settings. The recognition of risk factors coupled with appropriate intervention can save lives. Risk factors can be modifiable or nonmodifiable. The APA clinical practice guideline (2010) notes genetics, family history, and demographics as nonmodifiable risk factors. Knowing the older adult's risk factors can aid the healthcare worker in risk calculation but does not precisely predict attempts. The National Council on Aging (NCA) (2021) notes loneliness as the top reason for suicidal ideations, followed by suicidal intent caused by feelings of deep grief over a loved one, mourning the loss of autonomy and self-sufficiency, chronic illness and pain that decrease the quality of life, cognitive impairment and dementias, and financial stress that causes an inability to pay bills. The older adult's increased suicide risk is also consistent with a mental health diagnosis of depression, schizophrenia, posttraumatic stress disorder, substance use disorders, an inclusion of trauma, an experience of discrimination based on sexual identity, access to lethal means, and sleep disturbances (LeFevre & Force, 2014).

The suicidal older adult with access to lethal means should trigger the healthcare worker to immediately assess for safety. Statistics show that older adults plan more thoroughly for suicidal completion and are most likely to use lethal means (firearms) than younger populations (NCA, 2021). Reasons stopping or preventing the older adult from following through on suicidal thoughts, intent, and plans are called protective factors. Protective factors that apply to the older adult are cultural views, spiritual beliefs, coping skills, personality traits, social support systems, and past responses to stress/loss/bereavement (APA, 2010). Assessment can be completed during the psychiatric interview. The healthcare worker can use an informal format or systematic questioning to elicit safety responses. No formal training is needed to administer the brief suicide screener called the Columbia Suicide Severity Rating Scale (C-SSRS) (SAMHSA, 2022a). All healthcare workers can administer the C-SSRS. The tool probes the older adult about their intent, plan, and preparation for death. If the questions are answered honestly, it can indicate older adults who are at high risk of suicide completion (The Columbia Lighthouse Project, 2016).

To garner the greatest gains, the healthcare worker must utilize empathy to nurture an environment of trust within the therapeutic alliance with the older adult during this part of the assessment. The APA (2010) recognizes the use of a suicide contract commonly called a no harm contract between a mental healthcare provider and a patient. There is no evidence to prove its effectiveness in prevention and it is cautioned against as a replacement for a thorough suicide risk assessment. But it can be a useful method for discussing protective factors and a safety plan of action. The healthcare worker has decisions to make based on the level of risk verbalized by the older adult. The approach for intervention will depend on the severity of risk, workplace policy, and state legalities—especially related to breaching confidentiality. The healthcare worker will abide by the individualized plan of action for suicide prevention according to protocol and treatment setting.

Anxiety

Anxiety is commonly found in early or middle adulthood but can be seen after 60 years of age, although initial panic disorders are very rare (Sadock et al., 2015). The symptom profile for older adults experiencing anxiety is different than younger populations. Older adults tend to be less symptomatic, yet they are equally as troubled. The decreased symptoms have been attributed to a decreased autonomic nervous system (Sadock et al., 2015). Older adults have a vast life experience that can include change, transition, loss, and death. Upon assessment, loss, grief, and bereavement can look like anxiety. When assessing anxiety, it's necessary to establish the underlying etiology, length of symptom interference, and cultural considerations. A thorough psychiatric history is needed for clarity of diagnosis. Degrees of clinical anxiety are mild, moderate, severe, and panic (Boyd, 2017). Anxiety often accompanies depression. The older adult with depression is at a higher risk for suicide; therefore, anxiety symptoms coupled with depression need a critical safety assessment (Sadock et al., 2015).

There are medical conditions that can mimic anxiety symptoms in the elderly. Further assessment is needed to rule out stroke, multiple sclerosis, cardiac dysfunction, irritable bowel syndrome, hypoglycemia, hyperthyroidism, hepatic failure, vitamin B deficiencies (1, 6, and 12), and decreased folic acid (Subramanyam et al., 2018). Laboratory studies can also confirm the presence of interference when considering the diagnosis of anxiety. If anxiety is found in the older adult, assessment for substance use and abuse is needed. Alcohol is often the drug of choice to self-medicate anxiety, but it is an inappropriate and ineffective method for anxiety treatment (Boyd, 2017). Treatment can be tailored to the individual needs of each patient. The AGS (2019) provides a list of potentially inappropriate medications for older adults, and it includes the benzodiazepines alprazolam (Xanax), lorazepam (Ativan), and diazepam (Valium) and offers alternatives for medicating anxiety with buspirone (Buspar) and SSRIs like citalopram (Celexa) and sertraline (Zoloft). Nonpharmacological approaches are plentiful for the treatment of anxiety in the older adult. The clinical practice guideline for geriatric anxiety recommends

nonpharmacological methods of treatment: lifestyle modifications (sleep, diet, exercise, social support), behavioral therapy (relaxation), cognitive-behavioral therapy, mindfulness, yoga, art/dance/music therapy, or alternative therapies (Subramanyam et al., 2018). Knowing how the older adult has coped in the past is helpful when establishing strengths and weaknesses for current treatment focuses. The healthcare worker can assess for anxiety and offer treatment suggestions that are available and acceptable to the needs of the older adult.

Bipolar

Bipolar is a disease typically diagnosed earlier in life than older adulthood. The average age of onset is 25 years old and portends a short life expectancy (Sadock et al., 2015). Even though older adult onset is rare, bipolar is a diagnosis for life. Therefore, a healthcare worker would need knowledge of common bipolarity symptoms that can be found in bipolar I and bipolar II: mood lability, agitated and cyclic depression, episodic sleep irregularities, possible impulsivity (often involving high-stakes behavior like unsafe sexual activity, gambling, or substance use), deep depressive crashes (can coincide with suicidal ideations), and historical failure of antidepressant treatments (Sadock et al., 2015). Older adults with bipolar can still experience mania or hypomania, but the incidence decreases with age. Older adults with bipolar often suffer from multiple comorbidities such as cardiovascular disease, cancer, lung diseases associated with smoking, hypertension, diabetes, and substance use and abuse (Sajatovic et al., 2013).

The physical and mental health of the older adult can be quite compromised. More severe comorbidities are associated with poorer outcomes. A thorough psychiatric history of symptoms and treatments should be assessed. The assessment priority for the older adult with bipolar having a manic or depressive episode is safety. Interviewing family, friends, and caregivers can be helpful for addressing potentially harmful activities for the older adult. Immediate intervention can be taken if needed, in accordance with workplace policy or state law. The healthcare worker meeting the mental health needs of the older adult with bipolar is likely to see psychiatric mood-stabilizing medication. The most common pharmacological treatments for bipolar are lithium carbonate (Lithium), divalproex sodium (Depakote), and lamotrigine (Lamictal) (Boyd, 2017).

Successful past pharmacological treatment can be reviewed and taken into consideration for current treatment options. Since the older adult with bipolar is likely to have comorbidities, special considerations should be taken when prescribing or altering their medication regimen(s). Older adults metabolize, tolerate, and respond to medications differently than younger populations; therefore, lower doses of bipolar medications might be needed and are associated with good outcomes (Sajatovic et al., 2013). Lower rates of mood-stabilizing medication in elderly patients will also decrease side effects and possibly ease medication longevity. Recent findings for nonpharmacological approaches to bipolar treatment can be applied to the older adult population. A new treatment approach utilizes peer mentors who can provide support and hope (Sajatovic et al., 2013). The treatment settings and goals for the older adult with bipolar will depend on the current mental status of the patient.

Schizophrenia

Like bipolar, schizophrenia is a diagnosis expected to impact the remainder of life. Schizophrenia onset is typically in late adolescence to early adulthood, but an older adult diagnosis is possible (Boyd, 2017). Psychosis is classically associated with schizophrenia.

Definition of psychosis (APA, 2022h):

1. An abnormal mental state involving significant problems with reality testing It is characterized by serious impairments or disruptions in the most fundamental higher brain functions—perception, cognition and cognitive processing, and emotions or affect—as manifested in behavioral phenomena, such as delusions, hallucinations, and significantly disorganized speech.
2. Historically, any severe mental disorder that significantly interferes with functioning and ability to perform activities essential to daily living.

Psychosis requires immediate intervention and is handled according to workplace policy and state law for the healthcare worker. Older adults with schizophrenia usually have improved symptoms with age and experience fewer relapses (Boyd, 2017). The healthcare worker should be aware of common symptoms of schizophrenia. Schizophrenia symptoms are classified as positive, negative, and neurocognitive (Boyd, 2017):

- Positive symptoms happen in addition to regular functioning, most commonly as hallucinations (can involve any of the five sense) and delusions (unreasonable beliefs, involving thoughts only).
- Negative symptoms are an absence of regular functioning such as flat affect and diminished emotional expression and activity.
- Neurocognitive impairment is expressed as disorganized speech, thought, or behavior.

Prior to the diagnosis of schizophrenia, an assessment would include ruling out medical causes of schizophrenia symptoms, mainly psychosis. Underlying medical etiology can present as psychosis in the older adult. The top five psychosis-inducing medical conditions to check the older adult for are substance abuse, thyroid disorders, delirium cause by infection, dementia, and vitamin B12 deficiency (Gaddey & Holder, 2021). A thorough assessment of the older adult is prudent prior to an initial diagnosis of schizophrenia. If the older adult with a diagnosis of schizophrenia is exhibiting symptoms out of their ordinary, a sweep for known medical conditions that mimic psychosis is also warranted. A differential diagnosis of brief psychotic disorder, major depressive disorder (MDD), and posttraumatic stress disorder (PTSD) can also be considered for the older adult. Collateral information from family, friends, and caregivers would be prudent if given consent. Breaches of confidentiality would need to be reviewed if the older adult is a danger to self or others during an acutely psychotic episode. Many factors must be considered during the assessment of the older adult with schizophrenic symptoms or psychosis.

The healthcare worker can present psychosocial intervention and treatment modality options that fit the mental health needs of the older adult. The National Alliance on Mental Illness (NAMI) has found four types of psychosocial intervention that greatly improve self-esteem and quality of life for an older adult living with schizophrenia: CBT, functional adaptation skills training (FAST), vocational rehabilitation, and technology communication connection (e.g., it provides reminders for medications and appointments). FAST is a unique treatment approach for schizophrenia that seeks to build necessary life skills that can address social determinant barriers to mental healthcare (Cepla, 2014). For example, an older adult with schizophrenia who lacks personal transportation can be taught how to navigate public transportation. Enhancing transportation for the older adult can address access to care issues and increase resource availability for items such as groceries, clothing, and medications. Psychosocial interventions strengthen the quality of care and life for an older adult living with schizophrenia.

Schizophrenia is treated pharmacologically with antipsychotic medications. First- and second-generation antipsychotics are most frequently seen as front-line treatment options, although third-generation antipsychotics are up and coming. Antipsychotic medications are used in patients with schizophrenia because they primarily block dopamine, a known cause of psychotic symptoms, and can alter other neurotransmitters (Sadock et al., 2015). Antipsychotic medications carry a difficult side effect risk profile. Seda-

tion, postural hypotension, anticholinergic effects, extrapyramidal symptoms, and tardive dyskinesia are some of the most concerning side effects of antipsychotic medications (Boyd, 2017).

Definition of anticholinergic effects (APA, 2022a):

> Side effects are characteristic of anticholinergic drugs and are also associated with other agents (e.g., tricyclic antidepressants, monoamine oxidase inhibitors) that exert antagonist effects at muscarinic receptors. They include dry mouth, blurred vision, urinary hesitancy or retention, and constipation. Similar antagonistic effects may occur at nicotinic receptors as well. Depending on the specific receptors involved, these effects may also be called antimuscarinic effects or antinicotinic effects.

Definition of extrapyramidal symptoms (APA, 2022d):

> A group of adverse drug reactions attributable to dysfunction of the extrapyramidal tract, such as rigidity of the limbs, tremors, and other Parkinson-like signs; dystonia (abnormal facial and body movements); and akathisia (restlessness). Extrapyramidal symptoms are among the most common side effects of the high-potency antipsychotics and have also been reported with the use of other drugs (e.g., SSRIs). Also called extrapyramidal syndrome (EPS).

Definition of tardive dyskinesia (TD) (APA, 2022i):

> A movement disorder associated with the use of antipsychotics, particularly conventional antipsychotics that act primarily as dopamine- receptor antagonists. It is more common with prolonged use (months or years), and older patients, females, and patients with mood disorders are thought to be more susceptible. Symptoms include tremor; so-called choreoathetoid movements; and spasticity of muscle groups, particularly orofacial muscles and muscles in the extremities. Onset is insidious and may be masked by continued use of the antipsychotic, only appearing when the drug is discontinued or the dose lowered. Its incidence is estimated at up to 40% of long-term users of conventional antipsychotics; the incidence is lower with atypical antipsychotics. No effective treatment is known.

Older adults need special considerations for medications to treat schizophrenia. Older adults with schizophrenia often need adjustments to medication regimens with lower doses or divided doses throughout the day when possible (Sadock et al., 2015). The AGS releases and continually updates safety criteria to guide the treatment of the older adult population. The AGS (2019) recommends only patients with schizophrenia receive antipsychotic medication, which increases the risk of stroke, diminishes cognitive ability, and contributes to early death.

The healthcare worker should investigate all medications being taken by the older adult with acute notation of antipsychotics drugs and their known side effects. Table 6 is a snapshot of antipsychotic medication options and is presented to increase understanding of decreased dose ranges and the comparative difficulty of side effect risk profiles for antipsychotics in older adults.

Table 6. A Snapshot of Decreased Older Adult Dosing and Side Effect Risk Profiles

Drug	Adult Dosage (mg/day)	Geriatric Dosage (mg/day)	Sedation	Postural Hypotension	Anticholinergic Effects	EPS	TD
Clozaril (clozapine)	300–450	12.5–25	High	Moderate	High	Low	Low
Olanzapine (Zyprexa)	25–50	25	Moderate–high	Moderate	Moderate–high	Low	Low
Quetiapine (Seroquel)	150–750	50–200	Moderate	Moderate	High	Low	Low
Risperidone (Risperdal)	4–16	0.25–1.5	Low	Low	Low	Low	Low
Haloperidol (Haldol)	1–15	0.25–0.5	Low	Low	Low	Very high	Yes

Note: Information taken from https://www.Medscape.com

Neuroleptic malignant syndrome (NMS) is a life-threatening condition that can happen in response to antipsychotic medications. Early recognition and intervention are the most important things a healthcare worker can do for a patient experiencing NMS. The primary symptoms of NMS are mental status changes, severe muscle rigidity, and autonomic changes (historically presenting with high fever ranging between 101 and 103 degrees Fahrenheit, tachycardia, and fluctuating blood pressure) (Boyd, 2017). Emergency intervention is needed for NMS. The healthcare worker should intervene as workplace policy dictates to get the patient to appropriate medical care as soon as possible.

A delicate balance is needed to lessen problematic schizophrenic symptoms and antipsychotic medication side effect profiles, which can be dangerous to the older adult. The healthcare worker can help assess the older adult with schizophrenia and seek to find interventions and treatments that can be modified if needed. With an individualized plan of care and proactive planning, the healthcare worker can increase the quality of mental health services provided, in turn increasing the quality of life for the older adult living with schizophrenia.

Self-Assessment Quiz Question #5

The healthcare worker is assessing the older adult taking antipsychotic medication. What life-threatening condition warrants immediate attention?:

a. Postural hypotension.
b. Sedation.
c. Anticholinergic effects.
d. Neuroleptic malignant syndrome.

SERIOUS MENTAL ILLNESS (SMI)

The healthcare worker should be able to identify the older adult who suffers with serious mental illness so that the complexity of the accompanying intervention and treatment can be addressed. SMI is a significant functional impairment caused by one or more mental disorders (most commonly schizophrenia, bipolar, or MDD). Approximately 4.8% of older adults in the U.S. live with SMI (SAMHSA, 2022b). An older adult who suffers with SMI often needs greater medical and mental illness intervention than someone without SMI. The healthcare worker will need to assist with a comprehensive treatment plan. Older adults with SMI are likely to have comorbidities that complicate their quality of life and increase their risk of mortality (SAMHSA, 2021). The most common medical conditions contributing to earlier death are cardiovascular diseases, followed by diabetes, chronic obstructive pulmonary disease (COPD), obesity, and tobacco use (Bartels et al., 2020). Specific psychopharmacological interventions are individualized for the older adult with SMI and are chosen to best meet the specifics of their medical and mental illnesses. Older adults with SMI have better physical and mental health outcomes with psychosocial interventions that focus on improving independent living, teaching social skills, enhancing social support with peer mentors, and education about physical and mental illness management for better self-management lifestyles (Bartels et al., 2020). The healthcare worker can refer to case management or community resources, along with support from friends, family, and caregivers. Treatment options will be offered in accordance with appropriate care settings and social determinants for the older adult with SMI.

Psychosocial Interventions for the older adult with SMI include the following (Bartels et al., 2020):

- **Helping Older People Experience Success (HOPES)**: HOPES is a 12-month course that contains seven modules: Communicating Effectively, Making and Keeping Friends, Making the Most of Leisure Time, Healthy Living, Using Medications Effectively, and Making the Most of a Healthcare Visit. The courses are designed to meet weekly and teach a new skill set at every session. Weekly sessions provide active engagement for the older adult with SMI, and a wide range of potential tool sets offers the opportunity to meet a greater number of needs.
- **Cognitive Behavioral Social Skills Training (CBSST)**: CBSST individualizes training framed around personal functioning in a group setting. There are three modules that target self-management, communication techniques, and interpersonal problem solving. Each module meets weekly for one month. Unique goals are set for the older adult with SMI based on their needs and capabilities.
- **Health and Recovery Peer (HARP)**: HARP is a mental health program with peer support inclusion for the older adult with SMI that evolved from the chronic disease self-management program. The six topics it covers are illness self-management, exercise and physical activity, pain and fatigue management, healthy and affordable eating, medication management, and the importance of continuity of physical and mental healthcare. HARP helps older adults with SMI set short- and long-term goals for all topics covered.
- **Targeted Training in Illness Management (TTIM)**: TTIM is a combination focus for older adults with SMI and comorbid diabetes. This approach contains two sections. The first section has a nurse educator and peer mentor running weekly sessions for three months that address medication management, nutrition, exercise, substance use, problem-solving skills, engaging social support systems, and setting personal goals. The second half of the training is offered through telephone consultation with the goal of self-sustainment.

The healthcare worker meeting the mental health needs of the older adult will most likely be collaborating with a team to maximize the quality of care. Older adults with SMI are more likely to need acute care and premature permanent nursing home placement when compared to older adults without SMI; therefore, it is important to place greater emphasis on intervention and treatment options to increase autonomy (Bartels et al., 2020). A team approach between medical and psychiatric care is necessary for the healthcare worker addressing the mental health needs of the older adult with SMI.

RECOVERY PRINCIPLES AND HEALTHY AGING

Recovery and healthy aging should be initiated at the first psychiatric interview, systematically evaluated at every subsequent meeting, and adjusted as needed for the older adult with mental illness. Recovery is defined as the ability to overcome and adapt with positivity to any health disorder in order to reach one's potential and life goals (SAMHSA, 2022c). Striving toward prioritizing recovery and healthy aging brings mental healthcare in the direction of biopsychosocial interventions and functioning toward maximizing the quality of care for the older adult. This is an important goal of every mental health interaction and will be unique to each older adult client. Healthy aging is defined as healthy choices, connections, and prevention and management of health conditions that contribute to quality of life (HHS, 2022). There is more than one path to healthy aging and recovery. Deciding which practices and treatments (medications, therapies, community resources, etc.) are best suited for the older adult with mental illness will be a multifaceted assessment process, possibly including other healthcare disciplines. SAMHSA (2022c) classifies four major dimensions for recovery implementation, and HHS recognizes nine topics for healthy aging. Table 7 combines SAMSHA recovery dimensions and HHS healthy aging topics, and it highlights older adult considerations for the healthcare worker to address.

The healthcare worker can use recovery dimensions as factors for assessing an older adult. A review of an older adult's health, home, purpose, and community can signify protective factors or barriers to recovery, each able to alter the length of recovery. Recovery dimension barriers can be targets for intervention. In addition to recovery dimensions are recovery principles for the healthcare worker meeting mental health needs. The healthcare worker can view the 10 SAMSHA recovery principles and their applicability to the older adult in Table 8.

Table 7. SAMSHA Recovery Dimensions, HHS Healthy Ageing and Older Adult Considerations			
SAMSHA Recovery Dimension	**SAMSHA Dimension Definition**	**HHS Healthy Aging Topics**	**Older Adult Considerations**
Health	Living a lifestyle of healthy choices that minimize symptoms and positively contribute to physical and emotional welfare.	• Staying Active. • Nutrition for the Older adult. • Locating Benefits & finding care. • Managing medication & treatment. • Brain health.	• Living arrangement. • ADLs. • Transportation (driving safety). • Access to care (Medicare). • Access to resources like healthy food and medications. • Nutrition assistance (Meals on Wheels). • Food safety. • Access to healthcare. • Older adult specific treatment. • Physical exercise and activity. • Strengthening cognition and memory. • Ethical and legal implications
Home	Physical residence that includes safety.	• Staying connected to your community.	• Living arrangement. • Assisted living, long-term care, nursing home. • Fall prevention. • Family, friends, caregivers involved. • Access to support. • Lower risk of violence.
Community	The connection to others that provide comfort and support (friendship, love, intimacy, and hope).	• Staying connected to your community.	• Marital status. • Support network. • Group therapy. • Religious or spiritual considerations. • Sexual activity.
Purpose	Existential stability, sense of purpose and being, ability to find meaning and satisfaction in self and others.	• Learning about diseases, conditions, and injuries. • Understanding mental health.	• Developmental task completion. • Job(s). • Volunteer position(s). • Purposeful involvement. • Hobbies. • Cultural considerations. • Religious and spiritual inclusion.
Note: Information combined from SAMHSA (2022c) and HHS (2022)			

Table 8. SAMHSA Recovery Principles and Definitions with Older Adult Applicability		
SAMSHA Recovery Principle	**Recover Principle Definition**	**Older Adult Applicability**
H o p e (The crux for recovery)	• Internalized drive. • Future focused. • Optimism.	• Hope can be instilled by self or others. • Hopelessness is a safety concern (assess for suicide).
Person-Driven	• Self-direction. • Taking responsibility.	• Focus on autonomy and incorporation for decision-making in life.
Many Pathways	• Personalization. • A nonlinear process.	• Based on personal strength, talent, capabilities, and coping skills
Holistic	• Whole life. • Mind, body, spirit, community.	• All recovery dimensions of health, home, purpose, and community.
Peer Support	• Sense of belonging. • Support.	• Peers can be family, friends, professionals. • Some psychosocial treatments include peer support.
Relational	• Connectedness. • Social networks. .	• Family, friends, caregivers, neighbors, faith groups, community groups and members. • Citizenship.
Culture	• Diversity inclusion. • Uniqueness.	• Cultural awareness. • Cultural sensitivity. • Culture humility.

Table 8. SAMHSA Recovery Principles and Definitions with Older Adult Applicability		
SAMSHA Recovery Principle	**Recover Principle Definition**	**Older Adult Applicability**
Addresses Trauma	• Verbal, physical, emotional, domestic violence, sexual, war, natural disaster, financial, substance.	• Assess past and present. • Establish trust. • Promote safe space. • Ethical and legal implications.
Strengths/Responsibility	• Resource availability for self and community. • Empowerment.	• Personal responsibility in recovery and resources. • Find barriers and protective factors.
Respect	• Acceptance. • Self-esteem.	• Eliminate discrimination and bias. • A sense of identity beyond the diagnosis. • Avoid labels.
Note: From SAMHSA (2012)		

Hope, the first listed SAMSHA recovery principles in Table 8, has been studied in the older adult population. Verbalized hope in older adults has been proven to have a positive correlation with better overall physical and mental health, as evidenced by decreased mortality, fewer chronic conditions, lower cancer rates, fewer sleep disturbance problems, decreased stress, improved sense of purpose, and increased life satisfaction (Hernandez & Overholser, 2021). The healthcare provider can assess for social connections and support in the older adult. Family, friends, caregivers, community members, and healthcare workers are all capable of instilling hope in the older adult. Hopelessness can be experienced after loss (Kübler-Ross & Kessler, 2005). Hopelessness can be a target for intervention in the older adult. Individual, group, and community hope-based treatments have been found to be effective for increasing hope, which in turn optimizes physical and mental health for the older adult (Hernandez & Overholser, 2021). Hope holds positivity for the older adult, yet is only one of 10 principles where the healthcare worker can assess and intervene.

Focusing on the recovery and healthy aging of the older adult, beginning with the initial interview, promotes a journey toward recovery as a fluid process with dimensions and principles to guide the healthcare worker. Healthy aging and recovery strategies can be preventive for mental health or goals set during any stage of mental health illness. Together, the healthcare worker and patient can maximize quality of life for the older adult.

Conclusion

Aging provides irrevocable changes and modifications to the human body, but it is not synonymous with mental health degradation. Theories of aging provide references for the healthcare provider who is assessing, intervening, and treating the older adult with mental health needs. Communication tailored to the older adult enhances the ability to build trust and rapport for the therapeutic relationship, the integral connection with the older adult. The healthcare worker might need to modify their communication with the older adult due to hearing, visual, or cognitive impairments. The healthcare worker is charged with considering the unique presentation of the older adult when assessing social determinants (protective factors or barriers) and biopsychosocial factors. Knowing risk factors, symptoms, and treatment options for older adults with mental health needs enables the healthcare worker to provide treatment options that maximize safety, recovery, and quality of life for the older adult.

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MENTAL HEALTH CONCERNS AND THE OLDER ADULT

Self-Assessment Answers and Rationales

1. The correct answer is A.

Rationale: Erik Erikson's eighth and final stage of psychosocial development is targeted at the older adult and called integrity versus despair. The main conflict in older age happens between integrity (the sense of satisfaction people feel reflecting on a life lived productively) and despair (the sense that life has little purpose or meaning).

2. **The correct answer is D.**

Rationale: The National Institute on Aging (2017) provides recommendations for improving communication with the older adult. They recommend using an older client's preference for being addressed; including their proper titles, such as Mr., Mrs., Ms., Dr.; and avoiding endearing terms such as honey and dear.

3. **The correct answer is A.**

Rationale: The U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion (ODPHP, 2022) in Healthy People 2030 names five areas related to social determinants of health: education access and quality, healthcare access and quality, neighborhood and built environment, social and community context, and economic stability. Healthcare access and quality includes telemental healthcare for the older adult with the ability and means to utilize the Internet to receive care electronically.

4. **The correct answer is B.**

Rationale: The National Institute of Aging (2020) lists signs of abuse in the older adult and recognizes that long-term health effects include decreased physical and psychological health, severed social support, financial loss, and early death.

5. **The correct answer is D.**

Rationale: Neuroleptic malignant syndrome is a life-threatening condition that can happen in response to antipsychotic medications. Early recognition and intervention are the most important things a healthcare worker can do for a patient experiencing NMS. The primary symptoms of NMS are mental status changes, severe muscle rigidity, and autonomic changes (historically presenting with high fever ranging between 101 and 103 degrees Fahrenheit, tachycardia, and fluctuating blood pressure) (Boyd, 2017).

MENTAL HEALTH CONCERNS AND THE OLDER ADULT

Final Examination Questions

Select the best answer for each question and complete your test online at **EliteLearning.com/Book**

31. The older adult is struggling to understand the meaning of their life and the finality of their death. At which psychosocial stage from Erik Erikson's psychosocial stages of development does the healthcare worker identify these tasks?
    a. Trust versus mistrust.
    b. Autonomy verses shame and doubt.
    c. Initiative versus guilt.
    d. Integrity versus despair.

32. The healthcare worker is planning care for the older adult client by examining personal beliefs and feelings. The healthcare worker recognizes this as which therapeutic principle?
    a. Empathy Positive.
    b. Image.
    c. Self-awareness.
    d. Self-disclosure.

33. The healthcare worker is assessing a 72-year-old woman who lost her partner nearly three weeks ago. The woman has recently become less emotional and expresses that few things in her life have meaning right now. The healthcare worker wants to use clarification as the therapeutic response. What might the healthcare worker say to her?
    a. "I am worried that you are showing signs of complicated grieving."
    b. "I know you are angry. It is ok to let it out."
    c. "You should focus on the things in life that you still enjoy."
    d. "Tell me more about how you are feeling about your loss."

34. A healthcare worker is caring for a 78-year-old African American man whose wife died recently. The patient admits that he has never received any mental healthcare due to feelings of shame and guilt. The healthcare worker associates his feelings with which healthcare barrier?
    a. Telemedicine.
    b. Medicare eligibility.
    c. Education access and quality.
    d. Stigma.

35. Assessment considerations for the older adult include exceptions to confidentiality. All of the following are exceptions to confidentiality for the healthcare worker EXCEPT:
    a. The client has an intent to harm self or others.
    b. Litigation is involved.
    c. There is a driving disability.
    d. Elder abuse is suspected or involved.

36. The healthcare worker is doing an assessment on a widowed older adult who describes her mood as low and her self-esteem as poor. She states that her caregiver has been insulting her for several months and she is scared. The healthcare worker would document this as what?
    a. Secondary victimization.
    b. Psychological abuse.
    c. Abandonment.
    d. Physical abuse.

37. The healthcare worker is listening to an older adult bitterly grieve and yearn for her husband who passed over two years ago. The healthcare worker analyzes the interactions to support which of the following?
    a. Bereavement.
    b. Complicated grief .
    c. Traumatic grief.
    d. Uncomplicated grief.

38. The healthcare worker is caring for an older adult patient with multiple comorbidities and chronic pain. During a full physical health assessment, the healthcare worker should also screen for what common symptoms and possible disorder associated with chronic illness and suffering in the older adult population?
    a. Anxiety.
    b. Depression.
    c. Bipolar.
    d. Schizophrenia.

39. An older adult with multiple comorbidities is struggling to achieve restful sleep. Which of the following is considered the safest primary treatment for sleep disorders?
    a. Zolpidem (Ambien).
    b. Alprazolam (Xanax).
    c. Sleep hygiene.
    d. Eszopiclone (Lunesta).

40. A healthcare worker is preparing to offer treatment options to an older adult with a mental illness. Which of the following would be most appropriate for the nurse to do in regards to recovery?
    a. Tell the client that she must take her medication.
    b. Encourage the client to participate in the treatment decisions.
    c. Restrain the client before administering the medications.
    d. Notify the physician about the client's refusal of the medication.

41. The older adult is struggling to understand the meaning of their life and the finality of their death. At which psychosocial stage from Erik Erikson's psychosocial stages of development does the healthcare worker identify these tasks?
    a. Trust versus mistrust.
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    c. Initiative versus guilt.
    d. Integrity versus despair.

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    b. Encourage the client to participate in the treatment decisions.
    c. Restrain the client before administering the medications.
    d. Notify the physician about the client's refusal of the medication.

51. Connecting with the older adult can be challenging if:
    a. The older adult has dementia.
    b. If the Family of the older adult is difficult.
    c. The healthcare worker harbors conscious or unconscious bias or stereotypes.
    d. The older adult does not want assistance.

52. When a client says things such as "You remind me so much of my son/daughter" or "You look like a girl/boy a grew up with," it's an example of:
    a. Countertransference.
    b. Acute Recognition.
    c. Association.
    d. Transference.

53. A brief review of verbal and nonverbal communication with older adult considerations can benefit the healthcare worker. Nonverbal communication is:
    a. Body language.
    b. Smile.
    c. Blink eyes.
    d. Stomping your foot.

54. Ensuring health literacy in the older adult with visual challenges includes the following practices EXCEPT:
    a. Use an average font size of 16 to 18.
    b. Do not use glossy paper.
    c. Use powerpoint.
    d. Ensure the written material can be read by the client.

55. How has the use of technology for healthcare dramatically increased with the COVID-19 pandemic?
    a. Telemedicine providing access to care.
    b. Older adults communicate with each other more easily.
    c. Older adults can file Medicare claims online.
    d. Communicating with Family decreases depression.

56. Health risks of loneliness include the following EXCEPT:
    a. Dementia risk increases by 50%.
    b. Heart disease risk increases by 32%, leading to higher rates of stroke.
    c. Coincides with higher rates of depression, anxiety, and suicide.
    d. Overeating and Obesity.

57. At what age should Advanced care planning start?
    a. At age 55.
    b. At age 61.
    c. At age 50.
    d. Care planning can be completed for clients of any age.

58. Undue influence is defined as:
    a. Social influence.
    b. A dynamic between an individual and another person.
    c. A bully.
    d. Control.

59. How does the healthcare worker assess the older adult's ability to be autonomous?
    a. Observing the adult for 48 hours.
    b. Interviewing the family or caregiver.
    c. Using standardized measurement tools for assessing ADLs (Activities of Daily Living).
    d. All are correct.

60. What is the leading cause of death in the 65-74 year old population?
    a. Cancer.
    b. Driving.
    c. Falling.
    d. Suicide.

61. Which of these is NOT a Chronic Medical Conditions that requires Investigation for Driving Safety.
    a. Diabetic retinopathy.
    b. Glaucoma.
    c. Palpitations.
    d. Depression.

62. _____ is the most abused substance by older adults.
    a. Marijuana.
    b. Alcohol.
    c. Prescription Drugs.
    d. Opioid.

63. According to statistics, abuse is reported for around ___ of those age 65 years and older.
    a. 10%.
    b. 25%.
    c. 50%.
    d. 75%.

64. Which is NOT a sign of abuse in the older adult?
    a. Difficulty sleeping.
    b. Unkempt appearance.
    c. Low checking account balance.
    d. Outward signs of trauma and regression.

65. According to Kübler-Ross and Kessler, how many stages of grief are there?
    a. Five.
    b. Two.
    c. Four.
    d. Six.

Chapter 5: Monitoring Techniques for Optimal Diabetes Management and Control

2 Contact Hours

By: James A. Fain, PhD, RN, BC-ADM, FADCES, FAAN

Author Disclosure: James A. Fain and Colibri Healthcare, LLC do not have any actual or potential conflicts of interest in relation to this lesson.

Universal Activity Number (UAN): 0607-0000-22-047-H01-P
Activity Type: Knowledge-based
Initial Release Date: December 27, 2022
Expiration Date: December 27, 2025
Target Audience: Pharmacists in a community-based setting.
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Learning objectives

After reading this monograph, pharmacists should be able to:

- Distinguish the purpose, glycemic target levels, and recommended frequency of blood glucose monitoring for persons with diabetes using an intensive insulin regimen.
- Analyze the benefits and practices of blood glucose monitoring using a glucometer.
- Examine the advantages and disadvantages of continuous glucose monitoring (CGM) in facilitating achievement of managing glycemia.
- Select best practice tips for using CGM to facilitate patient engagement.

INTRODUCTION

Glycemic management is critical in preventing acute and chronic diabetes-related complications for people with type 1 and type 2 diabetes (Diabetes Control and Complications Trail Research Group[1,2]. Successful management of diabetes requires recognition of monitoring as a critical component of the treatment plan. However, with diabetes being a self-managed chronic illness, people still need healthcare professionals'

help, advice, and support in understanding parameters requiring monitoring. The 2022 Standards of Medical Care in Diabetes by the American

Diabetes Association (ADA) provides direction for best practices when monitoring diabetes management. Significant evidence exists that supports a variety of interventions to improve optimal diabetes management and outcomes[3,4].

Course content

Appropriate treatment for people with diabetes is based on personal characteristics and needs. A high level of engagement with therapy facilitates the achievement of treatment goals. Monitoring the person's condition, and focusing on regular assessment of glycemic targets, such as blood glucose levels, time in range, and A1C levels, should be performed with the most appropriate personalized, cost-effective method of delivering care. Glycemic targets are assessed by blood glucose monitoring (BGM), A1C measurement, and continuous glucose monitoring (CGM) using either time in range (TIR) or the glucose management indicator (GMI). With evidence-based clinical guidelines available to assist with managing type 1, type 2, and gestational diabetes, it is still essential to realize that "one size does not fit all." The use of clinical guidelines needs to be based on patients' attitudes, disease burden, comorbidities, and resources. This course will address issues related to assessing glycemic targets, focusing on using blood glucose monitoring with traditional glucometers and continuous glucose monitoring.

Healthcare Consideration: Appropriate language in diabetes care and education is essential when communicating with people with diabetes. Healthcare providers need to use terminology consistent with an empowerment approach[5]. In moving toward patient-centered care, health care providers need to use respectful, nonjudgmental, neutral language. For example, when discussing diabetes management activities, the word control places responsibility on the patient while also implying the need to strictly follow the advice of the health care provider who holds authority and power. Similarly, *adherence* and *compliance* suggest doing what someone else wants.

BLOOD GLUCOSE MONITORING

Home blood glucose monitoring (BGM) began in the late 1970s, with the first glucose meters marketed for home use in the early 1980s. Significant developments over the years in the design and technology of BGM have ensured the optimal and most cost-effective use. For example, glucose meters have become smaller, more precise, and accurate, sometimes even connecting to a cloud-based glucose data management system or automated counseling systems that contain messages to improve care.

Blood glucose monitoring is an integral part of diabetes management. BGM provides information to patients to help them understand how food, activity, and medications affect their blood glucose levels. In addition, BGM offers valuable information about the status of glycemic management. However, monitoring alone is not enough to achieve glycemic targets. Patients performing BGM need to know how to properly operate a blood glucose meter, their target blood glucose values, how to interpret the results, and when to call the healthcare provider. As a survival skill, all newly diagnosed patients with type 1, type 2, or gestational diabetes should learn BGM tailored to the individual and their treatment plan[6].

Evidence-Based Practice: Patients with type 1 and type 2 diabetes should be provided with blood glucose monitoring devices as indicated by their specific needs, skill level, preferences, and treatment. Blood glucose monitoring is an integral component of diabetes care for patients on an intensive insulin regimen[4]. Patients taking insulin are encouraged to check blood glucose levels when fasting, before meals, before exercise, at bedtime, when low blood glucose levels are suspected, and before carrying out critical tasks like driving.

Evidence is insufficient regarding how often BGM is needed for patients who do not use intensive insulin regimens, like those with type 2 diabetes who may take basal insulin with or without oral antihyperglycemic agents. BGM can provide awareness of the impact of healthy eating, physical activity, and medications on blood glucose levels. BGM may also help assess hypoglycemia, blood glucose levels during illness, or discrepancies between A1C and blood glucose levels when there is a concern that an A1C result may not be reliable in some patients[4].

Selecting a blood glucose meter

A variety of different blood glucose meters are available for home use. Choosing an appropriate blood glucose meter for individuals with diabetes requires consideration of several factors. Such factors include availability, cost, visual acuity, manual dexterity, meter size, readout options, optional features (e.g., memory capacity, computer download feature), and patient preference. The cost of meters and testing supplies varies, with insurance companies not always providing coverage. In many instances, initial selection of meter is based on insurance coverage.

There are more monitoring options than ever before, from basic to advanced, in design and capabilities. To determine the best option for the individual, it is also important to look at the ease of use and flexibility in where to draw blood samples, while also keeping in mind the cost. The American Diabetes Association provides tools and support to further assist the individual in making the best decision on available glycemic monitoring devices and technology. If there is a choice of meters, health care providers should present the various options, with selection based on the patient's needs and preferences. For example, older patients may need a large visual display with test strips that are easy to handle and maneuver. Younger patients may want a small, discreet system capable of providing rapid results. Patients with impaired visual acuity will need a meter that is enhanced with audio. An example of a blood glucose meter, lancing device, and test strip is shown in Figure 1.

Figure 1. The Sensor, Needle Holder, and Test Strips

From Celeda. (2020). The sensor, the needle holder, the test strips. (https://commons.wikimedia.org/wiki/File:Capteur_de_glyc%C3%A9mie_pour_personnes_diab%C3%A9tiques.jpg). CC CC0.

Ensuring blood glucose meter accuracy

Since the 1970s, the accuracy (ability to obtain a true value without systematic bias) and precision (ability to obtain highly reproducible results) of BGM results has been steadily improving. The accuracy of BGM results depends on blood glucose meter capabilities and the person performing the test. The U.S. Food and Drug Administration (FDA) requires all blood glucose meters to meet a minimum performance requirement set by the International Organization of Standardization (ISO). For home use BGM, the ISO standard requires 95% of meter results >100 mg/dL to be within 15% of the actual value and 95% of meter results <100 mg/dL to be within 15 mg/dL of the true value.

Several factors can influence the accuracy of test results to include hematocrit levels, ambient temperature, humidity, and plasma levels of ascorbic or salicylic acid. However, the most common reason for inaccuracy in testing is user error. Direct observation of the patient using their meter is the best way to assess their understanding of proper monitoring skills. Patients new to monitoring should practice using their equipment with a healthcare provider before discharge from the hospital or clinic. It is a good idea for the patient to demonstrate the monitoring technique to a qualified professional at least annually or when devices have been changed. Box 1 summarizes several aspects the patient needs to consider when performing BGM to ensure accurate results.

Box 1. Factors to Consider When Performing Blood Glucose Monitoring (BGM)

- Be sure the blood glucose meter is clean and free of dried blood.
- Ensure hands and fingertips are clean and dry.
- Properly store the blood glucose meter and strips (avoid extreme temperature variations and highhumidity).
- Use glucose testing strips that have not expired, are compatible with the meter, and defect-free.Check the date on the strip container to be sure they have not expired.
- Code the meter if the device needs coding.
- Perform a control-solution check with each new container of strips and more often if meter errors aresuspected.
- Apply an adequate size blood sample.

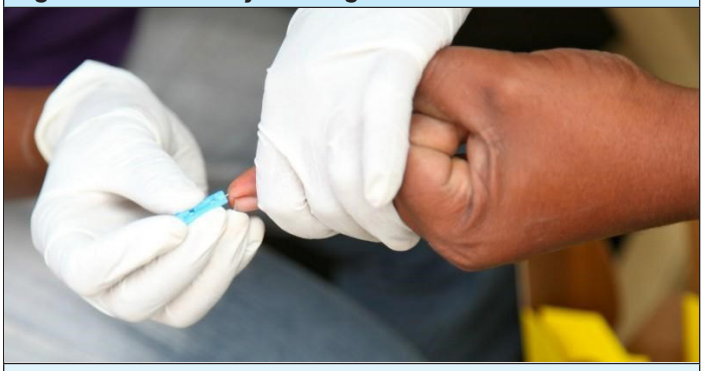
Securing an adequate blood sample

Typically, capillary blood samples are obtained from the fingertips. Capillary blood tests are quick and straightforward to perform, requiring a stick to the fingertip and a small drop of blood. However, fingertip testing is associated with considerable discomfort in some patients. Using the side of the fingertip rather than the finger pad lessens the discomfort.

To ensure an adequate blood sample, the patient should wash their hands with warm water to increase circulation, hold their hand at their side for 30 seconds to pool blood, and shake their arm as if shaking down a mercury thermometer. Then load the test strip into the blood glucose meter and put a lancet into the lancet device. A new lancet should be cused with each test. Using the same lancet more than once can cause the lancet to get dull and may cause greater discomfort when piercing the skin. Apply the lancet device against the side of the fingertip and puncture the skin using a consistent amount of pressure. Figure 2 illustrates use of a lancing device to obtain a blood glucose level. After the

finger is pricked, gently push the blood from the finger's base to the tip of the finger until the blood sample is the correct amount[7].

Figure 2. Phlebotomy-Drawing Blood With a Lancet



From USAID. (2013). Phlebotomy-drawing blood with a lancet. (https://commons.wikimedia.org/wiki/File:Phlebotomy- drawing_blood_with_a_lancet.jpg). In the public domain.

After obtaining an adequate blood sample, touch and hold the edge of the test strip to the drop of blood. Figure 3 is an example of applying blood to the test strip. If there is not an adequate blood sample, the meter will provide an error message signaling the blood sample is not large enough. If a patient reports this happening, the healthcare provider can ask them to demonstrate their meter technique and provide advice. Do not squeeze directly at the site that has been pierced. Squeezing could cause interstitial fluid to leak into the blood sample and lead to a false reading. If an adequate amount of blood is not obtained, the lancing device used to pierce the finger may be too shallow. Most lancet devices offer a choice of lancing depth. Adjusting the lancet device to a deeper setting can help produce a larger blood sample. Clarify with patients having trouble getting an adequate blood supply if they are changing their lancet each time; with repeat use the tip may become dull and result in a less successful finger stick[7]. It is important to note that most meters are slightly different. Always refer to the meter's user manual for specific instructions prior to the first use.

Figure 3. Blood Glucose Testing by Blood Glucose Meter

From Ganguly, B. (2011). Blood glucose testing by blood glucose meter.(https://commons.wikimedia.org/wiki/File:Blood_Glucose_Testing_-_Kolkata_2011-07-25_3982.JPG). CC-BY-3.0.

To reduce the discomfort of BGM, patients sometimes consider using alternative testing sites like the palm, upper arm, forearm, or thigh. There is, however, a wide discordance between blood glucose levels from fingertips and alternative testing sites related to the higher velocity of blood flow through the fingertips. When blood glucose levels change rapidly, the lag between alternative testing sites and fingertips contributes to inaccurate assessment of blood glucose levels. The use of alternative testing sites can provide accurate results when blood glucose levels are not changing rapidly. Box 2 highlights situations when alternative testing sites should not be used.

Box 2. Situations Where Alternative Testing Sites Are Not Recommended

- Patients who are prone to hypoglycemia
- During and after exercise
- When the patient suspects they are ill
- Before driving
- During pregnancy
- Anytime blood glucose levels are rapidly increasing or decreasing (within 2 hours ofingesting food)

Frequency of blood glucose monitoring

When to prescribe BGM and the frequency of blood glucose checks depend on several factors. There are no universal guidelines or evidence- based research associated with the ideal frequency of BGM. Determining when to test blood glucose levels is individualized for each patient; however, recommendations are available for patients based on medication regimens. The American Diabetes Association (ADA) and the American Association of Clinical Endocrinologists (AACE) have standards of care and recommendations that are revised and updated regularly. The 2022 ADA Standards of Medical Care in Diabetes highlight essential information on BGM in the context of therapy and specific goals related to different patient profiles[3,4]. Table 3 summarizes the ADA recommendations for the frequency of BGM.

Table 3. Blood Glucose Monitoring (BGM) Frequency Recommendations	
Patient Profiles (Medication Regimens)	**Recommendations**
Adult patients with type 1 diabetes (Intensive insulin regimen)	**4 to 10 times/day.** An intensive insulin regimen involves multiple insulin injections/day or insulin pump therapy. Consider monitoring before meals and snacks, occasionally postprandially, at bedtime, before exercise, when hypoglycemia is suspected, after treating hypoglycemia, and when undertaking hazardous tasks like driving.
Adult patients with type 2 diabetes (Taking basal insulin with or without antihyperglycemic agents)	**BGM recommended.** Evidence is insufficient regarding when and how often to perform BGM. Patients taking basal insulin may benefit from checking their fasting blood glucose daily, as it provides data enabling providers to appropriately adjust the dose of basal insulin. Additional testing before exercise or critical tasks is important if there is a tendency for hypoglycemia. If hypoglycemia occurs, testing should be done until the patients is normoglycemic. Testing when symptoms of hyperglycemia develop, or acute illness occurs will provide data helpful to determine a need for change in insulin or other medication dose.
Adult patients with type 2 diabetes (On noninsulin therapy)	**BGM recommended**. Although there isn't sufficient evidence that regular BGM in patients not on insulin therapy improves A1C, doing so may help patients identify the impact of dietary choices and activity level on blood glucose levels. Consider at the time of diagnosis and when helping with problem solving as part of ongoing diabetes self-management education (DSME).
Adapted from American Diabetes Association4.	

While there are recommendations regarding the frequency of testing, the frequency of BGM depends on the type of diabetes, the complexity of treatment, and individual characteristics along with how the data will be used. For example, the patient with well-controlled type 2 diabetes using meal planning and exercise may only need to monitor fasting levels daily or several times per week. The patient with type 2 taking oral medication may be asked to monitor fasting and postprandial levels. The patient using flexible insulin dosing and carbohydrate counting is likely to test before each meal, at bedtime, and periodically after meals. Patients are also encouraged to test more often when any changes to their treatment regimens occur. For example, the patient moving from oral agents to insulin or the patient moving from two to three daily injections will benefit from testing four times a day. Regardless of testing frequency, the most critical issue is whether the patient knows what to do with the information obtained with BGM[8,9]. Diabetes educators and other healthcare professionals often use BGM results to demonstrate the impact of exercise, medications, and specific foods on blood glucose levels.

It is also common for a patient to have elevated blood glucose values during periods of physiologic stress, such as during acute illness. For this reason, all patients are advised to monitor more often on sick days. Capillary blood glucose levels for hospitalized patients with diabetes should be performed four times daily.

Continuous glucose monitoring

Blood glucose levels fluctuate widely throughout the day and are influenced by a multiple of internal and external factors. Intermittent glucose testing regimens may not reflect these fluctuations and increased testing may be inconvenient or unachievable for a given patient. BGM is paramount in achieving optimal glycemic targets but only to the extent that the readings are accurate and timely. In the early 2000s, real-time continuous glucose monitoring (CGM) and intermittently scanned continuous glucose monitoring became available and recommended by the ADA and AACE for all persons with diabetes, especially those on intensive insulin therapy. Study findings have demonstrated that use of CGM

has significantly reduced hypoglycemia compared to BGM alone in patients with type 1 diabetes[10]. In addition, significant reductions have been shown in A1C among children, adults, and older adults[11,12] using CGM.

The technology of a CGM

A CGM device is a wearable body sensor that automatically and repeatedly measures blood glucose levels 24 hours a day (every 5 to 15 minutes). Parts of a CGM device include a wearable sensor, a transmitter that wirelessly sends readings, and a receiver that displays the readings to the user. Figure 4 displays the various parts of a CGM. A CGM provides an accurate picture of blood glucose levels, allowing the patient to assess glycemic patterns quickly.

Figure 4. CGM Device

From Popov, A. Woman holding smartphone in hand with bad level of blood sugar on the screen. (https://www.dreamstime.com/woman- holding-smartphone-hand-bad-level-blood-sugar-screen-woman-checking-blood-sugar-level-smart-phone-image182255889). Copyright © 2000-2022 Dreamstime. All rights reserved.

CGM works by utilizing a tiny sensor inserted under the skin via an applicator and secured with an adhesive patch. The sensor is inserted into the abdomen or back of the arm. Attached to the sensor is a glucose-oxidase platinum electrode that measures the glucose concentration found in interstitial fluid throughout the day and night. A transmitter connects to the sensor and sends real-time glucose readings wirelessly to a receiver to view the information. Data are viewed on the receiver and can be downloaded for reports. The technology used in CGM systems, and most home blood glucose meters, relies on measuring an electrochemical signal generated from the reaction of an enzyme, glucose-oxidase, with glucose.

CGM measures blood glucose continuously, as often as every 5 minutes, with close to 300 measurements per day. With so many glucose measurements throughout the day, CGM provides trend information about the direction and rate of changing glucose concentrations. Furthermore, many CGM devices sound alarms to warn of low or high, or falling or rising glucose levels. In addition, a CGM can connect to an insulin pump that automatically adjusts or suspends insulin delivery in response to glycemic trends[13].

Evidence-Based Practice: Continuous glucose monitoring (CGM) is clinically valuable in reducing risks of hypoglycemia and hyperglycemia, improving glycemic variability, and improving the quality of life for people with type 1 and type 2 diabetes[4]. CGM should be offered to everyone with diabetes who uses multiple daily insulin injections. Depending on the brand of CGM, it may have the ability to integrate with an insulin pump.

Self-Assessment Quiz Question #1

What is the added value of continuous glucose monitoring (CGM) over fingerstick blood glucose monitoring (BGM)?

a. CGM is less expense, since there is no need to purchase a lancet or test strips to use with a glucometer.
b. CGMs provide a direct measure of glucose in the plasma.
c. CGMs provide a more complete picture of how blood glucose levels change over time.
d. CGMs tell why blood glucose increases or decreases.

Selecting a CGM device

There are currently (as of September 2022) four continuous glucose monitors available for people with diabetes who are not using an insulin pump. Some of the insulin pumps have a specific CGM to be used in tandem with the specific insulin pump (e.g., the Tandem insulin pump integrates with a Decom G6 CGM, and the Medtronic insulin pump integrates with a Guardian 3 CGM). People not on an insulin pump can choose a Dexcom G6, a Libre 14, a Libre 2, or a Guardian Connect. Insurance companies vary in their requirements for coverage and the brands they cover. People also have the option to self-pay. The pumps are similar but vary in some of their features. For example, the Guardian Connect does not use a receiver, whereas the other three monitors do. Three of the monitors have an iPhone and an Android app, while the Libre 2 does not. The Dexcom G6 and Guardian Connect CGMs provide real-time readings, while the Libre models require the user to scan the sensor to get a reading. For most of the current CGMs, the sensor is worn on either the abdomen or the upper arm depending on the monitor. And only some monitors are designed to share results with family/friends, which may be an important consideration if the person with diabetes is a child or has cognitive impairment. The monitoring sensor should be replaced every 7 to 14 days depending on the CGM device.

Personal CGM devices

Personal CGM devices are purchased for personal use to monitor blood glucose levels and help guide decision-making about food intake, physical activity, and medication use. In addition, CGM devices keep track of blood glucose data by sending information to a receiver or smart device. The use of CGM devices identifies the need to respond to blood glucose variability and increase their confidence in blood glucose management for many[15].

Real-time versus intermittently scanned CGM devices

Two types of personal CGM devices are available: real-time CGM (rtCGM) and intermittently scanned CGM (isCGM). The rtCGM devices indirectly measure blood glucose levels every 5 minutes and send glucose data automatically to a receiver or smartphone. The 2022 Standards of Medical Care from the ADA recommend use of an rtCGM device for people with type 1 diabetes who do not meet individualized glycemic targets and experience hypoglycemia unawareness[4]. These rtCGM devices also can sound alerts and alarms in response to rising or falling blood glucose levels. Some patients get frustrated with the frequent alarms if they experience significant variability with their blood glucose levels[16]. If the alarms are too frequent, some wearers feel like their diabetes is controlling their lives. CGMs can be customized by setting the alarms at different glucose levels to limit alarms during work activities or school. Use of an isCGM device to retrieve blood glucose data, which requires manually scanning the sensor[16], is another approach to limiting frequent alarms.

The rtCGM devices provide real-time feedback to patients. There are select times, however, when a provider may choose to blind the wearer to the data and have the person use a professional CGM from the office. This can be useful when the person is not changing their behavior based on the blood glucose readings; instead, the data are being collected so that the healthcare provider can look at patterns then make recommendations. Having the individual wear a professional CGM from the office, may be indicated if someone's insurance will not cover the cost of a personal CGM on a regular basis. The professional CGM can be used intermittently to help with decision making regarding therapy recommendations.

The isCGM devices require the person to pass or swipe a scanner over the sensor/transmitter to receive blood glucose data. First-generation isCGM devices did not include alarms or alerts for high or low blood glucose readings. Newer CGM devices now offer added safeguards and alerts. isCGM devices may be helpful to patients who have a difficult time performing BGM with a glucometer and fingersticks as recommended because of dexterity issues or other related problems[16].

Interpreting CGM data

CGM systems are based off rtCGM or isCGM, which measure blood glucose levels in interstitial fluid. CGM systems also provide insight into direction, magnitude, duration, frequency, and rate of change (ROC) by displaying the information as a trend arrow on the sensor next to the actual blood glucose value. Such a feature is vital in helping patients anticipate future blood glucose levels. In addition, the visual representation of information in the form of arrows enables patients to take action to adjust their blood glucose levels promptly[15,17].

Each CGM system has a different representation of trend arrows but generally represents blood glucose levels changing at a rate of <1 mg/dL per minute (horizontal arrow) to up to >2–3 mg/dL per minute (single or double vertical arrows pointing upward), with the opposite for declining blood glucose levels (horizontal arrows pointing down). However, with no standardized guidelines or protocols for interpreting blood glucose values provided by trend arrows, healthcare providers need to make recommenda-

tions and clinical decisions by reviewing information provided by individual CGM systems[17].

The use of an ambulatory glucose profile (AGP) provides valuable information to health care providers and patients related to interpreting visual and statistical summaries of glucose metrics[18]. It is a practical tool and easy to read, providing a comprehensive assessment of patterns of glycemic variation and time spent in various blood glucose targets. For those who use a dedicated CGM reader with their CGM system, the

reader is plugged into a remote computer for data downloading. When using a mobile device as the CGM reader, data can be automatically uploaded to the cloud, with the ability to share data with family members or health care providers.

On the AGP report, there are many helpful blood glucose metrics from continuous glucose monitoring.

Time in range (TIR)

TIR is the percentage of time a person's blood glucose level remains in a proposed target range[3]. The ADA recommends a target range of 70 to 180 mg/dL. It may be helpful to explain the concept of TIR to persons with diabetes by having them think about the "number of hours per day" their glucose is within the desired range. For example, 75% TIR refers to a person's glucose level being within the target range for approximately 18 hours a day. The ADA defines the standardized CGM metric for TIR as 70 to 180 mg/dL for >70% of the time. For older adults or frail patients at risk for hypoglycemia, the TIR target range is >50% of the time[3].

Glucose management indicator (GMI)

GMI is a term related to estimating the mean glucose level from continuous glucose monitoring data[3]. It may differ from the A1C slightly, as it is using data from a shorter time interval than the 90 days reflected in an A1C value. The GMI can be helpful when assessing the effectiveness of changes to the diabetes management plan. For example, if a person's GMI decreased from 9 to 7.5% over the course of 2 weeks and they are not experiencing hypoglycemia, the change to the management plan is working.

Time in Hypoglycemia. This metric reports glucose levels <70 and >54 mg/dL and includes a separate report of glucose levels <54 mg/dL[3].

Time in Hyperglycemia. This metric reports glucose levels between 181 and 250mg/dL and includes a separate report of glucose levels >250 mg/dL[3].

Glucose variability (GV)

This refers to how much the glucose reading varies from the mean and the frequency of variations[3]. GV is associated with cardiovascular events such as cardiovascular disease, stroke, and renal failure; thus, revising management plans to decrease glucose variability is a goal[19].

Examples of AGP reports are displayed in Figures 5 through 7. In Figure 5, the results demonstrate excellent glucose management, with results being in range 97% of the time and no hypoglycemia. In Figure 6, the GMI is optimal at 6.1%; however, the patient is experiencing too many episodes of hypoglycemia, indicating a need to change the management plan. Finally, in Figure 7, an elevated GMI of 9.2% is observed and suboptimal TIR of 23% with excessive hyperglycemia, all demonstrating a need to change the management plan.

Figure 5. AGP Reflecting Excellent Glucose Management with a GMI of 6.1% Without Instances of Hypoglycemia

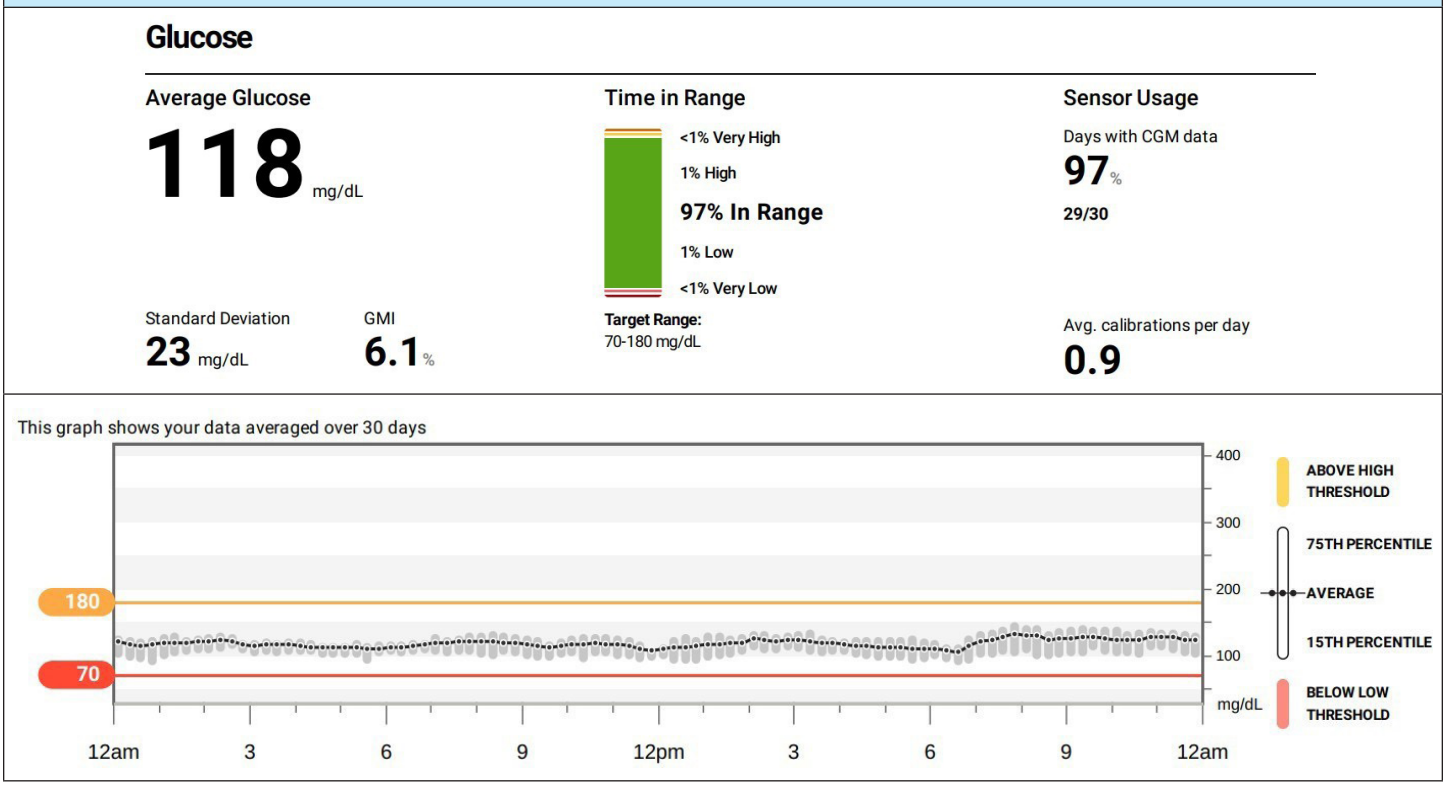
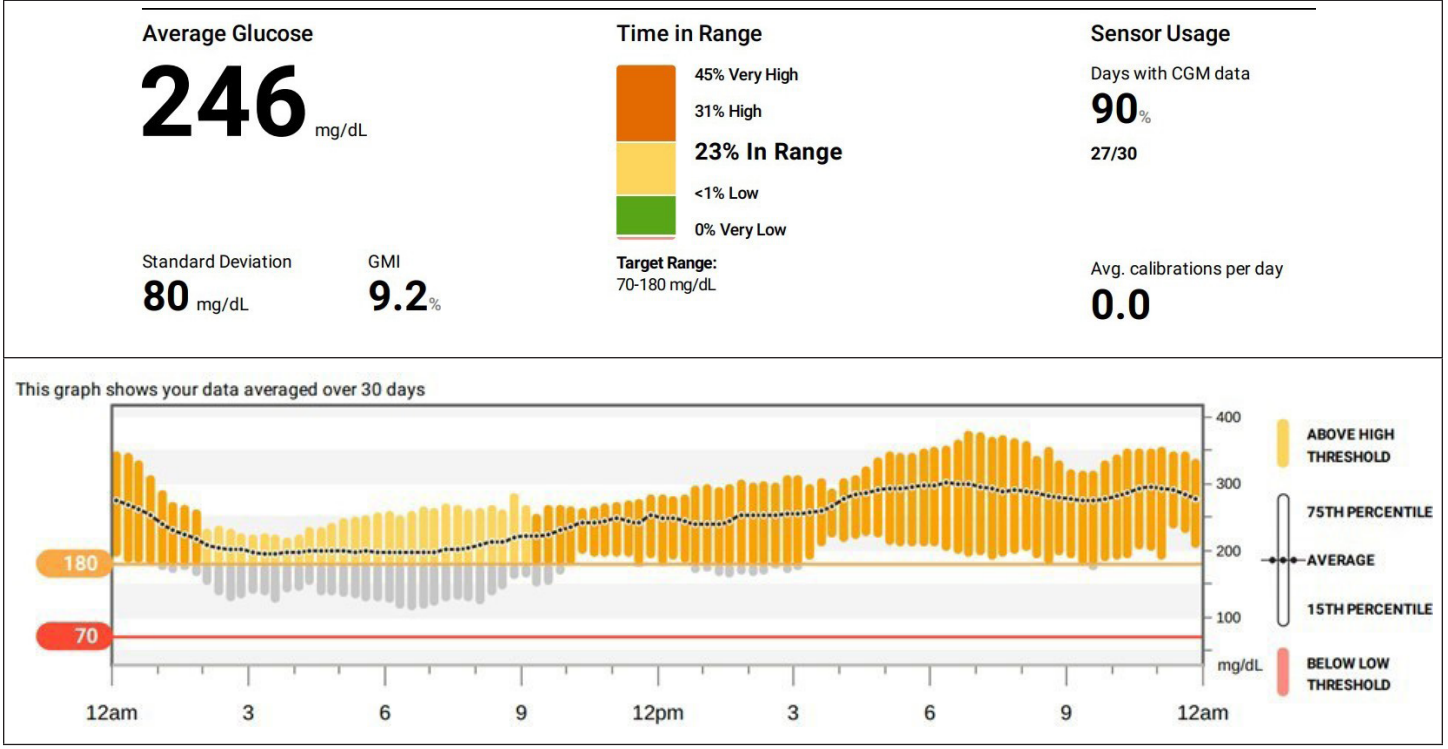


Figure 6. AGP Reflecting a TIM of 66% and a GMI of 6.1% with Excessive Hypoglycemia Requiring a Change in the Management Plan

Figure 7. AGP Reflecting a TIM of 23% and a GMI of 9.2% but Excessive Hyperglycemia Requiring a Change in Management Plan



Interpreting CGM data can be challenging and overwhelming. Healthcare providers are essential to help patients understand and use the data to optimize their glucose management. While technology can pose a barrier for some, diabetes self-management education and support (DSMES) can overcome these barriers and improve the lives and health of people with diabetes. Helping individuals with diabetes gain the knowledge, skills, and confidence to manage their symptoms and prevent complications is a goal of all who provide DSMES.

The use of a CGM device can educate and empower the wearer in real-time[20]. Access to blood glucose data has clearly been shown to decrease hypoglycemia and provide immediate feedback that reinforces positive behaviors related to food intake, physical activity, and medication-taking. People also become aware of the negative behaviors that worsen glycemic control, and this can be a motivator to change behavior as well.

Scenario

David is 31 years old with a 12-year history of type 1 diabetes. His A1C has been increasing (most recently it was 8.8%) despite some success with a healthy meal plan and walking three times a week. Upon initial diagnosis of type 1 diabetes, David would routinely check his blood glucose levels three times a day. However, over the past several years, David has not been consistent with BGM because of a busy travel schedule. David also acknowledged that he does not want to stop his life by constantly checking his blood glucose. During David's last office visit, his health care provider discussed the possibility of using a CGM. David reluctantly agreed to try a CGM so he would not have to prick his finger as frequently during the day. Three weeks later, David met with his health care provider and reviewed his blood glucose patterns. David was able to see a connection between his glucose levels and food intake, physical activity level, and use of medications. Many have commented that a CGM is a "game changer" as it provides the real-time data necessary to optimize blood glucose levels more closely. Also, having confidence that the CGM will alert the wearer to a potential hypoglycemic episode early enough to act (ingest carbohydrates) has encouraged many to maintain more euglycemic levels without fear of experiencing a significant hypoglycemic episode. David left his 3-week office visit armed with knowledge that will enable him to manage his blood glucose more easily, free him from cumbersome fingersticks, and have more confidence and freedom living with and managing his diabetes.

BGM and glycemic targets

Correlating BGM to achievement of glycemic targets may help patients appreciate the value and importance of regular BGM. Glycemic goals for pre-prandial and postprandial blood glucose values for nonpregnant adults with diabetes and without limited life expectancy are based on recommended guidelines through the American Diabetes Association.

Healthcare Consideration: In addition to monitoring blood glucose levels among patients with type 1 and type 2 diabetes, healthcare providers must promote a person-centered approach to increase patient engagement in self-care behaviors. Putting the patient at the center of all we do lends itself to shared decision making between patient and healthcare provider regarding glycemic targets that need to be individualized. In addition, a person-centered approach customizes the diabetes care plan, considering the patient's preferences, cultural values, and individual needs.

Stringent glycemic targets are appropriate for patients if they are achieved without significant hypoglycemic or adverse events. Being less stringent with glycemic targets is individualized based on hypoglycemic risk, duration of diabetes, life expectancy, comorbidities, established vascular complications, patient preference, and resources and support system[4,21]. Recommended glycemic targets for nonpregnant adults with diabetes and without limited life expectancy are shown in Table 4.

Table 4. Glycemic Targets for Nonpregnant Adults with Diabetes and without Limited Life Expectancy

	American Diabetes Association (ADA)	American Association of Clinical Endocrinologists (AACE)
Fasting and preprandial blood glucose (mg/dL)	80–130	<110
Postprandial blood glucose (mg/dL)	<180; 2 hours after start of a meal	<140; 2 hours after the start of a meal
A1C (%)	<7.0 without hypoglycemia	<6.5

Adapted from American Diabetes Association3.

Adapted from Comparison of the diabetes guidelines from the ADA/EASD and the AACE/ACE21.

Structured BGM with a glucometer

Knowing your actual blood glucose can be a powerful motivator to improve glycemic management. When a patient sees that their blood glucose level is above or below target, this may impact their selection of food intake and activity level as well as use of or dose of medication. The data from BGM enables patients to make decisions based on current glycemic management.

Using a structured approach to BGM (checking blood glucose levels at the same time every day) has effectively reduced A1C levels among patients performing BGM compared to those who do not perform BGM22. Structured BGM allows visualization of glycemic levels by allowing patients to record the results on a log or view on a graph that some glucometers now provide on their screen. The visualization of glycemic levels

facilitates understanding of the impact of diet choices, activity level, and medication use on blood glucose levels. An example of structured

testing for BGM for patients with type 1 and type 2 diabetes is displayed in Figure 8. Structured testing for BGM in patients with intensive insulin regimens requires patients to test a minimum of seven times/day for 3 to 4 days. Structured testing involves checking before and 2 hours after each meal and at bedtime.

Consider a case in which BGM for a person with type 1 diabetes reveals episodes of hypoglycemia before breakfast on Saturday and Sunday. Perhaps considering reducing their premeal insulin dose before breakfast is a consideration. In addition, if all post-dinner blood glucose values are above the target range of 180 mg/dL, an addition of medication may assist with glycemic management. Collecting data for 3 to 4 days provides an overview of blood glucose values and patterns.

Next, consider a case in which BGM for a person with type 2 diabetes reveals prebreakfast, pre-lunch, and predinner data within target ranges. However, post-meal values are above target ranges. These data suggest the person with diabetes needs more medication to manage their post– blood glucose excursions.

Figure 8. Structured Blood Glucose Monitoring Testing for Persons With Type 1 Diabetes

	Breakfast		Lunch		Dinner		Bedtime
	BB	AB	BL	AL	BD	AD	BT
Monday	80	136			122	244	
Tuesday	106	142			132	192	
Wednesday	110	138			130	264	
Thursday	92	122			126	252	
Friday	74	116			118	258	
Saturday	70	132			132	196	
Sunday	68	122			130	272	

Structured Blood Glucose Monitoring Testing for Persons With Type 2 Diabetes

	Breakfast		Lunch		Dinner		Bedtime
	BB	AB	BL	AL	BD	AD	BT
Monday		210					
Tuesday	130						
Wednesday				236			
Thursday			142				
Friday						263	
Saturday					128		
Sunday							

Note: BB: before breakfast; AB: after breakfast; BL: before lunch; AL: after lunch; BD: before dinner; AD: after dinner; BT: bedtime Note: All blood glucose values in the figure are mg/dL

There are many reasons for checking pre- and postprandial blood glucose levels. Knowing the premeal blood glucose may lead a patient to modify their food intake (especially if it is elevated before the meal) and to take a specific dose of insulin. Comparing the premeal blood glucose to a 2-hour postprandial blood glucose helps one to discern the impact of the food eaten on the blood glucose level. If using insulin, comparison of the pre- and post–blood glucose helps determine the appropriateness of the insulin dose.

It is important for people with diabetes to learn how to interpret and evaluate blood glucose values to best adjust food intake, physical activity, and medications. Understanding blood glucose data enables the person with diabetes to take a more active role in their diabetes management and care. Working with a certified diabetes care and education specialist to learn about BGM and glucose pattern management is critical at the time of diagnosis as well as whenever there is a change in medication or their condition or when glycemic goals are not being met6.

Evidence-Based Practice: Findings from the Diabetes Control and Complication Trial (DCCT), a prospective randomized control trial (RCT) of intensive glycemic management versus standard glycemic management in patients with type 1 diabetes, showed definitively better glycemic control with a 50%-76% reduction in the development and progression of microvascular complications (e.g., retinopathy, neuropathy, and chronic kidney disease) in patients. In addition, the Epidemiology of Diabetes Interventions and Complications (EDIC) study followed patients from the DCCT study two decades later and found persistent microvascular benefits despite loss of follow-up among some patients[23].

Self-Assessment Quiz Question #2

What is the overall benefit of blood glucose monitoring (BGM)?

a. Keeping a record of blood glucose control for the health care provider.
b. Determining how often a patient monitors their blood glucose.
c. Decreasing the need for frequent laboratory tests.
d. Monitoring the effectiveness of the diabetes treatment plan.

Self-Assessment Quiz Question #3

For nonpregnant adults with diabetes and without limited life expectancy, the American Diabetes Association (ADA) recommends that glycemic target levels for preprandial fasting blood glucose levels should be:

a. 60 to 90 mg/dL.
b. 70 to 100 mg/dL.
c. 80 to 130 mg/dL.
d. 110 to 140 mg/dL.

Hemoglobin A1C

The hemoglobin A1C level indicates the overall level of glucose stability or control. Glucose in the plasma is attached to the hemoglobin molecule in red blood cells by a process called glycation, thus giving rise to the terms glycated and glycosylated hemoglobin. The most common type of hemoglobin found in adults is hemoglobin A. With the average life span of the red blood cell being about 120 days, A1C levels reflect weighted mean glucose from the preceding 12 weeks, with the most recent glucose levels having a more significant impact. Blood glucose levels from the most recent 30 days have a more substantial effect on A1C

than those from the first 60 days. The more significant the amount of glycation present, the higher the A1C. Conditions that cause rapid turnovers of red blood cells, such as traumatic blood loss, chronic kidney disease, sickle cell disease, recent blood transfusions, or erythropoietin therapy, can interfere with A1C test accuracy. People with diabetes have higher A1C levels compared to people without diabetes. There is a strong relationship between high A1C levels and the risk of developing diabetes-related complications, including cardiovascular disease, retinopathy, and neuropathy.

Most laboratories in the U.S. report A1C levels per the National Glycohemoglobin Standardization Program (NGSP). Average values are standardized to the Diabetes Control and Complications Trial (DCCT) Research Group results. In persons without diabetes, the average A1C value ranges between 4 and 6 percent. In 2010, A1C levels were used as one criterion for diabetes. The ADA recommends monitoring A1C levels at least twice per year for well-managed diabetes and quarterly when patients are not achieving glycemic targets.

A1C testing and daily blood glucose monitoring provide useful information in the management of diabetes, but they are expressed in different ways. Daily blood glucose monitoring via a glucometer directly measures the amount of glucose in the blood at the time the sample is taken and is expressed as milligrams of glucose per deciliter of blood (e.g., 154 mg/dL). A1C also uses a blood sample, but it looks at the percentage of hemoglobin, a protein in red blood cells that has attached to glucose (e.g., 7.0 percent).

Evidence-Based Practice: An appropriate A1C goal for nonpregnant adults without a limited life expectancy is <7.0% (53 mmol/mol) without significant hypoglycemia. Less stringent A1C goals (e.g., <8.0%; 64 mmol/mol) may be appropriate for older persons or those with limited life expectancy, or where the harms of treatment are greater than the benefits. Health care providers must work with patients and consider adjusting glycemic targets to ensure safety and limit adverse effects[3].

Estimated average glucose (EAG) levels

Patients often have difficulty understanding the relationship between blood glucose levels and their A1C levels. The estimated average glucose (eAG) level can be used to quantify A1C levels in more familiar terms that closely represent daily blood glucose readings. Introduced by the ADA in 2010, any A1C level can be converted to an eAG by using the formula eAG = 28.7 × A1C – 46.7. For example, if a patient has an A1C level of 8.2, the health care provider can use the eAG conversion formula and show the patient their average blood glucose level is 189 mg/dL. Table 5 provides the estimated AG levels for A1C test results.

Table 5. Estimated Average Glucose (eAG) Levels

A1C (%)	mg/dL	mmol/L
5	97 (76 to 120)	5.4 (4.2 to 6.7)
6	126 (100 to 152)	7.0 (5.5 to 8.5)
7	154 (123 to 185)	8.6 (6.8 to 10.3)
8	183 (147 to 217)	10.2 (8.1 to 12.1)
9	212 (170 to 249)	11.8 (9.4 to 13.9)
10	240 (193 to 282)	13.4 (10.7 to 15.7)
11	269 (217 to 314)	14.9 (12.0 to 17.5)
12	298 (240 to 347)	16.5 (13.3 to 19.3)

Adapted from American Diabetes Association3.

Self-Assessment Quiz Question #4

An A1C of 9.2% correlates with a mean plasma blood glucose of:

a. 167 mg/dL.
b. 195 mg/dL.
c. 217 mg/dL.
d. 257 mg/dL.

Measuring blood glucose levels with point-of-care testing (POCT)

A1C and blood glucose levels are usually calculated in a laboratory using venous blood. Results are generally standardized to NGSP methodology and are reliable estimates of glycemic measures, referred to as central laboratory testing (CLT). Because it may take 24 hours or longer to obtain the results, neither the patient nor the health care provider has access to current glycemic measures during a patient's appointment. For this reason, it is becoming increasingly common in outpatient settings to use point-of-care testing (POCT), which analyzes a capillary sample in a desktop analyzer. The standard of care is teaching anyone doing POCT the importance of quality control with procedure.

POCT of blood glucose levels is widely used in hospitals and primary care settings to provide rapid results and facilitate the timely treatment of hypoglycemia and hyperglycemia as well as in-office decision making related to medications and glycemic management. POCT should not be used for diagnosing diabetes[14].

Case study 2

Joan is a 57-year-old Hispanic female with a history of type 2 diabetes for 10 years. Her BMI is 29.0, and she has stage 1 hypertension. Her medication regimen includes glipizide 20 mg daily; metformin 1,000 mg twice daily; and chlorthalidone 25 mg daily. Joan's A1Cs have been 8.4% and 9.2% in the past year. Joan states that she feels tired but otherwise is well. After Joan was diagnosed with type 2 diabetes, she learned how to test her blood glucose but has not done so in the last couple of years. Joan acknowledges that she has not felt confident performing blood glucose monitoring (BGM). She states her healthcare provider never asks her about testing her blood glucose or seeing her logbook.

Questions

1. How would you interpret the A1C results?
2. Would you recommend BGM for Joan?
3. What additional support would be appropriate for Joan?

Discussion

1. Joan's A1C results indicate her glycemic goals are not in the range recommended by the American Diabetes Association (ADA). During the last year, two A1C levels were done. Because neither of Joan's A1C values were in the target range of less than 7.0%, her A1C levels should be assessed quarterly.
2. Joan would likely benefit from BGM along with attending diabetes education classes. Performing BGM provides data that illustrate how food, physical activity, and medication use affects blood glucose levels. Blood glucose meters have evolved over the 10 years since Joan was diagnosed and selecting a new one that will meet her individual needs is important. To choose the best blood glucose meter for her, consideration should be given to Joan's preferences;

insurance coverage; and individual needs such as display size, auditory function, and meter size.

3. Joan would likely benefit from diabetes self-management education and support (DSMES). This need should be assessed and provided annually as appropriate. Joan's health care provider may suggest a change in her medications and encourage BGM until glycemic goals are achieved. It is important to tell Joan that if she is on Medicare, they will only pay for enough strips for one day of checking. Other insurance companies may vary unless the person with diabetes is on insulin three times/daily. Joan must bring her meter or logbook to every visit with her health care provider so they can go over the results and assist with clinical decision making.

ADDITIONAL MONITORING

The goals for the treatment of diabetes are purposeful to prevent or delay potential complications, which optimize the patient's quality of life. With that goal in mind, it is vital to understand that blood glucose levels only tell part of the story. Because diabetes is a leading risk factor for cardiovascular disease, stroke, and renal failure, it is essential to monitor and control the factors associated with these vascular complications. Blood pressure, lipid profile, and urine albumin levels should be measured at every routine clinical visit to alert the clinician to potential complications related to diabetes. For more information on the monitoring and treatment of the following conditions, please review the American Diabetes Associations Standards of Medical Care in Diabetes, released in January of 2022.

Hypertension

Hypertension is defined as a blood pressure (BP) sustained at or above 140/90 mmHg and is commonly associated with type 1 and type 2 diabetes[24]. Treatment recommendations for patients with diabetes and hypertension should be individualized with acknowledgment of patient preferences, cardiovascular risk assessment, potential adverse effects, significant drug-drug, drug-disease, or drug-food interactions, and accessibility of antihypertensive medications. Recommendations for individuals with diabetes and high cardiovascular risk should have a BP target of <130/80 mmHg if this BP can be safely attained; an individual with diabetes and a lower cardiovascular risk would benefit from a BP <140/90 mmHg. The patient's blood pressure should be measured at every outpatient visit and treated aggressively to achieve and maintain target pressure levels. All hypertensive patients would benefit from home blood pressure monitoring.

Dyslipidemi

Because dyslipidemia is common in patients with diabetes, lipid levels should be screened[24]. A lipid panel includes the total cholesterol, low- density lipoprotein (LDL), high-density lipoprotein (HDL), and triglyceride levels. Hypertriglyceridemia, high LDL cholesterol (especially the small, dense LDL particles), and low levels of HDL cholesterol commonly coexist with diabetes. For patients under the age of 40, it is recommended to obtain a lipid profile at the time of diagnosis, at the initial medical evaluation, and then every 5 years thereafter, unless there is a need for more frequent monitoring. If the patient is on medication for dyslipidemia, the recommendation is to obtain a lipid profile at the initiation of the medication, 4 to 12 weeks after initiation or a change in dose, and then annually monitor the response to therapy.

End-stage renal failure

End-stage renal failure is a common microvascular complication of diabetes. In fact, diabetic nephropathy is known as the leading cause of end- stage renal disease in the United States[24]. Screening for kidney disease involves urine testing for albumin levels. Albumin is a plasma protein particle that is typically too large to be eliminated by healthy kidneys. In diabetic nephropathy, renal tubules are damaged, and albumin begins to escape into the urine. The earliest sign of nephropathy is the appearance of persistent microalbuminuria. When measured directly, a microalbumin level of less than 30 mg per day is considered normal. A level between 30 and 299 mg per day is defined as microalbuminuria, and levels greater than 300 mg per day signify clinical albuminuria and incipient renal failure. Spot collections of urine to measure the microalbumin to creatinine ratio are generally recommended. Patients with type 1 diabetes are screened annually after the 5th year of a diabetic diagnosis and during pregnancy, regardless of the duration of diabetes. Patients with type 2 diabetes are screened at diagnosis for microalbuminuria and annually thereafter.

Self-Assessment Quiz Question #5

What is the primary purpose for treatment guidelines set in the management of diabetes for both type 1 and type 2?

a. To ensure the blood glucose levels are maintained as close to optimal as possible.
b. To prevent or delay potential complications caused by diabetes.
c. To prevent diabetes from being passed from generation to generation.
d. To educate the patient with diabetes on healthy living.

Conclusion

BGM, either with fingersticks and a glucometer or a continuous glucose monitor is an essential part of diabetes management plans. However, BGM alone does not improve diabetes outcomes. Patients must integrate results into their self-management plans to observe changes in blood glucose levels. A1C monitoring every 3 to 6 months for all persons with diabetes and a TIR for those using a CGM enables the health care provider to demonstrate to people how their self-monitoring at home correlates with the office monitoring of glucose management and is associated with the prevention of complications that occur with prolonged hyperglycemia. With advances in diabetes technology, CGM has moved beyond BGM by providing real-time data with an ability to detect glycemic trends, rate of change information, and glycemic variability in a range of time, all of which support efforts to minimize the complications associated with hypoglycemia and hyperglycemia.

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MONITORING TECHNIQUES FOR OPTIMAL DIABETES MANAGEMENT AND CONTROL

Self-Assessment Answers and Rationales

1. The correct answer is C.
Rationale: Continuous glucose monitoring (CGM) monitors glucose levels continuously, as often as every 5 minutes throughout the 24 hours of each day. BGM represents a blood glucose level at a given moment, indicating blood glucose levels at isolated times of the day.

2. The correct answer is D.
Rationale: Blood glucose monitoring (BGM) provides information about how eating, physical activity, and medication-taking affect blood glucose levels.

3. The correct answer is C.
Rationale: The American Diabetes Association (ADA) recommends 80 to 130 mg/dL for preprandial capillary blood glucose levels.

4. The correct answer is C.
Rationale: A1C levels can be converted to an estimated average glucose (eAG) using the following formula: 28.7 × A1C – 46.7 (28.7 × 9.2 – 46.7 = 217 mg/dL).

5. The correct answer is B.
Rationale: The goals for the treatment of diabetes are intended to prevent or delay potential complications, which affect the patient's quality of life in addition to mortality. With that goal in mind, it is vital to understand that blood glucose levels only tell part of the story.
Because diabetes is a leading risk factor for cardiovascular disease, stroke, and renal failure, it is essential to monitor and control the factors associated with these vascular complications. Blood pressure, lipid profile, and urine albumin levels should be measured as recommended by the American Diabetes Association to alert the clinician to potential complications related to diabetes.

Final Examination Questions

Select the best answer for each question and complete your test online at **EliteLearning.com/Book**

66. How frequently should a patient with type 1 diabetes on an intense insulin regimen monitor blood glucose levels?
    a. While fasting and 1 to 2 hours after meals.
    b. Twice daily at varying times.
    c. Before meals and snacks, before bedtime, and occasionally postprandially.
    d. At variable intervals depending on treatment program and patient characteristics

67. John is a 35-year-old male whose postprandial capillary blood glucose level was 165 mg/dL 2 hours after dinner. What conclusions can be drawn from these results?
    a. The blood glucose level is within recommendations for ADA glucose targets.
    b. The blood glucose level is higher than recommended for ADA glucose targets.
    c. The blood glucose level is lower than recommended for ADA glucose targets.
    d. The blood glucose level is higher than recommended for ADA targets in males.

68. What is the function of A1Cs?
    a. Provide information on glycemic variability or hypoglycemia.
    b. Strong predictive value for diabetes complication.
    c. Indirect measure of glycemia over the preceding 30 days.
    d. Direct measure of a random fasting glucose

69. Benefits of continuous glucose monitoring (CGM) include:
    a. Wearing 2 to 3 days, depending on the device.
    b. Recording glucose levels every 15 to 20 minutes.
    c. Equally effective as BGM.
    d. Providing fast, proactive response.

70. What continuous glucose monitoring (CGM) device collects blood glucose data and transmits it to a health care provider in a blinded mode?
    a. Personal.
    b. Professional.
    c. Open-loop
    d. Closed-loop.

71. Which of the following is a barrier to successful use of a CGM?
    a. A1C within an acceptable glycemic range.
    b. Use of regular insulin.
    c. Cost of CGM.
    d. Poor venous access.

72. The hemoglobin A1C measures:
    a. Mean glucose over the preceding 6 weeks.
    b. Weighted mean glucose from the preceding 12 weeks.
    c. Random glucose levels.
    d. Frequency of hypoglycemia.

73. Most continuous glucose monitoring (CGM) systems allow wireless sensors to stay in place for:
    a. 1 to 3 days.
    b. 3 to 7 days.
    c. 7 to 14 days.
    d. 21 days.

74. CGM measures glucose levels in which of the following?
    a. Interstitial fluid.
    b. Venous fluid.
    c. Transcellular fluid.
    d. Vascular fluid.

75. Time in range (TIR) is a useful glucose metric referring to:
    a. The percentage of time a person's blood glucose levels change throughout the day.
    b. The percentage of time a person's blood glucose levels capture high values.
    c. The percentage of time a person's blood glucose levels capture low value.
    d. The percentage of time a person's blood glucose level remains in a proposed target range.

Course Code: RPUS02DC

Chapter 6: Pharmacological Management: Type 2 Diabetes in Children, 2nd Edition

3 Contact Hours

By: Danielle McDonald, PharmD, BCPPS

Author Disclosure: Danielle McDonald, and Colibri Healthcare, LLC do not have any actual or potential conflicts of interest in relation to this lesson.

Universal Activity Number UAN: #0607-0000-23-003-H01-P
Activity Type: Knowledge-based
Initial Release Date: 4/13/2023
Expiration Date: 4/13/2026
Target Audience: Pharmacists in a community-based setting.

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Learning objectives

After completing this course, the learner should be able to:

- Identify the pathophysiology and risk factors for development of type 2 diabetes.
- Interpret diagnostic criteria of type 2 diabetes in comparison with type 1 diabetes in pediatric patients.
- Select goals of therapy for managing type 2 diabetes.
- Apply nonpharmacologic recommendations to care of a pediatric patients diagnosed with type 2 diabetes.
- Choose appropriate pharmacologic therapy for a pediatric patient diagnosed with type 2 diabetes.
- Recognize psychosocial barriers to success in the treatment of type 2 diabetes in pediatric patients.

INTRODUCTION

Type 2 diabetes mellitus (T2DM), also previously called adult-onset diabetes or noninsulin-dependent diabetes, is the most common type of diabetes in the U.S. (Centers for Disease Control and Prevention [CDC], 2022a). While commonly used colloquially, the previous misnomers do not fully describe the age range or current scope of treatment of T2DM. In recent years, the onset of T2DM in childhood and adolescence has become more common, and in certain patients, glycemic control may not be achievable without insulin. The prevalence of T2DM in pediatric patients is rising, so pediatric providers must be well versed in the ways in which presentation and management differ from both T1DM in children and T2DM in adults. Adult management cannot be easily extrapolated to care of children, and knowledge of pediatric-specific treatment and prevention is imperative for chronic care of this population. Physicians, nurses, and pharmacists are all well positioned to manage pediatric patients with T2DM. In this course, the healthcare professional will learn about the diagnosis and management of T2DM, including special considerations related to lifestyle management and newly approved pharmacologic options. Pediatric psychosocial challenges will also be addressed, along with guidance for management.

Case study: Billy

Billy is a 15-year-old male presenting to his pediatrician's office for an annual visit. All his vital signs are appropriate for his age, including blood pressure, heart rate, and respiratory rate. He has no current complaints and feels in decent physical condition. For years, Billy has struggled with unhealthy eating habits at home, and since the onset of the pandemic, he has not been involved in the sports he once loved to play. His body mass index is consistently above the 95th percentile for his age. On the physical exam, he has darkening skin folds around his neck but no other rashes or notable skin issues. He is not currently on any medications other than a multivitamin. The only pertinent item in his medical history is snoring, but he has never had a sleep study. His immunizations are all up to date, including his annual influenza vaccine. He has never had any surgeries or overnight hospital stays. His parents are both overweight, and his father has type 2 diabetes. He lives at home with both parents and his younger sister. He attends a local public high school and screens negative for any concerning psychosocial issues.

OVERVIEW OF PEDIATRIC DIABETES

Pediatric diabetes is traditionally attributed to type 1 diabetes mellitus (T1DM), which is an autoimmune process that leads to destruction of pancreatic ß cells (American Diabetes Association [ADA] et al., 2022a). This process results in absolute insulin deficiency, and onset is typically in childhood. In recent years, childhood-onset T2DM has become more prevalent. The pathophysiology and progression of this disease state differ considerably from T1DM. In T2DM, insulin secretion from ß cells is reduced progressively. This is often termed insulin resistance and can progress over time to insulin deficiency with management and complications similar to T1DM.

Epidemiology

Diabetes is one of the most common disease states in adults and children in the U.S. (CDC, 2022a). In the pediatric population, T1DM is more prevalent than T2DM, but T2DM is on the rise. The Centers for Disease Control and Prevention estimate there are 5,700 new T2DM diagnoses among children and adolescents 10 to 19 years of age per year. It is estimated that the prevalence of T2DM in this age group will quadruple in 40 years (ADA et al., 2022g). In recent years, rates have especially been increasing among non-Hispanic Black children. Prediabetes, which is the presence of impaired glucose tolerance without the diagnosis of

diabetes, is also prevalent among adolescents. A recent study estimates that approximately one in five adolescents in the U.S. have prediabetes (Andes et al., 2020). Male adolescents are nearly twice as likely to have prediabetes compared to their female counterparts.

Pathophysiology

In T2DM, pancreatic ß-cell function declines in a progressive fashion, which is unrelated to an autoimmune process (Arslanian et al., 2018). The cause of ß-cell dysfunction is less defined in T2DM and may be multifactorial. Dysfunction of ß cells results in inadequate insulin secretion, which leads to disordered metabolism of glucose. Without proper insulin function, the body is unable to utilize glucose effectively for energy, and blood glucose levels rise above normal values in the bloodstream. Most patients with T2DM are overweight, are obese, or carry a large percentage of body fat in the abdominal area. These characteristics may contribute to insulin resistance, which occurs when insulin levels appear to be elevated but are insufficient to control blood glucose levels (ADA et al., 2022a). When insulin resistance develops, insulin secretion must continuously increase to balance the circulating blood glucose levels. Eventually, the pancreas cannot produce enough insulin to compensate for this resistance, and glucose homeostasis is compromised (Arslanian et al., 2018).

In pediatric patients, decline in ß-cell function is noted to be more rapid, and associated complications arise earlier in the disease course as compared with their adult-onset counterparts (ADA et al., 2022g). In fact, many individuals with childhood-onset T2DM present with microvascular complications, including nephropathy, retinopathy, and neuropathy in young adulthood. An unhealthy lifestyle, which is common in individuals with complicated social and financial situations, may contribute to the prevalence of T2DM in certain communities. Youth with T2DM are also more likely to present with concomitant metabolic syndrome, including elevated liver enzymes and systolic blood pressure, than are children with T1DM (Arslanian et al., 2018).

Risk factors

Several genetic and environmental factors contribute to the development of T2DM (ADA et al., 2022a). Risk factors for the development of T2DM include older age, higher body mass index (BMI), and a sedentary lifestyle. Most pediatric patients are not diagnosed with T2DM until after puberty or at least 10 years of age (ADA et al., 2022g). There is also a strong genetic link to the development of T2DM, especially if noted in first-degree relatives. Additional risk factors include female sex, adiposity, and low socioeconomic status (ADA et al., 2022g). High-risk races and ethnicities include Native Americans, African Americans, Asian Americans, Latinos, and Pacific Islanders. In adult patients, history of cardiovascular disease, hypertension, and increased high-density lipoprotein cholesterol or triglyceride levels are additional risk factors for the development of prediabetes or diabetes.

While many risk factors are nonmodifiable, including genetic predisposition, there are several modifiable risk factors, which are the focus of intervention. These include low physical activity and a surplus of caloric intake, along with stress, depression, and sleep-related disorders (Arslanian et al., 2018).

Healthcare Consideration: During the COVID-19 pandemic, children and adolescents experienced significant social, emotional, and physical disruptions to their normal lives. A longitudinal study found that the pandemic decreased physical activity and increased sedentary behavior in young adults (Zheng et al., 2020). These lifestyle changes may contribute to the development of diabetes and should be intervened upon in the post-pandemic era. For those that continue to participate in remote education and/or work, incorporating home-based exercises may decrease sedentary time.

Despite known risk factors and concomitant interventions, rates of childhood obesity and T2DM are on the rise (CDC, 2022a). It is vital to examine alternative risk factors, which may elucidate novel areas of intervention and prevention. The gut microbiome is undergoing study, as its composition may be related to obesity, allergies, and other chronic diseases (Kumbhare et al., 2019). The microbiome is especially vulnerable to alteration in the first 2 years of life, which may have lifelong consequences. A study explored the association of antibiotic or acid suppressant exposure during the first 2 years of life with the development of childhood obesity (Stark et al., 2019). An association was found with both types of medications, and stronger associations were noted with prolonged courses or exposure to multiple classes of antibiotics. Since obesity is strongly associated with the development of T2DM, antimicrobial stewardship and reduction of inappropriate acid suppression are important areas of study for prevention.

Healthcare Consideration: Data from a national registry in Finland was recently analyzed to determine if prior antibiotic exposure was associated with subsequent diagnosis of type 2 diabetes (Nuotio et al., 2022). More than 25,000 participants were included for analysis. Information regarding early life parental smoking, physical activity, socioeconomic status, and dietary habits were collected to aid in adjustment for potential confounders. Study authors determined that individuals with >5 courses of antibiotics were twice as likely to be subsequently diagnosed with type 2 diabetes compared to those who received ≤1 antibiotic course. This value remained unchanged after adjustment for age, sex, and additional confounders. Antibiotic exposure was also associated with increased risk of being overweight or obese. These findings are meaningful, but of course correlation does not equate causation in studies with an observational design. Prospective, randomized trials are required to confirm causation. While the scientific community awaits these studies, healthcare professionals can work together to minimize inappropriate antibiotic use to reduce impact on the microbiome.

Another study specifically examined gut microbial diversity and its association with insulin resistance and T2DM (Chen et al., 2021). Conducting a review of more than 2,000 participants, greater microbial diversity was associated with less T2DM and lower insulin resistance. Along with this diversity, more butyrate-producing gut bacteria was associated with less T2DM. Butyrate, which is produced by certain bacteria from fermentation of dietary fiber, may have beneficial metabolic effects throughout the body. Although this was theorized to contribute to the study's findings, butyrate concentrations in the blood and stool were not measured. Future studies may elucidate clearer risk factors for T2DM related to the microbiome, which may uncover new methods of prevention and treatment. The production of butyrate can be modulated via dietary intake of fermentable fiber, so confirmation of this theory may help guide nutritional management in the future.

Presentation

Many children with T2DM will not present with classic symptoms of diabetes because the development is much more gradual than is seen with T1DM (Arslanian et al., 2018). Children with T1DM may experience dehydration, unintentional weight loss, polydipsia, and polyuria, but children with T2DM may be initially asymptomatic (Arslanian et al., 2018). Diagnosis is typically made based on screening laboratory values. An objective finding in children with T2DM is acanthosis nigricans, which is a darkening and thickening of skin folds, most commonly in the neck, armpits, or groin (ADA et al., 2022g). Another objective finding is vulvovaginal can-

didiasis, which can occur in girls secondary to increased urinary excretion of glucose.

Commonly, children with T1DM present in diabetic ketoacidosis (DKA), a life-threatening complication of diabetes (ADA et al., 2022g). In the absence of insulin and the ability to utilize glucose, the body uses fat for energy, which produces ketones and creates an acidotic state (Glaser et al., 2022). In response to the inability to utilize glucose, counterregulatory hormones, such as glucagon, catecholamines, and cortisol, are released, which increases glucose production. Diabetic ketoacidosis is considered a medical emergency and typically requires hospitalization for monitoring and treatment. This is a rarer occurrence in children with T2DM unless triggered by a concomitant illness or hyperglycemia-inducing medication (ADA et al., 2022a). Only about 6% of youth present with DKA at the onset of T2DM (ADA et al., 2022g).

Patients with T2DM who present with severe hyperglycemia (defined as a blood glucose ≥ 600 mg/dL) may experience hyperglycemic hyperosmolar state (HHS; ADA et al., 2022g). Hyperglycemic hyperosmolar state is similar to DKA but without the significant accumulation of ketone bodies. Hyperglycemic hyperosmolar state results in decreased uptake of glucose into peripheral tissues, but since insulin is still being produced, ketogenesis is generally inhibited (Glaser et al., 2022). Similar to DKA, this "starvation" process causes counterregulatory hormones to be released, which further increases glucose levels in the bloodstream. Hyperglycemia increases serum osmolarity, which causes free water to be drawn out of the extracellular space and excreted in the urine. This process can cause moderate to severe dehydration and electrolytes losses. While HHS is more common than DKA in T2DM, it is still relatively rare in children. When HHS does occur, it is usually precipitated by an infectious process. Hyperglycemic hyperosmolar state has a high mortality rate and typically requires hospitalization for aggressive fluid resuscitation.

Self-Assessment Quiz Question #1

Which of the following is FALSE regarding the pathophysiology of type 2 diabetes mellitus?

a. Insulin resistance leads to increased insulin secretion.
b. Antibody-mediated ß-cell destruction contributes to insulin dysfunction.
c. Pancreatic ß-cell dysfunction progresses more rapidly in youth-onset type 2 diabetes compared to adult-onset type 2 diabetes.
d. Surplus body fat contributes to insulin resistance.

DIAGNOSIS

According to the American Diabetes Association (ADA) 2022 criteria, diabetes is defined by one of the following criteria (ADA et al., 2022a):

- Hemoglobin A1C (HbA1C) ≥ 6.5%.
- Fasting (no caloric intake for ≥ 8 hours) plasma glucose ≥ 126 mg/dL.
- Oral glucose tolerance test (75-gram glucose load) with 2-hour plasma glucose ≥ 200 mg/dL.
- Random plasma glucose ≥ 200 mg/dL with classic hyperglycemic symptoms.

In the absence of symptomatic hyperglycemia, diagnosis of diabetes should be confirmed with a second abnormal result during a subsequent screening (ADA et al., 2022a). Patient-specific factors that alter hemoglobin, including sickle cell disease, pregnancy, and recent blood loss, can affect the accuracy of the HbA1C result. If there exists a discordance between the HbA1C value and plasma glucose levels, the latter is more reliable and accurate, especially in patients with hemoglobinopathies.

Children and adolescents who are overweight (defined as BMI ≥ 85th percentile for age) or obese (defined as BMI ≥ 95th percentile for age) are at risk for T2DM, especially if they have additional risk factors (ADA et al., 2022g). Obese or overweight children with one or more additional risk factors should be screened for prediabetes and T2DM after the onset of puberty or ≥ 10 years of age, whichever occurs earlier. Additional risk factors for screening, as outlined by the ADA, are maternal history of diabetes or gestational diabetes during the child's gestation, family history of T2DM in a first- or second- degree relative, high-risk race or ethnicity, and signs of insulin resistance or associated conditions. Signs of insulin resistance include acanthosis nigricans, hypertension, dyslipidemia, polycystic ovary syndrome, and small-for-gestational-age birth weight (ADA et al., 2022a). In children with these risk factors whose tests are normal, repeat testing is recommended at 3-year intervals or sooner if their BMI continues to increase. Identification of prediabetes is critical for early intervention and prevention of progression to diabetes. Prevention may help lower rates of developing retinopathy and nephropathy, which are complications of diabetes.

Case study: Billy

Question

Billy presents to his annual visit with concerns about risk factors for prediabetes and type 2 diabetes mellitus. Which of his risk factors meet screening criteria?

Discussion

Screening for prediabetes and diabetes should begin at ≥10 years of age or puberty for pediatric patients who are overweight with additional risk factors or symptoms of diabetes. Billy's body mass index is over the 95th percentile, which meets criteria for obesity, and he has poor eating habits and a sedentary lifestyle. These unhealthy habits are not criteria for screening but may contribute to Billy's obesity and put him at risk for prediabetes and diabetes. He has a first-degree relative with diabetes and darkening of skin folds, which could be indicative of acanthosis nigricans, a condition strongly associated with type 2 diabetes and a sign of insulin resistance. These two criteria are listed by the American Diabetes Association as risk factors for screening. Although he is not otherwise symptomatic, Billy may be found to have elevated blood glucose levels and insulin resistance, and he should be screened for prediabetes and type 2 diabetes.

Children who present with hyperglycemia and symptoms of diabetes require further testing to differentiate a T1DM diagnosis from a T2DM diagnosis (ADA et al., 2022a). In T1DM, detection of islet autoantibodies is a clear indication of ß-cell destruction. Islet autoantibody testing should always be performed to exclude the diagnosis of T1DM, even in patients with classic findings of T2DM.

Healthcare Consideration: Although obesity is a risk factor for and is associated with type 2 diabetes, overweight and obese pediatric patients who meet criteria for a diabetes diagnosis may have type 1 diabetes (ADA et al., 2022g). One study demonstrated that nearly 10% of youth clinically diagnosed with type 2 diabetes were positive for circulating antibodies (Klingensmith et al., 2010). Although a patient's presentation may align with one type of diabetes, the initial diagnosis must often be reconsidered.

A diagnosis of "prediabetes" may be made in individuals who do not yet meet the ADA criteria for diagnosis of diabetes but who are displaying signs and symptoms of abnormal carbohydrate metabolism (ADA et al., 2022a). An impaired fasting plasma glucose, defined as 100 to 125 mg/dL, or poor glucose tolerance, defined as a 2-hour plasma glucose of 140 to 199 mg/dL during a 75-gram oral glucose tolerance test, may be attributed to prediabetes. Another potential marker is HbA1C between 5.7% and 6.4%. The most common finding in adolescents is impaired fasting glucose

(Andes et al., 2020). While prediabetes is not a separate disease state, it is a risk factor for the progression to diabetes. Prediabetes also poses several cardiovascular risks, and patients with elevated plasma glucose and/or HbA1C should be screened for other cardiovascular complications.

Self-Assessment Quiz Question #2

Billy undergoes testing for prediabetes and diabetes. Which of the following findings meets American Diabetes Association criteria for diabetes diagnosis? Note that Billy's last meal was 6 hours prior to testing.

a. Plasma glucose of 126 mg/dL.
b. Plasma glucose of 180 mg/dL.
c. Hemoglobin A1C of 6%.
d. Hemoglobin A1C of 8%.

COMPLICATIONS AND RELATED CONDITIONS

Chronic complications of T2DM are tied directly to the degree and duration of sustained hyperglycemia (ADA et al., 2022a). Comorbidities, including hyperlipidemia and hypertension, may already be present at diagnosis and should be detected and treated as early as possible (ADA et al., 2022g). Polycystic ovary syndrome (PCOS), a complex endocrine disorder that causes menstrual irregularities, is bidirectionally associated with T2DM (Cioana et al., 2022). Insulin resistance contributes to the pathogenesis of PCOS, and PCOS contributes to decreased insulin sensitivity. The syndrome is also associated with many cardiometabolic diseases and mental health disorders. A recent systematic review and meta-analysis estimates that up to one in five girls with T2DM are diagnosed with PCOS (Cioana et al., 2022). Although diagnostic criteria varied among the included studies, this high percentage highlights the importance of assessment for PCOS in the T2DM population.

Microvascular and macrovascular complications, along with diabetes-associated conditions, should be actively screened for and treated, as appropriate (ADA et al., 2022g). Table 1 summarizes recommendations regarding onset of screening and follow-up frequency. Specific treatment of these conditions, if detected, is beyond the scope of this course. Generally, glycemic control and lifestyle modifications can serve as prevention and therapy for a majority of the listed conditions.

Although preventing complications is centered on glycemic control and lifestyle modifications, additional interventions can improve patient health and quality of life (ADA et al., 2022c). As an example, oral contraceptive pills may be utilized in the treatment of PCOS and to prevent unplanned pregnancies in adolescent girls. Beginning at the onset of puberty, females should be counseled about the potential risks to a fetus exposed to poor metabolic control. In those who are or who plan to become sexually active, effective contraceptive methods should be discussed and provided (ADA et al., 2022g).

Children with diabetes are at increased risk of infection due to alterations in the immune system (Calliari et al., 2020). Possible mechanisms include decreased T-cell response, reduced neutrophil function, and microbiome alterations. The etiology of this dysfunction is attributed to prolonged periods of hyperglycemia in addition to factors associated with pathophysiology and treatment of the disease. In turn, active infection creates stress on the body, which results in hyperglycemia and insulin resistance. During periods of illness, blood glucose should be monitored more frequently, and patients should remain adequately hydrated to prevent escalation to DKA or HHS.

Table 1: Screening for Complications and Diabetes-Associated Conditions

Condition	Type of Screening	Onset of Screening	Follow-Up, if Normal
Nephropathy	Albumin-to-creatinine ratio	Upon diagnosis	Annually
Neuropathy	Foot exam	Upon diagnosis	Annually
Retinopathy	Dilated fundoscopy	Soon after diagnosis	Annually
Dyslipidemia	Lipid profile	After resolution of hyperglycemia	Annually
Hypertension	Blood pressure monitoring	Upon diagnosis	Every office visit
Nonalcoholic fatty liver disease	Liver enzymes	Upon diagnosis	Annually
Obstructive sleep apnea	Symptom screening	Upon diagnosis	Every office visit
Polycystic ovarian syndrome	Symptom screening	Upon diagnosis (female adolescents)	Every office visit

Note: Adapted from American Diabetes Association Professional Practice Committee, Draznin, B., Aroda, V. R., Bakris, G., Benson, G., Brown, F. M., Freeman, R., Green, J., Huang, E., Isaacs, D., Kahan, S., Leon, J., Lyons, S. K., Peters, A. L., Prahalad, P., Reusch, J., & Young-Hyman, D. (2022g). Children and adolescents: Standards of medical in diabetes, 2022. *Diabetes Care, 45*(Suppl 1), S208-S231. https://doi.org/10.2337/dc22-S014

Common sites of infection include the respiratory tract, skin and soft tissue, the urinary tract, and surgical sites (Calliari et al., 2020). Candidiasis is also common, especially in the vulvovaginal area, as previously discussed. Hyperglycemia increases urinary excretion of glucose, which serves as a nutrient for *Candida*. Therefore, inadequate glycemic control increases the risk of *Candida* colonization. Colonization increases with age, especially in the postpubertal period, and may result in clinical infection.

In children, respiratory infections are the most common infectious process, and two of the main causes are *Streptococcus pneumoniae* and influenza viruses. Although adequate glycemic control can help regulate the immune system and potentially prevent infections, immunizations are a key strategy in reducing morbidity and mortality in this population. The ADA (2022g) recommends all children with diabetes receive age-based standard immunizations, including influenza and high-risk pneumococcal vaccines. All children are recommended to receive the pneumococcal conjugate vaccine, but those with diabetes should also receive the 23-valent polysaccharide vaccine after completion of the primary

conjugate series. In patients due for both, the conjugate vaccine should be prioritized, and a minimum 8- week interval of time must pass between administration of the pneumococcal conjugate vaccine and pneumococcal polysaccharide vaccine. Immunization recommendations related to the COVID-19 pandemic are evolving, and up-to-date guidance can be found on the CDC vaccination schedule (CDC, 2022b).

Self-Assessment Quiz Question #3

Billy undergoes screening for diabetes-related complications. Which of the following tests are used to detect a microvascular complication?

a. Foot exam.
b. Blood pressure monitoring.
c. Lipid profile.
d. Liver enzymes.

TYPE 2 DIABETES MELLITUS: MANAGEMENT

Goals of therapy

Functionally, goals of T2DM treatment in children include preservation of pancreatic ß cells, achieving healthy weight loss that does not interfere with growth and development, and maintaining glucose control (Karavanaki et al., 2022). Glycemic control aims to reduce the development of long-term microvascular and macrovascular complications related to diabetes. Psychologically, providers should aim to reduce diabetes-related stress, manage concomitant psychosocial issues that may become barriers to therapy, and incorporate the patient's cultural and social values into lifestyle plans.

Generally, the target for glycemic control is a goal HbA1C level, which reflects average glucose levels over a 3-month period (ADA et al., 2022e). Although HbA1C is a good indicator of chronic glycemic values, it does not capture daily fluctuations of blood glucose levels, including periods of hypoglycemia. As previously discussed, this value may not be reliable in patients with certain conditions that affect red blood cell turnover. A goal HbA1C <7% is generally recommended to reduce the risk of microvascular complications. This HbA1C level corresponds to an average blood glucose of 154 mg/dL. While stricter goals may offer slightly improved outcomes in select patients, the risk of hypoglycemia may outweigh this marginal benefit. As an alternative to HbA1C, glucose monitors may be utilized to gauge daily control of blood glucose. This method of measurement is especially valuable in patients at risk for hypoglycemia on insulin therapy. Blood glucose meters measure glucose periodically throughout the day, and new technology can even measure these values continuously. Continuous glucose monitors are becoming more widely used in the T1DM population and may have a role in T2DM patients who have substantial enough insulin deficiency to require exogenous insulin as part of their therapy.

Healthcare Consideration: A hemoglobin A1C target of <7% is typically recommended to reduce microvascular complications in patients with type 2 diabetes (ADA et al., 2022e). Although there may be an additional yet smaller benefit of lowering this goal to 6%, the extra reduction in the risk of microvascular complications must be weighed against the risk of hypoglycemia. This risk is of particular concern in patients controlled on medications that may induce hypoglycemia, such as insulin. If patients are able to maintain a hemoglobin A1C closer to 6% without significant hypoglycemic events, therapy need not be de-intensified.

Prevention

Primary prevention of T2DM is best targeted at individuals with impaired glucose tolerance, as opposed to those with isolated impaired fasting glucose or elevated HbA1C (ADA et al., 2022a). In children and young adults with prediabetes, progression to diabetes can be prevented or slowed via several strategies (ADA et al., 2022b). Lifestyle modifications are the primary therapy aimed at adolescents with prediabetes (Esquivel Zuniga & DeBoer, 2021). Physical activity can reduce abdominal fat and improve insulin sensitivity, which is why the ADA recommends at least 150 minutes per week of moderate- intensity activity. Optimally, a combination of daily aerobic activity, such as brisk walking, and three-times-weekly resistance training should be implemented. Along with physical activity, nutrition should be optimized to promote healthy weight loss. While there is no single superior dietary pattern, general recommendations include limiting processed food and consuming more whole grains, fruits, and vegetables. Saturated fat intake should be reduced, and sugar-sweetened beverages eliminated. Diets including high fiber intake may aid in slowing absorption of carbohydrates and increasing satiety. For successful intervention, nutritional strategies must be individualized based on the patient's age, level of activity, and food preferences.

Smoking, including electronic cigarette use, should be discouraged in all patients, especially those with diabetes (ADA et al., 2022d). Tobacco use increases the risk of long-term cardiovascular disease, diabetes-related microvascular complications, and even premature death.

Evidence-Based Practice: Pediatric patients with prediabetes are at increased risk of progression to type 2 diabetes (ADA et al., 2022a). In a 4-year retrospective study, more than 100 adolescents with prediabetes received medical nutrition therapy (Parajuli et al., 2022). Patients who attended two or more nutrition visits per year, compared to those who attended one or no visit, were observed to achieve a fourfold reduction in the likelihood of progression to type 2 diabetes. In addition, those who progressed to diabetes in the higher visit group had a mean delayed onset of diagnosis in comparison to the lower visit group. Overall, nutrition visits, which are indicative of lifestyle modifications, demonstrate a significant preventative benefit in children at high risk for developing diabetes.

Self-Assessment Quiz Question #4

Which of the following exercise regimens is most appropriate to recommend for prevention of progression from prediabetes to diabetes?

a. Core exercises, including planks and crunches, to improve abdominal strength.
b. Running five miles every day.
c. Brisk 30-minute walks five days per week with resistance training on Mondays, Wednesdays, and Fridays.
d. Resistance training once weekly with 20-minute jogs twice weekly.

TREATMENT: NONPHARMACOLOGIC INTERVENTIONS

All pediatric patients with T2DM should be educated on appropriate lifestyle adjustments, and patients' caregivers should be included in the discussion and planning (ADA et al., 2022g). A family-centered approach is optimal for implementing change. Adolescents who are overweight or obese are recommended to achieve a 7%–10% decrease in excess weight. The plans for achieving this goal should incorporate culturally appropriate and sustainable methods of weight reduction so that patients can adhere to the new lifestyle in the long term. The plan should incorporate recommendations for exercise and nutrition management, similar to those recommended in the prevention of T2DM. Children and adolescents should complete at least 60 minutes of daily moderate to vigorous physical activity along with strength training multiple days of the week, ideally at least three times weekly (ADA et al., 2022g). Sedentary behavior is linked to worsened outcomes and should be strongly discouraged.

Although there is no standard diet for diabetes management in children, some general recommendations exist (Karavanaki et al., 2022). Children and adolescents should consume two to three portions of fresh fruit and vegetables daily, along with whole grains, nuts, low-fat dairy products, fish, and lean meats. Of course, dietary preferences may limit or modify the sources of nutrition for select patients. Carbohydrate counting, which is part of standard T1DM management, is not necessary for the vast majority of patients with T2DM. Beverages should be sugar free, and snacks with added sugar should be limited or eliminated. Salt intake should also be limited and maintained within recommended values for age. Regular, consistent meals, including daily breakfast, should be enforced to promote satiety and improve metabolic outcomes. Since pediatric patients are still growing and developing, calorie restrictions should not be extreme and should still provide the nutrients necessary for healthy maturation.

Insulin resistance in T2DM may be mitigated by weight loss and exercise; however, these measures alone are unlikely to restore normal pancreatic function (ADA et al., 2022a). While lifestyle interventions should be recommended to all patients who are overweight or obese with diabetes, concomitant medication is often necessary to achieve glycemic control.

Evidence-Based Practice: As technology becomes more integrated into society, children are exposed to a variety of screens, such as phones, tablets, and televisions, which may increase sedentary time. Exergames are video games that require physical activity, and these products can transform sedentary game playing into active play. In a recent study, a group of overweight/obese children were provided with a gaming console with exergames and given a gameplay curriculum consisting of 1-hour sessions 3 times per week along with virtual fitness coaching (Staiano et al., 2018). After a 24-week study period, children in the exergames program were compared to those in a control group. Compared to the control group and with the exclusion of one outlier, those playing exergames significantly reduced their body mass index. Although based on a small sample size, these findings indicate that exergaming can improve health in pediatric patients, especially if paired with fitness coaching to encourage and monitor adherence.

Healthcare Consideration: Lifestyle management for type 2 diabetes should include nutritional changes and physical activity (ADA et al., 2022g). Patients must be encouraged to maintain a healthy weight and eat a balanced diet consisting of a variety of nutrients, including fruits and vegetables. Physical activity should include both muscle-strengthening and bone-strengthening exercises in addition to aerobic activity. Interventions targeted only at the patient may not be sufficient, especially for a child who is dependent on caregivers for sustenance and daily planning. A family-centered approach is far more likely to be sustained, since the child will feel supported and surrounded by a positive environment. While immediate interventions are critical, the goal of care is to create lifelong healthy habits.

TREATMENT: PHARMACOLOGIC INTERVENTIONS

Patients who progress from prediabetes to diabetes despite lifestyle changes will require pharmacologic therapy to achieve glycemic control (ADA et al., 2022g). Upon diagnosis of T2DM, pharmacologic therapy should be implemented alongside nutrition and physical activity changes. Table 2 summarizes treatment options and associated adverse effects of available pharmacologic therapy. The medication of choice will depend on the patient's initial presentation.

For patients that are metabolically stable and asymptomatic with an HbA1c < 8.5%, metformin is the treatment of choice (ADA et al., 2022g). Of note, the youngest age of approval for the use of metformin is 10 years. Metformin is classified as a biguanide and works by decreasing hepatic glucose production and intestinal absorption of glucose (Lexicomp, 2022). It improves insulin sensitivity by increasing peripheral glucose uptake and utilization. While it is not metabolized by the liver, it is renally cleared, so renal function should always be assessed prior to initiation. Therapy may need to be delayed in patients with acute kidney injury, which may be a finding in those that present in DKA. In addition, patients at risk for lactic acidosis should not receive metformin, as this is a dose-related effect of the medication. Metformin can inhibit mitochondrial electron transport, thereby increasing anaerobic metabolism, which can lead to the accumulation of lactate. Patients are at increased risk for this effect if clearance is decreased, which can occur in the setting of acute kidney injury, if hepatic function is impaired, or in hypoxic states. Metformin is generally withheld in patients who are critically ill. Symptoms of lactic acidosis are often nonspecific but may present as abdominal pain, malaise, or muscle aches. Patients with acidosis in the absence of ketoacidosis should be evaluated for metformin-associated lactic acidosis.

Metformin is typically dosed at 500 mg to 1,000 mg by mouth per day and incrementally titrated every 1 to 2 weeks, as tolerated, to a maximum daily dose of 2,000 mg/day (Lexicomp, 2022). There are tablets and oral suspensions on the market to accommodate patients unable to swallow pills. The traditional immediate-release formulations are typically dosed twice daily, but newer extended-release formulations enable once-daily dosing and may result in fewer adverse effects. The dose-limiting effect is typically gastrointestinal symptoms, including diarrhea, nausea, vomiting, and abdominal pain. While the mechanism is not fully understood, these symptoms most frequently occur at the onset of therapy and subside after several weeks of continuous use. Another major adverse effect of metformin is vitamin B12 deficiency, as absorption may be affected. Unlike gastrointestinal symptoms, this effect takes time and is detected after chronic use. Patients should be evaluated every 2 to 3 years for vitamin B12 deficiency or sooner if corresponding anemia or neuropathy are detected. Supplementation may be needed if adequate levels cannot be achieved via nutritional optimization.

Self-Assessment Quiz Question #5

Billy is initiated on immediate-release metformin to treat his type 2 diabetes. Which of the following is true regarding metformin therapy?

a. Metformin should be continued in patients with diabetic ketoacidosis to control glucose levels.
b. Metformin should be started at the highest dose to achieve maximal glycemic control.
c. Patients should be evaluated for vitamin B12 deficiency one month into metformin therapy.
d. Metformin should be started at a lower dose and incrementally titrated to effect.

While metformin monotherapy can be effective in asymptomatic patients, patients who are symptomatic or who have marked hyperglycemia may require more intensive therapy (ADA et al., 2022g). Symptoms include polyuria, polydipsia, and weight loss. These symptoms may also be indicative of T1DM, and patients may need to be managed under this diagnosis until more patient data is available. Marked hyperglycemia is defined as a blood glucose level ≥250 mg/dL or an HbA1C ≥8.5%. These patients should receive insulin therapy in addition to metformin. Insulin therapy is usually given via a long-acting formulation once daily to mimic pancreatic basal release. If patients present with ketosis or ketoacidosis as part of their symptoms, both basal insulin and rapid-acting insulin may be required. In the most severe cases, patients may need to be admitted for treatment of DKA and receipt of intravenous insulin therapy. In these patients, metformin should be added once the acidosis resolves.

Table 2: Pharmacologic Therapy for Pediatric Patients with Type 2 Diabetes

Medication	Adverse Effects	Impact
Metformin	Gastrointestinal symptoms, lactic acidosis, vitamin B12 deficiency.	Decreases hemoglobin A1C by ~1.1%.
Insulin	Hypoglycemia.	Dose- and formulation-dependent.
Liraglutide	Gastrointestinal symptoms, hypersensitivity reactions, local injection site reactions.	Decreases hemoglobin A1C by ~1%.
Exenatide	Gastrointestinal symptoms, local injection site reactions.	Extended-release demonstrated to decrease hemoglobin A1C by 0.85%– 1.9%.

Note: Adapted from by Jones, K. L., Arslanian, S., Peterokova, V. A., Park, J. S., & Tomlinson, M. J. (2002). Effect of metformin in pediatric patients with type 2 diabetes: A randomized controlled trial. *Diabetes Care, 25*(1), 89-94. https://doi.org/10.2337/diacare.25.1.89; Lexicomp. (2022). Insulin products. https://online.lexi.com

Case study: Julia

Julia is a 16-year-old female who was diagnosed with type 2 diabetes when she was 14 years old. She presents for a routine endocrinology visit to evaluate her therapy. At the office visit, she shared that she joined a running club at school, which keeps her active most days of the week. She and her family have also been cooking more meals at home and working to make healthy lifestyle choices. For her diabetes, she is on metformin immediate-release tablets 1,000 mg twice daily and a once-daily long-acting insulin. Despite adherence to lifestyle changes and this regimen, her most recent hemoglobin A1C is 8.2%, and her body mass index is in the overweight range for her age. She does not have any other symptoms or complaints currently, and all other laboratory values are within normal range.

Long-acting insulin is available in the form of insulin degludec, insulin detemir, and insulin glargine. These insulin formulations are administered subcutaneously and typically last for approximately 24 hours, but the effect can be dose dependent. Long-acting insulin formulations do not result in a significant peak and thereby mimic steady insulin release throughout the day. They are dosed in a weight-based fashion starting at 0.5 unit/kg/day and titrated every 2 to 3 days as needed (ADA et al., 2022g). Patients who are unable to achieve glycemic control with long-acting insulin may need additional rapid-acting insulin. In these cases, treatment shifts to T1DM-related management, which assumes near or absolute insulin deficiency. Patients may need coverage for hyperglycemia and meals, utilizing an insulin sensitivity factor and insulin-to-carbohydrate ratio, respectively, to calculate doses. Rapid-acting insulin is available as insulin aspart, insulin glulisine, and insulin lispro. These formulations start taking effect about 15–30 minutes after injection with a peak effect of about 2 hours and a duration of about 5 hours, depending on the formulation.

Healthcare Consideration: Initial pharmacologic therapy for treatment of type 2 diabetes in youth is dependent on the patient's hemoglobin A1C and degree of acidosis at presentation (ADA et al., 2022g). Patients with a hemoglobin A1C <8.5% with no acidosis or ketosis can be managed on metformin alone. Those with more elevated A1C values will need insulin in addition to metformin. If acidosis is present, patients must be evaluated for diabetic ketoacidosis and hyperglycemic hyperosmolar state. Management of these conditions should be prioritized, and then metformin and insulin can be initiated once resolved.

Insulin can be administered via one of three different delivery met hods:

- Insulin vials for administration via insulin syringes.
- Insulin pens.
- Insulin vials for administration via insulin pump.

Selection of an insulin delivery method is largely dependent on the patient's insulin requirements, insurance coverage, and dexterity (ADA et al., 2022f). Patients requiring basal insulin as an adjunct to metformin will likely only need once-daily injections given via a syringe or pen. While insulin pumps can adjust basal rates of insulin throughout the day for variable insulin requirements, this feature is likely not to be of significant benefit in patients who do not also require rapid-acting insulin boluses.

If patients elect to utilize insulin vials, insulin is withdrawn from a vial using a needle and syringe for subcutaneous injection (ADA et al., 2022f). Syringes with attached needles are preferred to enhance dosing accuracy, and a new needle should be utilized with each injection (Frid et al., 2016). Insulin vials should always be inspected prior to use to ensure there are no precipitates. For most accurate results, patients should draw up air into the syringe at a volume equivalent to the intended dose. After insertion of the needle into the vial, the air should be pushed from the syringe into the vial, and then the vial should be inverted. Once inverted, the appropriate volume of insulin can be withdrawn into the syringe. Prior to removal from the vial, the syringe should be inspected for air bubbles. These must be removed by gently tapping the

syringe to ensure the patient is not under-dosed. Of note, insulin syringe markings are in units rather than milliliters to enable more precise dosing. Patients should be counseled that other syringe types are not interchangeable. Insulin vials should be refrigerated until opened and then stored at room temperature while in use for a maximum of 30 days or per manufacturer guidance. A new insulin vial should be allowed to warm to room temperature prior to administration to reduce potential for pain upon injection. Insulin should never be frozen. If needed to be taken on an excursion on a hot day, insulin can be stored in an insulated container, such as a lunch box, but care should be taken not to accidentally freeze insulin by placing it on ice.

Insulin pens function similarly, but the patient does not need to withdraw the dose from a vial into a syringe (ADA et al., 2022f). Instead, the syringe and insulin supply are combined into a single device. Prior to use, the pen must be primed with an attached subcutaneous needle by dialing the dose to a small volume (e.g., 2 units) and pushing the thumb depressor until at least one drop of insulin appears. Priming the pen ensures unobstructed flow and complete delivery of the desired dose. After priming, the patient's dose can be dialed and directly injected. As with syringe injections, a new needle must be used for each injection. Storage and stability instructions are similar to insulin vials but should always be confirmed per manufacturer labeling.

Needle selection and insulin injection technique are critical for successful management of insulin in diabetes (Frid et al., 2016). Needle gauges range from 22 to 33, but a 23- to 25-gauge needle is most commonly recommended for pediatric subcutaneous injection. The higher the gauge number, the thinner the needle. While thinner needles cause less pain, they require slower administration and run the risk of breaking in patients with thicker skin. In terms of needle length, 4 mm is almost always adequate to penetrate subcutaneous tissue, but the thickness of the skin and the distance from skin to muscle varies per patient based on a variety of factors (Frid et al., 2016). In general, prepubertal and low-BMI patients have a thinner subcutaneous layer than older, higher-BMI individuals. If a longer needle is prescribed, patients must ensure administration is still subcutaneous and not intramuscular. Accidental intramuscular injection results in unpredictable absorption of insulin, which may cause hypoglycemia or hyperglycemia, depending on the rate of absorption. Intramuscular injection also tends to result in more pain and bruising. In general, the shorter the needle, the lower the likelihood of inadvertent intramuscular injection, which is key for therapeutic success.

Once the dose is prepared and an appropriate needle is selected, the patient must identify the site of administration for injection. Appropriate locations include the abdomen, the upper third anterior lateral aspect of both thighs, the posterior lateral aspect of the upper buttock, and the middle third posterior aspect of the upper arm (Frid et al., 2016). In children, it is preferred to inject at least two adult fingerbreadths away from the umbilicus. Sites of injection should be rotated frequently to avoid lipohypertrophy, which is swelling and hardening of fat tissue. This complication may lead to unpredictable and variable absorption of insulin if injections continue to be administered in the hardened location. Injection sites should be spaced at a minimum distance of 1 centimeter from previous injections, and areas of infection or swelling should be avoided.

Prior to injection, the injector should wash their hands, and the site of injection should be disinfected with alcohol and allowed to dry completely (Frid et al., 2016). Once prepared, the needle attached to the syringe or pen should be injected into the skin at a 90-degree angle. After injection, the syringe can be depressed, or the pen's thumb button can be pushed. For pens, it is recommended to hold the needle in the skin and count to 10 before withdrawing to ensure the complete dose is administered. Throughout the duration of counting and withdrawing, pressure should be maintained on the thumb button. This practice is not necessary for syringe-injected doses. Once withdrawn, needles must be disposed of immediately in a sharps container. For all injection methods, needles should never be reused or shared.

Self-Assessment Quiz Question #6

Which of the following is FALSE regarding insulin injection technique?

a. A 4-mm needle is typically adequate to penetrate tissue.
b. Insulin should always be injected intramuscularly.
c. Insulin injection sites should be rotated frequently.
d. Prior to injection, the injector should wash their hands.

If multiple daily doses of insulin are required in addition to basal dosing, insulin pump therapy may be considered, although this is not standard therapy in T2DM (ADA et al., 2022f). Insulin pump therapy, also referred to as continuous subcutaneous insulin infusion, delivers continuous, rapid-acting insulin at a basal rate in lieu of long-acting insulin. Bolus doses can be programmed throughout the day for meals or hyperglycemia. Insulin reservoirs containing rapid-acting insulin are either directly affixed to the skin via a patch or connected to an infusion set via a catheter. As with syringe and pen methods of administration, infusion sites should be rotated with each application (Frid et al., 2016). Selection of an insulin pump will depend on patient preference, insurance coverage, insulin requirements, and other desired features. Some pumps are waterproof, others can be paired with serum glucose monitors, and select pumps feature automated suspension of basal administration upon detection of hypoglycemia. While pumps have many benefits, they do have the potential to fail, and failure may result in poor glycemic control or even DKA in patients with absolute insulin deficiency. As such, it is a good idea to frequently assess insulin pump function via glucose monitoring. Patients and caregivers must retain the ability to administer insulin via conventional methods as a back-up for failures.

Self-Assessment Quiz Question #7

Insulin injections may be required for type 2 diabetes management. Which of the following insulin types is appropriate for once-daily injections?

a. Insulin glargine.
b. Insulin lispro.
c. Insulin glulisine.
d. Insulin aspart.

The most notable adverse effect of insulin therapy is hypoglycemia, which is defined as blood glucose 70 mg/dL (ADA et al., 2022e). Signs of hypoglycemia include irritability, shakiness, confusion, and hunger. Younger patients may be prone to hypoglycemia unawareness, as they are unable to detect and communicate symptoms until they are severe. In a conscious patient, the preferred treatment of hypoglycemia is oral administration of glucose in the form of an easily digested carbohydrate. Dosing ranges from 15 to 20 grams of glucose, which is roughly equivalent to:

- ~3 to 4 glucose tablets.
- ~1 tube glucose gel.
- ~4 ounces fruit juice.
- ~15 pieces Skittles.
- 1 tablespoon honey or syrup.

A repeat blood glucose level should be measured 15 minutes postingestion. If the glucose is still <70 mg/dL, the treatment can be repeated. Once the hypoglycemia is resolved, the patient should eat a meal or snack to prevent future episodes.

All patients at risk of moderate to severe hypoglycemia should be prescribed glucagon along with their insulin therapy (ADA et al., 2022e). Glucagon works via stimulation of adenylate cyclase, which increases cyclic AMP (Lexicomp, 2022). This mechanism results in hepatic glycogenolysis and gluconeogenesis, and therefore increases blood glucose levels without ingestion of exogenous glucose. Glucagon is available as a powder for reconstitution

for injection, as a ready-to-inject subcutaneous syringe, and as an intranasal spray. The dosing and type of glucagon prescribed is age- and insurance- dependent.

Evidence-Based Practice: Pediatric patients with newly diagnosed type 2 diabetes are often initiated on insulin therapy. A recent study analyzed data from the Pediatric Diabetes Consortium, focusing on youth who were initiated on insulin then switched to intensive lifestyle intervention or metformin alone (Wolf et al., 2022). The primary endpoint was the time to treatment failure, which was defined as the need to restart insulin or metformin. A total of 183 participants with a mean age of 15 years were included in the analysis, and 54% of these patients experienced treatment failure. In the subset of patients who were switched to intensive lifestyle intervention alone, 81% were restarted on insulin or metformin. Study authors identified that a higher hemoglobin A1C at study enrollment was a risk factor for treatment failure. These findings emphasize the importance of closely monitoring patients weaned off of insulin therapy, especially those with higher hemoglobin A1C values at diagnosis. The study also highlights the need for novel therapies to treat type 2 diabetes in children and adolescents.

In addition to metformin and insulin, other medications have recently been approved for the treatment of T2DM in pediatric patients (ADA et al., 2022g). Liraglutide is a long-acting glucagon-like peptide-1 (GLP- 1) receptor agonist that works to lower blood glucose via several mechanisms (Lexicomp, 2022). Glucagon-like peptide-1 is an incretin hormone, which is secreted from the intestine upon ingestion of glucose. Analogs of GLP-1 increase glucose-dependent insulin secretion, decrease inappropriate glucagon secretion, increase pancreatic ß-cell growth, slow gastric emptying, and decrease food intake. Liraglutide is administered as a 0.6-mg once-daily subcutaneous injection and is increased weekly to achieve glycemic control, typically to a maximum daily dose of 1.8 mg. It is approved for use in children 10 years of age and older, similar to metformin. Also, like metformin, gastrointestinal symptoms are the most common dose-limiting adverse effects, and these symptoms appear to decrease over time. Other notable adverse effects include acute kidney injury, which may be related to dehydration secondary to gastrointestinal symptoms, and hypersensitivity reactions, including angioedema and anaphylaxis. In animal studies, thyroid C-cell tumors were noted, but these findings are undetermined in humans. Due to this potential risk, patients with a personal or family history of medullary thyroid carcinoma or multiple endocrine neoplasia syndrome type 2 should avoid GLP-1 therapy. Other reported adverse reactions include gallbladder disease and pancreatitis, but these are not fully understood and the frequency in pediatric patients is not characterized. In clinical trials, patients receiving liraglutide along with basal insulin therapy were able to reduce their insulin doses by approximately 20% after titration to goal.

Exenatide, another analog of the hormone incretin, is available in an extended-release formulation (Lexicomp, 2022). It is administered as a 2-mg dose subcutaneously on a weekly basis. This medication was recently approved in children 10 years of age and older. Common adverse effects are mainly gastrointestinal or localized at the injection site. A warning regarding risk of thyroid carcinomas exists, as this is a noted class effect in animal studies. Other adult-approved GLP-1 receptor agonists are undergoing study in pediatrics, but approval is pending.

Evidence-Based Practice: In an international randomized study of patients age 10 to <18 years with type 2 diabetes, patients on standard of care therapy were given once weekly exenatide or placebo (Tamborlane, Bishai, et al., 2022). Standard of care therapy included nutrition therapy and exercise alone or in combination with metformin and/or insulin for at least 2 months prior to enrollment. After 24 weeks of therapy, the mean between-group difference in hemoglobin A1C was 0.85%, in favor of exenatide. Although there was a relatively small sample size, the findings support improved glycemic control when exenatide was utilized as add-on therapy.

Patients receiving metformin and/or GLP-1 receptor agonist therapy who are also receiving basal insulin may need therapy modifications. For those who are meeting targets for glycemic control, insulin can be tapered by 10%–30% every few days over several weeks (ADA et al., 2022g). For those who are not meeting their goals, multiple daily injections with rapid-acting insulin may need to be added. This may include prandial bolus doses or use of an insulin pump, similar to management of T1DM.

Case study: Julia

Question

Julia presents to her endocrinology office visit with a hemoglobin A1C that is above goal despite lifestyle changes and a pharmacologic regimen of metformin with insulin. What options does she have to improve her glycemic control?

Discussion

All patients should be encouraged to continue making lifestyle changes to promote a healthy weight. While Julia seems to have made significant improvements, she should ensure she is incorporating moderate-intensity exercises of adequate duration each day of the week, including aerobic and strengthening activities. In addition, her nutrition should be reviewed to ensure the family home cooking incorporates a balanced, appropriately portioned diet with fruits and vegetables. While these lifestyle changes will be beneficial for weight loss and diabetes management, she will also require intensification of her pharmacologic therapy to decrease her hemoglobin A1C. The highest recommended daily dose of metformin is 2,000 mg, so this therapy is maximized. Her insulin can be titrated to effect with either an increase in her basal dose or the addition of intermittent bolus doses. While effective, multiple daily doses of insulin can be burdensome and may place the patient at increased risk of hypoglycemia. Alternatively, a glucagon-like peptide-1 receptor agonist can be added to her therapy. Since she requires an approximate 1.3% reduction in her hemoglobin A1C, glycemic control may be possible without additional insulin. Approved options for her age are either once-daily liraglutide or once-weekly exenatide. If started on one of these two medications, her blood glucose should be closely monitored in the event that she requires a basal insulin reduction over the weeks following initiation.

Monitoring

Blood glucose monitoring depends on the patient's pharmacotherapy and subsequent risk of hypoglycemia (ADA et al., 2022g). At a minimum, glycemic status, typically via HbA1C, should be measured and assessed every three months. Values above the HbA1C goal may indicate nonadherence or the need for more intensive therapy. Many patients with T2DM require closer monitoring of blood glucose levels, secondary to insulin treatment or acute illness. Rather than every-3-month HbA1C, blood glucose can be measured on a daily or hourly basis with blood glucose meters.

Traditional methods of glucose monitoring require a lancing device, lancets, test strips, and a blood glucose meter (ADA et al., 2022f). Meters and test strips must be compatible for use, which often depends on the brand name, and test strips should be routinely checked for expiration. Specific instructions vary per manufacturer, but generally steps are similar across product types. First, the patient should wash their hands and dry them well. This limits interference with the reading and increases accuracy of the result. Alternatively, an alcohol pad can be used to wipe the finger clean. Once the user's hands are clean, they can insert a test strip into the port of the blood glucose meter in preparation for the blood

sample. Next, using a lancing device and lancet, the side of a fingertip should be pricked. Lancing the side of the finger tends to be less painful than the tip and is preferred by many patients. If no blood appears, the finger can be gently massaged or squeezed around the lanced area. The user should then take the inserted test strip and touch the edge of the strip to the drop of blood. Within seconds, the meter should display a blood glucose level. The test strip can be disposed of in a regular trash can, but the lancet should be ejected into a sharps container.

In patients receiving insulin, continuous glucose monitors may be helpful to capture more precise metrics (ADA et al., 2022f). A continuous glucose monitor trends serum glucose levels throughout the day and can be worn in water and during sleep. Similar to traditional monitors, instructions for use are manufacturer dependent. Generally, the user should clean and dry the site of application, and then a sensor can be inserted under the skin. The sensor stays in place with adhesive edges and may remain on the patient for up to two weeks, depending on the model. Blood glucose levels are automatically checked by the sensor, and these data can be linked to a smart device or receiver. Alarms may be set on the monitor for hyperglycemia or hypoglycemia, and historical data can be downloaded to share with providers for evaluation of glucose control. These metrics serve to minimize periods of hypoglycemia and increase time within normal blood glucose range.

Evidence-Based Practice: Continuous glucose monitoring is becoming more widely adopted in patients with type 1 diabetes, but adolescents with type 2 diabetes may benefit as well. In a small pilot study of adolescents and young adults with type 2 diabetes and hemoglobin A1C >7%, patients were given continuous glucose monitors to use over a 12-week period (Chesser et al., 2022). A majority of participants were using insulin as part of their treatment regimen. A statistically significant increase in patients' diabetes-related quality of life was observed, as measured by a validated survey. In subsequent focus groups, patients noted an increased awareness of their glucose levels, which motivated positive behavioral changes. Due to the small sample size of the study, glycemic benefits were not determined, but similar studies in adults demonstrate improvement in glycemic control. This is the first study in pediatric patients with type 2 diabetes to demonstrate the feasibility and assess the impact of continuous glucose measurement. Larger studies may elucidate other benefits in addition to quality-of-life improvement.

Other considerations

In addition to approval for treatment of T2DM, liraglutide can be utilized at higher doses for weight management in children and adolescents 12 years of age and older (ADA et al., 2022g). Patients must weigh at least 60 kg with an elevated BMI, corresponding to that of ≥30 kg/m2 in adults. For this indication, the dose is still initiated at 0.6 mg and titrated up, but it is titrated to a higher maximum dose of 3 mg (Lexicomp, 2022). Several small trials evaluated the efficacy of exenatide for treatment of pediatric obesity. Study results demonstrate modest reduction in BMI, but data are currently insufficient for approval for this indication (Ryan et al., 2021). Metformin has limited data for treatment of obesity as an adjunct therapy to lifestyle interventions. Studies included patients as young as 6 years, but data and efficacy are limited, so metformin is not routinely recommended for this indication in pediatric patients (Lexicomp, 2022).

The ADA guidelines address the option of metabolic surgery in adolescents with T2DM and severe obesity, defined as BMI >35 kg/m2 (ADA et al., 2022g). These patients must also have either uncontrolled glycemic values or serious comorbidities that persist despite optimization of lifestyle changes and pharmacologic therapy. Referral to a specialized team is required for evaluation and preparation for surgical management.

Self-Assessment Quiz Question #8

Julia is prescribed liraglutide in addition to her current diabetes regimen. Her mother is concerned about the risks of taking this medication. Which of the following adverse effects is/are most likely to occur?

a. Medullary thyroid carcinoma.
b. Constipation, diarrhea, and nausea.
c. Weight gain.
d. Anaphylaxis.

TYPE 2 DIABETES MELLITUS: PSYCHOSOCIAL BARRIERS TO SUCCESS

Education and empowering patients to self-manage their diabetes are key components of glycemic control and long-term success in management. The ADA recommends utilizing empowering language with patients and their families to encourage ownership over their chronic illnesses (ADA et al., 2022c). Although descriptive in assessing therapy compliance, common terms such as *nonadherence* and *noncompliance* infer passivity. Because disease control is highly dependent on self-management, these terms are not preferable when communicating with patients and can come across as judgmental. Facilitating communication via open-ended questions and empathy is key in optimizing motivation and identifying barriers to success. Patients should be continuously educated and assessed for psychosocial factors that limit nonpharmacologic and pharmacologic adherence.

Psychosocial care should be implemented for all patients with diabetes and integrated into each office visit (ADA et al., 2022d). Screening may include general quality-of-life questions to assess the patient's attitude toward the diagnosis, as well as inquiries about medication management. Providers should evaluate patients for symptoms of depression, anxiety, disordered eating, and diabetes-related distress. Lifelong management of diabetes presents emotional and financial stressors that may worsen life outlook and self-management of the disease. Poor emotional and psychosocial health can have a negative impact on glycemic control and clinical outcomes. Lack of motivation and psychological comorbidities may limit medication adherence, positive lifestyle habits, and long-term self-care. Interventions for psychosocial concerns, including referral to specialists, are demonstrated to improve HbA1C and other health-related outcomes.

A recent meta-analysis evaluated the prevalence of depression and anxiety among children with diabetes (Akbarizadeh et al., 2022). The analysis included 109 studies of more than 50,000 children with T1DM and T2DM. Among the children with T2DM, the prevalence of depression and anxiety was found to be 17.7%, and the prevalence of depression was 22.7%. Overall, the prevalence of depression tended to be higher among girls and in lower-middle-income countries.

In adult patients with T2DM, studies evaluated cognitive behavioral therapy and mindfulness interventions as a means of improving depression, anxiety, and glycemic control (Pinhas-Hamiel & Hamiel, 2020). These studies variably demonstrate improvement in one or more of those outcomes. Cognitive-behavioral therapy (CBT) aims to identify unconscious negative thoughts that are associated with events and affect moods and actions. The goal is to modify this association over time as a means of improving depression and other psychiatric disorders. Third-wave CBT similarly identifies these thoughts, but rather than changing them, aims to create distance that minimizes their effects on feelings and actions. Mindfulness interventions involve practicing awareness of negative thoughts and emotions without judgment while centering oneself in the present moment.

Very limited data exist regarding CBT and mindfulness in the pediatric T2DM population, and all published reports focus on ad-

olescent girls (Pinhas-Hamiel & Hamiel, 2020). In one study, participants were randomized to a CBT group or a health education group (Shomaker et al., 2016). After 6 weeks, adolescents in the CBT group with moderately elevated depressive symptoms had greater reductions in those symptoms compared to the health education group. These reductions were associated with improvements in insulin sensitivity. After 1 year of follow-up, patients in both groups had decreased depressive symptoms, but a majority of findings were not significantly different between the two groups (Shomaker et al., 2017). Another study demonstrated a reduction in eating in the absence of hunger in adolescent girls who endorsed higher levels of dispositional mindfulness (Annameier et al., 2018). These findings suggest that mindfulness practices may be an important skill in the management of diabetes and related psychosocial concerns.

Self-Assessment Quiz Question #9

At her endocrinology office visit, Julia is screened for symptoms of depression, anxiety, and other psychosocial concerns. She endorses sadness about her diabetes diagnosis as well as her difficulties with weight loss. Although these symptoms do not appear to be interfering with her adherence to therapy, she is interested in a referral for an intervention to help improve her depressive symptoms. Which of the following is the LEAST appropriate recommendation for Julia?

a. Referral to a psychiatrist.
b. Cognitive-behavioral therapy.
c. Mindfulness-based interventions.
d. Modification of therapy to an insulin-only regimen.

In addressing barriers to glycemic control, the patient's customs and culture may need to be incorporated into recommendations (ADA et al., 2022g). Balanced nutrition and healthy habits should be individualized to accommodate different cuisines and ethnic traditions. Providers may be biased in their recommendations based on their own upbringing, and standard interventions may not be feasibly incorporated into the lives of individuals from different cultural backgrounds. As an example, Native Americans are particularly prone to developing diabetes, and indigenous communities may differ regarding nutritional habits and wellness practices. Effective diabetes-related interventions in these communities involve traditional cooking classes, holistic health self-management programs, and storytelling with elder teachings and prayers (Bonin et al., 2022).

Evidence-Based Practice: Native Americans are a high-risk group for the development of type 2 diabetes. Eating fresh and nutritious food can aid in the prevention and management of diabetes, but resources are limited in some areas. Community gardening demonstrates improvement in physical activity, mental health, and access to fresh ingredients (Brown et al., 2020). A recent study evaluated the impact of a gardening program in a Native American community, which included the development of a gardening bed near the tribal diabetes clinic (Brown et al., 2020). The study found that growing food in traditional ways is of high importance to the group, and stakeholders felt positively about gardening together. The intervention demonstrated some improvement in psychosocial questionnaires, although these findings were not statistically significant. Authors attributed this to the short duration of the study and small sample size. Overall, gardening may be an effective community-based intervention to empower tribal groups to be active, stay connected, and eat nutritious food.

TYPE 2 DIABETES MELLITUS: FUTURE DIRECTIONS

Compared to adult patients with T2DM, pediatric patients currently have limited therapeutic options for management (Wu et al., 2022). Although recent approval of GLP-1 receptor agonists expanded the armamentarium for children and adolescents, the rising rates of diagnosis and limitations of current agents highlight the need for expanded treatment options. A recent systematic review and meta-analysis examined trials that reported safety and efficacy of medications used for children and adolescents with T2DM (Wu et al., 2022). A total of four clinical trials and eight published articles were included in the review. Medications studied, in addition to the four currently approved treatment options, included saxagliptin, linagliptin, sitagliptin, glimepiride, and dapagliflozin. Of the reviewed studies, the combination of saxagliptin plus metformin demonstrated the greatest reduction in HbA1C, although this conclusion is based on two clinical trials analyzing a total of 14 randomized patients. Saxagliptin is a dipeptidyl peptidase 4 (DPP-4) inhibitor currently approved for treatment of T2DM in adult patients (Lexicomp, 2022). This inhibition results in prolonged active incretin levels, which helps to regulate glucose homeostasis by increasing insulin synthesis and release while decreasing glucagon secretion. Most notable adverse events in the adult population are arthralgia, dermatologic and hypersensitivity reactions, and pancreatic events, including acute pancreatitis. There are also conflicting reports that saxagliptin may exacerbate underlying myocardial dysfunction. Additional safety and efficacy information in the pediatric population is required prior to approval and routine use.

Linagliptin and sitagliptin are also DPP-4 inhibitors approved for use in adult patients with T2DM (Lexicomp, 2022). Linagliptin was studied in a double-blind, randomized trial comparing two doses versus placebo (Tamborlane et al., 2018). The study demonstrated a dose-dependent reduction in mean HbA1C, which was noted to be 0.63% in the higher-dose group. The medication was well tolerated, but additional studies are needed in the pediatric population. Most recently, sitaglipin was evaluated in two studies, one in combination with metformin and one as monotherapy (Jalaludin et al., 2022; Shankar et al., 2022). Both studies demonstrated that sitagliptin was relatively well tolerated but did not provide significant improvement in glycemic control.

Glimepiride is a sulfonylurea, which stimulates release of insulin from pancreatic ß cells, reduces glucose output from the liver, and increases insulin sensitivity peripherally (Lexicomp, 2022). Due to this mechanism, glimepiride has the potential to cause hypoglycemia, similar to exogenous insulin. One study compared glimepiride to metformin in pediatric patients and found that it resulted in a similar HbA1C reduction with comparable safety (Gottschalk et al., 2007). Although these findings are promising, the authors concluded that a larger sample size and study of longer duration would be necessary prior to widespread use in children and adolescents. These subsequent studies have not yet been conducted.

Dapagliflozin, a sodium-glucose cotransporter 2 (SGLT2) inhibitor, was also recently studied in pediatric patients (Tamborlane, Laffel, et al., 2022). This medication and other SGL2 inhibitors are currently approved for use in adult patients with T2DM (Lexicomp, 2022). They work by reducing reabsorption of filtered glucose in the proximal renal tubules, which increases urinary excretion of glucose and decreases plasma glucose concentrations. Dapagliflozin can cause several adverse reactions related to this mechanism, including acute kidney injury, volume depletion, and genitourinary infection. Unfortunately, the phase 3 study of children and young adults did not demonstrate a significant reduction in HbA1C compared with placebo in the intent-to-treat analysis (Tamborlane, Laffel, et al., 2022). In a subgroup of patients who were protocol-compliant, a significant difference was observed; however, these data may need confirmation in larger studies. The most common adverse events observed were headache, nasopharyngitis, and vitamin D deficiency. Although 28% of participants in the dapagliflozin arm experienced hypoglycemia, many were also receiving insulin as part of their T2DM regimen.

Dulaglutide, another once-weekly GLP-1 receptor agonist, was recently studied in pediatric patients in a double-blind, placebo-controlled, randomized trial (Arslanian et al., 2022). At baseline, patients were treated with or without metformin or basal insulin therapy. After 26 weeks, mean HbA1C decreased by 0.9% in the higher-dose group. Reduction was significantly greater in the treatment arm versus the placebo group. Similar to the previously discussed pediatric-approved GLP-1 receptor agonists, gastrointestinal events were the most common adverse effects and were mostly transient. If approved, this medication may be a convenient alternative to currently available options.

Overall, many medications used in adult patients with T2DM do not have pediatric indications or data to support their use. Limited information is available from published phase 3 studies and clinical trials involving a sulfonylurea, DPP-4 inhibitors, and an SGLT2 inhibitor, but data are insufficient for approval. Expanded pediatric research is imperative to develop medications that are effective in the prevention and treatment of T2DM with favorable side effect profiles.

Conclusion

The prevalence of T2DM is on the rise in the pediatric population. While primary interventions should be aimed at preventing clinical disease, many patients progress from prediabetes to T2DM despite lifestyle modifications and a family-centered approach to physical activity, nutrition, and weight loss. Medications aimed at treating T2DM in children and adolescents include metformin, insulin, liraglutide, and exenatide. Additional treatment options are available for adults with T2DM and are undergoing study in pediatric patients, but currently the data are insufficient to support approval and routine use. Achieving and maintaining glycemic control while addressing psychosocial concerns is essential to improve quality of life and longevity in T2DM patients.

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PHARMACOLOGICAL MANAGEMENT: TYPE 2 DIABETES IN CHILDREN, 2ND EDITION

Self-Assessment Answers and Rationales

1. **The correct answer is B.**
Rationale: In type 2 diabetes mellitus, pancreatic ß-cell dysfunction is not an autoimmune- mediated process. The dysfunction is multifactorial and related to insulin resistance. Islet autoantibodies are an indicator of type 1 diabetes, regardless of other patient characteristics traditionally associated with type 2 diabetes. This is an important differentiator between the two diagnoses.

2. **The correct answer is D.**
Rationale: Hemoglobin A1C = 6.5% is a criterion for diabetes diagnosis. Since there are conditions that may impact the findings of this result, and Billy is not currently presenting with classic hyperglycemic symptoms, the diagnosis should be confirmed with a second test. Ideally, fasting blood glucose should be measured, or an oral glucose tolerance test should be performed to confirm elevated hemoglobin A1C findings

3. **The correct answer is A.**
Rationale: Microvascular complications include nephropathy, retinopathy, and neuropathy. All of these complications should be screened for upon or soon after diagnosis and annually thereafter if findings are normal. Other conditions associated with diabetes should also be screened for regularly, as indicated in Table 1.

4. **The correct answer is C.**
Rationale: The American Diabetes Association recommends at least 150 minutes of moderate-intensity physical activity to prevent progression from prediabetes to diabetes. Recommendations should be tailored to the patient's level of fitness so that the goals are realistic and achievable. In general, physical activity should serve to reduce sedentary time and promote healthy weight loss.

5. **The correct answer is D.**
Rationale: Metformin causes gastrointestinal symptoms in many patients, which may limit their tolerance of the medication. A strategy to mitigate this adverse effect is to start at a low dose and titrate weekly, as tolerated, to a higher dose. Symptoms usually resolve after consistent use over time, and patients should be encouraged to continue the medication if at first they experience diarrhea, nausea, or abdominal pain.

6. **The correct answer is B.**
Rationale: Insulin should be injected subcutaneously. Intramuscular injection may result in unpredictable absorption of insulin with subsequent fluctuations in blood glucose levels. The minimum length needle should be selected to avoid accidental injection into muscle.

7. **The correct answer is A.**
Rationale: Once-daily insulin injection is typically required for basal dosing of insulin. The desired effect can be achieved with a long-acting insulin, which does not have a significant peak and lasts for a duration of approximately 24 hours. Long-acting insulins are insulin glargine, insulin degludec, and insulin detemir.

8. **The correct answer is B.**
Rationale: Gastrointestinal symptoms are one of the most common adverse effects associated with liraglutide and other glucagon-like peptide-1 receptor agonists. Although there are many other adverse effects and potential risks, most are rare in otherwise healthy adolescents without a family history of medullary thyroid carcinoma. Gastrointestinal symptoms are most common soon after initiation and are dose-related. Patients may need to be maintained on a lower dose with slow titration if symptoms are intolerable.

9. **The correct answer is D.**
Rationale: Depression and anxiety are common among adolescents with type 2 diabetes. Screening is essential at each office visit, and intervention may help alleviate symptoms and indirectly improve glycemic control. Although evidence is limited in the pediatric population, the focus of existing studies is based on addressing the underlying psychosocial concern.

Modifying type 2 diabetes therapy to an insulin-only regimen does not demonstrate a benefit in depression and may increase the burden of management. Insulin-based regimens require multiple painful injections, increase the need for supplies and training, and put patients at risk for hypoglycemia. Although some patients may require insulin for glycemic control, other agents are preferred for individuals who are able to achieve a goal hemoglobin A1C without insulin.

Final Examination Questions

Select the best answer for each question and then proceed to **EliteLearning.com/Book** to complete your final examination.

76. Compared to adult-onset type 2 diabetes, pediatric patients' decline in ß-cell function is _____, and associated complications arise _____ in the disease course.
    a. Slower; later.
    b. Slower; earlier.
    c. Faster; later.
    d. Faster; earlier.

77. Which of the following is NOT a risk factor associated with the development of type 2 diabetes?
    a. History of celiac disease.
    b. Sedentary lifestyle.
    c. Native American ethnicity.
    d. History of polycystic ovary syndrome.

78. Which of the following symptoms is more closely associated with type 2 diabetes than type 1 diabetes?
    a. Unintentional weight loss.
    b. Acanthosis nigricans.
    c. Diabetic ketoacidosis.
    d. Polyuria.

79. Which of the following laboratory values does NOT meet American Diabetes Association criteria for diabetes diagnosis?
    a. Hemoglobin A1C = 8%.
    b. Fasting plasma glucose = 130 mg/dL.
    c. Hemoglobin A1C = 7%.
    d. Oral glucose tolerance test with 2-hour plasma glucose = 180 mg/dL.

80. An albumin-to-creatinine ratio would be helpful in screening for which of the following complications or diabetes-associated conditions?
    a. Hypertension.
    b. Nephropathy.
    c. Nonalcoholic fatty liver disease.
    d. Retinopathy.

81. Which of the following is an appropriate goal of therapy for a pediatric patient newly diagnosed with type 2 diabetes?
    a. 25% decrease in excess weight.
    b. Hemoglobin A1C < 6%.
    c. Average blood glucose < 154 mg/dL.
    d. 150 minutes of aerobic activity and strength training daily.

82. Nutritional therapy for type 2 diabetes should incorporate all of the following EXCEPT:
    a. Carbohydrate counting.
    b. Fresh fruits and vegetables daily.
    c. Sugar-free beverages.
    d. Regular, consistent meals.

83. A newly diagnosed type 2 diabetes patient presents with no symptoms but a hemoglobin A1C of 9%. Which of the following is appropriate initial pharmacologic therapy?
    a. Metformin only.
    b. Metformin and insulin.
    c. Metformin and liraglutide.
    d. Exenatide only.

84. Which of the following pharmacologic therapies for type 2 diabetes is dosed once weekly?
    a. Metformin.
    b. Insulin.
    c. Liraglutide.
    d. Exenatide.

85. Which of the following statements is FALSE regarding psychosocial concerns in the pediatric type 2 diabetes population?
    a. Depression and anxiety are common findings in patients with diabetes.
    b. All pediatric patients with diabetes should be referred to a psychiatrist for psychosocial management.
    c. Cognitive-behavioral therapy may be beneficial for adolescent girls with diabetes and depressive symptoms.
    d. Lifestyle interventions should be tailored to the patient's culture and social customs.

Course Code: RPUS03TT

Chapter 7: Prescribing Controlled Substances Safely: A DEA Requirement

8 CE Hours

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Author Disclosure: Humberto Reinoso and Colibri Healthcare, LLC do not have any actual or potential conflicts of interest in relation to this lesson.

Universal Activity Number (UAN): 0607-0000-23-008-H08-P
Activity Type: Knowledge-based
Initial Release Date: May 1, 2023
Expiration Date: May 1, 2026
Target Audience: Pharmacists in a community-based setting.
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Learning objectives

After completing this course, the learner will be able to:

- Differentiate among substance use disorders and associated concepts, including diversion.
- Examine the roles of the DEA, FDA, and HHS in scheduling-controlled substances and enforcing controlled substance laws and regulations.
  a. Controlled substance act.
- Differentiate the DEA Controlled Substance Schedules and prescribing regulations.
  a. DEA Controlled Substance Schedules.
  b. Schedules of a controlled substance (I, II, III, IV, V).
- Examine medical marijuana legislation.
- Describe essential considerations when prescribing controlled substances, including regulatory exceptions and clinical concerns.
  a. Nurse practitioners prescribing controlled substances: requirements.
  b. Integrative Therapies.
- Controlled substance prescribing practices.
  a. Prescription drug monitoring programs (PDMPs).
  b. Electronic prescribing of controlled substances (EPCS).
  c. Facsimile and oral prescriptions for Schedule II controlled substances.
  d. Schedules III-V controlled substance prescribing considerations.
  e. FDA warning for codeine- and hydrocodone-containing cough and cold products.
  f. Special considerations for nurse practitioners prescribing controlled substances.

Course overview

Nurse Practitioners (NPs), Physician Assistants (PAs), Pharmacists, and Dentists care for patients with disorders in many healthcare settings. Individuals may seek care for an acute illness or worsening of a chronic condition. Often, pain is the leading reason for seeking medical care. Appropriate prescribing practices are critical for all medications, but controlled substances require special attention. The Drug Enforcement Agency (DEA), the Food and Drug Administration (FDA), and the U.S. Department of Health and Human Services (HHS) all have a role in controlled medication schedules. Prescribers must understand federal and state requirements for all controlled substances. This course will provide a general review of federal and state-controlled substance regulations and the prescribing practices for controlled substances. Additionally, substance use disorders are complex phenomena affecting many lives. This course also reviews common substance use disorders, including alcohol, anxiolytics, stimulants, hallucinogens, and tobacco/vaping. However, the focus is on clinical safety considerations when prescribing non-cancer-related opioid medications for acute/chronic pain in adults.

INTRODUCTION

Substance use disorders are a significant public health problem with a wide range of negative effects on individuals' mental, physical, and social well-being. Mental health problems co-occurring with substance use disorders include depressive, anxiety, and psychotic disorders, as well as organic brain syndromes (American Psychiatric Association [APA], 2013). Substance use disorders share many of the same features but differ in pharmacology and associated behaviors that account for the unique effects of each substance (Boland & Verduin, 2022). Alcohol, opioids, central nervous stimulants, cannabinoids, and tobacco describe the phenomenon associated with substance disorders. The hallmark of substance use disorders includes cognitive, behavioral, and physiological symptoms of intoxication, withdrawal, and dependence (APA, 2013). Diagnosis is based on pathological patterns of substance use. All substances activate the same brain reward pathway via dopaminergic neurotransmission (Paxos & Teter, 2019).

NEUROBIOLOGY OF SUBSTANCE USE DISORDERS

Substance use disorders (SUDs) are complicated physiologic and psychologic disorders with multiple intersecting factors, such as drug use behaviors and poor judgment influenced by the pharmacodynamics and pharmacokinetic actions of the drug (Boland & Verduin, 2022). The central element of drug dependence is drug-using behavior. Drug use initiates a cascade of rewarding or aversive physical, psychological, and social consequences that determine the likelihood of subsequent use (Boland & Verduin, 2022).

The development and persistence of SUDs are primarily based on key components within the basal ganglia, amygdala (extended), and prefrontal cortex (U.S. Department of Health and Human Services [HHS], 2016). The basal ganglia and its subnetworks are responsible for reward, pleasure, and the formation of habitual substance use (HHS, 2016). The amygdala is responsible for uneasy feelings, anxiety, and withdrawal irritability. The prefrontal cortex is involved in executive function and exerts control over the individual's cognitive inability to reject substance use based on neurocircuitry, namely impulsivity and compulsivity (Stahl, 2020). These endophenotypes are found trans-diagnostically present across many psychopathologies.

Impulsivity causes the individual to act without forethought and with lack of reflection on previous behavior. Compulsivity is characterized by inappropriate actions which persist regardless of the situation (Stahl, 2020). Over time, impulsive substance use becomes compulsive addiction as this dysregulation becomes a dependent conditioned response. The impulses in the ventral loop of reward and motivation migrate dorsally because of neuroplasticity and engage in a *habit* system, creating the conditioned response of addiction (Stahl, 2020). Impulsive drug use produces a *high*, which, if experienced too often, cause the migration to compulsive use (addiction) to reduce the unpleasant effects of withdrawal. The mesolimbic pathway is hypothesized to be the final common pathway of reward and reinforcement in the brain, where all addictive drugs increase dopamine, especially with habitual use (Stahl, 2020; Wise & Jordan, 2021). Arising in the ventral tegmental area (VTA), it projects into the nucleus accumbens (NA) and prefrontal cortex (PFC).

The psychology of substance use disorders reflects psychodynamic theories dating back 100 years (Boland & Verduin, 2022). Disturbed ego functions, self-medication, and *alexithymia* (inability to describe feelings) are common among substance users. Aside from pharmacologic effects, positive reinforcement is gained from paraphernalia and associated behaviors with drug use (Boland & Verduin, 2022). Conditioned responses (similar to Pavlovian phenomena), such as cravings and withdrawal, promote relapsing behaviors (Boland & Verduin, 2022). Individuals aged 18-24 years have a high prevalence rate for every substance disorder.

Implicit bias and stigma in substance use disorders

The language used by clinicians, such as *addicts*, can stigmatize individuals with substance use disorders reflecting misconceptions that these behaviors are choices rather than compulsions (NIDA, 2022). Negative biases can dehumanize individuals and affect the therapeutic alliance, and, ultimately, the course of recovery (NIDA, 2022). Clinicians who stereotype drug use as a criminal activity marginalize disadvantaged groups and negatively influence treatment plans, which may increase drug use (NIDA, 2022.) Stigma and implicit biases impact fear of disclosing substance use, decreased quality of care, or reduced access to care (NIDA, 2022). To this end, the word addiction has been eliminated from the *DSM-5® (Diagnostic and Statistical Manual of Mental Disorders*, 5th ed.) in favor of the more neutral term *substance use disorder* (APA, 2013).

Healthcare Considerations: Every member of our community may help to lessen stigma and prejudice against those who suffer from drug use disorders by:

- Understanding substance use disorders are chronic, treatable medical conditions.
- Changing stigmatizing language with more empowering, preferred language that does not equate people with their condition or have negative connotations.
- Addressing systemic racism, sexism, and other forms of discrimination leads to multiple layers of stigma for many people with addiction. (NIDA, 2022)

Risk factors for substance use disorders

Adult risk factors for substance use disorders include the following:

- Ability to afford drugs.
- Avoidant coping style.
- Bereavement.
- Caucasian ethnicity,
- Chronic pain.
- Chronic physical illness/comorbidity.
- Physical disabilities or reduced mobility.
- Transitions in care/living situations.
- Poor health status.
- Significant drug burden/polypharmacy.
- Unexpected or forced retirement.
- Social isolation (living alone or with nonspousal others).
- History of alcohol problems.
- Previous or concurrent substance use disorder.
- Previous or concurrent psychiatric illness.

(Kuerbis, 2020)

Evaluating Substance Use Disorder (Abbreviated)		
Instrument	**Purpose**	**Interpretation**
Addiction Severity Index	• Assessment tool. • The clinician administers the semi-structured interview.	• 200 items, normed national data.
Alcohol Use Disorders Identification Test (AUDIT) **Alcohol Use Disorder Identification Test-Consumption (AUDIT-C)**	• Screening tool. • Clinician/self-administered. • Evaluates the quantity and frequency of drinking.	• 10 items.
Cage Questionnaire	• Screening tool. • Clinician/self-administered. • Identifies the presence of problematic drinking.	4 items: • positive score ≥ 2.
Clinic Institute Withdrawal Assessment-Alcohol Revised (CIWA-Ar)*	• Assessment tool. • Clinician administered. • *Gold standard for alcohol withdrawal assessment.	10 items: • <10, mild withdrawal. • 10-18, moderate withdrawal. • >18 severe withdrawal.
Clinical Opiate Withdrawal Scale (COWS)	• Assessment tool. • Clinician administered. • Used to follow the course of opiate withdrawal and effectiveness of medication regimen-no standard cutoff.	• 5-12 mild withdrawal. • 13-24 moderate withdrawal. • 25-36 moderately severe withdrawal. • >36 severe withdrawal.
Screening, brief intervention, and referral to treatment (SBIRT)	• Comprehensive, integrated public health approach to early intervention and treatment for persons with or at risk for substance use disorders.	• Universal screening. • 5-10 minutes. • Scored low to severe risk. • Achieved at moderate risk; brief intervention implemented. • For use in alcohol, tobacco with growing evidence of illicit drug use.
Note. Paxos & Teter, 2019; SAMSHA, 2022.		

SUBSTANCE USE INTOXICATION

Substance intoxication is associated with and without substance use disorders. The most common changes with intoxication include disturbances in wakefulness, attention, thinking, judgment, psychomotor, and interpersonal behaviors (APA, 2013). Specific routes of administration produce rapid absorption into the bloodstream, escalating intoxication effects and likelihood of patterns of use. Intoxication often begins in the teens and is the first substance-related experience. Withdrawal is usually, but not always, associated with substance use disorders but can occur at any age. Short-acting substances have a higher potential for withdrawal than longer-acting substances. The substance's half-life parallels withdrawal (APA, 2013).

Diagnosing substance use disorders

Substance use disorders occur from mild to severe, based on symptomology and fluctuation of the disease process (APA, 2013). Individuals demonstrate a problematic pattern of substance use that leads to significant impairment as manifested by two or more criteria over 12 months for substance use disorder:

- Substance taken in more significant amounts over a more extended period than was intended.
- Persistent desire or unsuccessful efforts to cut down or control the use of the substance.
- A great deal of time spent in activities to obtain the substance.
- Craving or strong desire to use the substance.
- Recurrent substance use failing to fulfill significant role obligations at work, school, or home.
- Continued substance use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the substance.
- Important social, occupational, or recreational activities are given up or reduced because of substance use.
- Recurrent substance use in situations in which it is physically hazardous.
- Continued substance use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by substance.
- Tolerance:
  - A need for markedly increased amounts of the substance to achieve intoxication or desired effect.
  - A markedly diminished effect with continued use of the same amount of the substance.
- Withdrawal:
  - The characteristic substance withdrawal syndrome.
  - The substance is taken to relieve or avoid the withdrawal symptoms.

(Levin et al., 2014)

Individuals who demonstrate a chronic loss of control or compulsive use of substances and a wide range of adverse risks (mental, physical, and social well-being) meet the criteria for substance-related disorders (Boland & Verduin, 2022). Standardized screening is important to determine the stage of substance use, consequences, and functional impairment (Paxos & Teter, 2019).

Alcohol addiction is a chronic relapsing disorder associated with compulsive drinking (NIAAA, 2021). Alcohol use is a common disorder defined by a cluster of behavioral and physical symptoms and can include withdrawal, tolerance, and craving (APA, 2013). Approximately 69.5% of ages 18 and older reported drinking alcohol in the past year, with 59.4% in the last month (NIAAA, 2022). Alcohol is a potent drug that causes physiological changes in almost every body system. The severity of the disorder is based on the number of diagnostic criteria in a given individual, along with changes in the severity of alcohol use across time, reflected by reductions in the frequency of alcohol consumed (APA, 2013). Alcohol use disorder has a variable course characterized by remissions and relapses (APA, 2013). Alcohol use disorder is associated with increased risks of accidents, violence, and suicide (APA, 2013). Severe alcohol use is associated with comorbid conditions such as depression or other disinhibitions of feelings which contributes to suicide attempts as well as completed suicides (APA, 2013). Other disorders associated with alcohol use disorders include psychosis, bipolar disorders, anxiety disorders, sleep disorders, and neurocognitive disorders (Levin et al., 2013).

Addiction cycle in alcohol use disorder

Alcohol consumption is linked to health and social consequences interfering in personal relationships, heart and liver disease, cancer, motor vehicle collisions, and violence (NIAAA, 2021). The powerful effects on the brain account for euphoria and pleasurable feelings, increasing the motivation to use substances despite the risk of harm (HHS, 2016). The addiction cycle is based on three concepts: (1) binge/intoxication, (2) withdrawal/negative effects, and (3) preoccupation/anticipation (NIAAA, 2021). Individuals may experience all stages during the day, over weeks or months:

- **Binge/intoxication stage** is when an individual experiences a rewarding experience, including euphoria, anxiety reduction, and easing of social interactions. Repeat activation of the basal ganglia reinforces the likelihood of repeated consumption through motivation and routine behaviors. The repeated activation of the basal ganglia changes the way an individual responds to stimuli, which triggers powerful urges to consume the substance over time (NIAAA, 2021).
- **Negative affect/withdrawal stage** occurs when an individual stops drinking and withdrawal symptoms occur. These symptoms can be physical (sleep disturbances, pain, and ill feelings) or emotional (dysphoria, irritability, anxiety, and emotional pain). Negative feelings associated with alcohol withdrawal come from two sources. Diminished activation in the reward system makes it difficult to experience the euphoria associated with everyday living. Increased activation of brain stress contributes to anxiety, irritability, and unease (NIAAA, 2021). The individual consumes alcohol to escape the lows of chronic alcohol use.
- **Pre-occupation/anticipation** stage occurs when an individual seeks alcohol after abstinence. This stage can be triggered by various factors such as stress, social situations, or environmental associated with previous substance use. These triggers can create a psychological and physiological response in the brain, leading to a strong urge to use alcohol. The prefrontal cortex, responsible for executive function, is compromised in alcohol use disorder (NIAAA, 2021).

Alcohol intoxication

Alcohol intoxication usually develops over minutes to hours and lasts about several hours (APA, 2013). The first episode of alcohol intoxication likely occurs in the mid-teens, but alcohol use disorder is not identified in the late teens or early 20s. The essential feature of alcohol intoxication is the presence of behavioral or psychological changes, including inappropriate sexual or aggressive behavior, mood lability, impaired judgment, and levels of incoordination that may interfere with the performance of usual activities (APA, 2013). The degree of intoxication increases with the blood alcohol concentration, especially when combined with other sedation producing substances (APA, 2013).

Blood Alcohol Concentrations (BAC) with Impairment	
20-30 mg/dL	Slowed motor impairment with decreased thinking ability.
30-80 mg/dL	Increased motor and cognitive problems.
80-200 mg/dL	Incoordination and judgment errors with deterioration in cognition.
200-300 mg/dL	Nystagmus, slurred speech, and blackouts.
>300 mg/dL	Impaired vital signs and possible death.

If an individual lacks significant impairment at 150 mg/dL pharmacodynamic tolerance may be present (Boland & Verduin, 2022). Repeated alcohol intoxication can predispose individuals to depressed immune function leading to repeated infections and some cancers (APA, 2013).

Blackouts

Blackouts are identified as anterograde amnesia (the inability to form new memories while under the influence of alcohol) occurring with alcohol intoxication. During blackouts, individuals' remote memory remains intact but short-term memory is deficient. Likely, the hippocampus and temporal lobe structures are affected. Intellectual faculties remain intact, and the individual can perform complicated tasks. It's important to note that blackouts are not the same as passing out, which occurs when a person loses consciousness due to alcohol intoxication.

Alcohol withdrawal

The decision to stop drinking is usually in response to a crisis followed by weeks of abstinence and then controlled nonproblematic drinking (APA, 2013). However, consumption escalates rapidly, and severe problems likely occur (APA, 2013). Individuals will often continue consumption to decrease the unpleasant side effects of withdrawal. A repetitive and intense use pattern develops, and individuals spend time consuming alcohol (APA, 2013).

Alcohol withdrawal can be severe, including seizures and autonomic hyperactivity (diaphoresis, tachycardia). The classic sign of alcohol withdrawal is tremulousness (Boland & Verduin, 2022). Other withdrawal symptoms include nausea; vomiting; insomnia; transient visual, tactile, and auditory hallucination or illusions; psychomotor agitation; anxiety; and seizure (APA, 2013). The estimated progression of alcohol withdrawal symptoms is presented here:

Progression	Symptoms	Time to Presentation
Mild	Tremulousness.	6-8 hours.
Moderate	Perceptual disturbances.	8-12 hours.
Severe	Seizures.	12-24 hours.
Life Threatening	Delirium tremens.	Within 72 hours.
Note. Boland & Verduin, 2022.		

Withdrawal seizures

Alcohol withdrawal produces generalized tonic-clonic seizures, but status epilepticus is rare (Boland & Verduin, 2022). Long-term alcohol use can produce hypoglycemia, hyponatremia, and hypomagnesemia, which also produces seizures (Boland & Verduin, 2022).

Delirium

Although confusion and changes in the level of consciousness are not criteria for alcohol withdrawal, delirium may occur. Individuals with delirium are dangerous to themselves and others (Boland & Verduin, 2022). Delirium tremens occurs on the third day after reduction or cessation of alcohol and has a mortality

of 20% if left untreated. Individuals demonstrate confusion, disorientation, hallucinations, delusions along with autonomic hyperactivity, anxiety, and fluctuating levels of psychomotor activity (Boland & Verduin, 2022).

Alcohol induced disorders

Wernicke encephalopathy (alcoholic encephalopathy) is characterized by ataxic gait, vestibular dysfunction, confusion, horizontal nystagmus, lateral orbital palsy, and gaze palsy (Boland & Verduin, 2022). The condition is reversible but may progress to Korsakoff syndrome (Boland & Verduin, 2022). Korsakoff syndrome is a chronic amnestic syndrome that follows Wernicke encephalopathy (Boland & Verduin, 2022). The main feature is anterograde amnesia, with possible confabulation (Boland & Verduin, 2022). Thiamine deficiency is the pathophysiologic between these two syndromes (Wernicke-Korsakoff syndrome) (Boland & Verduin, 2022). Thiamine is involved in the conduction of axon potential and synaptic transmission (Boland & Verduin, 2022).

Antidipsotropic medications

- **Acamprosate** is the most effective medication for maintaining abstinence in alcohol use disorder (France, 2022). Acamprosate is thought to target GABA and N-methyl-D-aspartate glutamatergic receptor activity, thereby decreasing cravings and relapse (France, 2022). The individual must be alcohol-free at initiation and is contraindicated in severe renal disease. Side effects include diarrhea and nausea. Dosing is weight based, and titration is not required (Mariani, 2014).
- **Disulfiram** is a second-line treatment to treat individuals who are dependent on alcohol but are motivated to discontinue use (Stokes & Abdijadid, 2022). Alcohol consumption increases serum acetaldehyde causing diaphoresis, palpitations, facial flushing, nausea, vertigo, hypotension, and tachycardia. These symptoms are known as *disulfiram-alcohol reaction* and discourage alcohol intake (Stokes & Abdijadid, 2022). Side effects include headache, skin rash, drowsiness, and metallic aftertaste; adverse reactions include hepatitis and peripheral neuropathy.
- **Naltrexone** is a first-line treatment for alcohol and opioid dependence by blocking the μu receptor (Singh & Saadabadi, 2022). Additionally, naltrexone also modifies the hypothalamic-pituitary-adrenal axis to suppress alcohol consumption (Singh & Saadabadi, 2022). Absorption is almost complete after administration but has an extensive first pass effect. Nausea and abdominal pain are common. Caution is needed in hepatic and renal impairment.

Healthcare Considerations: Delirium tremons should be considered a medical emergency and can be fatal if not managed. The best-validated tool to assess the severity of alcohol withdrawal is the Clinical Institute Withdrawal Assessment for Alcohol, Revised (CIWA-Ar). The main treatment objectives for alcohol withdrawal are controlling agitation, lowering seizure risk, and reducing morbidity and mortality. Benzodiazepines are the first-line treatment for all alcohol withdrawals. Barbiturates are used for those patients who are refractory to benzodiazepines. Propofol in conjunction with benzodiazepines could be used in patients refractory to barbiturates; however, this would require mechanical ventilation (Hoffman & Weinhouse, 2023).

ANXIOLYTICS OR SEDATIVE-HYPNOTIC RELATED DISORDERS

Sedative hypnotics are among the most commonly prescribed psychoactive drugs by clinicians in primary care (Ehrlich, 2022). These drugs are frequently taken orally to obtain a steady intoxicated state. Individuals with sedative-hypnotic or anxiolytic use disorders are frequently treated in the outpatient setting, as the overall stability requires less monitoring. Sedative drugs decrease activity diminishes excitement, and calm the individual (Mihic & Mayfield, 2023). Sedatives are often used to alleviate unwanted side effects of other substances (APA, 2013). Hypnotic drugs produce drowsiness and facilitate the onset and maintenance of sleep that resembles electroencephalography where the individual is easily aroused (Mihic & Mayfield, 2023).

The usual course of these disorders begins in the teens or 20s, with social patterns, moving into daily use with high tolerance levels (APA, 2013). A less frequent pattern begins with prescription use and reports of anxiety, insomnia, or other complaints (APA, 2013). Individuals demonstrating a problematic pattern of substance use that leads to significant impairment as manifested by two or more criteria over a 12-month period meet the criteria for sedative, hypnotic, or anxiolytic use disorder:

1. Sedatives, hypnotics, or anxiolytics often taken in larger amounts or over a longer period than was intended.
2. A persistent desire or unsuccessful efforts to cut down or control sedative, hypnotic, or anxiolytic use.
3. A great deal of time spent in activities necessary to obtain the sedative, hypnotic, or anxiolytic or to use, or recover from the sedative, hypnotic, or anxiolytic.
4. Craving or a strong desire or urge to use the sedative, hypnotic, or anxiolytic.
5. Recurrent sedative, hypnotic, or anxiolytic use resulting in a failure to fulfill major role obligations at work, school, or home.
6. Continued sedative, hypnotic, or anxiolytic use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of sedative, hypnotic, or anxiolytic.
7. Important social, occupational, or recreational activities are given up or reduced because of sedative, hypnotic, or anxiolytic.
8. Recurrent sedative, hypnotic, and anxiolytic use in situations in which it is physically hazardous (driving, operating machinery).
9. Sedative, hypnotic, or anxiolytic use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the sedative, hypnotic, or anxiolytic.
10. Tolerance:
    a. A need for markedly increased amounts of the sedative, hypnotic, or anxiolytic to achieve intoxication or desired effect.
    b. A markedly diminished effect with continued use of the same amount of sedative, hypnotic or anxiolytic.
11. Withdrawal:
    a. Characteristic withdrawal syndrome.
    b. Sedatives, hypnotics, or anxiolytics are taken to relieve or avoid withdrawal symptoms.

(APA, 2013)

Benzodiazepines (BZDs) are one of the most widely prescribed drug classes in the United States, known for depressant effects on the central nervous system (Edinoff et al., 2021). BZDs are Federal Drug Administration (FDA) indicated for anxiety disorders, insomnia, acute status epilepticus, induction of amnesia, spastic disorders, and agitation (Edinoff et al., 2021). Non-FDA-approved indications include Tourette's syndrome, delirium, delirium tremens, sleep disorders, and abnormal medication movements (Edinoff et al., 2021).

Barbiturates were popular before the introduction of benzodiazepines. Pentobarbital and secobarbital have short half-lives and are lethal, producing coma and death. Barbiturates produce profound respiratory depression, especially when added to another substance. These drugs are not widely utilized. Individuals with sedative-hypnotic or anxiolytic disorders are frequently treated in the outpatient setting as the overall stability requires less monitoring.

FDA Approved Benzodiazepines		
Generic	**Trade**	**Indication**
Alprazolam	Xanax	Anxiety, panic disorders, agoraphobia.
Chlordiazepoxide	Librium	Alcohol withdrawal syndrome.
Clonazepam	Klonopin	Panic disorder and agoraphobia; myoclonic and absence seizures.
Quazepam	Doral	Chronic insomnia.
Temazepam	Restoril	Onset and sleep maintenance in insomnia.
Diazepam	Valium	Alcohol withdrawal management.
Lorazepam	Ativan	Anxiety disorders.
Midazolam (in-patient)	Versed	Procedural sedation.
Triazolam	Halcion	Sleep onset in insomnia.
Note. Bounds & Nelson, 2022.		

Non-benzodiazepines including zolpidem, zaleplon, and eszopiclone (Z-drugs) have clinical effects similar to BZDs but are more prone to misuse and dependence (Borland & Verduin, 2022).

Anxiolytics or sedative-hypnotic drugs can be viewed on a continuum based on sedating properties of the class. Physical and psychological dependence does occur, and all these drugs have withdrawal symptoms. Alcohol with other drugs in this class has additive effects (Boland & Verduin, 2022). The essential features of this drug class are maladaptive behavioral or psychological changes. Memory impairment causes anterograde amnesia similar to *blackouts* (Boland & Verduin, 2022).

Sedative, hypnotic, or anxiolytic intoxication
Low doses of sedative, hypnotic, or anxiolytic drugs can lead to intoxication during or shortly after use. Clinically maladaptive behavior or psychological changes can lead to:

- Drowsiness or sedation.
- Slurred speech.
- Incoordination.
- Unsteady gait.
- Nystagmus.
- Impaired cognition.
- Stupor or coma.

Healthcare Considerations: In an emergency setting, treatment for benzodiazepine and barbiturate intoxication is primarily supportive. In cases of severe benzodiazepine intoxication, particularly if the patient is becoming hypoxic, flumazenil may be administered (Jahan & Burgess, 2022).

Sedative, hypnotic, and anxiolytic withdrawal
The severity of withdrawal varies with dose and duration; however, it can occur with short-term, relatively low dose BZDs (Boland & Verduin, 2022). Withdrawal symptoms include:

- Autonomic hyperactivity (diaphoresis, tachycardia).
- Hand tremors.
- Insomnia.
- Nausea/vomiting.
- Transient visual, tactile, or auditory hallucinations.
- Psychomotor agitation.
- Anxiety.
- Grand mal seizures.

Deprescribing benzodiazepines is an important clinical skill and the first goal of treatment in detoxification (Drugs.com, 2022). Certain individuals may not require long term BZDs. When deprescribing BZDs, consider duration of treatment, dose, and half-life of the BZD. Consider a taper over several weeks or months. Often switching to a long-acting BZD is an effective method in an individual who has serious abuse problems. Tapering is effective in cases of long active benzodiazepines, but not as effective in short-acting benzodiazepines. Example: An individual who has been taking a BZD for 12 weeks, taper for 10-25% per week (PsychDB, 2021).

Common adverse effects of BZDs include respiratory arrest, drowsiness, confusion, headache, syncope, nausea/vomiting, diarrhea, and tremors (Bounds & Nelson, 2022). Central nervous system (CNS) adverse effects include euphoria, diplopia, ataxia, and cognitive impairment with long-term use. BZDs are contraindicated in angle-closure glaucoma and have a black box warning with concomitant use of opioids, which leads to severe respiratory depression, coma, and death (Bounds & Nelson, 2022).

Several groups are at high risk for abuse; caution is essential when prescribing. Individuals who consume large amounts of alcohol often present for treatment of anxiety and insomnia, and there is a high likelihood of abuse (Ciraulo, 2014). Polysubstance use frequently involves benzodiazepines, especially in methadone clinics. Individuals self-medicate for insomnia, anxiety, and withdrawal; additionally, benzodiazepines increase hedonistic effects of methadone (Ciraulo, 2014). Older individuals utilize benzodiazepines more than younger individuals. The greatest concern in this population is risk of falls and cognitive impairment and is not recommended according to *Beers' Criteria* (Ciraulo, 2014).

STIMULANT RELATED DISORDERS

Stimulant use disorders include a range of issues related to illicit cocaine, methamphetamine, ecstasy, as well as prescription stimulants, including methylphenidate and amphetamine. Approximately 5 million individuals misused prescription amphetamines ages 12 and older (CDC, 2020). Stimulant use and disorders are associated with physical, psychological, and societal harm. Acute adverse effects can cause acute conditions, including tachycardia, vasoconstriction, and bronchodilation, as well as hyperthermia. Psychological and neurological effects include panic attacks, hostility, paranoia, psychosis, and even violent behavior (SAMSHA, 2020). The *highs* and *lows* from these drugs create a *binge and crash pattern* (NIDA, 2019). Chronic stimulant use can alter brain structures with decreased attention span, confusion, impaired memory, inhibited impulse, and reduced motor skills (SAMSHA, 2020).

Stimulant Drugs by Schedules	
Schedule I	Aminorex; methyl-aminorex; methcathinone, animal use only (3,4-Methylenedioxymethamphetamine) commonly known as MDMA.
Schedule II	Amphetamines, dextroamphetamine; methamphetamine, methylphenidate; phentermine, cocaine.
Schedule III	Clortermine, not currently in use Phendimetrazine, weight loss; benzphetamine, weight loss.
Schedule IV	Diethylpropion, weight loss; Modafinil.
Schedule V	Pyrovalerone.

Cocaine is a naturally occurring alkaloid obtained from the *Erythroxylon* coca shrub (Holstege et al., 2021). After its first use by ancient Peruvians, Freud later proposed cocaine to treat depression, asthma, and cachexia (Holstege et al., 2021). Today, cocaine has limited medical use but is widely used as an illicit drug through inhalation (snorting) and other routes. When snorted, the onset of

action is within 5 minutes and typically peaks within 30 minutes. The half-life of cocaine is 30-90 minutes, and it can be absorbed across any mucosal surface, including respiratory, gastrointestinal, and genitourinary tracts (Holstege et al., 2021).

The drug has numerous adverse health effects on all organ systems (Holstege et al., 2021). Cocaine increases dopamine in the brain, reinforcing drug-taking behaviors that are desensitized over time. Individuals with cocaine use present with many different symptoms. Physical effects of cocaine include constricted blood vessels, dilated pupils, increased body temperature, tachycardia, tremors, or restlessness (NIDA, 2020).

Methamphetamine is a highly addictive psychostimulant chemically related to amphetamine. In the central nervous system, amphetamines block presynaptic reuptake of catecholamines, such as dopamine and norepinephrine, causing hyperstimulation at selected postsynaptic neurons (Richards, 2023). Other non-catecholaminergic central and nervous pathways are hyperstimulated. CNS dopaminergic alterations cause changes in mood, excitation, motor and sensory movements, and appetite. Serotonin contributes to mood changes and psychotic and aggressive behavior (Richards, 2023). This drug is inexpensive and readily synthesized from cheap chemicals, such as pseudoephedrine, anhydrous ammonia, red phosphorus, and hydrochloric acid (Richards, 2023) Snorting or smoking methamphetamine causes excessive tooth and gum disease (meth mouth); snorting methamphetamine causes anosmia and deviated septum; smoking this drug causes lung and airway damage (SAMSHA, 2020).

MDMA is commonly known as ecstasy *(*E or X*)* and is derived from methamphetamine. MDMA is an indirect sympathomimetic that stimulates the release and inhibits the reuptake of epinephrine, norepinephrine, and dopamine. MDMA can cause tachycardia, elevated blood pressure, mydriasis, increased energy, anorexia, and increased concentration (Preda, 2018). Adverse effects can include nausea, diaphoresis, anorexia, tremors myoclonus, tics, paresthesia nystagmus, hyperreflexia, hypertension, urinary retention, and ataxia (Preda, 2018).

Individuals exposed to these stimulants can develop stimulant use disorder within one week (APA, 2013). Individuals demonstrating a problematic pattern of substance use that leads to significant impairment as manifested by two or more of the following over a 12-month period meet the criteria:

- The stimulant is taken in larger amounts than intended.
- There is a persistent desire or unsuccessful efforts to cut down or control stimulant.
- A great deal of time is spent in activities to obtain the stimulant.
- Craving is an urge to use the stimulant.
- Recurrent stimulant use results in a failure to fulfill work and home obligations.
- Stimulant use continues despite persistent or recurrent interpersonal problems.
- Important social, occupational, or recreational activities are given up or reduced due to stimulant use.
- Recurrent stimulant use occurs in situations when physically hazardous.
- Stimulant use is continued despite the knowledge of having physical or psychological problems that may have been caused or exacerbated by the stimulant.
- Tolerance develops:
  - A need for increased amounts of the stimulant to achieve intoxication.
  - Diminished effect with continued use of the same amount of the stimulant.
- Withdrawal occurs:
  - Characteristic withdrawal syndrome for stimulant.
  - The stimulant is taken to relieve or avoid the withdrawal.

(APA, 2013)

Stimulant intoxication

As in other situations, behavioral and psychological changes occur in stimulant intoxication. Auditory hallucinations or paranoid ideations may be prominent (APA, 2013). Signs and symptoms of intoxication develop during or shortly after use, including:

- Tachycardia or bradycardia.
- Pupillary dilation.
- Elevated or lowered blood pressure.
- Perspiration or chills.
- Nausea or vomiting.
- Evidence of weight loss.
- Psychomotor agitation or retardation.
- Muscular weakness, respiratory depression, chest pain, or cardiac arrhythmias.
- Confusion, seizures, dyskinesias, dystonias, or coma.

Stimulant intoxication is not a criterion for substance use disorder (APA, 2013). A specific antidote does not exist; therefore, activated charcoal is warranted in this situation. Otherwise, supportive treatment is prescribed in the case of an overdose.

Stimulant withdrawal

The essential feature of stimulant withdrawal is characterized by the development of dysphoria along with:

- Fatigue.
- Vivid or unpleasant dreams.
- Insomnia or hypersomnia.
- Increased appetite.
- Psychomotor retardation or agitation.

Bradycardia is often present and can be a measure of withdrawal (APA, 2013). Additionally, anhedonia and drug craving can also be present. Withdrawal lasts up to 1-3 weeks. Pharmacotherapeutics utilized in withdrawal include trazodone, benzodiazepines, and neuroleptics as part of a comprehensive treatment plan (Preda, 2018).

HALLUCINOGEN RELATED DISORDERS

A long history of using hallucinogenic plants exists among humans for ceremonial and religious purposes. It is difficult to define psychoactive drugs that are so diverse in chemical structures. Hallucinogens are a group of drugs that alter an individual's awareness of surroundings, emotions, and thoughts. Despite their name, hallucinogens do not consistently cause hallucinations (Forrest, 2020). These are divided into two categories, including classic hallucinogens and dissociative drugs.

Classic hallucinogens

Common *classic* hallucinogens include the following:

- **D-lysergic acid diethylamide (LSD)** is one of the most potent mind-altering chemicals. Theis clear or white odorless substance is derived from a fungus that grows on rye or grains (NIDA, 2019).
- **Psilocybin** originates from mushrooms in tropical and subtropical regions of South America, Mexico, and the United States (NIDA, 2019).
- **Peyote (mescaline)** is a small, spineless cactus with mescaline as its main ingredient (NIDA, 2019).
- **DMT (N,N-dimethyltryptamine)** is a powerful chemical found in plants in the Amazon. Ayahuasca is a tea from these plants, called *hoasca*, *aya*, and *yagé* (NIDA, 2019).
- **251-NBOMe** is a synthetic hallucinogen similar to LSD and MDMA but much more potent.

Classic hallucinogens temporarily disrupt communication through the brain and spinal cord (NIDA, 2019). Additionally, some interfere with serotonin, which regulates mood, sensory perception, sleep, hunger, body temperature, sexual behavior, and intestinal muscle control (NIDA, 2019). These hallucinogens cause individuals to see images, hear sounds, and feel sensations that seem real, which generally begin within 20-90 minutes and can last from 15 minutes to 12 hours. These are commonly referred to as a trip by the individual. The short-term effects can range from tachycardia and nausea to seeing intense colors and changes in the

sense of time (NIDA, 2019). Other short-term effects of hallucinogens include increased blood pressure, tachypnea, hyperthermia, loss of appetite, dry mouth, spiritual experiences, relaxation, uncoordinated movements, excessive sweating, panic, paranoia, psychosis, and bizarre behaviors (NIDA, 2019). Long-term effects include persistent psychosis and hallucinogen persistent perception disorder, which are also evident in individuals with mental illness (NIDA, 2019).

Dissociative hallucinogens

Common *dissociative* drugs include the following:

- **PCP (phencyclidine)** was developed as a general anesthetic but is no longer used because of serious side effects. Now it is found in a variety of forms.
- **Ketamine** is a dissociative anesthetic for animals and humans. Unfortunately, much of it is obtained illegally from veterinary offices. This is also used as a *date rape drug* (NIDA, 2019).
- **Dextromethorphan (DXM)** is an over-the-counter cold and cough medicine.
- **Salvia** is a plant common to southern Mexico and Central and South America. This drug is ingested by chewing fresh leaves and drinking the extracted juice.

Dissociative hallucinogens interfere with glutamate, which regulates pain perception, environmental response, emotion, and learning and memory (NIDA, 2019). Dissociative drugs can cause numbness, disorientation, loss of coordination, hallucinations, and increased blood pressure, heart rate, and body temperature; long-term effects cause speech problems, memory loss, weight loss, anxiety, and depression or suicidal thoughts (NIDA, 2019). PCP can be addictive.

Individuals demonstrating a problematic pattern of substance use which leads to significant impairment as manifested by two or more of the following over a 12-month period meet the criteria for a hallucinogen use disorder (PCP):

- PCP is taken in larger amounts than intended.
- There is a persistent desire or unsuccessful efforts to cut down or control PCP.
- A great deal of time is spent in activities to obtain PCP.
- Craving is an urge to use PCP.
- Recurrent PCP use results in a failure to fulfill work or home obligations.
- PCP use is continued despite persistent or recurrent interpersonal problems.
- Important social, occupational, or recreational activities are given up or reduced due to stimulant use.
- Recurrent PCP use occurs in situations when physically hazardous.
- PCP use is continued despite the knowledge of having physical or psychological problems that may have been caused or exacerbated by PCP.
- Tolerance develops:
  - A need for increased amounts of PCP to achieve intoxication.
  - Diminished effect with continued use of the same amount of the stimulant.
- Withdrawal occurs:
  - Characteristic withdrawal syndrome for PCP.
  - PCP taken to relieve or avoid the withdrawal.

(APA, 2013)

INHALANT USE DISORDER

Inhalants produce chemical vapors that can be inhaled to induce psychoactive or mind-altering effects. The range of chemicals have a variety of pharmacologic effects found in hundreds of products (NIDA, 2022). Precise categorization of these products is difficult, but they generally are identified as volatile solvents, aerosols, gases, and nitrates:

- Solvents include paint thinner, gasoline, lighter fluid, and glue.
- Aerosols include spray paint, hair spray, and vegetable oil sprays.
- Gases include propane tanks, whipped cream aerosols; and butane lighters and nitrous oxide.
- Nitrates include room deodorizers and leather cleaner.

(NIDA, 2022)

People who use inhalants will abuse any available substance. Inhalants are CNS depressants and influence gamma- aminobutyric acid (GABA). Physiological effects of inhalant use include a variety of body functions. Most of the damage initially affects the brain, observed through tremors and uncontrolled shaking (Brannon, 2019). Headaches and seizures are common. Personality changes, memory loss, and decreased cognitive functioning may also develop. Inhalants can also cause lung damage with hypoxia, sinus discharge, coughing, and cyanosis. Arrhythmias, heart block, and heart failure are also possible with inhalant use. Other medical effects associated with inhalant use include gastrointestinal, liver, and kidney failure; bone marrow damage; and peripheral nervous system damage (Brannon, 2019). Psychological effects of inhalant use include impaired judgment, hyperactivity, aggressive behavior, speech problems, and increased accidents, especially unplanned suicides in children who use inhalants (Brannon, 2019).

Individuals demonstrating a problematic pattern of substance use that leads to significant impairment as manifested by two or more of the following over a 12-month period meet the criteria for a hydrocarbon-based disorder:

- A hydrocarbon-based inhalant substance is taken in larger amounts than intended.
- There is a persistent desire or unsuccessful efforts to cut down or control hydrocarbon-based inhalant substance use.
- A great deal of time is spent in activities to obtain the hydrocarbon-based inhalant substance.
- Craving is an urge to use hydrocarbon-based inhalant substances.
- Recurrent hydrocarbon-based inhalant substance use results in a failure to fulfill work and home obligations.
- Hydrocarbon-based inhalant substance use continues despite persistent or recurrent interpersonal problems.
- Important social, occupational, or recreational activities are given up or reduced due to hydrocarbon-based inhalant substance use.
- Hydrocarbon-based inhalant substance use recurs in situations when physically hazardous.
- Hydrocarbon-based inhalant substance use is continued despite the knowledge of having physical or psychological problems that may have been caused or exacerbated by hydrocarbon-based inhalant substances.
- Tolerance develops:
  - A need for increased amounts of a hydrocarbon-based inhalant substance to achieve intoxication.
  - Diminished effect with continued use of the same amount of the hydrocarbon-based inhalant substance.
- Withdrawal:
  - Characteristic withdrawal syndrome for hydrocarbon-based inhalant substance.
  - Hydrocarbon-based inhalant substance taken to relieve or avoid the withdrawal.

(APA, 2013)

The individual can overdose on inhalants when the ingested drug causes a toxic reaction, resulting in harmful symptoms or death (NIDA, 2020). The concentration of chemicals can cause cardiac arrest within minutes, which can occur in an otherwise healthy individual, called *sudden sniffing death*. Individuals who try to quit inhalants may experience withdrawal symptoms including nausea, loss of appetite, diaphoresis, problems sleeping, and mood changes.

TOBACCO USE DISORDERS/VAPING

Tobacco use is widespread in the United States, and its deleterious effects are well documented (NIDA, 2021; CDC, 2022). Smoking cigarettes leads to disease and disability in almost every organ in the body (CDC, 2022) including cancer, heart disease, stroke, lung disease, diabetes, and chronic obstructive pulmonary disease. Additionally, there is an increased risk for tuberculosis, eye diseases, and immune diseases (CDC,2022). Secondhand smoke also harms nonsmoking adults and children including stroke, lung cancer, sudden infant death syndrome, middle ear disease, worsening asthma, acute respiratory infections, and slowed lung growth (CDC, 2022). The strongest predictors of nicotine addiction are the time to first cigarette and total cigarettes per day (Lande, 2018).

Cigarettes are a highly efficient drug delivery system. On average, the individual takes in 1-2 milligrams of nicotine per lit cigarette and takes 10 puffs over a 5-minute period. This equates to 200 hits of nicotine to the brain daily (CDC, 2022). The adrenaline rush increases blood pressure, respiration, and heart rate while stimulating reward pathways in the brain. While nicotine is addictive, multiple dosing is needed to prevent withdrawal symptoms. Tobacco use disorders are documented in the *DSM-5*:

- An individual takes opioids in larger amounts over a longer period than intended.
- The individual experiences a persistent desire or unsuccessful efforts to cut down on opioid use.
- A great deal of time is spent in activities necessary to obtain opioids.
- An individual has a craving or strong desire or urge to use opioids.
- Recurrent opioid use involves failing to fulfill major work obligations.
- Opioid use continues despite having persistent, recurrent social and interpersonal problems caused by opioids.
- Important social, occupational, or recreational activities are given up or reduced because of opioid use.
- Recurrent opioid use occurs in situations that are physically hazardous.
- Continued opioid use occurs despite knowledge of persistent or recurrent psychological or physical problems.
- Tolerance means a need for a markedly increased amount to achieve intoxication and markedly diminished effect with continued use of the same number of opioids.
- Withdrawal occurs.

(APA, 2013)

Tobacco withdrawal

Withdrawal symptoms are often a barrier to stopping tobacco use, often due to nicotine deprivation (APA, 2013). Withdrawal symptoms begin within 24 hours of abruptly quitting tobacco and include:

- Irritability, frustration, or anger.
- Anxiety.
- Difficulty concentrating.
- Increased appetite.
- Depressed mood.
- Insomnia.

(APA, 2013)

Symptom intensity is higher in individuals who smoke cigarettes or use smokeless tobacco but peaks 2-3 days after abstinence and lasts approximate 2-3 weeks (APA, 2013). However, nicotine replacement therapies (NRTs) and other medications are available to augment quitting (CDC, 2022) The following represents NRTs but is not meant to be an inclusive list or offer individual medical advice.

NRT	Advantages	Disadvantages	Side Effects	Precautions
Nicotine Patches	Can be used with other modalities; steady dosing; OTC.	Unable to change doses; may need augmented therapy.	Headache; sleep disturbances; skin sensitivity.	Myocardial infarction (MI) within 2 weeks of starting; arrhythmia; angina; pregnant or breastfeeding; age < 18 years.
Nicotine Lozenges	Can be used regularly with withdrawal symptoms or urges; can control amount of nicotine delivered; may help substitute for a cigarette in the mouth; over the counter (OTC).	Use it regularly; do not eat/drink for 15 minutes before using or when the mouth; can cause dyspepsia.	Nausea; hiccups; insomnia; headache; cough.	MI within 2 weeks of starting; arrhythmia, angina; pregnant or breastfeeding; age < 18 years.
Nicotine Gum	Can be used regularly with withdrawal symptoms or urges; can control amount of nicotine delivered; may help substitute for a cigarette in the mouth; OTC.	Use it regularly; do not eat/drink for 15 minutes before using or when the mouth; can cause dyspepsia; may be hard to use with dentures/ dental work.	Mouth/jaw soreness; stomach; hiccups; nausea/ vomiting.	MI within 2 weeks of starting; arrhythmia, angina; pregnant or breastfeeding; age < 18 years; temporomandibular joint (TMJ) disease.
Nicotine Oral Inhaler	Can be used regularly with withdrawal symptoms or urges with patches; can control amount of nicotine delivered; may help substitute for a cigarette in the mouth.	Use it regularly; do not eat/drink for 15 minutes before using or when the mouth.	Mouth and throat irritation; runny nose; cough, headache, hiccups.	MI within 2 weeks of starting; asthma and chronic lung disease; arrhythmia, angina; pregnant or breastfeeding; age < 18 years; TMJ disease.

NRT	Advantages	Disadvantages	Side Effects	Precautions
Nicotine Nasal Spray	Can be used regularly; delivers nicotine most rapidly of all NRTs.	More addictive than other forms of NRT; some do not prefer nasal spray; requires prescription.	Nasal irritation; tearing; runny nose, sneezing or cough headache.	MI within 2 weeks of starting; sinus issues; asthma; arrhythmia, angina; pregnant or breastfeeding; age < 18 years; TMJ disease.
Bupropion SR	Simple to use; may help with depression; combined with patches.	More possible side effects than other medicines; cannot be used if history of bulimia/anorexia; or recently took monoamine oxidase (MAO) inhibitor; requires a prescription.	Nausea, dizziness; insomnia; constipation, dry mouth, rash, seizures, changes in mood or behavior; anxiety.	History of seizures; do not taking bulimia/anorexia; taking MAO inhibitor; liver disease, pregnant or breastfeeding; < age 18 years.

E-cigarettes/vaping

Vaping was introduced to the U.S. market in 2007, containing both nicotine and tetrahydrocannabinol (TCH), which are poorly regulated (Werner et al, 2020). Unfortunately, there is not enough data to determine short-term or long-term effects or the type of components to blame (Broderick, 2023). Vaping is a delivery system similar to a nebulizer; however, the vaping system coats the lungs in harmful chemicals masked in a variety of flavorings and aromatic additives. Vitamin E is often used as part of the delivery system and thickening agent in the e-liquid, which is thought to be an irritant to the lungs. Other common substances found in the e-liquid include (1) diacetyl, which is a food additive (buttery taste in microwave popcorn) known to damage small passages in the lungs; (2) formaldehyde, which contributes to lung and heart disease; and (3) acrolein, which is used as a weed killer and can also damage lungs (Broderick, 2023). Several lung diseases are associated with vaping.

Bronchiolitis obliterans (popcorn lung) is a rare condition resulting from damage of the small airways from diacetyl. Inhaling this additive causes coughing, wheezing, chest pain, and shortness of breath. Symptomatic treatment is available; however, there is no lasting treatment (Broderick, 2023).

Vaping-related lipoid pneumonia develops when fatty acids enter the lungs from the oily substances found in the e- liquid. This induces inflammatory responses in the lungs, demonstrated by chronic cough, shortness of breath, and blood- tinged mucus. The most important treatment is eliminating vaping while the lungs heal themselves (Broderick, 2003).

Primary spontaneous pneumothorax. Those who develop a collapsed lung due to vaping often develop air blisters on the top of the lungs that rupture and create tiny tears (Broderick, 2003). Rapid growth found in adolescence are prone to blisters that create a weak point. The blisters do not produce symptoms but smoking and vaping increase the risk for pneumothorax (Broderick, 2003). Signs of a pneumothorax include sharp chest or shoulder pain and dyspnea. Immediate treatment includes oxygen and chest radiograph (CXR) confirmation with supportive treatment.

E-cigarette/vaping-associated lung injury (EVALI) is strongly associated with vitamin E, which is found in lung fluid of individuals with EVALI but not in those without EVALI (CDC, 2021). EVALI is a diagnosis of exclusion, but rapid recognition is critical to reducing severe outcomes. During a comprehensive review of systems, the clinician should ask about the recent use of e-cigarettes or vaping. If confirmed, ask about the type of substance (THC, nicotine) utilized. Laboratory tests should be guided by clinical findings as well as practice guidelines. Community-acquired pneumonia and influenza are evaluated since EVALI is difficult to differentiate from these diagnoses (CDC, 2020).

OPIOID USE DISORDERS

Opioid use disorder (OUD) has reached epidemic proportions with substantial negative impacts on society. OUD is a chronic, relapsing disease influenced by genetics, stress response, and prior experimentation or exposure (Brown & Capili, 2020). Mu opioid receptors (MORs) modulate nociception, stress, temperature, respiration, endocrine activity, memory, mood, and motivation (Herman et al., 2022). MORs bind opioids, delta opioids, kappa opioids, and nociception receptors to increase drug tolerance. Physical dependence can develop between 2 and 10 days of continuous use, with withdrawal symptoms occurring when stopped abruptly (Herman et al., 2022).

Nurse practitioners (NPs) care for patients with many ailments in many healthcare settings. Patients might seek care for an acute illness or the worsening of a chronic condition. Often, pain is the leading reason for seeking medical care. Appropriate prescribing practices are critical for all medications, but drugs considered controlled substances require additional attention. The Drug Enforcement Agency (DEA), the Food and Drug Administration (FDA), and the U.S. Department of Health and Human Services (HHS) all have a role in determining the scheduling of prescription medications. As prescribers, NPs must understand federal and state requirements for prescribing all controlled substances. In addition, inappropriate prescribing practices resulting in misuse/or abuse of opioids have led to many changes, including new safety and quality recommendations. Prescribing any medication must be performed with care while considering possible patient-specific risks. Prescribing controlled substances requires a heightened awareness for both patient and provider. Federal and state laws and regulations must be followed when prescribing controlled substances.

Additionally, other issues, including the more widespread availability of medical marijuana and the opioid epidemic, have increased the complexity of the controlled substance prescribing process. All prescribers must be aware of federal and state laws regulating controlled substances. Prescribing opioid analgesics for acute and chronic pain has come under intense scrutiny as the opioid epidemic has worsened. In 2020, the U.S. Department of Health and Human Services estimated that 10.1 million people misused prescription opioids. Opioid overdoses, prescription and illicit, accounted for 42,000 deaths; 40% involved a prescription opioid (HHS, 2021). Appropriately prescribing first-time opioid analgesics for acute pain is critical in preventing future opioid abuse (Goldstick et al., 2021). Individualized tapering plans minimize symptoms of opioid withdrawal while maximizing pain treatment with nonpharmacologic therapies and nonopioid medications (CDC, 2022a). Understanding patient-specific risk factors and prescribing strategies for chronic pain management is also critical in preventing misuse and abuse of opioid analgesics.

OUD can occur at any age but is usually first identified in the late teens or early 20s (American Psychological Association [APA], 2013). It is considered a problematic pattern of opioid use leading to clinically significant impairment or distress, with at least two of the following in a 12-month period.

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[APA], 2013). It is considered a problematic pattern of opioid use leading to clinically significant impairment or distress, with at least two of the following in a 12-month period:

- An individual takes opioids in larger amounts over a more extended period than intended.
- A persistent desire or unsuccessful efforts to cut down on opioid use occur.
- A great deal of time is spent in activities necessary to obtain opioids.
- An individual has a craving or strong desire or urge to use opioids.
- Recurrent opioid use occurs despite failing to fulfill significant work obligations.
- Opioid use continues despite having persistent recurrent social and interpersonal problems caused by opioids.
- Important social, occupational, or recreational activities are given up or reduced because of opioid use.
- Recurrent opioid use occurs in situations that are physically hazardous.
- Continued opioid use occurs despite knowledge of persistent or recurrent psychological or physical problems.
- Tolerance means a need for a markedly increased amount to achieve intoxication and markedly diminished effect with continued use of the same amount of opioids.
- Withdrawal occurs.

(APA, 2013)

Epidemiology of opioid use disorders

From 1999 to 2020 more than 564,000 individuals died from an overdose involving opioids (CDC, 2020). The rise in opioid overdose deaths is outlined in three distinct waves. The first wave began in 1999 with increased opioid prescribing. The second wave started in 2010 with rapid increases in overdose deaths involving heroin. Finally, the third wave started in 2013 with synthetic opioids like fentanyl, which now comes across the border and is responsible for hundreds of thousands of deaths (CDC, 2022).

Risk factors in opioid use disorders

In general, individuals take substances for a variety of reasons, including (1) pleasure; (2) an escape from social anxiety, stress, and depression; (3) to increase performance; (4) curiosity and social pressure (National Institute on Drug Abuse [NIDA], 2020). Therefore, no single factor determines whether an individual becomes addicted to drugs, whether biological or environmental (NIDA, 2020).

Biological influences include genetics, gender, and mental disorders, while environmental impacts include chaotic home situations, parental use and attitudes, peer influences, community attitudes, and low academic achievement (NIDA, 2020). Risk factors for substance abuse include (1) aggressive behavior in childhood, (2) lack of parental supervision, (3) peer refusal skills, (4) drug experimentation, (5) availability of drugs at school, and (6) community poverty (NIDA, 2020). Protective factors reduce an individual's risk of substance use and include (1) self-efficacy affected by personal and home situations, (2) parental monitoring and support, (3) positive relationships, (4) extracurricular activities, (5) anti-drug policies at school, and (6) neighborhood resources (NIDA, 2020).

One of the most significant changes during development in adolescence is the maturing prefrontal cortex, which is responsible for assessment of situations, making sound decisions, and keeping emotions and desires under control (NIDA, 2020). These changes place the adolescent at a greater risk of substance abuse. In addition, introducing substance use during this time can interrupt the development of neuronal connections, which are affected by environmental forces that determine how these connections operate as individuals age (NIDA, 2020).

Root causes of opioid use disorder

It appears likely that there are several root causes of the current opioid epidemic (Blumenthal & Seervai, 2017).

Prescribers

At the root of the opioid epidemic is the *pain* epidemic. It has been acknowledged that during the mid-1990s, to treat pain better, physicians overprescribed opioid medications in the absence of adequate attention to negative consequences. This may have responded to several experts at the time contending that pain was being undertreated in routine medical practice (Blumenthal & Seervai, 2017).

Pharmaceutical companies

Many have implicated the sales practices of opioid manufacturers and marketers. Investigations have established that drug makers may have partially fueled the epidemic by their efforts to enhance the sales of their opioid medications (Blumenthal & Seervai, 2017). In a current example, federal prosecutors have leveled racketeering charges against several executives of INSYS Therapeutics, alleging that they were part of a scheme involving aggressive sales of fentanyl. More specifically, the indictment suggests that prescribers offered bribes and kickbacks in exchange for higher prescribing rates for their product SUBSYS, a spray form of fentanyl (Thomas, 2016).

Health insurance

Although receiving less attention in the media, recent examinations have suggested that in some cases, insurance practices provide easy access to opioid medications while restricting access to less addictive but more expensive pain medication. In addition, in some cases, access to addiction treatment may also be curtailed (Blumenthal & Seervai, 2017).

Socioeconomics

An association can be established between opioid misuse/abuse and unemployment, lack of health insurance, and poverty among adults. Unfortunately, it is difficult to confirm that financial disadvantage is a cause. Rather, this condition could result from the epidemic (Blumenthal & Seervai, 2017). Nonetheless, it remains probable that feelings of hopelessness and social trauma are at least somewhat to blame.

Further, the geographic distribution of the opioid problem is revealing. Racial and ethnic minorities in cities have historically had high addiction rates. Some of the highest addiction rates in the United States occur where social dislocation is found, including densely populated urban regions and Appalachia. Since the 1970s, rural communities have suffered from employment declines. As a result of higher unemployment rates, financial problems, and limited upward mobility, the stage was set for increases in substance use and abuse (Blumenthal & Seervai, 2017). The drive for opioids combined with poverty often results in criminal activity.

In 2012, a total of 259 million opioid prescriptions were written. This is adequate to provide each American adult with a medication bottle. It is estimated that of each five new heroin users, four got their start with painkillers. A 2014 survey of people suffering from opioid addiction showed that 94% of respondents chose to use heroin because of the costs; prescription opioids are more expensive and difficult to obtain (ASAM, 2017).

CONTROLLED SUBSTANCE ACT (CSA)

The Comprehensive Drug Abuse Prevention and Control Act of 1970, or the Controlled Substance Act (CSA), regulates pharmaceutical and illicit controlled substances in the United States (DEA, 2010b). The CSA requires registration, outlines specific rules about dispensing pharmaceutical controlled substances, and determines the legality of these substances (DEA, 2018a). The U.S. Drug Enforcement Agency (DEA) was formed in 1973 to enforce the CSA. For pharmaceutical controlled substances, the DEA is responsible for preventing the diversion and abuse of controlled drug substances. The agency also ensures that an adequate and uninterrupted supply of pharmaceutical controlled substances is available to meet legitimate medical, scientific, and research needs. Along with state and other federal agencies, the DEA regulates the registration of manufacturers, distributors, and dispensers of controlled pharmaceutical substances and the import and export of these substances. The DEA prosecutes anyone who violates this law (DEA, 2020a).

Evidence-Based Practice: The U.S. federal agencies involved in scheduling controlled substances include the Drug Enforcement Agency (DEA), the Food and Drug Administration (FDA), and the Department of Health and Human Services (HHS).

CONTROLLED SUBSTANCE SCHEDULES

The CSA categorizes medications into five schedules based on medical benefits, relative abuse potential, and the likelihood of causing dependence when abused (DEA, 2018b). The U.S. attorney general may add, remove, or change the controlled substance schedule of a given compound. In addition, by the authority of the U.S. attorney general, the DEA may add or transfer substances between programs by rule (i.e., it does not require a change in statute). Other substances deemed to have the potential for abuse may be removed from the plan if they do not meet the requirements for inclusion in any schedule (DEA, 2020b).

Before adding, removing, or changing the controlled substance schedule of a drug or substance, the attorney general must request a medical and scientific evaluation and recommendation from the secretary of the HHS. The FDA, which reports to the secretary of the HHS, usually performs this evaluation. These recommendations are considered binding, and the DEA must follow them. The following factors are considered when deciding how to schedule a pharmaceutical product or substance:

- Its actual or relative potential for abuse.
- Scientific evidence of its pharmaceutical effect, if known.
- The state of current scientific knowledge regarding the drug or other substance.
- Its history and current pattern of abuse.
- The scope, duration, and significance of abuse.
- What, if any, risk there is to public health.
- Its psychic or physiological dependence liability.
- Whether the substance is an immediate precursor of a substance already on the controlled substance list.

(DEA, 2018b)

The DEA ultimately decides whether to initiate rulemaking proceedings to reschedule a controlled substance. However, there are circumstances where the DEA is not required to follow these procedures. First, suppose a substance is an immediate precursor of a substance already on the list. In that case, the attorney general may place the immediate precursor in the same or any other schedule with a higher designation.

Additionally, the DEA may, without regard to standard procedures, assign a drug or substance temporary Schedule I status if it has determined an imminent hazard to public safety. When issuing an order for provisional Schedule I status, the attorney general is only required to consider the history and pattern of abuse; the scope, duration, and significance of abuse; the risk to public safety; actual abuse; a diversion from legitimate channels; and clandestine importation, manufacture, or distribution. The DEA must issue a notice in the *Federal Register* of the intention to issue the temporary Schedule I status; the temporary status will become official 30 days after the publication of the notice in the *Federal Register*. The temporary status is in effect for 2 years, with a potential extension of 1 additional year. Human clinical trials may determine whether the substance produces adverse effects sufficient to provide an imminent hazard to public safety. Once the DEA receives scientific and medical evaluation from the secretary of the HHS, an interim final rule is issued, which becomes effective immediately (DEA, 2018c).

Recently, the DEA has invoked the right to assign a substance Schedule I status based on an imminent hazard to public safety for substances identified as controlled substance analogs. A controlled substance analog intended for human consumption is structurally or pharmacologically substantially similar to a Schedule I or Schedule II substance. It is not an FDA-approved medication in the United States (DEA, 2018b). Under federal law, any controlled substance analog is considered a Schedule I controlled substance (DEA, 2022a). Commonly controlled substance analogs include synthetic cannabinoids and synthetic opioids, particularly fentanyl. In addition, substances found in illicit substances of abuse, such as K2 or "spice" (i.e., synthetic cannabinoids), heroin (i.e., synthetic fentanyl compounds), "bath salts," or other new psychoactive substances (e.g., synthetic cathinones). Abuse of these synthetic compounds has increased significantly, leading to clinical management challenges for first responders and emergency medicine clinicians.

Healthcare Consideration: Prescribers must be able to differentiate between the various controlled substance schedules and know the types of drugs in each schedule on a federal and state level. This allows nurse practitioners to adhere to legal mandates and appropriately control and monitor the distribution of such drugs and their effects on patients.

Schedules of controlled substances

A complete list of the scheduled controlled substances is published annually in the DEA regulations (Title 21 of the *Code of Federal Regulations (CFR)*, Sections 1308.11 through 1308.15). These lists describe the primary or parent compound and do not include the salts, esters, or salts of isomers that may be controlled substances. Therefore, a substance may be regulated as a controlled substance analog even though it is not included on these lists. Final rules are found in the *Federal Register* before the publication of the next *CFR* (DEA, 2018c).

Schedule I Controlled Substances

Substances in this class have no accepted medical use within the United States, lack appropriate safety levels under medical supervision, and have a high level of abuse (DEA, 2018b).

Examples include:

- Heroin.
- Marijuana (cannabis).
- Peyotes.
- Methylene-dimethoxy-methamphetamine (MDMA [ecstasy]). Lysergic acid diethylamide (LSD).

The CSA allows medical research on Schedule I substances if the researcher is certified by the FDA and the research protocol is approved. Researchers who meet these criteria must obtain separate registration from the DEA to conduct research with Schedule I substances (DEA, 2020b). Such research is essential to determine if a given substance offers any medical benefit and to identify other safety factors, such as drug interactions and possible adverse effects.

Schedule II/IIN Controlled Substances
Substances in this class have a high potential for abuse that may lead to severe psychological or physical dependence, and they also have accepted medical use (DEA, 2018b).

Examples of Schedule II narcotics:
- Codeine.
- Hydrocodone (Vicodin, Zohydro ER).
- Hydromorphone (Dilaudid).
- Methadone (Dolophine).
- Meperidine (Demerol).
- Morphine (MSContin, Roxanol).
- Opium.
- Oxycodone (Roxicodone, OxyContin, Percocet).
- Fentanyl (Sublimaze, Duragesic).

Examples of Schedule IIN non-narcotics:
- Amobarbital.
- Amphetamine (Dexedrine, Adderall).
- Nabilone (Cesamet).
- Methamphetamine (Desoxyn).
- Methylphenidate (Ritalin).
- Pentobarbital.

Schedule III/IIIN Controlled Substances
Substances in this schedule have less of a potential for abuse than substances in Schedules I and II, and abuse may lead to low to moderate physical dependence and high psychological dependence (DEA, 2018b).

Examples of Schedule III narcotics:
- Products containing no more than 90 mg of codeine (Tylenol with Codeine).
- Buprenorphine (Suboxone).

Examples of Schedule IIIN non-narcotics:
- Benzphetamine (Didrex).
- Butalbital (Fiorinal).
- Dronabinol (Marinol).
- Ketamine.
- Anabolic steroids.
- Testosterone (Androderm).

Schedule IV Controlled Substances
Substances in this schedule have a low potential for abuse relative to substances in Schedule III (DEA, 2018b).

Examples of Schedule IV controlled substances:
- Alprazolam (Xanax).
- Carisoprodol (Soma).
- Clonazepam (Klonopin).
- Clorazepate (Tranxene).
- Diazepam (Valium).
- Eszopiclone (Lunesta).
- Lorazepam (Ativan).
- Midazolam (Versed).
- Modafinil (Provigil).
- Phenteramine (Adipex-P).
- Temazepam (Restoril).
- Triazolam (Halcion).
- Zaleplon (Sonata).
- Zolpidem (Ambien).

Schedule V Controlled Substances
Substances in this schedule have a low potential for abuse relative to substances in Schedule IV and primarily include preparations containing limited quantities of certain narcotics (DEA, 2018b).

Examples of Schedule V controlled substances:
- Cough preparations containing not more than codeine 200 mg/100 mL or codeine 200 mg/100 mg (Robitussin AC, Phenergan with Codeine).
- Diphenoxylate (Lomotil).
- Lacosamide (Vimpat).
- Opium preparations.
- Pregabalin (Lyrica).

Physician Assistance (PAs)
PAs are authorized to prescribe Schedule II-V in 44 states and DC. Five states allow III-V. However, PAs are not authorized to prescribe in Kentucky. Physicians directly oversee these practitioners, but PAs are considered "mid-level" practitioners. This designation allows PAs and other healthcare providers to prescribe controlled substances. State by state requirements can be accessed here https://deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf

Self-Assessment Quiz Question #1

If there is accidental ingestion of a known or unknown substance with no respiratory distress, who should you call?

a. Poison Control (1-800-222-1222).
b. Emergency Services (911).
c. American Medical and Lawyer Referral Service (411-PAIN).
d. CVS or local pharmacist.

MEDICAL MARIJUANA LEGISLATION

Medical marijuana refers to using the whole, unprocessed marijuana plant or its essential extracts to treat symptoms of illness and other conditions. The FDA has neither recognized nor approved the marijuana plant as a medicine. The DEA considers marijuana a Schedule 1 controlled substance due to the lack of scientific research. However, a growing body of literature (scientific and anecdotal) has led to the increasing use of medical marijuana for various conditions, including pain, seizures, posttraumatic stress disorder (PTSD), and other disorders.

The DEA considered rescheduling marijuana to Schedule II in August 2017 but decided against it (LaBruyere, 2022). The DEA has agreed to support additional research on marijuana and make the process easier for researchers. However, despite the lack of scientific confirmation, over 50% of the states and the District of Columbia have legalized marijuana, while other states maintain restricted access. In 2013, the federal government took a lenient approach to federal law enforcement regarding marijuana and provided guidance allowing states to legalize medical marijuana. However, in January 2018, this memo was rescinded (DOJ, 2018), and now the status of state-level legalization of medical marijuana is uncertain. The medical marijuana debate has highlighted the issue of state rights versus the federal government. Since 2018, another 19 states have legalized recreational marijuana, and 39 states have legalized medical marijuana. Attorney General Merrick Garland has reiterated that the Department of Justice will not prioritize prosecuting marijuana use "given the nation's ongoing opioid and methamphetamine epidemic[s]."

Medical marijuana is the same as or similar to the plant used for recreational purposes but is prescribed by an authorized clinician. Each state has regulations regarding qualified practitioners who can recommend medical marijuana and the recommendations for types of legal, medical marijuana. In addition, states may require individuals to obtain a medical marijuana card, allowing them to purchase medical marijuana from a dispensary. Medical marijuana products vary from plant to extracted oils or edible products (e.g., cookies, butters, lozenges, and others).

It is important to note that the FDA does not oversee or regulate medical marijuana as it does prescription medications. Therefore, the quality of medical marijuana, including purity, strength, and ingredients, may vary significantly depending on where and when it is purchased. The FDA has approved marijuana-derived prescription medications (see Table 1). Two products are synthetic derivatives: Dronabinol is synthetic delta-9-tetrahydrocannabinol, while nabilone is a derivative of cannabinol, one of the many chemical constituents of marijuana. The FDA approved Epidiolex, which contains cannabidiol (CBD) purified from marijuana plants, in 2018 as a Schedule I. While Epidiolex is FDA-approved for treating seizures related to Lennox-Gastaut syndrome and Dra-

vet syndrome, it also treats other off-label conditions. In 2020, Epidiolex was approved to treat seizures associated with tuberous sclerosis complex (TSC) in one year and older patients. Under the CSA, CBD is currently a Schedule I controlled substance because it is a chemical component of the cannabis plant. The FDA has submitted a medical and scientific analysis of CBD, including data from studies to assess the abuse potential of CBD, to the DEA to change the scheduling of CBD. In 2020, the DEA removed Epidiolex from a downgraded Schedule V and descheduled it entirely, meaning Epidiolex is no longer subject to the CSA and its tracking and monitoring requirements (HB6095, 2021).

Table 1: Marijuana-Derived Pharmaceutical Products

Generic Name	Brand Name	FDA Status	FDA -Approved or Under Review Indications	Pharmacology
Dronabinol	Marinol	FDA-approved controlled substance Schedule III.	Appetite stimulant in the management of anorexia associated with AIDS.	Synthetic delta-9-tetrahydrocannabinol (delta-9-THC) is the primary active compound of marijuana.
THC	Syndros (capsules)		Treatment of chemotherapy-induced nausea/vomiting.	
Nabilone	Cesamet (capsules)	FDA-approved controlled substance Schedule II.	Treatment and prevention of chemotherapy- induced nausea/vomiting.	Derivative of cannabinol, a nonpsychoactive constituent of marijuana.
Cannabidiol (CBD)	Epidolex (oral solution)	Descheduled by the DEA; no longer subject to the CSA.	Treatment of Lennox-Gastaut syndrome, Dravet syndrome, and tuberous sclerosis complex.	Plant-derived cannabidiol (CBD) accounts for 40% of cannabis extracts.
Cannabidiol (CBD) and delta-9-tetrahydrocannabinol	Sativex (oro-mucosal spray)	Under investigation in the United States, Phase II/III trials.	Clinical trials for pain treatment in cancer patients who experience inadequate analgesia during optimized chronic opioid therapy.	Combination of delta-9-THC, the primary active compound, and cannabidiol, a nonpsychoactive component of marijuana.

Healthcare Consideration: Although marijuana remains a federal Schedule I controlled substance, many states have approved or are considering supporting the medical and recreational use of marijuana. As these regulations differ from state to state, NPs must carefully review regulations and applicable requirements in their practice state.

PRESCRIBING PRACTICES FOR CONTROLLED SUBSTANCES

A physician, dentist, podiatrist, veterinarian, or advanced practice provider (i.e., chiropractor, nurse practitioner, midwife, optometrist, pharmacist) may issue a prescription for a controlled substance. Others may give a prescription under the following conditions:

- Authorized to prescribe controlled substances by the jurisdiction of practice.
- Registered with the DEA or exempted from registration (e.g., U.S. Public Health Service, Federal Bureau of Prisons, or military practitioners); to obtain a DEA registration, the clinician must complete DEA Form 224 (http://www.DEAdiversion.usdoj.gov).
- Effective May 11, 2022, DEA now requires all registration applications and renewal forms to be submitted electronically.
- An agent or employee of a hospital or other institution acting in the normal course of business or employment under the registration of the hospital or other institution that is registered instead of the individual practitioner being registered, provided additional requirements as outlined in the CFR (DEA, 2018c).

DEA registration grants federal authority to practitioners to handle controlled substances as part of their professional practice or research. A clinician may prescribe controlled substances only under the state laws where their practice is located. When federal and state laws differ, the practitioner should follow the more stringent aspects of both the federal and state requirements. This principle has led to much concern about the state legalization of medical marijuana, despite the DEA maintaining its controlled substance Schedule I status.

The DEA may deny, suspend, or revoke a clinician's DEA registration upon finding the registrant has:

- Materially falsified any application filed.
- Been convicted of a felony relating to a controlled substance or a Schedule I chemical.
- Had their state license or registration suspended, revoked, or denied.
- Committed an act that would render the DEA registration inconsistent with the public interest.
- Been excluded from participation in the Medicaid or Medicare program.

Clinicians who are agents or employees of a hospital or other institution (e.g., interns, residents, staff physicians, advanced practice providers) may, in the normal course of their duties, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution provided that:

- The dispensing, administering, or prescribing is in the ordinary course of practice.
- Practitioners are authorized by the state in which they practice.
- The hospital or institution has verified that the practitioner is permitted to dispense, administer, or prescribe controlled substances within the state.
- The practitioner acts within the scope of employment in the hospital or institution.
- The hospital or institution authorizes the practitioner to dispense or prescribe under its registration and assigns a specific internal code for each practitioner so authorized.

In response to the opioid epidemic, many states have enacted policies to address the crisis yet still provide access to appropriate pain management. Procedures include guidelines for or limits

on opioid prescriptions in Title 21 of the CFR, Sections 1308.11 through 1308.15 (DEA, 2018c).

The DEA (2010a) defines a *prescription* as an order for medication dispensed to or for an end user. Furthermore, to be effective, a prescription for a controlled substance must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of their professional practice. The responsibility for properly prescribing and dispensing controlled substances is upon the prescribing practitioner, but a corresponding responsibility rest with the pharmacist who fills the prescription (DEA, 2010b).

Laws and regulations vary from state to state; thus, the prescribing clinician must ensure that the prescription follows all requirements. Prescriptions for controlled substances must be written in indelible ink or typewritten. The controlled substance prescription must be dated and signed on the date issued. Additional requirements for a controlled substance prescription include the following:

- Patient's full name and address.
- Prescriber's full name, address, and DEA registration number.
- Drug name.
- Strength.
- Dosage form.
- Quantity prescribed.
- Directions for use.
- Number of refills authorized (not applicable for Schedule II drugs).
- Prescriber's signature.
- Date issued.

The regulations provide that "the secretary or agent may prepare [a] prescription for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations" (DEA, 2010b). The CSA does *not* permit a prescribing practitioner to delegate to an agent or any other person the practitioner's authority to issue a prescription for a controlled substance. A practitioner acting in the usual course of their professional practice must determine a legitimate medical purpose for a controlled substance prescription; an agent may *not* make this determination.

Prescribing controlled substances: Nurse practitioner requirements

While the CSA allows NPs to prescribe controlled substances, each state has different regulations (DEA, 2022). Nurse practitioners may prescribe Schedules III, IV, and V controlled substances in all states. However, state laws to determine NPs' prescriptive authority differ considerably. Some states allow full practice for NPs where they may prescribe medications with a level of autonomy comparable to physicians. On the other hand, many states restrict NP prescriptive authority and require physician supervision. The American Association of Nurse Practitioners categorizes state practices into restricted, reduced, and complete practice authority (AANP, 2022). Twenty-two states allow full practice, where NPs have similar prescriptive authority to physicians. In 16 states, NPs have reduced authority and work alongside physicians in joint practice agreements. States with reduced prescriptive authority have varying limitations on medications that NPs can prescribe to patients. NPs are categorized as restricted in the remaining 12 states and require physician supervision or delegation when prescribing controlled substances.

Each NP should verify their state's legal requirements and regulations for prescribing and dispensing controlled substances. There are a variety of restrictions imposed on NPs, including:

- Limits to the allowed controlled substance schedules prescribed.
- Required controlled drug substance registration or licensure.
- Required written agreement between physician and nurse practitioner.
- Limits on the number of controlled substances prescribed.
- Limits on the daily supply of a prescribed controlled substance.
- Limits placed on controlled substances prescribed in the healthcare setting.
- Requirements for a certain number of controlled substances–oriented continuing education hours.

(DEA, 2022)

Self-Assessment Quiz Question #2

Interns, residents, staff physicians, and advanced practice providers may prescribe controlled substances under the registration of the hospital provided that:

a. The dispensing, administering, or prescribing is in the normal course of practice.
b. Practitioners are authorized to do so by the state in which they practice.
c. The hospital or institution has verified that the practitioner is permitted to dispense, administer, or prescribe controlled substances within the state.
d. The practitioner only acts within the scope of employment in the hospital or institution.
e. All of the above.

Special considerations for nurse practitioners prescribi ontrolled substances

While the laws vary from state to state, no prescribers, including nurse practitioners, should prescribe controlled substances for themselves or a family member. Prescribing for family members may have legal and ethical implications. Pharmacists will likely question a prescription written for the same-named individual who signs the prescription. Patients may attempt to fill prescriptions in a different state for various reasons. A pharmacist who receives an out-of-state prescription from a nurse practitioner may only fill the prescription if unsure of the rules in the other state.

Regardless of the method of transmission of a controlled substance prescription—by hand delivery, facsimile, phone call, or electronically—DEA regulations make it clear that the legal responsibility for issuing a valid prescription that "conform[s] in all essential respects to the law and regulations" rests upon the prescribing practitioner. As noted, however, a pharmacist is responsible for dispensing controlled substances. Further, "A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by DEA regulations" (DEA, 2018c). Therefore, a pharmacist must carefully review all purported controlled substance prescriptions to ensure the drug meets all legal requirements for a valid prescription. In addition, pharmacists must inquire further about the satisfaction of any or all of the legal requirements for a valid prescription depending upon the particular circumstances, including the condition that the prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. Finally, the pharmacist must be satisfied that the prescription is consistent with CSA and DEA regulations before dispensing the controlled substance to the ultimate user (DEA, 2018c).

Healthcare Consideration: The number of drug overdose deaths increased by nearly 5% from 2018 to 2019 and has quadrupled since 1999. Over 70% of the 70,630 deaths in 2019 involved an opioid (CDC, 2021). Therefore, competence with both state and federal regulations should be maintained.

CDC CLINICAL PRACTICE GUIDELINES FOR PRESCRIBING OPIOIDS FOR PAIN

This clinical practice guideline is intended for clinicians who are treating outpatients aged ≥18 years with acute (duration of <1 month), subacute (duration of 1–3 months), or chronic (duration of >3 months) pain and excludes pain management related to sickle cell disease, cancer-related pain treatment, palliative care, and end-of-life care (Dowell et al., 2022). This clinical practice guideline is intended to assist clinicians in weighing the benefits and risks of prescribing opioid pain medication for painful acute conditions (e.g., low back pain, neck pain, other musculoskeletal pain, neuropathic pain, dental pain, kidney stone pain, acute episodic migraine), and postoperative pain, and pain related to oral surgery procedures (Dowell et al., 2022).

CDC Clinical Practice Guidelines for Prescribing Opioids for Pain	
Determining whether or not to initiate opioids for pain	**Recommendation 1:** Nonopioid therapies are at least as effective as opioids for many common types of acute pain. Clinicians should maximize nonpharmacologic and nonopioid pharmacologic therapies as appropriate for the specific condition and patient and only consider opioid therapy for acute pain if benefits are anticipated to outweigh risks to the patient. Before prescribing opioid therapy for acute pain, clinicians should discuss with patients the realistic benefits and known risks of opioid therapy. **Recommendation 2:** Nonopioid therapies are preferred for subacute and chronic pain. Clinicians should maximize the use of nonpharmacologic and nonopioid pharmacologic therapies as appropriate for the specific condition and patient and only consider initiating opioid therapy if the expected benefits for pain and function are anticipated to outweigh risks to the patient. Before starting opioid therapy for subacute or chronic pain, clinicians should discuss with patients the realistic benefits and known risks of opioid therapy, should work with patients to establish treatment goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks.
Selecting opioids and determining dosages	**Recommendation 3:** When starting opioid therapy for acute, subacute, or chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release and long-acting (ER/LA) opioids. **Recommendation 4:** When opioids are initiated for opioid-naïve patients with acute, subacute, or chronic pain, clinicians should prescribe the lowest effective dosage. If opioids are continued for subacute or chronic pain, clinicians should use caution when prescribing opioids at any dosage, should carefully evaluate individual benefits and risks when considering increasing dosage, and should avoid increasing dosage above levels likely to yield diminishing returns in benefits relative to risks to patients. **Recommendation 5:** For patients already receiving opioid therapy, clinicians should carefully weigh benefits and risks and exercise care when changing opioid dosage. If the benefits outweigh the risks of continued opioid therapy, clinicians should work closely with patients to optimize nonopioid therapies while continuing opioid therapy. If the benefits do not outweigh the risks of continued opioid therapy, clinicians should optimize other therapies and work closely with patients to gradually taper to lower dosages or, if warranted based on the individual circumstances of the patient, appropriately taper and discontinue opioids. Unless there are indications of a life-threatening issue, such as warning signs of impending overdose (e.g., confusion, sedation, or slurred speech), opioid therapy should not be discontinued abruptly, and clinicians should not rapidly reduce opioid dosages from higher dosages.
Deciding the duration of initial opioid prescriptions and conducting follow-up	**Recommendation 6:** When opioids are needed for acute pain, clinicians should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. **Recommendation 7:** Clinicians should evaluate benefits and risks with patients within 1–4 weeks of starting opioid therapy for subacute or chronic pain or dosage escalation. Clinicians should regularly reevaluate the benefits and risks of continued opioid therapy with patients.

CDC Clinical Practice Guidelines for Prescribing Opioids for Pain	
Assessing risk and addressing potential harms of opioid use	**Recommendation 8:** Before starting and periodically during the continuation of opioid therapy, clinicians should evaluate the risk for opioid-related harms and discuss the risk with patients. Clinicians should work with patients to incorporate into the management plan strategies to mitigate the risk, including offering naloxone. **Recommendation 9:** When prescribing initial opioid therapy for acute, subacute, or chronic pain, and periodically during opioid therapy for chronic pain, clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or combinations that put the patient at high risk for overdose. **Recommendation 10:** When prescribing opioids for subacute or chronic pain, clinicians should consider the benefits and risks of toxicology testing to assess for prescribed medications as well as other prescribed and non-prescribed controlled substances. **Recommendation 11:** Clinicians should use particular caution when prescribing opioid pain medication and benzodiazepines concurrently and consider whether the benefits outweigh the risks of concurrent prescribing of opioids and other central nervous system depressants. **Recommendation 12:** Clinicians should offer or arrange treatment with evidence-based medications to treat patients with opioid use disorder. Detoxification on its own, without medications for opioid use disorder, is not recommended for opioid use disorder because of increased risks for resuming drug use, overdose, and overdose death.
Note: Dowell, et al., 2022.	

Healthcare Consideration: State boards of nursing are an excellent source of information for NPs on how state laws and regulations impact practice. NPs and other prescribers must know all the details about advanced practice in their state— from signature authority to the number of CE hours required for licensure.

PRESCRIPTION DRUG MONITORING PROGRAM (PDMP)

All states maintain a prescription drug monitoring program (PDMP) for controlled substances to address overprescribing opioids and other controlled substances. Missouri was the last state to create a statewide prescription drug monitoring program with State Bill 63 (SB63, 2021). *Prescription drug monitoring programs* are a statewide electronic database that tracks all controlled substance prescriptions. State requirements for using PDMPs while prescribing controlled substances vary substantially; however, the White House Office of National Drug Control Policy and the CDC recommend creating and utilizing these programs when prescribing controlled substances, especially opioids. In addition, the CDC's National Center for Injury Prevention and Control is updating the *2016 CDC Guideline for Prescribing Opioids for Chronic Pain* (CDC, 2022a; Dowell et al., 2016).

PDMPs collect controlled substance prescription data from retail pharmacies (in-state, mail order, Internet), hospitals dispensing to emergency department patients (dispensing >48-hour supply), clinicians dispensing controlled substances from an office, and Department of Veterans Affairs pharmacies. Prescription data collected include patient information such as name, date of birth, gender, Social Security number, driver's license number), prescriber's name and DEA registration number, and prescription information (dates prescriptions were written and filled, quantity, days supplied, National Drug Code (NDC; provides drug name and strength), and source of payment. PDMPs do not track methadone dispensed at federally regulated clinics; controlled substances dispensed for administration to patients in hospitals, long-term care facilities, jails, or correctional facilities; pseudoephedrine (often tracked separately); military pharmacy dispensing; or Schedule I substances.

Most states share PDMP information with prescribers in other states through a nationwide network. As a result, authorized users can access prescription data such as medications dispensed and doses. PDMPs are tools (1) to promote safe prescribing and dispensing practices for Schedules II–V controlled substances to reduce the number of opioids and other controlled substances available for abuse; (2) that assist law enforcement in reducing drug diversion and illegal prescribing and dispensing; (3) for the health profession's licensure boards to support licensee reviews and investigations; and (4) for analysis of data that can help identify problematic trends with specific drugs, geographic regions, and patient demographics.

The purpose of PDMPs is to (1) improve medication safety for opioids and other controlled substances by allowing clinicians to identify patients who are obtaining controlled substances from multiple prescribers (i.e., doctor shopping), (2) calculate the total amount of opioids prescribed per day, and (3) identify patients who are being prescribed other substances that may increase risk of opioids, such as benzodiazepines (Dowell et al., 2016). However, the effect of PDMPs is uncertain, as studies have reported conflicting results. Suggested improvements to prescription drug monitoring programs include improved clinician training in using PDMPs, prescriber dashboards for higher-risk patients, proactive alerts, mandatory registration, mandatory querying for specific prescriptions, improved interfaces, and integration into electronic medical records (Robinson et al., 2021).

Electronic prescribing of controlled substances (EPCS)

In June 2010, the DEA published an interim final rule allowing for the electronic prescribing of controlled substances (EPCS) in all states. States had to meet specific requirements, including certification of the electronic prescribing and pharmacy applications, to sign, transmit, or process the controlled substance prescriptions; audits and certification reports for these applications; and two-factor authentication for prescribers (DEA, 2010a). However, implementation of EPCS has been slow; in 2015, only 2.2% of prescribers and less than 50% of pharmacies were enabled for EPCS, while over 70% of prescribers and 95% of pharmacies could e-prescribe or accept other prescriptions (AAFP, 2021). Delays included necessary updates to electronic health records and pharmacy systems and changes to state legislation to allow for EPCS.

As the opioid crisis worsened, the implementation of EPCS as a tool for increased security against diverted controlled substance prescriptions has been recognized (SureScripts, 2022a). E-prescribing continued raising the bar for safe, precise prescriptions in 2021 with better data quality and more efficient communication between pharmacists and prescribers. A Centers for Medicare & Medicaid Services (CMS) rule requiring that Part D providers use EPCS took effect January 1, , according to the requirements of the SUPPORT for Patients and Communities Act, and state legislation continued moving forward throughout the year (SureScripts, 2022b). With between 20% and 26% of U.S. adults using telemedicine every month in 2021, it is no surprise that e-prescribing use grew throughout the year. EPCS brings extra safety and security to controlled substance prescriptions, which is critical amid an opioid overdose crisis that spiked as the COVID-19 pandemic hit the United States. Already used by virtually all pharmacies, EPCS saw an 18% jump in the number of enabled prescribers in 2021 (SureScripts, 2022b).

Schedule II controlled substance prescribing considerations

Schedule II controlled substances require a written, signed prescription, except where states have enacted laws allowing EPCS. There is no federal law limiting when a signed prescription expires. A verbal order is permitted only in an emergency for Schedule II controlled substances. Written prescriptions for a Schedule II controlled substance may not be refilled. While there is no federal quantity limit for Schedule II controlled substance prescriptions, many states have enacted legislation limiting quantities for opioid prescriptions. As of 2018, 33 states passed legislation limiting it, guidance, or other requirements related to prescribing opioids (NCSL, 2019). In general, this legislation limits first-time opioid prescriptions for acute pain to a supply for a certain number of days (i.e., 3, 5, 7, or 14 days) or dosage limits (i.e., morphine milligram equivalents (MMEs); most states set exceptions for chronic pain treatment, cancer pain, and palliative care. In addition, some states have also set limits for minors (ORN, 2021).

Under federal law, a prescriber may issue multiple prescriptions authorizing the patient to receive up to a 90-day supply of a Schedule II controlled substance based on the following conditions:

- Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual professional practice.
- The prescriber provides written instructions on each prescription, indicating the earliest date a pharmacy may fill each prescription. The first prescription does not need a fill date on it if the prescriber intends for that prescription to be filled immediately.
- The practitioner concludes that providing the patient with multiple prescriptions in this manner does not create a risk of diversion or abuse.
- Issuing multiple prescriptions is permissible under applicable state laws.
- The practitioner complies with all other requirements of the CSA and any other provisions of state law.

Facsimile and oral prescriptions for schedule II controlled substances

Generally, a valid Schedule II controlled substance prescription is not allowed to be transmitted via facsimile. The CSA requires that a Schedule II controlled substance be dispensed by a pharmacy only according to a written prescription, except in emergencies, and prohibits Schedule II prescriptions from being refilled. Thus, in most cases, a pharmacist must receive the original, manually signed paper or electronic prescription before dispensing a Schedule II controlled substance (DEA, 2018c). Therefore, a prescriber may transmit a Schedule II prescription to the pharmacy via facsimile to expedite the filing. However, the original Schedule II prescription must be presented to the pharmacist for review before the controlled substance is dispensed.

In an emergency, a practitioner may call in a prescription for a Schedule II controlled substance to the pharmacy. The pharmacist may dispense the medication, provided the quantity prescribed and dispensed is limited to adequate enough to treat the patient only during the emergency period. The prescribing practitioner must provide the pharmacist with a written and signed prescription within seven days. The pharmacist must notify the DEA if the prescription still needs to be received in that timeframe.

The DEA has granted three exceptions to the facsimile prescription requirements for Schedule II controlled substances. As a result, the facsimile of a Schedule II prescription may serve as the original prescription as follows.

Regardless of the method of transmission of a controlled substance prescription—by hand delivery, facsimile, phone call, or electronically—DEA regulations make it clear that the legal responsibility for issuing a valid prescription that "conform[s] in all essential respects to the law and regulations" rests upon the prescribing practitioner. However, a pharmacist is responsible for properly prescribing and dispensing controlled substances:

- A practitioner prescribing Schedule II controlled substances to be compounded for direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may transmit the prescription by facsimile.
- Practitioners prescribing Schedule II controlled substances for residents of long-term care facilities may transmit a prescription by facsimile to the dispensing pharmacy. The practitioner's agent may also transmit the prescription to the pharmacy.
- A practitioner prescribing a Schedule II narcotic-controlled substance for a patient enrolled in a hospice care program certified and paid for by Medicare under Title XVIII or a hospice program licensed by the state may transmit a prescription to the dispensing pharmacy by facsimile. The practitioner or agent may transmit the prescription to the pharmacy and will note on the prescription that it is for a hospice patient.

As electronic prescribing of controlled substances becomes more widespread, the need to fax or call in a Schedule II controlled substance (or any other controlled substance) will decrease.

SCHEDULES III–V CONTROLLED SUBSTANCE PRESCRIBING CONSIDERATIONS

A prescription for controlled substances in Schedules III, IV, and V may be communicated verbally, written, or by facsimile to the pharmacist. It may be refilled if authorized on the prescription or by call-in. The CSA provides that a pharmacy may dispense Schedules III and IV controlled substances according to a "written or oral prescription." DEA regulations further specify that a pharmacist may dispense a Schedule III, IV, or V controlled substance according to "either a paper prescription signed by a practitioner [or] a facsimile of a signed paper prescription transmitted by the practitioner or the practitioner's agent to the pharmacy." Accordingly, an authorized agent may transmit such a practitioner-signed paper prescription via facsimile to the pharmacy on behalf of the practitioner (DEA, 2018c).

Schedules III and IV controlled substances may be refilled if authorized on the prescription. However, the prescription may only be refilled up to five times within six months of the date it was issued. After five refills or six months, whichever occurs first, a new prescription is required. Prescriptions for Schedules III through V controlled substances may be transmitted by facsimile from the practitioner, or an employee or agent of the individual practitioner, to the dispensing pharmacy. The facsimile is equivalent to the original prescription (DEA, 2020a). In addition, a pharmacist may dispense a controlled substance listed in Schedules III, IV, or V according to an oral prescription made by an individual practitioner. The pharmacist must promptly reduce writing of the oral prescription containing all information required for a valid prescription, except for the practitioner's signature.

FDA warning for codeine- and hydrocodone-containing cough and cold products

In 2018, the FDA further limited codeine-containing cough and cold products to adults older than 18 and restricted the use of cough and cold products containing hydrocodone to adults older than 18. Additionally, the FDA added black box warnings about the risks of misuse, abuse, addiction, overdose, respiratory depression, and death to codeine- and hydrocodone-containing cough and cold products. The FDA strengthened and added these warnings following recommendations from the FDA Pediatric Advisory Committee that stated the risk of these products outweighed the benefits in children and adolescents less than 18 years of age (FDA, 2022b). It is important to note that codeine-containing cough medicines are available over the counter in some states (see Table 2). The FDA is also considering regulatory action for these products (FDA, 2022e).

Table 2: Prescription Cough Medications Containing Codeine or Hydrocodone

Active Ingredients	Representative Brand Names (not inclusive of all available products)
Codeine, chlorpheniramine	Tuxarin ER, Tuzistra XR.
Codeine, phenylephrine, promethazine	Only generic products are available.
Codeine, promethazine	Only generic products are available.
Codeine, pseudoephedrine, triprolidine	Triacin C.
Hydrocodone, guaifenesin	Obredon.
Hydrocodone, pseudoephedrine, guaifenesin	Hycofenix, Rezira.
Hydrocodone, chlorpheniramine	Tussionex, Pennkinetic, Vituz.
Hydrocodone, chlorpheniramine, pseudoephedrine	Zutripro.
Hydrocodone, homatropine	Only generic products are available.

Morphine milligram equivalent (MME)

Morphine milligram equivalent (MME) thresholds guide the risk of overdose when prescribing opioids for pain. The morphine milligram conversion factor analyzes and normalizes opioid prescription data to determine a daily MME value (see Table 3). MME defines limits for the total amount of opioid analgesics prescribed to the patient as part of state legislation, Medicare/Medicaid, and other payers. The CDC recommends calculating the total daily dose of opioids (as MMEs) to identify patients who may benefit from closer monitoring, reduction, or tapering of opioids, prescribing naloxone (Narcan) or other measures to reduce the risk of overdose. MME calculations omit buprenorphine and other opioids used to treat opioid use disorder.

Compared to dosages of 1 to <20 MME/day, dosages of 50 to <100 MME/day increase the risks of opioid overdose by factors of 1.9 to 4.6 (Dowell et al., 2016). CDC guidance states that clinicians should carefully assess patients when considering increasing dosage to >50 MME/day and should avoid or carefully assess and justify a decision to increase the total opioid dose >90 MME/day (AAFP, 2021). While the CDC has not explicitly stated that opioids should not be used in quantities >90 MME/day, many states and payers limit opioid prescriptions to <90 MME/day regardless of the underlying condition (CDC, 2021) (see Table 4).

Table 3: Selected Opioid Oral MME Conversion Factors

Oral Opioids (doses in mg/day except where noted)	Conversion Factor
Codeine	0.15
Fentanyl transdermal (mcg/hour)	2.4
Hydrocodone	1
Hydromorphone	4
Methadone: 1-20 mg/day	4
21-40 mg/day	8
41-60 mg/day	10
61-80 mg/day	12
Morphine	1
Oxycodone	1.5
Oxymorphone	3
Tramadol	0.1

IMPORTANT: ***Do not use the MME conversion factor or the MME amount determined for conversion from one opioid to another or to guide dosing medication or assisted treatment for opioid use disorder. The MME conversion factor and amount may overestimate the amount for conversion, resulting in serious adverse effects such as respiratory depression or death.***

To calculate a daily MME for a patient:

1. Determine the total daily amount of each opioid the patient takes.
2. Convert each amount to MME by multiplying the total daily amount by the appropriate conversion factor (see Table 3).
3. Total all MMEs to obtain the MME/day for the patient.

Example MME calculation

Patients evaluated in the clinic report taking the following medication for their back pain:

- OxyContin: 20 mg twice daily.
- Oxycodone: 10 mg three times a day (usually).
- Flexeril: 10 mg three times a day.
- Xanax: 0.5 mg three times a day.

Total amount of oxycodone per day:

Since we are dealing with immediate-release oxycodone, the MME conversion factor remains the same as for OxyContin (1.5). Thus, the MME for oxycodone 10 mg three times a day would be:

10 mg x 3 (daily) x 1.5 = 45 MME/day

So, the total MME for the provided medication regimen is:

60 MME/day (OxyContin) + 45 MME/day (oxycodone) = 105 MME/day

Please note that MME calculations are approximate conversions used to compare the strength of different opioids to morphine.

Table 4: Examples of 50 and 90 MME/day for Commonly Prescribed Opioids

Opioid	Strength	50 MME/ Day	90 MME/Day
Hydrocodone-Acetaminophen	5 mg/325 mg	50 mg (10 tablets)	Exceeds acetaminophen maximum daily dose
	10 mg/325 mg	50 mg (5 tablets)	90 mg (9 tablets)
Oxycodone Sustained Release	15 mg	33 mg (~2 tablets)	60 mg (4 tablets)
	30 mg	33 mg (~1 tablet)	60 mg (2 tablets)
Methadone	5 mg	12 mg (<3 tablets)	~20 mg (4 tablets)

Note. CDC, 2022c.

PRESCRIBING OF OPIOIDS IN THE MANAGEMENT OF ACUTE AND CHRONIC NONCANCER PAIN IN ADULTS

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage (Cohen et al., 2021). It is critical to understand that pain is not only a neuronal response but also involves cognitive processes that make it a subjective experience that does not require identifiable tissue damage to be significant (Halpape et al., 2022). Pain perception may be related to the site of the pain, such as the face or eye pain. Pain in children and pregnant women has unique considerations that a specialist should evaluate. In addition, pain accompanied by other physical and psychological conditions needs to be evaluated. Masking a comorbid condition by simply treating the pain could result in exacerbating the condition. *Chronic pain* lasts beyond the average healing time for a given injury, operationalized as pain lasting greater than three months (Cohen et al., 2021). Chronic pain is often clinically distinguished as related to cancer (or other terminal illness) or noncancer/terminal illnesses.

The physiologic purpose of acute pain is to bring attention to potential or actual tissue damage so that appropriate action can alleviate the pain (e.g., remove your finger from the hot stove). The firing rate of peripheral neurons that detect painful stimuli, known as *nociceptors*, leads to the interpretation of pain intensity. However, the perception of nociceptor firing may influence the painful stimulus and the sensitization of the peripheral and central nervous systems. In most patients, acute pain resolves when the affected tissue heals; however, some patients progress from acute to chronic pain in a process called *pain chronification*. The underlying cause(s) is/are not established but may be related to central nervous system changes in pain facilitation and inhibition (Pak et al., 2018).

Pain chronification is based on acute pain (e.g., low back, postsurgical, diabetic neuropathy) and social and psychological factors, including maladaptive pain coping behaviors, concurrent psychiatric illness, and pain catastrophizing. Other factors associated with chronic pain include female gender, increased age, and lower household income (Pak et al., 2018). Chronic pain is characterized by persistent pain, disability, emotional disturbances, and social withdrawal symptoms that coexist and influence each other. The source of the pain may be known or unknown and may be considered a chronic disease syndrome (Halpape et al., 2022).

The role of opioid analgesics in managing acute and chronic pain is well established, and opioid prescriptions for pain- related issues increased dramatically in the 1990s. As a result, the number of ED visits, substance-abuse treatment admissions, hospital stays, and deaths due to unintentional drug overdoses increased substantially, and this led to a significant public health issue in the subsequent decades. Opioid prescriptions decreased by 44.4% between 2011 and 2020, including a 6.9% decrease from 2019 to 2020 (AMA, 2021). Along with the sharp decline in opioid prescriptions, prescribing practitioners and other healthcare professionals used the state PDMP more than 910 million times in 2020 (AMA, 2021). The 2021 *Overdose Epidemic* report issued by the AMA (2021) also highlights that more than 104,000 physicians and other healthcare professionals have an X-waiver to allow them to prescribe buprenorphine for the treatment of opioid use disorder. This is an increase of 70,000 providers since 2017, yet 80% to 90% of people with a substance use disorder receive no treatment (AMA, 2021).

The nation continues to see increases in overdose due to illicit fentanyl, fentanyl analogs, methamphetamine, and cocaine, according to the U.S. Centers for Disease Control and Prevention (2022d). In addition, state public health, media, and other reports show that drug-related overdose and death have worsened nationwide (CDC, 2022d).

Evidence-Based Practice: There is evidence that prescribing opioids for acute musculoskeletal injuries may result in long-term use and consequent harm. Riva et al. (2020) conducted a systematic review and meta-analysis of adults with opioid prescriptions for outpatient acute musculoskeletal injuries in an adjusted model that explored risk factors for prolonged use. The meta-analysis included 13,263,393 participants receiving prescriptions lasting more than seven days and higher morphine milligram equivalents per day. The study found that avoiding prescribing opioids for acute musculoskeletal injuries to patients with past or current substance use disorder restricted to seven days or less, and using lower doses when specified, are potentially important targets to reduce rates of opioid use.

Opioid analgesics in acute pain for adults

The decision of whether to use opioid analgesics for acute pain is difficult. Not all acute pain requires management with an opioid analgesic. It can be challenging to predict the intensity and duration of pain after an injury. Overprescribing opioids results in excess medication available for misuse and diversion. Studies have shown routine prescribing of excessive opioids for many types of surgical procedures and painful conditions treated in emergency departments (Kene et al., 2022). Riva et al. (2020) found that high-risk populations, that is, workers' compensation patients receiving disability benefits, Veterans Affairs claimants, and patients with a high prevalence of comorbid substance use disorder, were more likely to be on prolonged opioid use after a prescription for an acute musculoskeletal injury. Past or present substance abuse was the strongest indicator for prolonged opioid use. Therefore, it is essential to counsel patients regarding appropriate pain control and realistic expectations of pain management.

The prescriber must use clinical judgment and customize the care to the individual patient. Further, they should assess patient factors affecting pain management therapy (e.g., age, concurrent respiratory depressants, comorbid conditions), prior analgesic use, and degree and duration of expected pain requiring opioid analgesics. Additionally, prescribers should review the PDMP as part of their assessment process. Adjunctive therapy, such as physical therapy, should be explored with the patient. Counseling patients, caregivers, and other family members is essential to ensure realistic expectations, along with understanding the benefits of opiate therapy, proper use, storage and disposal, and the need for follow-up (Pino & Wakeman, 2022).

Common opioids for acute pain include oxycodone, hydrocodone, tramadol, and codeine. As the metabolism of codeine to morphine, the active form, may be variable, leading to incomplete pain relief, codeine is not a drug of choice for acute pain management. Regarding efficacy or tolerability, evidence shows similar results for oxycodone 5 mg, hydrocodone 5 mg, codeine 30 mg, and tramadol 50 mg, each in combination with acetaminophen or ibuprofen. It is important to note that the maximum recommended doses of acetaminophen and ibuprofen may limit the administration of the combination products. Oxycodone and hydromorphone as single-ingredient products may be alternatives when maximum dose limits prevent continued use of combination products (Pino & Wakeman, 2022). Serious adverse effects (e.g., excessive sleepiness, difficulty breastfeeding, or respiratory depression) could be fatal in the infant if codeine or tramadol is used in breastfeeding women (FDA, 2022c).

The CDC recommends avoiding short-acting (or immediate-release) opioids exclusively for treating acute pain in opioid- naïve patients; long-acting opioids or extended-release formulations should be avoided. In most situations, opioid analgesic treatment for acute pain should not exceed three days, and more than seven to ten days is rarely required (Pino & Wakeman, 2022).

Self-Assessment Quiz Question #3

If the prescriber institutes long-term opioid therapy, a written informed consent and treatment agreement are recommended. The informed consent may address which of the following?

a. Potential risks and benefits of opioid therapy.
b. Potential short- and long-term side effects of opioid therapy.
c. Risk of drug interactions and oversedation.
d. Risk of impaired motor skills.
e. All of the above.

Healthcare Consideration: A review of current guidelines or online references provides updated recommendations for managing acute pain following dental or surgical procedures or common emergency medical conditions. See, for example, recommendations developed by the University of Michigan (2022) at https://opioidprescribing.info/.

To reduce the overall burden of opioids, clinicians should consider nonopioid treatment modalities such as regional anesthesia, massage, or physical therapy. Follow-up within three to five days of initial treatment is essential. Reevaluate any severe pain that continues beyond the expected duration to adjust the pain management regimen appropriately. Consider a stepwise approach with the least invasive and least powerful pain management therapies appropriate for the patient (see Table 5).

Counsel patients regarding common adverse effects of opioids used for acute pain. Upon initiation of opioid therapy, it is common for patients to experience sedation, nausea or vomiting, and pruritus. In most cases, these effects resolve within a few days. It is important to note that opioid-induced itching does not always indicate an allergic reaction, as opioids induce the release of histamine. Treatment with antihistamines usually resolves the itching but may increase sedation. Ensure patients are aware of the risk of oversedation, respiratory depression, and overdose, and recommend that they not take more medication than prescribed without discussing it with their prescriber.

The FDA approved the Opioid Analgesic Risk Evaluation and Mitigation Strategies (REMS), which apply to all opioid analgesics for outpatient use. The REMS program requires that training be made available to all healthcare providers involved in managing patients with pain, including nurses and pharmacists (FDA, 2021). Prescribers are strongly encouraged to do all of the following:

- Complete a REMS-compliant education program offered by an accredited continuing education (CE) provider or another education program that includes all the elements of the FDA Education Blueprint for Health Care Providers Involved in the Management or Support of Patients with Pain.
- Use the patient counseling guide (PCG) to discuss the safe use, serious risks, and proper storage and disposal of opioid analgesics with patients and their caregivers.
- Emphasize to patients and their caregivers the importance of reading the medication guide provided by their pharmacist every time an opioid analgesic is dispensed to them.
- Consider using other tools to improve patient, household, and community safety, such as patient–prescriber agreements that reinforce patient–prescriber responsibilities.

Give special safety instructions to patients with young children, especially toddlers, and those who live with a child or adult who is cognitively impaired. For example, prescribing a controlled substance to a patient with Alzheimer's disease or other cognitive impairments must involve instructions to a responsible adult in the home.

Family members should also have a plan for accidental overdoses, including poison control (1-800-222-1222) for unintentional ingestion of a known or unknown substance. Family members should call 911 and initiate emergency services if the individual is in respiratory distress.

Table 5: Oral Opioids for Acute Pain in Opioid-Naïve Adults				
Medication	**Available Oral Strengths**	**Moderate Pain**	**Severe Pain**	**Clinical Considerations**
Codeine-acetaminophen • Tylenol with Codeine	**Tablets:** • 15 mg/300 mg • 30 mg/300 mg • 60 mg/300 mg	1 to 2 tablets every four hours as needed for pain.		Incremental efficacy decreases and increases in adverse reactions with increasing doses. Limit codeine to no more than 60 mg/dose. Do not exceed codeine 360 mg/24 hours. The maximum dose of acetaminophen is 4,000 mg/day (from all sources). Metabolism of codeine to morphine (its active form) varies between patients; drug interactions may affect response.
Hydrocodone-acetaminophen • Lorcet • Lortab • Norco • Vicodin	**Tablets:** • 2.5 mg/325 mg • 5 mg /300 mg • 5 mg/325 mg • 7.5 mg/300 mg • 7.5 mg /325 mg • 10 mg/300 mg • 10 mg/325 mg **Oral solution:** • 7.5 mg/325 mg per 15 mL • 10 mg/300 mg per 15 mL • 10 mg/325 mg per 15 mL	1 to 2 tablets PO every six hours as needed.	1 to 2 tablets PO every four to six hours as needed.	Dosage limited by acetaminophen maximum dose (4,000 mg/day [from all sources]).
Oxycodone-acetaminophen* • Endocet • Percocet • Primlev • Roxicet • Xolox	**Tablets:** • 2.5 mg/325 mg • 5 mg/325 mg • 7.5 mg/325 mg • 10 mg/325 mg **Oral solution:** • 5 mg/325 mg per 5 mL	1 to 2 tablets PO every six hours as needed.	1 to 2 tablets PO every four to six hours as needed.	Dosage limited by acetaminophen maximum dose (4,000 mg/day [from all sources]).
Tramadol-acetaminophen • Ultracet	**Tablets:** • 37.5 mg/325 mg	1 to 2 tablets PO every six hours needed.	1 to 2 tablets PO every four hours as needed.	Only FDA-approved for five days or less of treatment of acute pain. Maximum dose: Eight tablets/24 hours.
Ibuprofen-hydrocodone • Ibudone • Reprexain • Vicoprofen • Xylon	**Tablets:** • 5 mg/200 mg • 7.5 mg/200 mg • 10 mg/200 mg		1 tablet PO every four to six hours as needed.	FDA-approved for short-term, acute, severe pain (<10 days). Do not exceed five tablets/day.
Ibuprofen-oxycodone (Only available as generic)	**Tablets:** • 5 mg/400 mg		1 tablet PO every six hours.	Do not exceed four tablets/24 hours. The duration of therapy should not exceed seven days
Codeine (Only available as generic)	**Tablets:** • 15 mg • 30 mg • 60 mg	15 to 60 mg PO every four hours as needed.		A decrease in incremental efficacy and an increase in adverse reactions with increasing doses. Limit codeine to no more than 60 mg/dose. Do not exceed 360 mg codeine/24 hours. Metabolism of codeine to morphine (its active form) varies between patients; drug interactions may affect response.
Hydromorphone* • Dilaudid	**Tablets:** • 2 mg • 4 mg • 8 mg **Oral Solution:** • 5 mg/5 mL		2 to 4 mg PO every four to six hours as needed.	Used only for severe, acute pain, not as a first-line acute pain agent. Start with a low dose and titrate carefully.

Table 5: Oral Opioids for Acute Pain in Opioid-Naïve Adults				
Medication	**Available Oral Strengths**	**Moderate Pain**	**Severe Pain**	**Clinical Considerations**
Morphine* (Only available as generic)	**Tablets:** • 15 mg • 30 mg **Tablets:** • 10 mg/0.5 mL • 10 mg/5 mL • 20 mg/5 mL • 20 mg/5 mL • 100 mg/5 mL		10 to 30 mg PO every four hours as needed.	Utilized only for severe, acute pain; not a first-line acute pain agent. Start with a low dose and titrate carefully.
Oxycodone* • Oxaydo • Roxicodone • Roxybond	**Capsules:** • 5 mg **Tablets:** • 5 mg • 7.5 mg • 10 mg • 15 mg • 20 mg • 30 mg **Oral Solution:** • 5 mg/5 mL • 20 mg/5 mL • 100 mg/5 mL		5 to 15 mg PO every four to six hours.	Utilized only for severe, acute pain; not a first-line acute pain agent. Start with low a dose and titrate carefully.
Tramadol (Ultram)	**Tablets:** • 50 mg	1 to 2 tablets PO every four to six hours as needed.		Maximum dose (<75 years): 400 mg/day. Maximum dose (75 years and older): 300 mg/day
**Note*: Avoid extended-release formulations and long-acting opioids in acute pain.				

Healthcare Consideration: Assessment of acute or chronic pain should be multidimensional. Consideration should be given to several domains, including the physiological features of pain and its contributing factors, with physicians and other clinicians assessing patients for function, quality of life, mental health, and emotional health. In addition to a complete medical and medication history typically obtained at an office visit, document pain intensity, location, duration, and factors that aggravate or alleviate pain (AAFP, 2021).

INTEGRATIVE NURSING

Kreitzer and Koithan (2019) define integrative nursing as a "way of being-knowing-doing that advances the health and well- being of persons, families, and communities through caring/healing relationships. Integrative nurses use evidence to inform traditional and emerging interventions that support whole person/whole system healing" (p. 4). Integrative medicine and integrative nursing are the same. In the past, these therapies were called *complementary* because they were adjuncts to the prescribed treatment regimen. Some called these therapies nonsense. The opioid epidemic has pressured providers with the option to prescribe more controlled substances or offer alternatives.

Literature shows that integrative therapies positively affect patients' perception of pain. DeBar et al. (2022) found that primary care–based cognitive behavioral therapy intervention (CBT), using frontline clinicians, produced modest but sustained reductions in measures of pain and pain-related disability compared with usual care. Yoga and low back pain demonstrated a similar positive finding. A systematic review published in 2022 found that yoga revealed robust short- and long-term effects on pain, disability, physical function, and mental health compared with nonexercise controls (Anheyer et al., 2022).

In their book *Integrative Nursing*, Kreitzer and Koithan (2019) offer a tiered approach to pain management. Nurses have offered these therapies to their patients for years. The different tiers and integrative therapy approaches are shown in Table 6.

Table 6: Tiered Integrative Approaches to Pain Management*	
Tiered Intervention	**Integrative Approaches**
Tier 1	Hot/cold therapy
	Relaxation response
	Guided imagery
Tier 2	Aromatherapy
	Yoga
	Hydrotherapy
Tier 3	Cognitive-behavioral (pain management therapy
	Mindfulness-based stress reduction meditation
	Massage
	Acupressure

Table 6: Tiered Integrative Approaches to Pain Management*	
Tiered Intervention	**Integrative Approaches**
Tier 4	Homeopathy
	Chiropractic
	NSAIDs
	Transcutaneous electrical nerve stimulation
Tier 5	Pharmacological therapies
	Surgical procedures
	Nerve blocks
*Adapted from Integrative Nursing (Kreitzer & Koithan, 2019).	

Clinical case example

Ana is a 50-year-old female with chronic arthritis pain in her hands and knees. She states that the pain has worsened in the past two months, and she had previously tried therapies that do not alleviate the pain. She went for a morphine refill but was turned back to the pain specialist since the script was expired. So, Ana is asking the nurse practitioner for another prescription.

Given the information provided, which tier aligns with Ana's symptoms? Provide one short-term and one long-term intervention using the integrative approach examples:

Suggest **one** *immediate* intervention for your patient and provide a brief rationale.	Immediate interventions for Ana would include: • Therapeutic listening, presence, therapeutic use of self-touch. • Heat/cold therapy. Because of the recent change in pain and increase in the past two months, gather some diagnostics— check a rheumatoid factor, sed rate (ESR), and c- reactive protein (CRP).
Suggest **one** *long-term* intervention for your patient and provide a brief rationale	For long-term therapies, Ana could focus on some movement therapies, including: • Yoga. • Hydrotherapy. • Tai chi. These therapies might help with the circulation of joints. They might help with deep breathing exercises and a sense of appreciation for self.

Instruments for evaluating pain

Socrates

It is critical to gain as much information as possible about the specific complaint of pain to properly determine a course of treatment. The SOCRATES acronym is a useful tool that can be used to remember key points to be collected when assessing a complaint of pain:

- **S**ite: Where exactly is the pain?
- **O**nset: When did it start? Was it constant/intermittent? Was it gradual/sudden?
- **C**haracter: What is the pain like? Sharp? Burning? Tight?
- **R**adiation: Does the pain radiate/move anywhere?
- **A**ssociations: Is there anything else associated with the pain, such as sweating or vomiting?
- **T**ime course: Does it follow any time pattern? How long does it last?
- **E**xacerbating/relieving factors: Does anything make it better or worse?
- **S**everity: How severe is the pain? Consider using a 1–10 scale.

(Swift, 2019)

The physical examination conducted as part of the initial patient screening contains all the elements common to contemporary practice. A few areas should be emphasized because of the unique nature of opioid prescriptions (Clark & Galati, 2015). Here are topics to consider:

- A rigorous evaluation of the patient's nervous system.
- An assessment of allodynia (pain from the stimulation that would not normally evoke pain, such as light touch).
- Hyperalgesia (amplified pain response to stimulation that would normally evoke only mild pain).
- Pain insensitivity, which is also known as *congenital analgesia* and is one or more rare conditions in which a person cannot feel (and has never felt) physical pain.
- A sensory examination that could include response to light touch, light pressure, pinpricks, cold, or vibrations.

(Clark & Galati, 2015)

PQRST

P What provokes symptoms? What improves or worsens the condition? What were you doing when it started? Do position changes or activities make it worse?

Q Quality and Quantity of symptoms: Is it dull, sharp, constant, intermittent, throbbing, pulsating, aching, tearing, or stabbing?

R Radiation or Region of symptoms: Does the pain travel, or is it only in one location? Has it always been in the same area, or did it start somewhere else?

S Severity of symptoms or rating on a pain scale. Does it affect activities of daily living, such as walking, sitting, eating, or sleeping?

T Time or how long have they had the symptoms? Is it worse after eating, changes in weather, or time of day? Other tools, such as the Brief Pain Inventory form, provide an assessment of pain and gauge treatment (AAFP, 2021).

OPIOIDS FOR CHRONIC NONCANCER PAIN IN ADULTS

An estimated 100 million adults in the United States are affected by chronic pain and are commonly diagnosed with chronic low back pain, joint pain/arthritis, or headaches (Smith & Hillner, 2019). Chronic pain often has no cure; treatment will not provide complete resolution. Treatment interventions for chronic pain should focus on the long-term management of physical, psychological, and social symptoms to improve pain management and quality of life and decrease suffering. Thus, a multidisciplinary, multimodality approach is the most effective method to manage adults' chronic noncancer pain (Smith & Hillner, 2019).

Self-Assessment Quiz Question #4

Are integrative nursing therapies and complementary therapies the same?

a. Yes.
b. No.

Assessment of adults for chronic opioid therapy

A comprehensive assessment of the patient, caregiver(s), and family member(s) is necessary to determine an appropriate chronic pain management regimen. The goal is to determine the nature of the pain and how the pain affects the function and quality of life, assess prior treatment approaches, and detect

other conditions that could influence the decision to utilize opioid analgesics (AAFP, 2021). The assessment should include:

- Nature and intensity of pain.
- Past and current treatment regimens and responses, including adverse effects or reactions.
- How pain impacts physical and psychological function.
- How pain influences sleep, mood, work, relationships, leisure, and substance use.
- Identification of concurrent conditions that may increase the risk for adverse events (e.g., obesity, renal disease, sleep apnea, COPD).
- Review of current medications; identify interacting drugs and other CNS depressants.
- Social support, housing, employment, or recent military deployment.
- Patient and family history of mental health disorders (e.g., bipolar, attention deficit disorder (ADD) / attention deficit hyperactivity disorder (ADHD), depression, posttraumatic stress disorder).
- Patient and family history of substance use, addiction, or dependence.
- Determination of any history of physical, emotional, or sexual abuse and risk factors for substance abuse disorder; validated screening tools for substance abuse disorder help determine a patient's risk level.
- Review of PDMP results.
- Monitoring of PDMP regularly throughout chronic pain management follow-up to determine if the patient obtains other controlled substance prescriptions from other providers.

Informed consent and treatment plans for chronic opioid treatment

The patient-specific treatment plan should be developed and reviewed regularly to ensure that both the clinician and patient agree on the goals of the therapy, treatment regimen, and options. Consider different treatment modalities, such as an interventional approach, a formal pain rehabilitation program, physical medicine, psychological and behavioral strategies, or medications (nonopioids and opioids), depending upon the physical and psychosocial issues related to the pain. Opioid therapy is not the appropriate first-line treatment for most patients with chronic pain. It should be reserved for intractable chronic pain not adequately managed with more conservative or interventional methods. Other nonopioid medications, treatment modalities, and nonpharmacological therapy should be tried first. Practitioners should document the effectiveness or failure of these medications before initiating opioid therapy (CDC, 2022a; Dowell et al., 2016).

Suppose the prescriber determines that an opioid trial is an appropriate treatment option. In that case, the patient, caregiver(s), and family member(s) are informed of the risks and benefits of opioid analgesic therapy and the conditions under which the opioids are being prescribed. A trial implies that opioids are used for a short period (i.e., weeks or a couple of months), and continued use will be contingent upon demonstrated improvement in pain, physical function, and quality of life with no significant adverse reactions or aberrant behaviors (Kroenke et al., 2019).

If the prescriber institutes long-term opioid therapy, a written informed consent and treatment agreement are recommended. The informed consent may address several issues, such as:

- Limited evidence of the benefit of opioids or other medications in managing chronic pain (except for cancer).
- Potential risks and benefits of opioid therapy.
- Potential short- and long-term side effects of opioid therapy.
- The likelihood that tolerance to and physical dependence on the medication will develop.
- Risk of drug interactions and oversedation.
- Risk of impaired motor skills.
- Risk of substance abuse disorder, overdose, and death.
- The clinician's prescribing policies (e.g., number and frequency of refills, early refills, exceptions).
- Reasons a drug may be changed or discontinued; treatment may be discontinued without agreement from the patient, such as violations of the treatment agreement.
- Education for patients stating that complete elimination of pain should not be expected.

(HHS, 2019a)

Chronic pain treatment agreements that outline the responsibilities of the patient and the provider are indicated for long- term treatment with opioids or other medications with the potential for substance abuse disorder. The U.S. Department of Health and Human Services, Division of Indian Health Services, recommends that treatment agreements include the following tenets:

- Treatment goals are defined in terms of pain management, restoration of function, and safety.
- The patient is responsible for safe medication use (i.e., not taking more than prescribed; understanding the dangers of using in combination with alcohol, cannabis, benzodiazepines, or other CNS depressants unless closely monitored by the prescriber).
- The patient will ensure secure storage and safe disposal.
- The patient will obtain opioids from only one clinician or practice.
- The patient will fill the opioids at only one pharmacy.
- The patient will agree to periodic drug testing (i.e., urine drug screening).
- The clinician is responsible for making themselves available or having a covering clinician available to care for unforeseen problems and to prescribe scheduled refills.

(HHS, 2019a)

Complete pain relief is often not achieved; a 30% reduction in pain is considered a good clinical response (Dowell et al., 2016). In a function-based treatment strategy for chronic pain, treatment efficacy is measured by the patient's ability to achieve improved function rather than complete pain relief. These goals may include going to work, walking, achieving enhanced sleep, or improving social interactions. It may be beneficial to begin with more easily achievable goals and progress to more challenging ones after initial successes. This approach can be much more motivating than a plan resulting in early treatment failure (HHS, 2019b).

Initiating opioid therapy for chronic noncancer pain

When initiating opioid therapy for chronic pain, clinicians should start with immediate-release opioids and avoid extended- release formulations or long-acting opioids. Begin with the lowest effective dosage. Evaluate patients within one to four weeks of starting opioid therapy or dose escalation. Clinicians should evaluate patients every three months to assess the continued benefit and the development of any adverse effects once the opioid dose is stabilized. If the patient no longer benefits from the opioid therapy, the clinician should optimize the treatment regimen, including adding other treatment modalities or tapering off the opioid regimen (CDC, 2022b).

Some patient populations and patients with certain conditions require closer monitoring and counseling before initiation and during chronic pain treatment. For example, patients receiving other central nervous system depressants, especially benzodiazepines, require special attention because of an increased risk of adverse events, including increased sedation, confusion, difficulty driving or performing other tasks requiring high concentration levels, respiratory depression, and overdose. It is also necessary to assess how the patient uses work equipment that requires precise motor control, heavy machinery, or chemical or biohazardous materials. Pregnant women also require an enhanced level of caution because chronic opioid use during pregnancy increases the risk of harm to the newborn, specifically neonatal opioid withdrawal syndrome. Further, these medications must be used cautiously in breastfeeding women because some opioids can be transferred

to breast milk and may cause sedation or respiratory depression in the nursing infant. In elderly patients, clinicians should consider employing a lower starting dose, a slower titration period, and a longer dosing interval with more frequent monitoring.

Patients with psychiatric disorders are at increased risk of adverse events associated with chronic opioid therapy. Untreated depression and other mental health disorders place patients at increased risk for misuse and abuse of opioid analgesics, including addiction and overdose. In addition, untreated depression may interfere with pain resolution. In cases where the opioid dosage increases, the prescriber should educate the patient on the risk of cognitive impairment that can negatively impact their ability to drive or perform other activities.

Evidence-Based Practice: Is exercise effective in treating long-lasting low back pain?

Long-lasting (chronic) low back pain is a common cause of disability worldwide and is expensive in terms of healthcare costs and lost working hours. Exercise therapy aims to increase muscle and joint strength, improve muscle function and range of motion, reduce pain and disability, speed recovery, and return the patient to their usual activities. Examples of exercise therapies include general physical fitness programs delivered in a group setting, aerobic exercise in the form of walking programs, and strengthening specific muscles or groups of muscles to increase core stability.

Hayden et al. (2021) conducted a systematic review. They found moderate-certainty evidence that exercise treatment is more effective than no treatment, usual care, or placebo for pain intensity and functional limitations outcomes. That is, exercise may be more effective for pain and is probably more effective for disability than common treatments in the short and medium term.

Special considerations for extended-release and long-acting (ER/LA) opioids

The FDA advises that extended-release and long-acting (ER/LA) opioid analgesics be reserved for patients when alternative treatment options are ineffective, not tolerated, or inadequate to provide sufficient pain relief (FDA, 2018). Before prescribing these products, review FDA-approved REMS programs, medication guides, and black box warnings (BBW) (FDA, 2021). These products, listed in Table 7, are not for acute pain, pain that is mild or not expected to persist for an extended period, or use on an as-needed basis. In addition, the FDA-approved BBWs on these products advise clinicians of the following:

- ER/LA opioid analgesics expose users to addiction, abuse, and misuse risks, leading to overdose and death. Assess each patient's risk before prescribing and regularly monitor the development of these behaviors and conditions.
- Life-threatening severe or fatal respiratory depression may occur. Monitor closely, primarily upon initiation or following a dose increase. Instruct patients to swallow ER/LA opioid analgesics to avoid exposure to/ingestion of a potentially fatal dose.
- Accidental ingestion of ER/LA opioid analgesics can result in a fatal overdose, especially in children. (Note: Accidental pet ingestion has also led to a deadly dose.)
- Prolonged ER/LA opioid analgesics use during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated. In prolonged opioid use in pregnant women, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure appropriate treatment will be available.
- Initiation of CYP 3A4 inhibitors (or discontinuation of medications that induce CYP 3A4) can result in a fatal overdose.

Table 7: Common Opioids for Chronic Pain Management

Medication	Available Oral Strengths	Dosage	Clinical Considerations
Hydrocodone, extended-release tablets • Zohydro ER	**Tablets:** • 10 mg • 15 mg • 20 mg • 30 mg • 40 mg • 50 mg	**Initiate:** • 10 mg every 12 hours. • Titrate by 10 mg every 12 hours as needed every 7 to 10 days.	The conversion factor for daily oral opioids to Zohydro: • Hydrocodone: 1 • Oxycodone: 1 • Methadone: 1 • Oxymorphone: 2 • Hydromorphone: 2.67 • Morphine: 0.67 • Codeine: 0.1 Do *not* use it to convert Zohydro to other opioids, as it will result in overestimation and possible fatal overdose. During treatment with extended- release formulations, immediate- release formulations may be required for breakthrough pain.

Table 7: Common Opioids for Chronic Pain Management			
Medication	**Available Oral Strengths**	**Dosage**	**Clinical Considerations**
Hydrocodone, extended-release tablets • Hysingia ER	**Tablets:** • 20 mg • 30 mg • 40 mg • 60 mg • 80 mg • 100 mg • 120 mg	**Initiate:** • 20 mg every 24 hours. • Titrate dose by 10 to 20 mg every 3 to 5 days as needed.	The conversion factor for daily oral opioids to Hysingia: • Hydrocodone: 1 • Oxycodone: 1 • Methadone: 1.5 • Oxymorphone: 2 • Hydromorphone: 4 • Morphine: 0.5 • Codeine: 0.15 • Tramadol: 0.1 Do *not* use it to convert Hysingia to other opioids, as this will result in overestimation and possible fatal overdose. During treatment with extended- release formulations, immediate- release formulations may be required for breakthrough pain.
Hydromorphone, immediate release	**Tablets:** • 2 mg • 4 mg • 8 mg **Oral solution:** • 5 mg/5 mL	As the first opioid or in patients not opioid tolerant: • Tablets: 2 to 4 mg. PO every 4 to 6 hours. • Oral solution: 2.5 to 10 mg PO every 3 to 6 hours.	In opioid-tolerant patients, the dose and duration of pain relief will vary depending on the patient's tolerance. Commonly used for breakthrough pain in patients receiving around-the-clock hydromorphone.
Hydromorphone, extended-release tablets • Exalgo	**Tablets:** • 8 mg • 12 mg • 16 mg • 32 mg	Conversion from immediate release hydromorphone: • Calculate total daily hydromorphone dose and give orally once daily. • Titrate dose by 4 to 8 mg every 3 to 4 days as needed.	The conversion factor for daily oral opioids to Exalgo: • Hydromorphone: 1 • Codeine: 0.06 • Hydrocodone: 0.4 • Methadone: 0.6 • Oxycodone: 0.4 • Oxymorphone: 0.6 Do *not* use to convert Exalgo to other opioids, as this will result in overestimation and possible fatal overdose. During treatment with extended- release formulations, immediate- release formulations may be required for breakthrough pain.
• **Morphine, immediate release**	**Tablets:** • 15 mg • 30 mg **Oral solution:** • 10 mg/0.5 mL • 10 mg/5 mL • 20 mg/5 mL • 20 mg/5 mL • 100 mg/5mL	10 to 30 mg PO every 4 hours as needed.	Commonly used for breakthrough pain in patients receiving around-the-clock morphine.
Morphine, extended-release tablets • Arymo ER • Morphaond MS • Contin	**Tablets:** • 15 mg • 30 mg • 60 mg • 100 mg • 200 mg	Conversion from immediate-release morphine: • Calculate total daily morphine dose; give half every 12 hours or one-third every 8 hours. • Adjust dosage every 1 to 2 days based on complete daily morphine requirements.	Conversion ratios from other opioids to extended-release morphine formulations have not been defined. During treatment with extended-release formulations, immediate-release formulations may be required for breakthrough pain.

Table 7: Common Opioids for Chronic Pain Management			
Medication	**Available Oral Strengths**	**Dosage**	**Clinical Considerations**
Morphine, extended-release capsules • Avinza • Kadian	**Capsules:** • 10 mg • 20 mg • 30 mg • 40 mg • 60 mg • 80 mg • 100 mg • 200 mg	Conversion from immediate release morphine: • Calculate total daily morphine dose and give orally once daily • Adjust dosage every 1 to 2 days (Kadian) or 3 to 4 days (Avinza) based on total daily morphine requirements.	Conversion ratios from other opioids to extended-release morphine formulations have not been defined. During treatment with extended-release formulations, immediate-release formulations may be required for breakthrough pain.
Oxycodone, immediate release • Oxaydo • Roxicodone • Roxybond	**Capsules:** • 5 mg **Tablets:** • 5 mg • 7.5 mg • 10 mg • 15 mg • 20 mg • 30 mg **Oral solution:** • 5 mg/5 mL • 20 mg/5 mL • 100 mg/5 mL	**Initiate:** • 5 to 15 mg PO very 4 to 6 hours.	Commonly used for breakthrough pain in patients receiving around-the-clock oxycodone.
• **Oxycodone, extended-release tablets** • OxyContin	**Tablets:** • 10 mg • 15 mg • 20 mg • 30 mg • 40 mg • 60 mg • 80 mg	Conversion from immediate release oxycodone: • Calculate total daily oxycodone dose. • Divide into two equal amounts and give orally every 12 hours. • Titrate the total daily oxycodone dose by 25% to 50% every 1 to 2 days.	Due to drug interactions, particular drugs may need to be avoided, or dosage adjustments may be necessary. During treatment with extended-release formulations, immediate-release formulations may be required for breakthrough pain. To convert from fentanyl transdermal patch to oxycodone: • 10 mg PO every 12 hours for each 25 mcg/hour fentanyl transdermal patch beginning 18 hours after removal of the fentanyl transdermal patch.
Oxycodone (as a base), extended-release capsules • Xtampza	**Capsules:** • 9 mg • 13.5 mg • 18 mg • 27 mg • 36 mg	Conversion from immediate-release oxycodone: • Calculate total daily oxycodone dose. • Divide into two equal doses. • Give orally every 12 hours; titrate the total daily oxycodone dose by 25% to 50% every 1 to 2 days.	Due to drug interactions, certain drugs may need to be avoided, or dosage adjustments may be necessary. Use an alternate medication for patients who require a dose less than 9 mg. Maximum dosage limit: 288 mg/day (equivalent to 320 mg oxycodone HCl). During treatment with extended- release formulations, immediate- release formulations may be required for breakthrough pain.
Oxymorphone, immediate-release tablets • Opana	**Tablets:** • 5 mg • 10 mg	5 to 20 mg PO every 4 to 6 hours as needed.	Only for severe pain requiring an opioid analgesic when alternative therapy has been inadequate.

Table 7: Common Opioids for Chronic Pain Management			
Medication	**Available Oral Strengths**	**Dosage**	**Clinical Considerations**
Oxymorphone, extended-release tablets • Generic only	**Tablets:** • 5 mg • 7.5 mg • 10 mg • 15 mg • 20 mg • 30 mg • 40 mg	Conversion from immediate release oxymorphone: • Calculate total daily oxymorphone dose; divide into two equal doses and give orally every 12 hours. • Titrate by 5 to 10 mg/dose every 3 to 7 days as needed.	Conversion factor for daily oral opioids to oxymorphone, extended-release: • Oxymorphone: 1 • Hydrocodone: 0.5 • Oxycodone: 0.5 • Morphine: 0.333 • Methadone: 0.5 Do *not* use it to convert oxymorphone, or extended-release to other opioids, as this will result in overestimation and possible fatal overdose. During treatment with extended- release formulations, immediate- release formulations may be required for breakthrough pain.
Tapentadol, immediate- release tablets	**Tablets:** • 50 mg • 75 mg • 100 mg	**Initiate:** • 0 to 100 mg PO every 4 to 6 hours. • A second dose may be administered as soon as 1 hour after the first dose if pain control is not achieved. • Titrate dose as needed to the maximum dose.	Only for severe pain requiring an opioid analgesic when alternative therapy has been inadequate. Maximum dose of tapentadol immediate release is 700 mg/day on day one and 600 mg/day thereafter.
Tapentadol, extended-release tablets • Nucynta ER	**Tablets:** • 50 mg • 100 mg • 150 mg • 200 mg • 250 mg	Conversion from immediate release tapentadol: • Calculate total daily tapentadol dose. • Divide into two equal doses and give orally every 12 hours. • Titrate by no more than 100 mg/day every 3 days.	There are no established dosage ratios for direct conversion from other opioids to tapentadol. Generally, recommended to start at 50 mg PO twice daily and titrate by no more than 100 mg/day every 3 days. The maximum dose of tapentadol extended-release is 500 mg/day (250 mg PO twice daily).
Fentanyl, transdermal patch (72-hour) • Duragesic	**Patch Strength** • 12 mcg/hour • 25 mcg/hour • 37.5 mcg/hour • 50 mcg/hour • 62.5 mcg/hour • 75 mcg/hour • 87.5 mcg/hour • 100 mcg/hour	Conversion from a different opiate agonist to Duragesic: • Convert the previous 24-hour opioid analgesic requirement to an equianalgesic morphine dose. • Use conversion chart to determine Duragesic initial dosage. • Change the patch every 72 hours. • May titrate ate initial dosage after 3 days (72 hours). • Subsequent dose titrations should be made no more frequently than every 6 days. Monitor patients closely for respiratory depression the first 24 to 72 hours after initiating therapy or dose escalation Supplemental doses may be required	Recommended initial Duragesic based on daily morphine dose: • Morphine 60 to 134 mg/day PO: Fentanyl transdermal patch 25 mcg/hour. • Morphine 135 to 224 mg/day PO: Fentanyl, transdermal patch 50 mcg/hour. • Morphine 225 to 314 mg/day PO: Fentanyl transdermal patch 75 mcg/hour. • Morphine 315 to 404 mg/day PO: Fentanyl transdermal patch 100 mcg/hour. • Morphine 405 to 494 mg/day PO: Fentanyl transdermal patch 125 mcg/hour. • Morphine 495 to 584 mg/day PO: Fentanyl transdermal patch 150 mcg/hour. • Morphine 585 to 674 mg/day PO: Fentanyl transdermal patch 175 mcg/hour. • Morphine 675 to 764 mg/day PO: Fentanyl transdermal patch 200 mcg/hour. • Morphine 765 to 854 mg/day PO: Fentanyl transdermal patch 225 mcg/hour. • Morphine 855 to 944 mg/day PO: Fentanyl transdermal patch 250 mcg/hour. • Morphine 945 to 1034 mg/day PO: Fentanyl transdermal patch 275 mcg/hour. • Morphine 1035 to 1124 mg/day PO: Fentanyl transdermal patch 300 mcg/hour. ***Do not convert fentanyl transdermal patches to other opioids, as this will result in overestimation and possible fatal overdose.*** During treatment with extended- release formulations, immediate- release formulations may be required for breakthrough pain.

Table 7: Common Opioids for Chronic Pain Management			
Medication	**Available Oral Strengths**	**Dosage**	**Clinical Considerations**
Methadone, immediate release • Dolophine, Methadose	**Tablets:** • 5 mg • 10 mg **Oral solution:** • 5 mg/5 mL • 10 mg/5mL	Conversion from a different opiate agonist to methadone: • 30 to 40 mg/day (divided into 2 to 3 doses). • Titrated every 5 to 7 days in doses of 5 to 10 mg/day.	Due to the unique properties of methadone, dosage ratios for direct conversion to methadone are variable and can be inconsistent between patients. The duration of action of methadone is 4 to 8 hours, while the elimination half- life ranges from 8 to 59 hours. Increased monitoring for delayed adverse effects (i.e., respiratory depression) is required, especially during the first 24 to 72 hours after initiation or dose increase. The potency of methadone increases with repeated dosing. Immediate- release opioids may be required for breakthrough pain.
**Note*: While many ER/LA opioid analgesics are FDA-approved (at specific dosages) for opioid-naïve or non-opioid-tolerant patients, current guidelines for chronic pain management do not recommend these products to patients (Dowell et al., 2016); therefore, those doses are not provided in the table. It is recommended to stop all other around-the-clock opioid drugs upon initiation of a new ER/LA product.			

Equianalgesic dosing of opioids

Opioid medications have differing potencies. When converting from one opioid medication to another, it is critical to understand the equivalent analgesic (equianalgesic) dose to ensure continued efficacy without untoward side effects (see Table 8). The dose, administration route, and therapy duration must be considered. Multiple opioid conversion charts are available. Clinicians must consider individual patient factors and the characteristics of the opioid medications and delivery systems when converting between opioid products. Closely monitor patients following conversion for efficacy and potential adverse effects.

Table 8: Opioid Equianalgesic Table (Stanford College of Medicine, 2022)			
Medication	**Approximate Equianalgesic Oral Dose**	**Approximate Equianalgesic Intravenous Dose**	**Conversion Factor to Oral Morphine**
Morphine	30 mg	10 mg	Parenteral morphine is *3 times* as potent as oral morphine.
Oxycodone	20 mg		Oral oxycodone is roughly *1.5 times* more potent than oral morphine.
Hydrocodone	20 to 30 mg		Oral hydrocodone is roughly *1.5 times* more potent than oral morphine.
Hydromorphone	7 mg	1.5 mg	Oral hydromorphone is about *4 to 7 times* as potent as oral morphine. Parenteral hydromorphone is *20 times* as potent as oral morphine.
Fentanyl		100 mcg (0.1 mg) 15 mcg/hour	Transdermal fentanyl is *~80 times* as potent as oral morphine. (See Table 7 to convert morphine to fentanyl transdermal patches.)
Methadone	Variable	Variable	
Tramadol	300 mg		0.1
Codeine	200 mg		0.15
Meperidine	300 mg of oral meperidine	75 mg of parenteral meperidine	Oral morphine is about *10 times* more potent than oral meperidine and about twice as potent as parenteral meperidine (mg for mg).
*Note: To convert to ER/LA opioids, see conversion factors listed in Table 7.			

Calculation of equianalgesic dosages

Follow these three steps to calculate equianalgesic dosages when changing to a different opioid analgesic:

Step 1: Calculate the total daily dose of the current opioid.

Step 2: Determine the equianalgesic dose using the appropriate conversion factor or ratio.

Step 3: Reduce the new opioid analgesic dose by 33% to 50% to account for cross-tolerance, dosing ratio variation, and patient variability. Determine a new regimen based on the available dosage form(s) of the new opioid.

Clinical Case Example

CD is a 32-year-old female with chronic pain. She is taking Exalgo 16 mg once daily and hydromorphone immediate- release 4 mg three times daily for breakthrough pain. The patient should be transitioned to MS Contin due to insurance issues. What dose of MS Contin should be started?

Step 1:	*Calculate the total daily dose of the current opioid.*

Exalgo 16 mg once daily + hydromorphone immediate-release 4 mg three times daily

= 28 mg/day hydromorphone

Step 2:	*Determine the equianalgesic dose using the appropriate conversion factor or ratio.*

Oral hydromorphone to oral morphine conversion ratio: 4

28 mg hydromorphone/day × 4 = 112 mg morphine/day

OR

$$\frac{\text{28 mg hydromorphone}}{\text{7.5 mg}} = \frac{\text{equianalgesic dose of morphine}}{\text{30 mg}}$$

Equianalgesic dose of morphine/day = 112 mg

Step 3:	*Reduce dose by 33% to 50% to account for cross-tolerance; determine a new regimen based on available dosage forms of the new opioid.*

Total daily dose of morphine = 74 to 56 mg/day

New regimen: MS Contin 30 mg every 12 hours

(Total morphine dose = 60 mg/day)

NP Consideration: Opioid equianalgesic dose conversions are not the same as the MME conversions. Do not use MME factors to convert between opioid medications, as this may lead to serious adverse effects, including respiratory depression, overdose, and death.

Monitoring adults receiving chronic opioid therapy

Ongoing patient monitoring and reiterating vital components of the agreed-upon treatment plan are necessary during long- term therapy with opioids. In addition, continue to assess patient-specific improvement versus risks of opioid treatment to determine if changes or discontinuation of opioid therapy are required.

Functional improvements may be incremental and occur over months or years. Further, some patients who begin showing solid progress may plateau. In these cases, consider reassessment. Functional goals and objective evidence of achievement include:

- Participate in physical therapy sessions: Documentation of progress from physical therapist.
- Sleeping in bed instead of chair: Reported by a caregiver, family member.
- Participation in a pain support group: Letter from the group leader.
- Ability to walk around the block: Self-report, pedometer, caregiver, friend .
- Return to work: Pay stubs, a letter from the employer.

(HHS, 2019b)

Clinicians must be vigilant for aberrant behaviors indicating a patient may be at risk for misuse or abuse of opioids that could result in addiction and substance abuse disorder. A review of PDMP before prescribing or renewing may indicate if the patient is seeing other providers unbeknownst to the primary prescriber. Discuss any unexpected results thoughtfully, as errors in data have been known to occur. Urine drug screening may determine if the patient has ingested other medications or illicit substances beyond the agreed-to treatment plan. Urine screening tests may produce false positives. A qualitative test will confirm any positive result from a urine screening test. Review with patients the need for securely storing their opioid medications to prevent misuse by others and possible accidental exposure, especially to children and pets. When opioid treatment is discontinued, advise patients to return unused opioid medications to drug take-back programs sponsored by pharmacies, the DEA, or other local agencies. If these programs are unavailable, counsel patients to dispose of their medicines in the household trash by following these steps:

1. Remove drugs from their original containers and mix them with something undesirable, such as used coffee grounds, dirt, or cat litter. This makes the medicine less appealing to children and pets and unrecognizable to someone who might intentionally go through the trash looking for drugs.
2. Put the mixture in something that can be closed (e.g., a resealable plastic bag, empty can, or another container) to prevent the drug from leaking.
3. Throw the container in the garbage.
4. Delete personal information on empty prescription medication bottles or packaging to protect identity and privacy. Throw the packaging away.
5. Do not flush opioids down the toilet or drain, as this can contaminate the water supply. (Pino & Wakeman, 2022)

MANAGING OPIOID-INDUCED ADVERSE EFFECTS

An essential component of any chronic opioid therapy follow-up evaluation is assessment for opioid-related adverse effects. Tolerance to acute opioid-induced side effects (e.g., sedation, nausea/vomiting, itching) will develop; however, other adverse effects may continue to be an issue. Additionally, clinicians must be aware of long-term side effects.

Opioid-induced constipation is a risk throughout chronic opioid therapy. Therefore, prescribing scheduled use of stool softeners (e.g., docusate) and stimulants for those receiving chronic opioids is warranted. In addition, instruct patients to contact their prescriber if they do not have a bowel movement at least every 2 to 3 days to avoid developing impaction. In some cases, a prescription medication for opioid-induced constipation may be necessary.

Patients do not develop tolerance to the opioids' respiratory depressive effects, even with chronic therapy. Additionally, this risk increases if other CNS depressant agents (prescribed or illicit) or alcohol are concurrent. Consider prescribing naloxone (Narcan), an opioid antagonist, for any patient at risk of opioid-induced respiratory depression. When administered to a patient experiencing an opioid overdose and opioid-induced respiratory depression, naloxone can rapidly reverse all signs and symptoms of opioid intoxication. Many states have passed laws expanding access to naloxone, allowing pharmacists to dispense or distribute naloxone without a prescription under certain circumstances.

As part of the FDA's action plan regarding the safety of opioid analgesics, it has released several safety-related product labeling updates. In addition, the FDA (2018) updated warnings across the

entire class of opioids regarding drug interactions, adrenal issues, and alterations in sex hormone levels. Specifically, the FDA warns that opioids may interact with other medications that increase serotonin levels (e.g., certain antidepressants and migraine medications), which may lead to serotonin syndrome. In addition, opioids are rarely associated with adrenal insufficiency, and long-term use of opioids decreases sex hormone levels. Consider these potential drug interactions and adverse effects and discuss them with patients when determining the appropriateness of opioid therapy (FDA, 2022a).

The FDA issues a black box warning (BBW) for all prescription opioid pain and cough medications and all prescription benzodiazepines regarding the risk for the CNS depression and serious adverse effects, including respiratory depression and death. The BBW was issued after several studies showed an increasing trend in concomitant dispensing of opioid analgesics and benzodiazepines and an increasing frequency of combined benzodiazepine and prescription opioid misuse, abuse, and overdose as measured by national emergency department visit and overdose death rates from prescribed or greater-than-prescribed doses (FDA, 2021). In addition, other CNS depressants (e.g., barbiturates, antipsychotics, and neuroleptic drugs; antiepileptic and antiparkinsonian drugs; anesthetics; autonomic nervous system drugs; and muscle relaxants) contributed to deaths where opioids were also implicated (SureScripts, 2022b).

Tori et al. (2020) found that alcohol and benzodiazepine coinvolvement in opioid-involved overdose deaths was common, varied by opioid subtype, and was associated with state-level binge drinking and benzodiazepine prescribing rates. The FDA states that clinicians should limit prescribing opioid pain medicines with benzodiazepines or other CNS depressants only to patients with inadequate alternative treatment options. Avoid prescribing opioid-containing cough medicines to patients taking benzodiazepines or other CNS depressants, including alcohol. When prescribing medications, limit dosages and the duration of each drug to the least possible while achieving the desired clinical effect. Counseling patients regarding possible adverse severe reactions is critical (FDA, 2021).

The FDA clarified this warning for patients taking opioid-addiction medications. Specifically, the FDA advised that the opioid-addiction medications buprenorphine and methadone should not be withheld from patients taking benzodiazepines or other drugs that depress the CNS. Although the combined use of these drugs increases the risk of severe side effects, the harm caused by untreated opioid addiction can outweigh these risks. These medications are often used with counseling and behavioral therapies for patients undergoing MAT, and patients can be treated with them indefinitely. Careful patient monitoring is necessary when prescribing benzodiazepines or other CNS-depressant agents in combination with MAT and appropriate and continued patient counseling (FDA, 2022d).

Tapering of chronic opioid therapy (CDC, 2022A)

Sometimes, clinicians must decide whether to decrease or discontinue chronic opioid therapy. Many factors may contribute to this decision: patient request; lack of response; signs of substance abuse disorder, overdose, or other serious adverse events; or early signs of overdose risk. Therefore, any tapering schedule must be patient-specific to minimize withdrawal symptoms while maintaining adequate pain management.

A general recommendation is to begin with a 10% decrease of the initial dose per week. Some patients who have taken opioids for a long time may require slower tapers (e.g., 10% per month). Adjust the rate and duration of the taper based on the patient's response. It is advisable to slow or pause a taper to manage withdrawal symptoms rather than reversing the taper. It is essential to discuss the risk of overdose if a patient quickly returns to a prescribed higher dose. Consider prescribing naloxone to reverse possible overdose symptoms. After achieving the smallest available dose, the interval between opioid doses increases, and opioids stop when taken less than once a day.

Patients at high risk of harm, such as pregnant women or those with substance abuse disorder, may require coordination with treatment experts. Withdrawal symptoms are especially concerning in pregnant patients due to the risks to the mother and fetus. It is crucial to ensure patients receive appropriate encouragement and psychosocial support, including consultations with mental health providers and treatment for opioid use disorder as needed. Reassure patients that most people have improved function, without worse pain, after tapering opioids. In addition, some patients experience less pain after a taper, even though the pain may worsen initially.

Self-Assessment Quiz Question #5

Any tapering schedule must be patient-specific to minimize withdrawal symptoms. The CDC recommends what percentage while maintaining adequate pain management?

a. 10% decrease of the initial dose per week.
b. 15% decrease of the initial dose per week.
c. 25% decrease of the initial dose per week.
d. 45% decrease of the initial dose per week.

Naloxone for emergent opioid overdose

On average, every eight minutes, an individual dies from an opioid overdose (Skolnick, 2018). Individuals at higher risk for acute overdose include those who use prescription opioids, benzodiazepines, and alcohol, as well as individuals with substance or mental health use disorders. These factors affect the entire family since these individuals may obtain opioids from family members. Children are at risk when ingesting opioids in the home. Individuals who have lower tolerance due to incarceration, detoxification, or other controlled settings are also at higher risk for acute opioid overdose. Physiological damage can occur after 4 minutes, and death occurs in 4 to 6 minutes. Signs and symptoms of acute opioid overdose include:

- Unusual sleepiness or unresponsiveness.
- Decreased or absent breathing.
- Slow heartbeat or low blood pressure.
- Skin feels cold and clammy.
- Pinpoint pupils.
- Dusky nails and lips.

Naloxone hydrochloride is an opioid antagonist which blocks opiate receptors in the brain and other parts of the body (drugs.com, 2023). By occupying the receptor and blocking the action of the opioid, effects of naloxone reverse opioid effects by competing for opioid sites in the central nervous system, with a great affinity for the μu receptor (drugs.com, 2023). Naloxone nasal inhalation kits are widely accepted for opioid reversal in emergent situations (Skolnick, 2018).

The Substance Abuse and Mental Health Services Administration (SAMHSA) oversees the accreditation and standards for opioid treatment programs (OTPs). Many medication-assisted treatment (MAT) medications in opioid addiction are regulated under the CSA (SAMHSA, 2022a). The Drug Addiction Treatment Act of 2000 (DATA 2000 Act) permits physicians who meet set qualifications to manage opioid dependency with FDA-approved medications, such as buprenorphine, in treatment settings other than OTPs (see Table 9). The DATA 2000 Act allows physicians to obtain a waiver (i.e., DEA-X) to treat opioid use disorder with Schedules III, IV, and V medications (such as buprenorphine alone or in combination) that the FDA has approved for this indication (SAMHSA, 2022b).

Qualified practitioners can offer buprenorphine, a medication approved by the FDA, to treat OUD. The DATA 2000 Act and the Substance Use Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act of 2018 expands the use of medication-assisted treatment using buprenorphine to additional practitioners in various settings (SAMHSA, 2022c). Qualified practitioners include physicians, NPs, physician assistants (PAs), clinical nurse specialists (CNSs), certified registered nurse anesthetists (CRNAs), and certified nurse-midwives (CNMs).

Table 9: Buprenorphine-Containing Products FDA-Approved for Opioid Use Disorder

Product Name	Available Strengths	Route(s) of Administration
Bunavail buccal films	• Buprenorphine 1 mg/naloxone 0.2 mg • Buprenorphine 2.1 mg/naloxone 0.3 mg • Buprenorphine 4.2 mg/naloxone 0.7 mg • Buprenorphine 6.3 mg/naloxone 1 mg	Buccal
Probuphine implant	• Buprenorphine 74.2 mg	Subdermal
Sublocade extended-release solution for injection	• Buprenorphine 100mg/0.5 mL • Buprenorphine 300 mg/1.5 mL	Subcutaneous
Subutex sublingual tablets	• Buprenorphine 2 mg • Buprenorphine 8 mg	Sublingual
Suboxone sublingual tablets	• Buprenorphine 2 mg/naloxone 0.5 mg • Buprenorphine 8 mg/naloxone 2 mg	Sublingual
Suboxone sublingual films	• Buprenorphine 2 mg/naloxone 0.5 mg • Buprenorphine 4 mg/naloxone 1 mg • Buprenorphine 8 mg/naloxone 2 mg • Buprenorphine 12 mg/naloxone 3 mg	Sublingual, buccal
Zubsolv sublingual tablets	• Buprenorphine 0.7 mg/naloxone 0.18 mg • Buprenorphine 1.4 mg/naloxone 0.36 mg • Buprenorphine 2.9 mg/naloxone 0.71 mg • Buprenorphine 5.7 mg/naloxone 1.4 mg • Buprenorphine 8.6 mg/naloxone 2.1 mg • Buprenorphine 11.4 mg/naloxone 2.9 mg	Sublingual

The John S. McCain Opioid Addiction Prevention Act (S.724, 116) established a new registration requirement for clinicians who are licensed to prescribe controlled substances in schedules II, III, or IV. Specifically, a practitioner must agree to limit the supply of opioids prescribed for the initial treatment of acute pain as a condition of obtaining or renewing a registration through the DEA. An opioid approved and prescribed for addiction treatment is not subject to the limit (govtrack.us, 2019).

Evidence-based strategies can assist in the prevention of substance use disorder. The goal of 911 Good Samaritan laws is to reduce barriers for individuals who notify authorities about overdoses through limited immunity and other drug charges (CDC, 2022). Syringe programs are community-based programs that provide linkages to access to medical, mental health, and social services, in addition to treatment and injection equipment (CDC, 2022).

NATIONAL PAIN STRATEGY

Despite the need and market opportunities for better, safer pain options, a dramatic rise in opioid use still exists and is fueled by a pain epidemic. The National Pain Strategy (2020) is a comprehensive population-level health strategy to increase recognition of pain as a significant public health problem (IPRCC, 2022). The vision is of timely access to patient care with access to effective approaches for pain self-management. Chronic pain would be recognized as a complex disease process and a threat to public health and productivity (IPRCC, 2022). Evidence-based treatment provided by primary care clinicians moves toward pain prevention. These actions are just several in a comprehensive strategy to reduce the dual crises of pain and opioid dependence.

Programs to decrease inappropriate prescribing practices and opioid abuse should be balanced with quality pain management. Primary care clinicians are reluctant to prescribe opioids over concerns of dependence and opioid use disorder. Safe and effective care is a priority for all clients in preventing chronic pain.

National Institutes of Health Heal Initiative®

The Helping to End Addiction Long-term® (HEAL) initiative is an effort to stem the national opioid public health crisis (NIH, 2023). NIH is a research program that optimizes the delivery of services for individuals with opioid use disorders, mental health disorders, and suicide risk (NIH, 2023). Long-term solutions for the evolving opioid crisis include:

- Partnering with communities to evaluate implementation strategies.
- Intervening in communities to prevent opioid use for at-risk individuals.
- Understanding ways to help opioid-exposed individuals while uncovering long-term effects.
- Developing innovative treatment in all aspects of opioid addiction.
- Testing a range of non-opioid pain treatments for use in clinical practice.
- Uncovering early-stage development of non-opioid pain treatment.

(NIH, 2023)

SUBSTANCE USE AND DRUG DIVERSION

Drug misuse typically refers to prescription drugs and is defined as using them for a purpose other than for which they were prescribed. Examples include taking higher doses than prescribed, taking longer than prescribed, using drugs for purposes other

than prescribed, using drugs in conjunction with other medications that affect CNS or alcohol, and skipping doses or hoarding drugs.

Drug diversion is defined as "any criminal act or deviation that removes a prescription drug from its intended path from the manufacturer to the patient," including everything from outright theft of the drug to doctor shopping, prescription forging, manufacture or sales of counterfeit drugs, and international smuggling (CSTE, 2019). Diversion can occur at any point— from the manufacturer's distribution to the wholesalers to pharmacies and, in turn, to the patient. However, some drugs are more targeted than others: (1) anti-anxiety medications and sedatives, including benzodiazepines; (2) prescription pain medications, including opioids; (3) stimulants, including those used to treat attention deficit disorder and narcolepsy; (4) sleep aids; and (5) anesthetics, such as propofol. Healthcare providers can divert medications through false documentation, scavenging wasted medications, and theft by tampering (CSTE, 2019). Behavioral changes include subtle changes in appearance, increasing isolation from colleagues, inappropriate verbal/emotional responses, and diminished alertness, confusion, or memory lapses (NCSBN, 2018). Many healthcare workers with substance use disorders are unidentified, unreported, and untreated. These individuals continue to practice where the impairment is endangering the lives of others (NCSBN, 2018).

Healthcare Consideration: Misuse and abuse are distinct from medication mismanagement problems such as forgetting to take medications and confusion or lack of understanding about proper use. Medication mismanagement problems can also have serious consequences for patients, but they have different risk factors and typically require different types of interventions (SAMHSA, 2018).

The impact of substance use disorder is costly not only to the healthcare worker but also to families, colleagues, and the organizations for which they work. The cost can be measured in the potential loss of jobs, loss of income, and damage to health, resulting in increased medical expenses. Substance abuse also compromises interpersonal relationships with family members and friends and professional relationships with colleagues and employers. The interpersonal cost may be evaluated regarding divorce, termination of interpersonal relationships, compromised professional collaborations, and/or loss of emotional support systems. Loss of job productivity is common among those with addictions (DrugAbuse, 2019).

The effects of SUD on interpersonal relationships can be devastating. There are a number of signs that show how substance use is harming interpersonal relationships. Most relationships will not show all of the signs. However, even one of the following signs indicates that the person using drugs and/or alcohol needs help. Many arguments about substance use or issues relating to SUD (e.g., financial problems, failure to fulfill responsibilities at home) are occurring. Loved ones find themselves "covering" for someone abusing substances, such as reporting to an employer that the person using the substance is sick and cannot come to work. The substance user says they drink or use drugs to reduce stress related to arguments about substance use. Loved ones begin to consume alcohol and/or use drugs because they believe that such activities are the only ones, they can do with the person who is abusing the substance. The person with SUD begins to display violent behavior toward loved ones under the influence of drugs and/or alcohol. The person with SUD and loved ones must be drunk or high to show affection toward each other. People with SUD and loved ones avoid encounters with other friends or family members to hide the substance use problem.

The effects of SUD can seriously compromise safety culture. Nurses dealing with SUD cannot provide safe and appropriate patient care if their ability to function is impaired. Healthcare organizations have an obligation to make sure that effective systems and processes are in place to prevent drug diversion and to protect patients from the safety threats that may occur as a result of impaired nurses. It is essential to maintain a drug and alcohol-free working environment. Equitable policies and procedures must be applied across the organization:

- Defining impaired work performance, how to recognize it, the consequences of working in an impaired state, the consequences of failing to report impaired colleagues, and interventions to help the impaired person recover.
- Educating all employees regarding policies and procedures and how to implement such policies and procedures correctly.
- Establishing policies and procedures that provide safeguards regarding confidentiality; it is imperative that nurses and other employees believe that they can communicate their concerns without fear of retaliation.
- Providing continuing education programs that deal with the topic of impairment and SUD.
- Establishing mandates that all employees attend continuing education programs that deal with the topic of substance use disorder; such education must be appropriate for the employees' education, training, and roles that they fulfill.
- Explaining the resources available to help nurses and other employees who are dealing with SUD obtain the help that they need to recover. (NCSBN, 2018)

There are a number of reasons nurses do not report colleagues suspected of SUD. These include the following:

- Fear that the colleagues will lose their jobs if they are reported.
- Lack of explicit policies and procedures that address SUD, impairment, addiction, and reporting of such issues.
- A work environment that lacks compassion and willingness to help impaired nurses recover. (NCSBN, 2018a, 2018b)

In addition to protecting patients, employers have ethical and legal obligations to help nurses and other employees whose functioning is impaired due to substance use. State boards of nursing often have assistance programs designed to protect patients and save the lives and careers of those who are dealing with substance use disorder. Nurses must review the options offered by their respective state board of nursing. In general, these programs are designed to be confidential, nonpunitive, and therapeutic.

Economic impact

SUD is costly for society with billions of dollars in lost work productivity, drug law enforcement, and healthcare expenses. Research shows that excessive alcohol intake costs the United States about $223 billion annually in healthcare expenses, law enforcement costs, and lost productivity (DrugAbuse.com, 2019).

SUD can have a significant negative impact on society and is closely linked to poverty. Paying for an addictive substance can be expensive, regardless of the substance being used. For example, a $5 six-pack of beer consumed everyday costs

$150 per month. That's about $1,000 in six months. Persons using more expensive drugs such as cocaine may spend more than $10,000 annually to support their SUD and addiction (DrugAbuse.com, 2019). SUD is most expensive for vulnerable individuals. Research shows that a pack of cigarettes per day can cost 10% of their family's monthly income (DrugAbuse.com, 2019).

Treatment goals

The goal of identification and intervention is to encourage the nurse with SUD to participate in appropriate treatment and alternative programs rather than face punitive actions. Research shows that early identification and referral of persons to treatment programs leads to the following:

- Increased success in a treatment program.
- Better outcomes after treatment.
- Reduced time practicing with an undetected substance use disorder.
- Reduced number of relapses.

- Improved social and interpersonal functioning.
- Reduced threats to public health and safety.

(NCSBN, 2018)

Treatment and monitoring programs generally require that the nurse sign an agreement that identifies the responsibility of the nurse and treatment facility (NCSBN, 2018).

Nursing Consideration: Mandates may vary or change depending on individual state laws and specific programs. Therefore, nurses must understand that to receive current information, they must carefully review any alternative program mandates prior to participation.

To enter into an alternative treatment program, the healthcare provider must meet the following requirements:

- Abstain from all alcohol and alcohol-containing products unless prior approval is obtained from the alternative program.
- Abstain from drug use, including all over-the-counter medications and other mind-altering substances unless lawfully prescribed with prior approval of the alternative treatment program.
- Maintain a current state nursing license, including meeting competency and/or continuing education requirements.
- Complete a substance use, dependency, or mental health assessment.
- Complete treatment, continuing care, and after-care.
- Enter treatment and participate in all treatment recommendations.
- Cease nursing practice and agree to inactivate license until or unless approved to return to practice by the treatment professional and the alternative program.
- Provide counselors with the necessary forms to complete and return to the program.
- Undergo any additional evaluation as asked by the treatment provider or the alternative program.
- Agree to monitoring by the state board of nursing as well as the facility.

(NCSBN, 2018)

Several requirements relating to treatment and recovery monitoring are generally mandated, including but not limited to the following:

- Attending a minimum number of 12-step or other approved self-help meetings per week for the duration of the contract.
- Submitting required documentation to the alternative program at least monthly.
- Maintaining a consistent, active relationship with a sponsor.
- Participating in random drug screening on a schedule mandated by the alternative treatment program.
- After returning to practice, participating in drug screening as mandated.
- Reporting any prescriptions or over-the-counter medications to the alternative program within 24 hours.
- Providing contact information for one pharmacy, one health care provider, and one dentist to the alternative program.
- Notifying any healthcare providers of substance use history before receiving any prescription.
- Providing a written statement from the prescribing healthcare provider that verifies the provider's awareness of the nurse's history of substance use or dependence and their responsibility to confirm any prescription within 24 hours of prescribing.
- Having practitioners complete mediation verification forms and mediation logs provided by the program and submit them according to program mandates.
- Submitting medication logs every quarter.
- Obtaining a reassessment by a licensed addiction counselor in the event of a relapse or suspected relapse.
- Paying all expenses associated with being in the alternative program.
- Appearing in person for all routinely scheduled interviews or additional interviews as mandated by the alternative program.

(NCSBN, 2018)

Other clinicians should check with their state boards to determine requirements and alternative programs.

Ongoing education

All employees must receive education regarding SUD, how to recognize and report it, and options for recovery. Additional recommendations include:

- Beginning education on substance use disorder and other forms of addiction in the nurse's basic nursing education. Academic programs should include the topic as part of the nursing curriculum.
- Providing information on substance use disorder during orientation of new employees and as continuing education on an ongoing basis.
- Communicating clear protocols for reporting suspicion of substance use disorder as part of the education process.
- Establishing nurse well-being committees in the workplace. Members should receive training in order to provide compassionate assistance for colleagues who need help.
- Promoting the establishment of a culture of safety. Safety culture should be part of continuing education endeavors and part of the new employee orientation process as well.

Nursing Consideration: Success is measured in terms of recovery, patient safety, and appropriate referral to alternative treatment programs. Success for the nurse who is dealing with substance use disorder is measured in terms of adherence to program standards, completion of treatment, maintenance of negative drug test results, and demonstration of safe nursing practice. Nurses must also adhere to any and all mandates of drug screening and follow-up monitoring (NCSBN, 2018).

CHANGE PRINCIPLES APPLIED TO SUBSTANCE USE DISORDER

Integrative therapy emphasizes change principles rather than limited techniques and looks beyond a single psychotherapy approach. The stages of change identify an individual's readiness to change, which is the period of time and tasks completed to move toward the next stage (Norcross & Beutler, 2019). The stages are precontemplation, contemplation, preparation, action, and maintenance:

1. **Precontemplation** is where change is not in the foreseeable future. Individuals in this stage need to be made aware of the problem. Lack of insight prevents the individual from seeing the consequences of harmful/addictive actions. It is important to understand that the individual is in denial and tends to defend the actions. Resistant, unmotivated, and unwilling to change are descriptors for this stage. Additionally, the individual may obsess about the negative rather than focus on the benefits of change (Norcross & Beutler, 2019; Raihan & Cogburn, 2022).
2. **Contemplation.** The second stage is contemplation and is marked by an awareness of problematic behavior. However, the individual still determines if the problem is worthy of correcting. Therefore, the avoidance of conflict results in no commitment to the matter. The problem is at the center, but the individual never acts meaningfully. This causes the individual to remain stuck for about 6 months (Norcross & Beutler, 2019; Raihan & Cogburn, 2022).
3. **Preparation.** In the third stage, the individual can acknowledge the problematic behavior and commit to correction. The practice combines intentional conduct where individuals gather information from various sources like self-help books and psychotherapy while developing an action

plan. For example, individuals comment that smoking is terrible (Norcross & Beutler, 2019; Raihan & Cogburn, 2022).

4. **Action**. Change happens during the fourth stage. Total abstinence is expected for less than 6 months. During this stage, the individual has confidence that willpower will improve the journey of change. Individuals are willing to receive assistance and support and develop short-term positive reinforcement, which counteracts potential triggers that lead to relapse. Unfortunately, many individuals need clarification on this stage of change and forgo the work required to act on changing behavior (Norcross & Beutler, 2019; Raihan & Cogburn, 2022).
5. **Maintenance**. Continuing new behavior change is the focus of the fifth stage. Individuals have maintained total abstinence for more than 6 months. This stage gives individuals the confidence to maintain positive lifestyle changes without fearing relapse. Thoughts of old habits often return, but the temptation is resisted. Individuals require support as they reevaluate reasons for change, acknowledge success, and consider potential triggers (Norcross & Beutler, 2019; Raihan, N & Cogburn, M., 2022).

Ultimately, the goal is to create an action plan to prevent relapse since the first 3-6 months of abstinence is difficult to achieve. After that, treatment becomes individualized with a fluid and dynamic evolution (Norcross & Beutler, 2019; Raihan & Cogburn, 2022).

Intent to change practice

Some critical elements can be used to change practice and enhance recognition, intervention, and return-to-work issues. But first, everyone must take an active role in changing practice outcomes. Some elements of intent to change practice include the following:

- Encourage the delivery of and participation in SUD education.
- Review/establish specific policies and procedures that guide SUD recognition, reporting, consequences of not reporting, and support and treatment options for the person dealing with SUD.
- Encourage the development of programs that educate specific staff members as interventionists when confrontation is necessary.
- Examine one's own attitudes toward people with SUD and how they influence intervention.
- Volunteer to serve on committees, task forces, and so on to improve the safety culture of the organization, as a culture of safety must be maintained.

(Collins et al., 2018)

The current emphasis is on helping the nurses with substance use disorder recover and continue with their careers, not punishing them and taking disciplinary action against them. However, to benefit from this treatment emphasis, nurses have an obligation to participate in an approved alternative treatment program and adhere to all of its mandates, as well as to the mandates of state law and rules of their respective State Board of Nursing. Additionally, all nurses have an obligation to complete continuing education courses on the topic of substance use disorder, to act in the best interests of the patient, and to facilitate the treatment and recovery of their colleagues.

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PRESCRIBING CONTROLLED SUBSTANCES SAFELY: A DEA REQUIREMENT

Self-Assessment Answers and Rationales

1. The correct answer is A.

Rationale: Poison Control (1-800-222-1222) is available 24 hours a day to patients and clinicians to answer any questions concerning accidental ingestion or contact with known or unknown substances.

2. The correct answer is D.

Rationale: Clinicians who are agents or employees of a hospital or other institution (e.g., interns, residents, staff physicians, advanced practice providers) may, in the normal course of their duties, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution in which they are employed, provided that the dispensing, administering, or prescribing is in the normal course of practice; practitioners are authorized to do so by the state in which they practice; the hospital or institution has verified the practitioner is permitted to dispense, administer, or prescribe controlled substances within the state; the practitioner only acts within the scope of employment in the hospital or institution, and the hospital or institution authorizes the practitioner to dispense or prescribe under its registration and assigns a specific internal code for each practitioner so authorized.

3. The correct answer is D.

Rationale: If the prescriber institutes long-term opioid therapy, a written informed consent and treatment agreement is recommended. The informed consent may address several issues, such as evidence that the benefit of opioids or other medications in managing chronic pain is limited (except for cancer); potential risks and benefits of opioid therapy; potential short- and long-term side effects of opioid therapy; likelihood that tolerance to and physical dependence on the medication will develop; risk of drug interactions and oversedation; risk of impaired motor skills; risk of substance abuse disorder, overdose, and death; the clinician's prescribing policies (e.g., number and frequency of refills, early refills, exceptions); reasons the drug may be changed or discontinued, and that the treatment may be discontinued without agreement from the patient, such as with violations of the treatment agreement. Educate the patient that complete elimination of pain should not be expected.

4. The correct answer is A.

Rationale: Integrative medicine and integrative nursing are the same. In the past, these therapies were called complementary.

5. The correct answer is A.

Rationale: (Remediation) Any tapering schedule must be patient-specific to minimize withdrawal symptoms while maintaining adequate pain management. A general recommendation is to begin with a 10% decrease of the initial dose per week.

Final Examination Questions

Select the best answer for each question and complete your test online at **EliteLearning.com/Book**

86. Which of the following U.S. federal agencies is NOT involved in scheduling controlled substances?
    a. Drug Enforcement Agency (DEA).
    b. Food and Drug Administration (FDA).
    c. Centers for Medicare and Medicaid (CMS).
    d. Department of Health and Human Services (HHS).

87. Which DEA Controlled Substance Schedule is associated with the lowest risk of abuse?
    a. Schedule II.
    b. Schedule III.
    c. Schedule IV.
    d. Schedule V.

88. When prescribing controlled substances, refills may be prescribed on all prescriptions EXCEPT for:
    a. Schedule I.
    b. Schedule II.
    c. Schedule III.
    d. Schedule IV.

89. According to federal law, a controlled substance prescription may be transmitted in one of the following ways:
    a. Faxed prescription.
    b. Telephone prescription.
    c. Electronic prescription.
    d. All of the above.

90. Morphine milligram equivalents (MME) were developed to assist clinicians with determining equal dosages when converting patients from one opioid analgesic to another.
    a. True.
    b. False.

91. Factors that associate inappropriate prescribing of opioid analgesics and illicit drug use include all of the following EXCEPT:
    a. Acute pain opioid analgesic prescription for three days or less.
    b. Initial acute pain opioid analgesic prescription for a 10-day supply.
    c. Cumulative dose of 700 MME.
    d. Refill of acute pain opioid prescription.

92. Which concepts are NOT associated with appropriate prescribing and monitoring acute opioid analgesic therapy?
    a. Use the lowest effective dose for initial treatment.
    b. Utilize other nonopioid treatment modalities to decrease the opioid burden.
    c. The duration of treatment for acute pain is usually greater than 10 days.
    d. Secure storage of opioid prescriptions is important.

93. When individualizing opioid therapy regimens, which of the following would NOT lead to a heightened degree of caution?
    a. Patients receiving ACE inhibitors for the treatment of hypertension.
    b. Patients receiving benzodiazepine as a muscle relaxant.
    c. A woman who is breastfeeding.
    d. Patients with psychiatric disorders.

94. To treat pain, it is appropriate to use extended-release or long-acting opioids in opioid naïve patients.
    a. True.
    b. False.

95. Monitoring of patients with chronic pain should include which of the following?
    a. Objective assessment of functional improvements.
    b. Review of state POMP.
    c. Evaluation for any opioid-related side effects.
    d. All of the above.

Course Code: RPUS08DR

Chapter 8: Shingles Disease Process and Vaccination for Pharmacists

1 Contact Hour

By: Katie Blair, PharmD, RPh

Author Disclosure: Katie Blair, PharmD, RPh, and Colibri Healthcare, LLC do not have any actual or potential conflicts of interest in relation to this lesson.

Universal Activity Number UAN: 0607-0000-22-001-H06-P
Activity Type: Knowledge-based
Initial Release Date: 1/17/2022
Expiration Date: 1/17/2025
Target Audience: Pharmacists in a community-based setting.

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Learning objectives

After completing this course, the learner should be able to:

- Discuss the characteristics of varicella zoster virus, including primary infection and secondary reactivation of the latent virus, complications, and treatment.
- Discuss the efficacy, contraindications and precautions, adverse reactions, and administration of Shingrix.
- Explain the recommendations of the Advisory Committee on Immunization Practices (ACIP) for the use of shingles vaccinations.

Introduction

Herpes zoster, commonly known as *shingles*, affects approximately one out of every three Americans in their lifetime, resulting in an estimated 1 million cases in the United States each year. It is caused by the varicella zoster virus, the same virus that causes chicken pox. Shingles can potentially affect anyone who has had chicken pox, and it can affect any age group, though the risk of developing shingles increases significantly with age. The risk also increases for people with a weakened immune system, such as those with human immunodeficiency virus (HIV) or cancer, or those taking immunosuppressive medications such as steroids (Centers for Disease Control and Prevention [CDC], 2019).

Shingles causes a characteristic rash typically localized in one area of the body. Serious complications, which often depend on the rash location, can arise, such as pain that persists after the rash has cleared and even vision or hearing loss. Treatment typically focuses on antiviral therapy and symptom control. Shingles can be prevented through vaccination, which is recommended for adults over 50 since the immune system weakens with age. This course serves to review the disease process of shingles and the use of vaccinations to prevent shingles (CDC, 2019).

OVERVIEW OF SHINGLES

Initial infection with varicella zoster virus

Varicella, also known as *chickenpox*, is a contagious viral infection caused by the varicella zoster virus. The virus is commonly acquired through the respiratory tract, conjunctiva, and direct contact with skin lesions. After exposure, the virus enters an incubation period of approximately two weeks, while it replicates in the body (CDC, 2021).

Symptoms of primary infection with varicella zoster virus begin after the initial incubation period. Adults may have a fever or malaise for one to two days before developing a rash, while children often present with a rash as their first symptom. The rash progresses rapidly and typically starts at the head and spreads to the trunk and extremities, with the highest concentration of lesions on the trunk. Lesions can also occur on mucous membranes throughout the body. The lesions are small, raised, and itchy, and they contain clear fluid. They can continue to appear in successive crops over several days. The fluid contained in lesions is infectious, and contact can lead to infection in a person who has not had chickenpox (CDC, 2021).

In addition to the rash, children typically experience mild fever, malaise, and headache, symptoms which typically resolve within 2 to 4 days. Immunocompromised patients are at a higher risk of developing more severe chicken pox and complications, as well as those older than 15 years or younger than 1 year of age. Complications can include (CDC, 2021):

- Secondary bacterial infections of chicken pox lesions (most common in children less than 1 year of age).
- Pneumonia; viral pneumonia is a common complication among adults but is rare in immunocompetent children.
- Rarely, central nervous system complications such as meningitis or encephalitis.
- Reye syndrome, if aspirin is taken during acute illness.
- Rare hemorrhagic complications, such as thrombocytopenia.
- Rare inflammation of organs, such as heart, kidney, eyes, gonads, and liver.
- Serious infection of neonates, with a fatality rate as high as 30%, if mother has an infection with varicella that begins five days before through two days after birth.

Healthy children with chickenpox generally do not require oral medications, but topical treatments such as calamine lotion and oatmeal baths are often used to alleviate symptoms. Immunosuppressed children and adults can be prescribed acyclovir within 24 hours of symptom onset to prevent severe chickenpox. After the resolution of chicken pox, the varicella zoster virus remains in the body as a latent infection, persisting in the nervous system (Papadopoulos, 2020).

Reactivation of varicella zoster virus: shingles

People who have had chickenpox as a child continue to carry genetic material from the varicella zoster virus in the nervous system, typically in the sensory ganglia. The virus can reactivate later in life to cause herpes zoster, or shingles. Patients who were vaccinated against chickenpox as a child can also develop shingles later in life, though it considered less common than developing shingles after chicken pox disease. Estimates show that approximately one out of every three people in the United States will develop shingles in their lifetime; over 1.2 million cases occur per year in the United States. Risk factors for reactivation include (Albrecht & Levin, 2021):

- **Age**. A significant, age-related increase in incidence of herpes zoster starts at approximately 50 years of age, with 20% of cases affecting people between 50 and 59 years of age. Approximately 50% of 85-year- old patients have had an episode of herpes zoster.
- **Immunocompromised status**. The reduced T-cell immunity of patients who are immunocompromised increases the risk of herpes zoster in this group. This group includes patients with autoimmune disease, those who have had an organ transplant, and patients with human immunodeficiency virus (HIV).
- **Race**. White Americans experience significantly higher incidence of herpes zoster compared with African Americans.
- **Physical trauma**. Patients over 65 who experience trauma are significantly more likely to develop a case of herpes zoster.
- **Gender**. Women are more likely to develop herpes zoster than men.
- **Other comorbidities**. Other conditions that increase the risk of herpes zoster infection include malignancy, chemotherapy, and chronic lung or kidney disease.

Upon reactivation, the virus can spread along the sensory neurons until it reaches the skin, where it establishes infection. This infection results in inflammation and the characteristic shingles rash. Pain is typically related to nerve inflammation and hemorrhagic necrosis of nerve cells (Albrecht & Levin, 2021).

Symptoms

Before the characteristic rash appears, some patients with shingles experience fatigue or a general "run-down" feeling. Before developing a rash, around 75% of patients experience pain in the area of infection, known as *prodromal pain*. This prodromal pain is often misinterpreted as other diseases, such as appendicitis or cholecystitis, depending on the location (Albrecht & Levin, 2021).

Two to three days later, the shingles rash begins. It starts as red patches of skin with small bumps that develop into blisters over the course of several days. The blisters are associated with itchiness, and the pain is often described as a deep burning or stabbing sensation. The blisters typically dry up within 7 to 10 days, leaving behind scabs that are commonly yellow in color. Skin symptoms of shingles typically clear up within 2 to 4 weeks; pain lasts at least 30 days in 18% of patients. Shingles patients are considered contagious, after the lesions crust over. Fluid from blisters can cause chickenpox in patients without prior infection history (Albrecht & Levin, 2021).

The rash is commonly located in one area on a single side of the body, although it is possible to occur in multiple areas at once. Shingles most commonly affects the torso or chest, though it is possible to develop just about anywhere on the body, including arms, face, head, and even ears or eyes. A small percentage of patients present with only pain and skin sensations with no rash. Less than 20% of patients report flu-like symptoms during acute herpes zoster infections, and helplessness and depression have also been reported (Albrecht & Levin, 2021).

Complications

Patients with compromised immune systems are more likely to experience complications as well as a more severe, longer-lasting shingles rash. Pain and skin sensations associated with the shingles rash can persist for weeks, months, or even years, causing the most common complication of herpes zoster infection, referred to as post-herpetic neuralgia. Post-herpetic neuralgia is defined as significant pain that persists for at least 90 days after the onset of the shingles rash. It can affect between 10% and 15% of shingles patients. Risk of developing post-herpetic neuralgia increases with age, with 50% of cases occurring in patients over 60 years of age (Albrecht & Levin, 2021).

Scratching shingles blisters can cause a bacterial skin infection or lead to scarring. In rare cases, blisters can spread to neighboring skin areas and, even more rarely, spread over the whole body. This spread is often related to a significantly weakened immune system, similar to that occurring in cancer or transplant patients. Under these rare situations, shingles can be life-threatening. Changes in skin pigmentation can occur in the involved skin area after resolution of the infection, causing lighter or darker pigmentation than surrounding skin (Albrecht & Levin, 2021).

Other complications are related to the site of zoster infection. Involvement near the eye can lead to herpes zoster ophthalmicus, causing conjunctivitis, ulcers on the cornea, and even blindness. *Ramsey-Hunt syndrome,* also known as *herpes* zoster oticus, occurs when the varicella zoster virus affects the nerves that serve the ear. This syndrome can lead to ear pain, facial nerve palsies, shingles rash in the ear canal, balance issues, and hearing loss. Nerve palsies can affect other areas of the body, depending on the affected nerve (Albrecht & Levin, 2021).

Herpes zoster can also affect the nerves of the central nervous system, leading to meningitis, encephalitis, peripheral motor neuropathy, myelitis, Guillain-Barré syndrome, and stroke syndromes. These rare but serious complications appear to be more likely in patients with a significantly weakened immune system (Albrecht & Levin, 2021).

Diagnosis

Some people who develop shingles initially think they have a non-contagious skin infection, such as eczema. This initial misdiagnosis can delay a correct diagnosis and treatment. Diagnosis during the early stages of shingles development can be difficult because the characteristic rash often develops after pain starts. Depending on the affected area, other causes may be initially suspected, such as appendicitis, hernia, or myocardial infarction (Albrecht & Levin, 2021).

Diagnosis is often based on the characteristic rash that develops on one side of the body, as well as the accompanying pain and sensations related to nerve inflammation. If the diagnosis is unclear, fluid from blisters can be tested to determine whether it contains varicella zoster virus. Blood tests to detect antibodies to varicella zoster virus can also be helpful in the diagnostic phase (Albrecht & Levin, 2021).

Treatment

Antiviral medications, such as acyclovir, famciclovir, and valacyclovir, which are effective at inhibiting viral replication, are cornerstones in the management of herpes zoster. Goals of antiviral therapy include reducing the duration and severity of pain, promoting the healing of skin lesions, preventing new lesion formation, reducing viral shedding to decrease the contagious aspect of shingles, and preventing post-herpetic neuralgia. Antiviral therapy should be initiated as soon as possible after the rash appears to maximize effectiveness – ideally within 72 hours. Antivirals are most beneficial if initiated while new lesions are actively forming

since this formation of lesions indicates ongoing vital replication. The benefit of using antivirals after new lesions have stopped forming is unknown (Albrecht & Levin, 2021).

Acyclovir is the prototype antiviral medication, available for both oral and intravenous administration. It is less bioavailable than other antiviral options, and its frequent administration requirements make it less favorable for treating shingles. It is commonly administered at a dose of 800 mg five times daily for 7 days. Intravenous use is typically reserved only for patients with severe complications. Dose adjustments may be necessary in patients with severe renal insufficiency because of its renal clearance. Acyclovir is a generic medication, associated with the brand name Zovirax (Albrecht & Levin, 2021).

Valacyclovir is a prodrug of acyclovir, meaning it is converted into acyclovir in the body after ingestion. Valacyclovir is more bioavailable than acyclovir, with oral dosing producing antiviral blood levels similar to intravenous acyclovir. For treating shingles, it is commonly administered in a dose of 1000 mg three times daily for seven days. When compared with acyclovir, valacyclovir shows slightly higher effectiveness in decreasing pain severity of the shingles rash, as well as the duration of post-herpetic neuralgia. Dose adjustments may be necessary in patients with severe renal insufficiency because of its renal clearance. Valacyclovir is a generic medication, associated with the brand name Valtrex (Albrecht & Levin, 2021).

Famciclovir is another antiviral in the same drug class as acyclovir and valacyclovir. It has the best bioavailability of all three agents and has a longer half-life when compared with acyclovir. In treating shingles, it is commonly administered at a dose of 500 mg three times daily for seven days. Famciclovir is a generic medication associated with the brand name Famvir (Albrecht & Levin, 2021).

Selecting an appropriate antiviral agent should be individualized, based on patient-specific factors. Dosing schedule and cost are often considered in the selection process. All three antiviral medications are typically well-tolerated; adverse effects include nausea, vomiting, headache, dizziness, and abdominal pain (Albrecht & Levin, 2021). Patients who have been treated long term with acyclovir, as well as immunocompromised patients with persistent infections, are at an increased risk of developing resistance to acyclovir and may require alternative antiviral therapy (Shiraki et al., 2021).

Pain associated with shingles can often be treated with over-the-counter medications such as acetaminophen or non-steroidal anti-inflammatory agents. Stronger medications may be necessary in some patients; opiates and drugs used to treat neuropathic pain, such as gabapentin, can be used.

Despite variable results from clinical trials, prescribers may consider using oral corticosteroids to treat pain associated with shingles. Corticosteroids, such as prednisone, are thought to reduce nerve inflammation in shingles which leads to pain, and potentially reduce residual damage to the nerves involved. When used in conjunction with antivirals, prednisone has not been shown to reduce shingles-associated pain. Since steroids can induce immunosuppression, which can lead to the development of shingles, their use should be limited to patients over the age of 50, since these patients are at a higher risk of developing post-herpetic neuralgia. Patient-specific factors should also be considered to determine if a patient is a candidate for corticosteroid treatment (Albrecht & Levin, 2021; Kowalsky & Wolfson, 2019).

Adequate skin care is recommended in shingles patients. Lotions, such as calamine, as well as wet compresses and colloidal oatmeal baths can often relieve itching. Opened blisters that are showing signs of bacterial infection may require topical or oral antibiotics. Patients should be advised against scratching blisters, if possible, since the fluid in blisters is contagious, and scratching creates wounds that could become infected or leave scars. Shingles patients should also avoid direct contact with others who have unknown immunity to chicken pox, particularly immunosuppressed patients and pregnant women. Covering the rash and washing hands often can decrease the risk of spreading the varicella zoster virus (Albrecht & Levin, 2021; CDC, 2019).

PATIENT COUNSELING

Patients with shingles should be reminded about the contagious nature of the fluid contained in shingles blisters. They should be reminded to cover the rash and avoid scratching or touching blisters. Washing hands thoroughly after contact with lesions is recommended to prevent spreading varicella zoster virus. Patients with shingles should be counseled to avoid contact with immunocompromised people, such as pregnant women, premature infants, and those with weak immune systems. Contact should be avoided until the rash is no longer producing new blisters and crusts or scabs have developed (CDC, 2019).

Patients are often concerned about their ability to return to work after developing shingles. Return to work often depends on where the patient works and where the rash is located. If the blisters are located in an area that can be covered with bandages or clothing, patients can typically return to work when they are feeling well. Patients with blisters located on the face or an area that cannot be covered should not return to work until the blisters have crusted over, which commonly takes 7 to 10 days. Patients who work in childcare or healthcare settings should consult their employer to determine when it is safe to return to work (Albrecht, 2019).

VACCINATIONS TO PREVENT SHINGLES

At this time, only one vaccine is available in the United States to prevent reactivation of latent varicella zoster virus that leads to shingles. In October 2017, the FDA approved Shingrix for use in patients 50 and older. It has replaced the use of Zostavax, which is no longer available in the United States (GlaxoSmithKline, 2021).

Shingrix

Shingrix is now available for prevention of shingles caused by varicella zoster virus reactivation. It is a recombinant, adjuvanted vaccine for intramuscular injection and is FDA-approved for use in patients 50 and older (GlaxoSmithKline, 2021).

Shingrix is not a live vaccine; it contains varicella zoster virus antigen to trigger a targeted immune response and is combined with an adjuvant in order to enhance the immune response (GlaxoSmithKline, 2021). Adjuvanted vaccines are thought to trigger a more robust immune response, creating a stronger immune protection (CDC, 2020).

Efficacy

The manufacturer of Shingrix, GlaxoSmithKline, conducted two studies to assess its efficacy before FDA approval. The first study was an age-stratified, randomized, placebo-controlled study of over 14,000 subjects that assessed vaccine efficacy in subjects ages 50 and older. The study excluded those who were immunocompromised, had a previous history of shingles, those who were vaccinated against shingles or varicella, and those with significant comorbid conditions with an expected survival of less than four years. After following subjects for an average of three years, the study found that two doses of Shingrix resulted in a significant reduction – 97.2% – in the risk of developing shingles when compared with a placebo. The study also found a significant reduction in post-herpetic neuralgia with Shingrix, as no cases developed in the vaccinated group as compared with 18 cases in the placebo group (GlaxoSmithKline, 2021).

The second pre-approval study was a randomized placebo-controlled study of over 13,000 subjects that assessed vaccine efficacy in patients ages 70 and older. After an average follow-up of 3.9 years, vaccine efficacy was noted to be approximately 85% in

the fourth year after vaccination in this older patient population. Shingrix was also associated with lower rates of post-herpetic neuralgia in this age group when compared with placebo, with four cases reported in the vaccine group and 28 cases reported in the placebo group (GlaxoSmithKline, 2021).

When data were pooled between the two studies for patients ages 70 and older, researchers found a 91.3% reduction in the risk of developing shingles in those who have received two doses of Shingrix (GlaxoSmithKline, 2021).

Since data are not currently available to evaluate the long-term efficacy of Shingrix vaccination, modeled data based on the first four years of clinical trial data, as well as expert opinion, was used to assess long-term efficacy. Modeled data show that in adults over the age of 50, efficacy would wane to zero 19 years after vaccination, assuming vaccinated patients received two doses of Shingrix at recommended dosing intervals (Dooling et al., 2018).

Contraindications and precautions
Shingrix should not be administered to patients with a history of a severe allergic reaction to a previous dose of Shingrix or to any component of the vaccine. Patients who have a current episode of herpes zoster or post- herpetic neuralgia should not receive Shingrix during their acute episode of herpes zoster (Dooling et al., 2018).

Pregnancy and lactation
Vaccine-associated risk with Shingrix in pregnant human patients was not evaluated. Female rats who received Shingrix did not experience any vaccine-related fetal malformations or variations. Because of the lack of information in human pregnancy, it may be prudent to avoid administering Shingrix to pregnant women (GlaxoSmithKline, 2021).

It is unknown if Shingrix is excreted in breast milk, and no data is available to assess any effects of Shingrix on milk production or the breastfed infant. The manufacturer recommends weighing the benefits of breastfeeding and the mother's clinical need for Shingrix against any potential effects on the breastfed infant and the mother's underlying condition (GlaxoSmithKline, 2021).

Adverse reactions
The most common adverse reactions reported in the initial studies on Shingrix were injection-site reactions lasting for a median duration of two to three days. Pain was reported in 88% of Shingrix recipients ages 50 to 59, as compared to 14% of placebo recipients in the same age group. Redness and swelling also occurred at higher rates with Shingrix when compared to placebo (GlaxoSmithKline, 2021).

Other clinically significant adverse reactions reported in the initial studies include myalgia, fatigue, headache, shivering, fever, and GI side effects such as diarrhea, nausea, vomiting and abdominal pain. Systemic reactions were reported more frequently after the second dose of Shingrix as compared with the first. Rare serious adverse reactions that were found to potentially have a causal relationship with Shingrix included one case of lymphadenitis, one case of fever over 102.2°F, and three cases of optic ischemic neuropathy (Dooling et al., 2018; GlaxoSmithKline, 2021).

Before vaccination, clinicians should discuss potential local and systemic adverse reactions with vaccine recipients. Since adverse reactions to the first dose of Shingrix did not strongly predict adverse reactions to the second dose, patients should be encouraged to complete both doses even if they experienced a mild to moderate reaction to the first dose (Dooling et al., 2018).

Vaccine administration
Before administration, Shingrix must be reconstituted. The product contains two vials; the first has a blue-green cap and contains the AS01B adjuvant suspension component. The second vial has a brown cap and contains the lyophilized varicella zoster virus glycoprotein E (gE) antigen component. The adjuvant suspension should be slowly added to the antigen-containing vial, then gently mixed until the powder is dissolved completely. The mixed product should be an opalescent, colorless to pale-brown liquid, creating a single dose of 0.5mL (GlaxoSmithKline, 2021).

After reconstitution, the vaccine should be administered intramuscularly, with the preferred site being the deltoid region of the upper arm. If not used immediately after reconstitution, the reconstituted vaccine can be stored under refrigeration between 36°F and 46°F and used within six hours. If not used within six hours, the reconstituted vaccine should be discarded (GlaxoSmithKline, 2021).

Shingrix requires two doses for maximal efficacy, regardless of prior immunization with Zostavax. The second dose should be administered between two and six months after the first. Initial approval studies compared dosing at zero and two months to dosing at zero and six months; both dosing schedules produced comparable antibody levels. Immune response was also studied when Shingrix was administered at the same time as the quadrivalent flu vaccine, and no interference in immune response to either product was observed (GlaxoSmithKline, 2020).

Vaccine components and storage
Shingrix is supplied with two components: the antigen component in a vial with a brown cap, and the adjuvant component in a vial with a blue-green cap. Both vials should be stored under refrigeration, between 36°F and 46°F (2°C and 8°C). Vials should be protected from light, and if either vial becomes frozen, the frozen vial should be discarded. Shingrix is a preservative-free vaccine and does not contain any antibiotics. The vial stoppers do not contain latex (GlaxoSmithKline, 2020).

ACIP RECOMMENDATIONS

In January 2018, the Advisory Committee on Immunization Practices (ACIP) released its official recommendations for the use of herpes zoster vaccines. The committee recommends using the recombinant zoster vaccine Shingrix to prevent herpes zoster in immunocompetent adults ages 50 and older. This recommendation was based on high efficacy rates of Shingrix, as well as slow rates of waning protection, when studied for four years post vaccination. The committee noted that beginning vaccination at age 50 will help reduce the incidence of herpes zoster in midlife (Dooling et al., 2018).

Other considerations

Timing of Shingrix in patients previously vaccinated with Zostavax
Clinicians should consider the patient's age and the time since their Zostavax vaccination when determining when to administer Shingrix. Studies only evaluated immunogenicity and safety of Shingrix when administered more than five years after Zostavax; shorter intervals have not been evaluated to date. The ACIP notes that there are not any theoretical concerns or data indicating that Shingrix would be less effective or less safe if given within a shorter interval. In addition, since Zostavax demonstrated reduced efficacy in adults over the age of 70, a shorter interval for administering Shingrix may be considered to reduce the risk of developing herpes zoster. Overall, the ACIP notes that Shingrix should not be administered less than two months after Zostavax (Dooling et al., 2018).

Co-administration with other vaccinations
As per the Centers for Disease Control and Prevention's Best Practice Guidelines for Immunization, adjuvanted and recombinant vaccinations can be administered simultaneously with other adult vaccinations if given at different anatomic sites. Research on the administration of the quadrivalent flu vaccine with Shingrix did not indicate any concerns regarding safety or immune response to either vaccine. The concomitant administration of two adjuvanted vaccines has not been evaluated (Dooling et al., 2018).

Missed or early doses of Shingrix

If more than six months have passed since the initial dose of Shingrix, the vaccine series does not need to be restarted. However, the ACIP notes that the safety and efficacy of alternate dosing regimens has not been studied, and patients may remain at risk of developing herpes zoster if longer-than-recommended intervals between the first and second doses are utilized. If the second dose of Shingrix is administered less than four weeks after the first dose, the ACIP recommends repeating the second dose (Dooling et al., 2018).

Special populations

History of herpes zoster

Because of the potentially recurrent nature of herpes zoster, adults who have previously developed shingles should receive Shingrix. If the patient is currently experiencing a shingles episode, immunization should be delayed until the acute phase has passed and symptoms have resolved (Dooling et al., 2018).

Patients who are immunocompromised

The ACIP recommends using Shingrix in patients taking low-dose immunosuppressive medications, such as less than 20 mg per day of prednisone, as well as patients expecting to begin immunosuppressive therapy and those who have recently recovered from an immunosuppressive illness. Since patients taking moderate- to high-dose immunosuppressive therapy and those who are currently immune-compromised were excluded from efficacy studies, the ACIP has not recommended the use of Shingrix in these patients. As additional data becomes available, the committee is expected to further discuss this topic (Dooling et al., 2018).

Patients with chronic medical conditions

Shingrix is recommended in patients with chronic medical conditions such as diabetes, chronic obstructive pulmonary disease, chronic renal failure, and rheumatoid arthritis (Dooling et al., 2018).

Patients without a history of chicken pox

There is no recommendation to screen for a history of chicken pox before administration of Shingrix. However, in patients who have no prior history of chicken pox or vaccination against chicken pox, the ACIP recommends following guidelines for the administration of the varicella vaccination. (Dooling et al., 2018).

Conclusion

Since shingles has the potential to affect over 30% of Americans, it is important to be aware of the disease process, treatment, and prevention of this common disease state. The Shingrix vaccine has demonstrated significant efficacy in preventing shingles outbreaks, and its high efficacy rates have prompted the Advisory Committee on Immunization Practices (ACIP) to recommend it for the prevention of herpes zoster. Being aware of these recommendations allows pharmacy professionals to better serve and protect patients against this potentially harmful disease.

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Final Examination Questions

Select the best answer for each question and then proceed to **EliteLearning.com/Book** to complete your final examination.

96. After initial exposure, the varicella zoster virus enters an incubation period of approximately _____ , while it replicates in the body.
    a. 4 days.
    b. 7 days.
    c. 2 weeks.
    d. 4 weeks.

97. Herpes zoster, commonly known as shingles, affects approximately one out of every _____ Americans in their lifetime.
    a. Three.
    b. Two.
    c. Five.
    d. 10.

98. Around _____ of patients experience pain before developing the shingles rash, known as prodromal pain.
    a. 25%.
    b. 50%.
    c. 75%.
    d. 85%.

99. The most common complication of shingles is:
    a. Ramsey-Hunt syndrome.
    b. Post-herpetic neuralgia.
    c. Bacterial skin infections.
    d. Blindness.

100. In treating shingles, acyclovir is commonly administered at a dose of:
    a. 500 mg three times daily for 7 days.
    b. 1000 mg five times daily for 10 days.
    c. 800 mg five times daily for 7 days.
    d. 800 mg three times daily for 10 days.

101. Shingrix must be stored properly to ensure viability of the virus component of the vaccine. It must be stored between:
    a. -58°F and +5°F.
    b. 36°F and 46°F.
    c. 0°F and 25°F.
    d. 30°F and 50°F.

102. Shingrix is a recombinant, adjuvanted vaccine for intramuscular injection and is FDA approved for use in patients _____ years of age and older.
    a. 40.
    b. 60.
    c. 55.
    d. 50.

103. The Shingrix pre-approval study that assessed vaccine efficacy in subjects ages 50 and older found that two doses of Shingrix resulted in a significant reduction in the risk of developing shingles by _____ when compared with placebo.
    a. 51 percent.
    b. 97.2 percent.
    c. 89 percent.
    d. 62 percent.

104. If not used immediately after reconstitution, Shingrix can be stored under refrigeration and used within _____.
    a. 60 minutes.
    b. 30 minutes.
    c. 12 hours.
    d. 6 hours.

105. If the second dose of Shingrix is administered less than four weeks after the first dose, the Advisory Committee on Immunization Practices (ACIP) recommends:
    a. No further action.
    b. Restarting the series.
    c. Repeating the second dose.
    d. Drawing a titer to assess efficacy.

Course Code: RPUS01SH

Chapter 9: The Complications of Chronic Kidney Disease, Second Edition

2 Contact Hours

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Author Disclosure: Katie Blair, and Colibri Healthcare, LLC do not have any actual or potential conflicts of interest in relation to this lesson.

Universal Activity Number UAN: 0607-0000-23-005-H01-P
Activity Type: Knowledge-based
Initial Release Date: 7/10/2023
Expiration Date: 07/10/2026
Target Audience: Pharmacists in a community-based setting.

To Obtain Credit: A minimum test score of 75 percent is needed to obtain a credit. Please submit your answers either by mail, fax, or online at **EliteLearning.com/Book**

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Learning objectives

After completing this course, the learner should be able to:

- Discuss normal kidney function and the effects of chronic kidney disease on kidney function.
- Explain the definition of chronic kidney disease and causes of this disease state.
- Describe the complications associated with chronic kidney disease and their management.
- Review the medications used to treat common complications of chronic kidney disease.

Introduction

Chronic kidney disease (CKD) is often used as a broad term to describe many levels of decreased kidney function, from mildly decreased renal output to severe kidney failure. This worldwide public health issue affects a significant number of Americans, with a prevalence of approximately 15% in the general population. As many as 9 in 10 U.S. adults do not know that they have chronic kidney disease, and as many as 2 in 5 adults with severe disease are unaware of their condition (Centers for Disease Control and Prevention [CDC], 2021). The leading causes of chronic kidney disease are high blood pressure and diabetes; nearly half of all patients diagnosed with chronic kidney disease have diabetes and/or cardiovascular disease. People with chronic kidney disease are also at a higher risk for developing cardiovascular disease, complicating treatment for CKD patients (National Institute of Diabetes and Digestive and Kidney Diseases, 2016b).

Chronic kidney disease presents a significant cost burden in the U.S. In 2018, Medicare spending for chronic kidney disease in patients aged 66 years and older exceeded $70 billion, which encompassed over 23.8% of all Medicare spending for this age group. This cost represents a 7.3% increase over the previous year. More than 60% of this spending occurred in CKD patients with comorbidities of diabetes, congestive heart failure, or both (U.S. Renal Data System [USRDS], 2020). With such a high cost to society associated with chronic kidney disease, it is important to ensure patients are treated appropriately in order to slow disease progression and prevent adverse effects. This course serves as a review of chronic kidney disease and the medications used to prevent adverse effects of CKD and slow disease progression.

COMPLICATIONS OF CHRONIC KIDNEY DISEASE

Normal kidney function

The kidneys are two bean-shaped organs, each of which is approximately the size of a human fist. They are located toward the back side of the abdomen on each side of the spine, just below the rib cage. The primary function of the kidneys is to remove water and waste products from the body. They also produce the essential hormones erythropoietin and renin and convert vitamin D to its active form (DiPiro et al., 2019).

Each kidney contains approximately 1 million functioning units, called *nephrons*, which perform the functions of forming urine and removing unwanted substances from the bloodstream. Each nephron is made up of two major parts: a glomerulus and a tubule. The glomerulus filters the blood, removing waste products while keeping large molecules like proteins and blood cells in the bloodstream. The tubule receives and processes the fluid filtered by the glomerulus, saving necessary minerals for return to the bloodstream and removing waste products for removal through the urine (DiPiro et al., 2019).

The kidneys, when functioning normally, regulate the concentration of fluid in the body. They remove excess water if body fluids are too diluted and remove excess salts such as sodium and potassium when body fluids are too concentrated. In addition, the kidney plays a role in acid–base balance by excreting hydrogen ions when the blood is too acidic and excreting bicarbonate ions when the blood is too alkaline. Lastly, they remove metabolic byproducts such as creatinine, urea, and phosphorus that the body no longer needs (DiPiro et al., 2019).

In terms of hormones, the kidneys are responsible for converting vitamin D to its active form, calcitriol, which facilitates calcium absorption in the intestine. The kidneys also manufacture erythropoietin, a hormone that stimulates red blood cell production in the bone marrow. Renin is also produced in the kidneys and plays a significant role in sodium and blood pressure control (DiPiro et al., 2019).

Abnormal kidney function

As kidney function decreases, the kidneys are less able to maintain appropriate fluid concentrations in the body. Salts and fluids become increasingly difficult to remove from the bloodstream as the glomerular filtration rate (GFR) decreases, resulting in edema and hypertension. Edema, or fluid overload, can cause symptoms such as swollen ankles and legs, as well as shortness of breath due to an accumulation of fluid in the lungs, known as *pulmonary edema* (DiPiro et al., 2019).

A decline in kidney function can also result in a decreased ability to remove metabolic byproducts, such as phosphorus and creatinine. High phosphorus levels can lead to decreased blood calcium levels, which triggers the parathyroid glands to release more parathyroid hormones to stimulate the release of calcium from the bones into the bloodstream. If this mechanism is not suppressed, it can lead to an excessive release of calcium from the bones, resulting in bone demineralization, weaker bones, and bone pain. Since the kidneys activate vitamin D, lower levels of calcitriol can be seen in patients with kidney disease, exacerbating bone conditions. Blood creatinine levels predictably increase in patients with decreased kidney function. The increase in creatinine level is used to determine the level of kidney dysfunction, as it is a component in the calculation of glomerular filtration rate (DiPiro et al., 2019).

Decreased kidney function also can cause a decrease in erythropoietin production, which is typically seen in later stages of disease progression. This causes a decrease in red blood cell production, which leaves fewer red blood cells to carry oxygen through the bloodstream to the tissues. The resulting effect is anemia, which can cause patients to become tired more easily, feel weak, get dizzy easily, and develop shortness of breath after minimal activity. Chronic kidney disease patients with severe anemia may require administration of synthetic erythropoietin if the kidneys are unable to maintain production (DiPiro et al., 2019).

As kidney function declines, patients may be required to make diet modifications to prevent accumulation of unwanted substances. Renal diets typically involve decreasing potassium, sodium, and phosphorus intake to prevent overaccumulation of these substances. Fluid restriction may also be required depending on the level of kidney disease. Medications to bind phosphates and supplement vitamin D levels may be required, depending on the severity of accumulation (DiPiro et al., 2019).

Symptoms may emerge when waste products begin to accumulate, causing a syndrome called *uremia*. Uremia typically occurs as a result of end-stage kidney disease, when the kidneys are unable to filter toxins through the urine. Patients with uremia can experience headaches, fatigue, nausea, vomiting, decreased appetite, decreased ability to concentrate, and an increased tendency to bleed. High phosphorus levels may also cause itching. Treatment typically involves dialysis or kidney transplantation (DiPiro et al., 2019).

Self-Assessment Quiz Question #1

Renal diets can involve decreasing the intake of all of the following to prevent over accumulation EXCEPT:

a. Potassium.
b. Sodium.
c. Phosphorus.
d. Calcium.

CALCULATING KIDNEY FUNCTION

Overall kidney function is estimated by calculating the glomerular filtration rate (GFR). This rate describes the flow rate of fluid filtered by all glomeruli, presented as milliliters per minute, and can be calculated in several different ways. The National Kidney Foundation recommends using the CKD-EPI creatinine equation to estimate GFR. This equation takes age, sex, and serum creatinine level into account to calculate an estimated glomerular filtration rate. The calculation is as follows (National Kidney Foundation, 2021):

$$\text{GFR} = 142 \times \min(S_{cr}/k, 1)^{a} \times \max(S_{cr}/k, 1)^{-1.200} \times 0.9938^{age} \times 1.012 \text{ [if female]}$$

- S_{cr} = serum creatinine in mg/dL
- k = 0.7 for females and 0.9 for males
- a = –0.241 for females and –0.302 for males
- Min indicates the minimum of S_{cr}/k or 1
- Max indicates the maximum of S_{cr}/k or 1

There are many online calculators available to estimate GFR using this equation, such as the one provided by the National Kidney Foundation, found at https://www.kidney.org/professionals/kdoqi/gfr_calculator

Healthcare Consideration: In the past, many health care professionals were trained to calculate creatinine clearance using the Cockcroft–Gault equation to estimate kidney function. Creatinine clearance calculations using this equation tend to exceed true GFR by between 10% and 20% or more, depending on the proportion of urinary creatinine derived from tubular secretion. In the past, this error was balanced by a nearly equivalent error in measuring serum creatinine, but national standardization of blood creatinine assays has essentially removed this error. Therefore, creatinine clearance measurements using the Cockcroft–Gault equation typically reflect a GFR that is falsely inflated, which should be considered when calculating medication dosages for patients with kidney disease (Inker & Perrone, 2021).

DEFINING CHRONIC KIDNEY DISEASE

The Kidney Disease: Improving Global Outcomes (KDIGO) Work Group defines chronic kidney disease as abnormalities of kidney structure or function, present for greater than three months, with implications for health. This can be measured by a glomerular filtration rate (GFR) of less than 60 mL/min/1.73m^2, or it can be defined by one or more markers of kidney damage (kidney disease: Improving Global Outcomes [KDIGO] Work Group, 2013a).

Chronic kidney disease is classified into five stages, with stage 1 indicating the mildest form of disease and stage 5 representing kidney failure (KDIGO Work Group, 2013):

- **Stage 1**: Markers of kidney damage found, but GFR is normal or increased (>90 mL/min/1.73 m^2).
- **Stage 2**: Mildly reduced GFR (60–89 mL/min/1.73 m^2).
- **Stage 3a**: Mildly to moderately reduced GFR (45–59 mL/min/1.73 m^2).
- **Stage 3b**: Moderately to severely reduced GFR (30–44 mL/min/1.73 m^2).
- **Stage 4**: Severely reduced GFR (15–29 mL/min/1.73 m^2).
- **Stage 5**: Kidney failure (GFR <15 mL/min/1.73 m^2 or dialysis).

In stages 1 and 2, the GFR alone should not be used to diagnose chronic kidney disease because GFR greater than 60 mL/min/1.73 m^2 may be considered borderline normal. In these cases, the presence of one or more markers of kidney damage should be used to determine the diagnosis (KDIGO Work Group, 2013):

- Albuminuria (albumin excretion >30 mg/24 hr or albumin:creatinine ratio >30 mg/g).
- Urine sediment abnormalities.
- Electrolyte and other abnormalities related to tubular disorders.
- Histology abnormalities.
- Structural abnormalities of the kidney, often detected using imaging studies.
- History of kidney transplantation.

Case study

Seventy-five-year-old Sally presents for her annual checkup with her provider. She had previously been diagnosed with diabetes and high blood pressure, but when asked about her medication compliance, she says she stopped her medications because they had been causing diarrhea. Her doctor is concerned that her kidney function may be declining, and Sally is scared that this means she will have to go on dialysis.

After Sally's lab results came back with her serum creatinine came at 1.2mg/dL, an estimation of her glomerular filtration rate needs to be made. Some additional information from Sally's chart that may be needed in the calculation includes:

- *Age: 75 years.*
- *Ethnicity: Chinese.*
- *Height: 5 feet 3 inches.*
- *Weight: 165 pounds.*

Self-Assessment Quiz Question #2

The clinic protocol is to use the calculation recommended by the National Kidney Foundation for estimating GFR. Which of the following would be most appropriate to use?

a. CKD-EPI creatinine equation.
b. Cockroft–Gault equation.
c. 24-hour urine collection.
d. Jelliffe equation.

Self-Assessment Quiz Question #3

Using the recommended equation, what is Sally's estimated GFR?

a. 65 mL/min/1.73m^2.
b. 25 mL/min/1.73m^2.
c. (correct) 44 mL/min/1.73m^2.
d. 36 mL/min/1.73m^2.

Self-Assessment Quiz Question #4

Due to her low GFR, Sally's provider is ready to diagnose her with chronic kidney disease. In order to determine the most appropriate treatment options to discuss with the patient, the stage of her disease should be determined. Given her GFR calculated in the previous question, what stage of CKD would she fall into?

a. Stage 2.
b. Stage 3a.
c. Stage 3b.
d. Stage 4.

EPIDEMIOLOGY

According to the Centers for Disease Control and Prevention, some level of chronic kidney disease can be seen in one out of every seven American adults (CDC, 2021). Chronic kidney disease is noted to be the ninth leading cause of death in the U.S. (US Department of Health and Human Services, 2019). Chronic kidney disease prevalence increases significantly with age, occurring in approximately 10% of adults under 65 years of age, and approximately 39% of adults 65 years of age and older. End-stage renal disease (ESRD) incidence rates appear to be increasing, with roughly 2,200 cases occurring per 1 million people in 2018, an increase of 2.3% from 2017 (U.S. Renal Data System, 2020).

Chronic kidney disease occurrence can vary with gender and race. Incidence rates of end-stage renal disease in the U.S. for Black patients are around 16%, compared to 13% for White patients and 14% for Hispanic patients. Chronic kidney disease is slightly more common in women compared to men, affecting 14% of women and 12% of men (CDC, 2021). It is also noted that specific causes of chronic kidney disease can occur at different frequencies for different races. For example, the risk of nephropathy associated with diabetes or hypertension is higher in Hispanic and Black races (U.S. Renal Data System, 2020).

CAUSES OF CHRONIC KIDNEY DISEASE

There are a wide variety of causes of chronic kidney disease. Diabetes and high blood pressure are among the most common causes of CKD. The increased blood sugar levels associated with diabetes can damage the kidney's ability to filter waste and fluid over time, thus reducing kidney function. High blood pressure can damage blood vessels in the kidneys, reducing their ability to remove fluid and waste. This can lead to fluid retention and further increases in blood pressure, perpetuating the cycle of damage. Less common causes of chronic kidney disease include (DiPiro et al., 2019; National Institute of Diabetes and Digestive and Kidney Diseases, 2016b):

- Vascular disease, such as renal artery stenosis or renal vein thrombosis.
- A genetic disorder causing cysts to grow in the kidneys, known as *polycystic kidney disease*.
- Glomerular disease, such as focal and segmental glomerulosclerosis (FSGS).
- Glomerular disease can also be secondarily caused by a variety of conditions including lupus, rheumatoid arthritis, scleroderma, endocarditis, HIV, parasitic infections, and heroin use.
- Tubulointerstitial disease, which can be caused by infections, certain medications such as sulfonamides and allopurinol, chronic hypercalcemia or hypokalemia, heavy metal poisoning, and radiation.
- Urinary tract dysfunction or obstruction, which can be caused by kidney stones, benign prostatic hypertrophy, tumors, neurogenic bladder, and urethral stricture.
- Congenital defects of the kidney or urinary system.
- Acute kidney injury due to infection, medications, or illicit drug use.

COMPLICATIONS OF CHRONIC KIDNEY DISEASE

Volume overload

In chronic kidney disease, salt and water processing is impaired, decreasing sodium and free water excretion. Failure to remove adequate fluids and salts can cause volume overload. Since the body develops alternative methods for dealing with this reduction in fluid and salt removal, clinical manifestation of this impairment is often seen when the GFR falls to less than 10–15 mL/min/1.73m^2, after alternative systems have been exhausted. Volume overload can also be seen in patients with a higher GFR if ingested quantities of water and salts exceed the body's decreased ability for removal. Volume overload can lead to edema, worsening congestive heart failure, and hypertension (Rosenberg, 2021).

Chronic kidney disease patients in volume overload often respond to a combination of diuretic medications and dietary sodium restriction. Loop diuretics, such as furosemide, are often used for diuresis in symptomatic patients. The KDIGO Work Group recommends restricting dietary sodium to less than 2 grams per day in all adult CKD patients unless contraindicated (Rosenberg, 2021; KDIGO Work Group, 2013).

Hypertension

High blood pressure affects over 80% of chronic kidney disease patients and can be both a cause and consequence of CKD. Hypertension is often a result of volume overload and salt retention, due to the reduced ability of the kidneys to remove excess fluid and salts. In addition, the renin– angiotensin–aldosterone system, which plays a significant role in regulating blood pressure, is located in the kidneys and can be overactivated in chronic kidney disease. Since hypertension can cause chronic kidney disease, adequate control of blood pressure and suppression of the renin–angiotensin–aldosterone system are critical to preventing disease progression and reducing cardiovascular complications. The use of angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs) are often recommended for this purpose (Rosenberg, 2021).

Hyperkalemia

Hyperkalemia can develop in patients with chronic kidney disease due to a reduced ability to excrete potassium through the kidneys, particularly in patients with GFR less than 20–25 mL/min/1.73m^2. High potassium levels can also be seen in earlier stages of chronic kidney disease, particularly in patients who eat a potassium-rich diet or those with low aldosterone levels. When kidney function declines, the hormone aldosterone increases excretion of potassium in the gastrointestinal tract, but this mechanism is often insufficient to maintain normal potassium levels in patients with severe or end-stage kidney disease (Rosenberg, 2021).

Preventative measures can be applied to patients with CKD to avoid hyperkalemia. Initiation of a low-potassium diet, with restriction between 1,500 and 2,700 mg/day, can reduce the amount of potassium available for absorption. Avoiding medications that increase potassium levels such as nonsteroidal anti-inflammatory agents can also be beneficial. Potassium levels should be closely monitored in CKD patients at risk of hyperkalemia (Rosenberg, 2021).

Dyslipidemia

Abnormal lipid levels are common in chronic kidney disease patients, particularly hypertriglyceridemia. All patients with CKD should be evaluated for dyslipidemia. Since high lipid levels can increase cardiovascular risk and cause atherosclerosis, treatment may be required, depending on the level of severity and the patient's underlying cardiovascular risk (Rosenberg, 2021).

Metabolic acidosis

Acid–based balance is maintained by the renal excretion of acids produced daily in the body. Chronic kidney disease can cause a decreased production of ammonia in the proximal tubules, which aids in the excretion of acids produced by the body by forming ammonium. Lower levels of ammonia production led to increased acid levels. Additionally, accumulation of phosphates, sulfates, and organic anions can also contribute to increased acid levels (Kovesdy, 2021; Rosenberg, 2021).

Metabolic acidosis, or high blood acid levels, can occur in late-stage chronic kidney disease. Metabolic acidosis can negatively impact protein balance, leading to reduced protein creation and processing and causing protein–energy malnutrition, muscle weakness, and a loss of lean body mass. Since bone can act as a buffer when blood acid levels are high, metabolic acidosis can also lead to bone mineral loss. Metabolic acidosis is associated with higher mortality and more rapid disease progression among CKD and ESRD patients (Kovesdy, 2021; Rosenberg, 2021).

Anemia

Anemia often begins early on in chronic kidney disease and progresses in occurrence and severity as renal impairment progresses, affecting about 8% of CKD stage 1 patients and nearly 53% of CKD stage 5 patients. Decreased renal production of erythropoietin in CKD patients reduces stimulation of the bone marrow to produce red blood cells, leading to reduced oxygen-carrying capacity of the blood and reduced red blood cell survival. Uremia, or buildup of waste products in the blood, can also cause platelet dysfunction which increases the risk of bleeding (Arora, 2021).

Anemia is evaluated in CKD patients when the hemoglobin level is less than 12 g/dL in females and 13 g/dL in males, and other causes of anemia are excluded, such as iron, folate, or vitamin B12 deficiency. Anemia is often associated with the following clinical observations (Arora, 2021; Rosenberg, 2021):

- Decreased exercise capacity.
- Fatigue.
- Reduced immune and cognitive function.
- Cardiovascular disease development, leading to increased cardiovascular mortality.
- Development or worsening of heart failure.
- Decreased quality of life.

The KDIGO Work Group suggests checking hemoglobin levels when clinically indicated, and at least annually in CKD stage 3 patients, at least biannually in CKD stages 4 and 5 patients, and at least quarterly in patients on dialysis in patients not already diagnosed with anemia. For those patients diagnosed with anemia, hemoglobin levels should be checked when clinically indicated, at least quarterly in CKD stages 3 to 5 patients, and monthly in patients on hemodialysis (KDIGO Work Group, 2013; Rosenberg, 2021).

Bone and mineral disease

Bone and mineral disorders are a frequent complication of chronic kidney disease, due to the altered balance of mineral levels in the body, and can be collectively referred to as chronic kidney disease bone and mineral disease (CKD-BMD). In healthy individuals, phosphate and calcium levels are carefully balanced in the body and have opposing effects on each other—increases in calcium levels cause decreases in phosphate levels, and vice versa. Dietary calcium and phosphate are absorbed through the small intestine and are filtered and reabsorbed through the kidneys. Phosphate binds with calcium for storage in the bone, which serves as a reservoir to provide additional phosphate and calcium when levels are low. To maintain calcium and phosphate in balance, parathyroid hormone (PTH) aids in lowering blood phosphate levels and increasing blood calcium levels. Activated vitamin D, known as *calcitriol*, helps to raise blood phosphate and calcium levels (DiPiro et al., 2019; Rosenberg, 2021).

Patients with chronic kidney disease experience increased secretion of parathyroid hormone early in the course of chronic kidney disease, around the time the GFR drops below 60 mL/min/1.73m^2. This increase in PTH helps to maintain normal blood calcium and phosphate levels. However, when the GFR falls to below 30 mL/min/1.73m^2, the kidneys can no longer keep up with excretion of excess phosphate, which results in hyperphosphatemia. High phosphate levels then trigger more release of parathyroid hormone, contributing to high parathyroid levels, or hyperparathyroidism (DiPiro et al., 2019; Rosenberg, 2021).

Vitamin D levels are reduced in CKD patients due to reduced activation of vitamin D in the kidneys. This results in a reduction in calcium absorption from the small intestine, contributing to lower blood calcium levels, as well as a decrease in bone uptake of calcium. When phosphate levels are high, calcium can precipitate

with phosphate, contributing to lower blood calcium levels and additional release of parathyroid hormone (Rosenberg, 2021).

Overall, these mineral abnormalities contribute to specific types of bone structure abnormalities commonly seen in CKD patients, such as osteitis fibrosa, osteomalacia, and adynamic bone disease. Preventative measures such as dietary phosphate restriction and phosphate binders can help prevent the progression of bone and mineral disease. Parathyroid hormone levels can be assessed to help determine the most appropriate preventative measures for chronic kidney disease patients (Rosenberg, 2021).

Healthcare Consideration: Symptoms of vitamin D deficiency may include bone pain and muscle weakness, but the symptoms are often subtle and can be confused for other conditions. Pharmacists can encourage assessment of vitamin D levels as part of preventive health screening. Low blood levels of vitamin D have been associated with the following (Kheiri et al., 2018):

- Increased risk of cardiovascular disease.
- Cognitive impairment in older adults.
- Increased risk of bone disorders and fractures.
- Insulin resistance.

Sexual dysfunction

Patients with advanced kidney disease frequently experience abnormalities in reproductive and sexual function. More than 50% of men with uremia experience symptoms that include decreased libido, erectile dysfunction, and reduced frequency of intercourse. Women with CKD commonly experience menstruation disturbances, which often progress to amenorrhea by the time end-stage renal disease develops. Women with a creatinine level greater than 3 mg/dL are rarely able to carry a pregnancy to term (Rosenberg, 2021).

Other effects of chronic kidney disease

Other clinical syndromes associated with end-stage renal disease, particularly in patients who are not receiving adequate dialysis, include (Arora, 2021):

- Gastrointestinal effects such as nausea, vomiting, diarrhea, or anorexia.
- Malnutrition and failure to thrive.
- Neurological effects, including restless leg syndrome, peripheral neuropathy, and encephalopathy.
- Dermatological effects such as pruritus, dry skin, and ecchymosis.
- Pericarditis.
- Platelet dysfunction, leading to an increased risk of bleeding.

MANAGEMENT OF CHRONIC KIDNEY DISEASE

The focus of chronic kidney disease management should be on determining the underlying cause of kidney disease and implementing secondary prevention measures to slow or potentially stop disease progression. Treatment of the underlying condition, as well as treatment and prevention of adverse effects of chronic kidney disease, should be implemented soon after diagnosis. Referral to a nephrologist should occur in patients with a GFR of less than 30 mL/min/1.73m^2 in order to discuss and plan for kidney replacement therapy. Patients with a rapid decline in kidney function should also see a nephrologist in order to ensure the best possible outcomes (Rosenberg, 2021).

Clinical practice guidelines have been published by the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (KDOQI) to guide management of all CKD stages, as well as associated complications. Recommendations to delay or cease CKD progression include (Arora, 2021; KDIGO Work Group, 2013):

- Treating the underlying condition causing chronic kidney disease.
- Treating high lipid levels to bring levels to targets established by current guidelines.
- Aggressive treatment of high blood pressure to bring levels to targets established by current guidelines.
- Aggressive treatment of high blood sugar in diabetic patients to bring levels to targets established by the American Diabetes Association, such as hemoglobin A1C levels of less than 7%.
- Avoiding nephrotoxic medications such as IV contrast dyes, aminoglycosides, and nonsteroidal anti-inflammatory drugs.
- Using medications that block the renin–angiotensin system, such as angiotensin-converting enzyme inhibitors (ACE inhibitors) or angiotensin receptor blockers (ARBs) in patients with proteinuria.
- Using sodium-glucose cotransporter 2 (SGLT2) inhibitors to slow disease progression

Cardiovascular risk management

The KDIGO workgroup guidelines recommend wide use of statins to reduce cardiovascular risk in patients with chronic kidney disease. Their recommendations include (KDIGO Work Group, 2013b):

- Treatment with a statin or statin plus ezetimibe for adults aged 50 and older with an estimated GFR of less than 60 mL/min/1.73m^2 who are not on long-term dialysis or treated with kidney transplantation.
- Adults aged 50 and older with CKD and an estimated GFR of greater than 60 mL/min/1.73m^2 should also receive a statin.
- Adults 18-49 with an estimated GFR of less than 60 mL/min/1.73m^2 who are not on long-term dialysis or treated with kidney transplantation should receive a statin if they have coronary disease, prior ischemic stroke, diabetes, or an estimated 10-year risk of coronary death or nonfatal myocardial infarction greater than 10%.
- Statins should not be started in patients on dialysis, though those already on a statin when dialysis begins should continue.
- Kidney transplant patients should receive a statin, as these patients are at a higher risk of coronary events.
- LDL alone is an insufficient test to identify cardiovascular risk in CKD patients; a complete lipid profile should be assessed. The majority of adults with CKD do not require follow-up measurement of lipid levels.

Blood pressure control

Aggressive control of blood pressure can help slow the decline in kidney function in CKD patients. The KDIGO Work Group suggests a target systolic blood pressure less than 120 mmHg in CKD patients. Kidney transplant patients should have blood pressure treated to a target of less than 130/80 mmHg (KDIGO Work Group, 2021). A 2012 study by Peralta et al. noted that high systolic blood pressure (SBP) accounted for the majority of the risk of progression to end-stage kidney disease. Risk began at a SBP of 140 mmHg and was found to be highest among patients with SBP of at least 150 mmHg (Peralta et al., 2012).

Patients with high blood pressure and CKD should be advised to spend at least 150 minutes per week undertaking moderate-intensity physical activity, or a level compatible with their physical and cardiovascular tolerance. This should be implemented on a patient-specific basis, while considering the patient's physical limitations, risk of falls, and cognitive function. Even if physical

activity falls below general population targets, there may still be important health benefits for CKD patients with hypertension (KDIGO Work Group, 2021).

The use of angiotensin-converting enzyme (ACE) inhibitors or angiotensin-receptor blockers (ARBs) is recommended as tolerated, as these medications have been shown to decrease the risk of long-term dialysis and mortality. Patients must be closely monitored for kidney disease progression and hyperkalemia, a known side effect of these two classes of medication. A small increase in serum creatinine levels is common with ACE inhibitors and ARBs, but if an increase of more than 30% occurs within four weeks of starting or increasing the dose, these medications should be stopped. Patients with advanced renal failure or renal artery stenosis should avoid these medications (KDIGO Work Group, 2021).

Since hypertension in CKD is often related to volume expansion, diuretics are recommended to remove excess fluids and reduce the patient's weight to their "dry weight," or their normal weight without edema. Thiazide diuretics such as chlorthalidone and loop diuretics such as furosemide are recommended for this purpose. Thiazide diuretics are not typically used to treat hypertension and edema in CKD patients because their effectiveness decreases when the estimated GFR falls below 30 mL/min/1.73m^2, though some agents such as chlorthalidone appear to remain effective at lower GFRs. Loop diuretics are more commonly used in patients with GFRs of less than 30 mL/min/1.73m^2 due to their effectiveness (KDIGO Work Group, 2021).

Case study, continued

While at her checkup appointment with her primary care provider, Sally discusses her blood pressure control with her doctor. She has a preexisting diagnosis of high blood pressure but stopped taking her blood pressure medication because she was experiencing side effects. Her doctor wants to start her on a new agent to get her blood pressure under control and prevent the progression of her chronic kidney disease. Sally agrees to this and wants the best medication that will prevent long-term complications.

Self-Assessment Quiz Question #5

Which of the following blood pressure medications would decrease Sally's risk of long-term dialysis and mortality?

a. Metoprolol.
b. Amlodipine.
c. Diltiazem.
d. Lisinopril.

Avoiding nephrotoxic medications

A frequent cause of worsening kidney function is the administration of medications that adversely affect renal function. Medications to avoid in patients with chronic kidney disease include (Rosenberg, 2021):

- Aminoglycoside antibiotics, such as gentamycin.
- Nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen and meloxicam.
- IV contrast dye used in certain MRI and CT scans.

Many other medications may be considered potentially nephrotoxic but may not require strict avoidance in chronic kidney disease patients. Oftentimes, when dosed appropriately and closely monitored, potentially nephrotoxic medications can be used safely in early-stage CKD patients. References should be consulted prior to initiating new medications in CKD patients to ensure appropriate medications are used at appropriate dosages to prevent nephrotoxicity and adverse effects (DiPiro et al., 2019).

Protein restriction

Since excess dietary protein intake can lead to the accumulation of waste products in the body, the KDIGO Work Group recommends reducing protein intake to 0.8 g/kg/day in patients with GFR less than 30 mL/min/1.73m^2 and avoiding high-protein diets that include more than 1.3 g/kg/day in early-stage CKD patients at risk of progression. Restricting dietary protein must be done cautiously because insufficient protein intake can decrease lean body mass and lead to malnutrition. Advanced chronic kidney disease is associated with protein wasting syndrome, which causes increased morbidity and mortality, so protein restriction may be inappropriate in late-stage patients. Dietary changes should be patient-specific and target individual goals (KDIGO Work Group, 2013).

Renal diet

Patients with chronic kidney disease may need to make changes to their diet to prevent disease progression. A reduction in salt intake can aid in slowing the progression of chronic kidney disease, in part by helping to lower blood pressure, a significant risk factor for disease progression. Hypertensive, volume overloaded, or proteinuric patients with a GFR of less than 60 mL/min/1.73m^2 may benefit from reducing sodium intake to less than 2 grams per day (Rosenberg, 2021).

Other dietary restrictions may be indicated depending on the patient. Fluid restriction can be used in patients with edema to reduce or avoid fluid overload. Phosphorus restriction to less than 0.8 to 1 gram per day is often recommended, since some studies suggest dietary phosphorus can alter fibroblast growth factor production, which affects serum phosphate concentrations. Potassium restriction is typically reserved for hyperkalemic patients (Cho & Beddhu, 2021).

Renal replacement therapy (Dialysis)

There are a number of clinical indicators that show dialysis may be necessary in a patient with severe chronic kidney disease. While there is not a specific GFR at which dialysis should be initiated, it is common for clinical signs and symptoms of kidney failure to occur when the GFR is between 5 and 10 mL/min/1.73m^2. Clinical indicators used to determine when to initiate dialysis include (Rosenberg, 2021):

- Pericarditis or pleuritis.
- Progressive uremic neuropathy or encephalopathy, exhibited by confusion, myoclonus, foot or wrist drop, or seizures.
- Clinically significant bleeding attributable to uremia.
- Fluid overload that is refractory to diuretics.
- Evidence of malnutrition.
- High blood pressure that is poorly responsive to antihypertensive agents.
- Persistent nausea and vomiting.
- Persistent, refractory metabolic disturbances such as metabolic acidosis, hyponatremia, hyperkalemia, hyper- or hypocalcemia, and hyperphosphatemia.

Relative indications for initiating dialysis include decreased cognition, persistent pruritis, depression, and restless leg syndrome. Asymptomatic patients may require dialysis when their GFR reaches low levels, such as less than 10 mL/min/1.73m^2, to prevent the development of potentially life-threatening complications of uremia. Some providers choose to monitor these patients frequently, such as weekly, and plan to initiate dialysis when symptoms of uremia develop. Other factors may influence the choice to initiate dialysis, including the rate of renal function decline and life expectancy (Rosenberg, 2021).

Healthcare Consideration: In patients with progressive CKD, providers must be vigilant in determining the presence of clinical indicators that dialysis is necessary. Patients should also be educated on the symptoms of uremia and to contact their providers appropriately if symptoms develop (Rosenberg, 2021).

Self-Assessment Quiz Question #6

Sally read that her diagnosis of chronic kidney disease can increase her risk of cardiovascular disease, and she wants to do what she can to prevent it. She does not want a heart attack or stroke to affect her ability to spend more time with her grandkids. Since Sally is 75 years old and has a GFR of 44 mL/min/1.73m^2, which of the following are recommended to reduce her cardiovascular risk?

a. Fish oil supplements.
b. Statins.
c. Fenofibrate.
d. Ibuprofen.

TREATMENT OF CHRONIC KIDNEY DISEASE COMPLICATIONS:

Medication usage

A reduction in kidney function can affect the body's ability to remove medications from the bloodstream. This reduced function can cause differing effects depending on the medication in question. Some medications may require dosage adjustments based on the patient's estimated GFR, while others are contraindicated in moderate or severe renal impairment due to accumulation of the medication or its metabolites. Whenever a new medication is added in a patient with chronic kidney disease, appropriate references should be consulted to determine if any dosage adjustments are necessary. Dosages may need to be lowered, or administered at extended intervals, to prevent accumulation and adverse effects (DiPiro et al., 2019).

Treatment of hyperphosphatemia

The KDIGO Work Group guidelines recommend maintaining serum phosphate levels within the normal range of 2.5 to 4.5 mg/dL in CKD patients who are not on dialysis. Dialysis patients have a higher target phosphate goal between 3.5 to 5.5 mg/dL due to the difficulty in maintaining lower levels and unclear benefit on outcomes in these patients. Phosphate levels can be reduced through dietary phosphate restriction as well as the use of phosphate binders. Dietary phosphate can be restricted to approximately 900 mg/day, and processed foods such as cola should be restricted over high biologic value foods such as meat and eggs (Berkoben & Quarles, 2021).

Patients with persistently high phosphate levels over 5.5 mg/dL despite one to two months of dietary phosphate restriction may require the use of phosphate binders. Phosphate binders work by binding dietary phosphate in the gastrointestinal tract to reduce the amount of phosphate available for absorption. Phosphate binders can be divided into several categories: calcium- containing phosphate binders, non-calcium-containing phosphate binders, iron-based phosphate binders, and aluminum-based phosphate binders. Most patients are recommended to use non- calcium-containing phosphate binders, with exceptions when serum calcium is low and parathyroid hormone is high, or if non-calcium-containing phosphate binders are not affordable or available. This is due to the risk of side effects seen with calcium-containing phosphate binders, and potential mortality benefits with the use of non-calcium containing phosphate binders (Berkoben & Quarles, 2021).

Calcium-containing phosphate binders

Calcium-containing phosphate binders include calcium acetate and calcium carbonate. Calcium acetate may be a more efficient phosphate binder than calcium carbonate. Their calcium content can potentially lead to hypercalcemia, and when combined with high phosphate levels, can lead to extraskeletal calcium–phosphate deposits. Vascular calcification and adynamic bone disease can also be seen in patients taking calcium-containing phosphate binders, leading to increased morbidity. Calcium levels should be monitored in patients on calcium-containing phosphate binders, and these medications should be reduced or discontinued if hypercalcemia develops (Berkoben & Quarles, 2021).

Calcium acetate (PhosLo) is the most commonly used calcium-containing phosphate binder. It is typically started at a dosage of 1,334 mg three times daily with each meal and can be increased every two to three weeks until phosphate levels are in target range. Side effects associated with calcium acetate include hypercalcemia, nausea, vomiting, and constipation (Berkoben & Quarles, 2021; DiPiro et al., 2019).

Non-calcium-containing phosphate binders

Non-calcium-containing phosphate binders include sevelamer and lanthanum. It appears both products are equally effective in lowering phosphate levels, though more long-term safety data is available for sevelamer (Berkoben & Quarles, 2021).

Sevelamer is available in two forms: sevelamer hydrochloride, sold under the name Renagel, and sevelamer carbonate, sold under the name Renvela. Sevelamer works by binding phosphate through ion exchange. It is typically administered three times daily, at a dose of 800 mg TID for phosphate levels between 5.6 and 7.4 mg/dL, or 1,600 mg TID for phosphate levels greater than 7.5 mg/dL. The cost of sevelamer is significantly more than calcium-containing phosphate binders, a factor that may need to be considered when choosing a phosphate management regimen for chronic kidney disease patients (Berkoben & Quarles, 2021; DiPiro et al., 2019).

Lanthanum is a rare earth element that has effectiveness in reducing phosphate levels in chronic kidney disease patients. It is sold under the brand name Fosrenol. It appears to cause reduced rates of hypercalcemia and parathyroid hormone oversuppression when compared with calcium carbonate. Lanthanum tablets are chewable rather than swallowed whole, which may be a benefit over sevelamer to some patients. It is typically initiated at a dose of 500 mg three times daily and is increased by 750 mg per day every two to three weeks until target phosphate levels are achieved (Berkoben & Quarles, 2021; DiPiro et al., 2019).

Short-term safety studies of up to two years have not uncovered any severe adverse effects with lanthanum treatment. Gastrointestinal effects were the principal adverse effects that developed, and no evidence of hepatic toxicity was found. Long-term effects on bone and other organs remain unclear; since lanthanum accumulated in several organs in animal studies, such as the liver, further research may be needed to evaluate this possibility. Short-term use appears to be unlikely to cause lanthanum toxicity (Berkoben & Quarles, 2021; DiPiro et al., 2019).

Iron-based phosphate binders

Sucroferric oxyhydroxide is an iron-based chewable phosphate binder sold under the name Velphoro. It is a U.S. Food and Drug Administration (FDA) approved for treating hyperphosphatemia in patients with a GFR of less than 15 mL/min/1.73m^2. Sucroferric oxyhydroxide has comparable efficacy to sevelamer in reducing phosphate levels. Sucroferric oxyhydroxide appears to have more frequent side effect rates and more frequent drug discontinuation rates due to side effects. Adverse reactions are similar to those experienced with administration of iron and include diarrhea, nausea, constipation, vomiting, and changes in taste. A typical starting dose of sucroferric oxyhydroxide is 2.5 g three times daily with meals (Berkoben & Quarles, 2021; DiPiro et al., 2019).

Ferric citrate, sold under the brand name Auryxia, is another iron-based phosphate binder used to treat hyperphosphatemia. While effective in reducing serum phosphorus levels, citrate in any form has been proven to increase intestinal absorption of aluminum, thus increasing aluminum toxicity risk. Since this can be a potentially severe reaction in patients with chronic kidney disease, some references recommend avoiding all citrate products in chronic kidney disease patients. Ferric citrate can also increase iron levels, and potentially cause iron overload, so ferritin and iron saturation levels should be monitored at baseline and periodically thereafter. Other adverse reactions are related to the iron content and include nausea, vomiting, diarrhea, constipation, and dark stools (Berkoben & Quarles, 2021; DiPiro et al., 2019).

Aluminum-based phosphate binders

Aluminum hydroxide is an effective phosphate binder, but due to the risk of aluminum toxicity in patients with chronic kidney disease, it is recommended only for short-term treatment of severe hyperphosphatemia for less than four weeks. Its use is infrequent in chronic kidney disease patients due to the aluminum toxicity risk, which can cause anemia, muscle and bone pain, dementia, and vitamin D–resistant osteomalacia (Berkoben & Quarles, 2021; DiPiro et al., 2019).

Hyperparathyroidism: Vitamin D analogs

Since reduced levels of activated vitamin D in chronic kidney disease patients can contribute to the development of hyperparathyroidism, treatment with calcitriol or vitamin D analogs may be necessary to maintain normal parathyroid hormone levels. More selective vitamin D analogs such as paricalcitol or doxercalciferol were developed to reduce the risk of hypercalcemia and hyperphosphatemia associated with calcitriol, but the selectivity of these agents has not been consistently proven in chronic kidney disease patients. Studies show all vitamin D analogs demonstrate the potential to increase calcium and phosphate levels, particularly at high doses, leading to increased mortality; adding a phosphate binder may be necessary to maintain normal phosphate levels (Quarles & Berkoben, 2021).

All three agents appear to have comparable efficacy in reducing parathyroid hormone levels, and studies have not shown a preference for one agent over others. Price and insurance coverage may be the deciding factor, with many insurance companies preferring calcitriol due to its lower cost (Quarles & Berkoben, 2021).

Calcitriol, paricalcitol, and doxercalciferol should not be administered until blood phosphorus and calcium levels have been controlled. This is due to the risk of increasing calcium levels in the presence of high phosphorus levels, which can lead to precipitation, increasing the risk of vascular calcification (Quarles & Berkoben, 2021).

Treatment regimens that limit the dose of calcitriol or vitamin D analogs may be beneficial due to the ability of these agents to induce hypercalcemia and hyperphosphatemia. Despite this risk, a number of benefits have been noted with administration of calcitriol and vitamin D analogs, including reduced all-cause death and cardiovascular mortality in hemodialysis patients with adequate vitamin D levels (Quarles & Berkoben, 2021).

Calcitriol

Calcitriol is the activated form of vitamin D. It is available in an oral preparation, associated with the brand name Rocaltrol, and an IV preparation, associated with the brand name Calcijex. Oral preparations are typically used in chronic kidney disease patients; IV administration is generally reserved for dialysis patients with significant hypocalcemia. Oral administration can be started at a dose of 0.25 mcg once per day and adjusted after four to eight weeks based on calcium and parathyroid hormone levels. Calcitriol should be discontinued if hypercalcemia develops (Quarles & Berkoben, 2021; DiPiro et al., 2019).

Paricalcitol

Paricalcitol is a vitamin D analog approved for the treatment of hyperparathyroidism, sold under the brand name Zemplar. It is typically started at a dose of 1 mcg daily and adjusted based on parathyroid hormone, calcium, and phosphate levels every two to four weeks (Quarles & Berkoben, 2021; DiPiro et al., 2019).

Paricalcitol appears to have comparable effectiveness to calcitriol in reducing parathyroid hormone levels. However, a long-term study has found significantly lower mortality rates with paricalcitol when compared with calcitriol in dialysis patients, beginning after 12 months of treatment. Paricalcitol was also associated with less elevation in serum phosphate and calcium levels.

Unfortunately, this study was not randomized and had significant differences in patient baseline characteristics, so this trial alone is not considered a reason to prefer paricalcitol over other agents (Quarles & Berkoben, 2021; DiPiro et al., 2019).

Doxercalciferol

Doxercalciferol is another vitamin D analog approved for the treatment of hyperparathyroidism, sold under the brand name Hectorol. It is available in both oral and IV forms, though the IV form is typically reserved for severe cases of hyperparathyroidism in dialysis patients. In nondialysis patients, it is started at a dose of 1 mcg daily and adjusted based on parathyroid hormone, calcium, and phosphate levels every two weeks up to a maximum dose of 3.5 mcg/day (Quarles & Berkoben, 2021; DiPiro et al., 2019).

Self-Assessment Quiz Question #7

Which of the following vitamin D analogs is the preferred medication for the treatment of hyperparathyroidism?

a. Paricalcitol.
b. Doxercalciferol.
c. Calcitriol.
d. There is not a preference for one agent over another.

Hyperparathyroidism: calcimimetics

Calcimimetics work by increasing the sensitivity of the calcium receptor in the parathyroid gland to calcium, which regulates parathyroid hormone secretion. This allows for a reduction in serum parathyroid hormone levels, as well as a decrease in calcium and phosphate levels. Unlike vitamin D analogs, calcimimetics can be administered in patients with hyperphosphatemia. There are two calcimimetics available in the U.S.: cinacalcet, an oral medication sold under the name Sensipar, and etelcalcetide, an IV product

sold under the name Parsabiv (Quarles & Berkoben, 2021; DiPiro et al., 2019).

Cinacalcet is effective in reducing parathyroid hormone levels, as well as helping patients achieve goal calcium and phosphate levels, which can be difficult to control as CKD progresses. It has been shown to be effective in patients unable to take adequate vitamin D doses due to high calcium and phosphate levels, though it appears to be more effective in targeting parathyroid hormone levels when administered in combination with vitamin D products. Cinacalcet was not shown to reduce mortality in hemodialysis patients under 65 years of age but may provide some benefit in older patients with a higher cardiovascular risk (Quarles & Berkoben, 2021; DiPiro et al., 2019).

Cinacalcet is typically started at a dose of 30 mg once daily and can be increased every two to four weeks by 30 mg per dose, up to 180 mg per day. It should not be started in patients with hypocalcemia. Adverse reactions associated with cinacalcet include hypocalcemia and gastrointestinal symptoms; GI symptoms may be reduced when the product is administered with food and typically resolved with chronic use. Serum calcium and parathyroid hormone levels should be frequently monitored to assess for effectiveness and prevent hypocalcemia (Quarles & Berkoben, 2021; DiPiro et al., 2019).

Etelcalcetide, approved by the FDA in February 2017, is approved for use in hemodialysis patients with hyperparathyroidism. It is administered after dialysis three times weekly. Short-term studies showed it produced a more robust reduction in parathyroid hormone levels over cinacalcet, though it also caused more hypocalcemia. Side effects with etelcalcetide include nausea, vomiting, and prolongation of the QT interval. Serum calcium and parathyroid hormone levels should be frequently monitored (Quarles & Berkoben, 2021; DiPiro et al., 2019).

Anemia

Since anemia is so common in patients with chronic kidney disease, all CKD patients should be screened for anemia by measuring hemoglobin levels upon initial evaluation for CKD. Patients with anemia should undergo further lab testing to evaluate the cause of anemia, including a complete blood count (CBC), serum iron, total iron-binding capacity (TIBC), percent transferrin saturation (TSAT), serum ferritin, serum folate, and vitamin B12 levels (Berns, 2021a).

Iron administration in deficient patients is typically based on lab values, such as ferritin and transferring saturation. Most CKD patients require iron supplementation when transferring saturation values are less than 20%, and/or serum ferritin is less than 100 ng/mL. Depending on the severity of anemia, iron can be administered intravenously or orally. The oral form is administered to most patients, due to its inexpensive cost and easy availability, while intravenous is preferred for patients who require rapid iron repletion, have a history of not responding to iron in the past, or have severe anemia (Berns, 2021a).

Several oral iron preparations are available, with the preferred agent being ferrous sulfate. Tablets containing 325 mg of ferrous sulfate contain 65 mg of elemental iron, and dosing is based on anemia severity, ranging from one to three times daily. Side effects of oral iron are typically gastrointestinal in nature and include nausea, vomiting, constipation, dyspepsia, and dark stools.

Ferrous gluconate typically contains less elemental iron, with 240 mg of ferrous gluconate containing 27 mg of elemental iron. This often results in a lower incidence of gastrointestinal side effects, though the lower iron content is less ideal when trying to replete iron stores. Oral iron should be administered between meals if tolerated; intestinal iron absorption can be reduced in patients with CKD and further reduced by food or antacids. Patients who are not at their iron goals within one to three months of adequately dosed iron therapy should be switched to intravenous iron (Berns, 2021a).

There are several intravenous iron products available, which appear to have equal efficacy in treating iron deficiency anemia (Berns, 2021a):

- Iron sucrose (Venofer) 200 mg doses given five times over two weeks.
- Ferric gluconate in sucrose complex (Ferrlecit) 250 mg weekly for three to four weeks.
- Ferumoxytol (Feraheme) 510 mg administered once, followed by a second 510 mg dose given three to eight days after the first dose.
- Ferric carboxymaltose (Injectafer) 750 mg per dose, given in two doses at least seven days apart.
- Iron dextran—not preferred for treating iron deficiency anemia in CKD patients due to a higher incidence of severe side effects, including anaphylaxis; if used, a 25-mg test dose is generally administered first; if tolerated, this is followed by a 500- to 1,000-mg infusion that can be repeated as needed.

Side effects associated with intravenous iron can be severe and include anaphylaxis; hypotension; and gastrointestinal effects such as nausea, vomiting, and abdominal discomfort (Berns, 2021a).

After ruling out or correcting iron deficiency, anemia treatment with erythropoiesis-stimulating agents may be necessary in patients with hemoglobin levels less than 10 g/dL. The KDIGO Work Group recommends considering the potential benefits of reducing anemia-related symptoms and avoiding blood transfusions versus the risks of potential harm of erythropoiesis-stimulating agents, such as hypertension, stroke, and vascular access loss in CKD patients with anemia. Patients who are not candidates for treatment with erythropoiesis-stimulating agents include (Berns, 2021b):

- Patients who have an active malignancy or recent history of malignancy, due to the risk of progression or recurrence of cancer.
- Patients who have experienced a stroke, due to the risk of recurrent stroke from erythropoiesis-stimulating agents.
- Inactive patients, such as those who are bedbound, have dementia, or have very limited functional capacity, since it is unlikely that these patients will experience the same benefit as patients who are more active and experiencing symptomatic anemia.

Two erythropoiesis-stimulating agents are available for use in CKD patients with anemia. Epoetin, sold under the names Procrit and Epogen, is administered subcutaneously at an initial starting dose of approximately 50 to 100 units/kg/week. Lower doses may be appropriate, particularly in patients with hemoglobin levels near 10 g/dL. In practice, many patients are dosed at an even number of units, since vials are available in 2,000; 3,000; 4,000; 10,000; 20,000; and 40,000 units per mL vials. Therefore, many patients are started at 4,000 to 10,000 units weekly or 10,000 to 20,000 units every other week. Outcomes appear to be similar with weekly and every other week dosing. Darbepoetin, sold under the name Aranesp, is also administered subcutaneously, with initial starting doses between 60 and 200 mcg every two to four weeks. If the choice to start an erythropoiesis-stimulating agent is made, using the lowest effective dose is recommended, as higher doses are associated with increased cardiovascular events and mortality (Berns, 2021b).

Target hemoglobin levels are not well defined, though many sources recommend goals between 10 and 11.5 g/dL using the lowest effective dose of erythropoiesis-stimulating agents. Therapy should be individualized based on patient-specific factors. Goal hemoglobin levels over 13 g/dL are not recommended, as this may increase the risk of mortality and cardiovascular events. Adverse effects associated with erythropoiesis-stimulating agents include hypertension, hypertensive encephalopathy, seizures, cardiovascular events, increased mortality, and malignancy (Berns, 2021b).

Conclusion

Since chronic kidney disease has the potential to affect nearly 15% of Americans, it is important to be aware of the disease process and treatment of this common disease state. The significant disease burden can affect many aspects of a patient's life and health. Complications associated with chronic kidney disease are numerous, and treatment can be overwhelming to patients. Pharmacists are perfectly poised to help educate patients on the disease process and treatment, and ensure patients are treated appropriately in order to slow disease progression and prevent adverse effects. Being aware of current treatment guidelines and recommendations allows pharmacy professionals to better serve patients with chronic kidney disease.

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THE COMPLICATIONS OF CHRONIC KIDNEY DISEASE, SECOND EDITION

Self-Assessment Answers and Rationales

1. **The correct answer is D.**
Rationale: Renal diets can involve decreasing potassium, sodium, and phosphorus intake to prevent overaccumulation of these substances.

2. **The correct answer is A.**
Rationale: The National Kidney Foundation recommends using the CKD-EPI creatinine equation to estimate GFR. This equation takes age, sex, race, and serum creatinine level into account to calculate an estimated glomerular filtration rate.

3. **The correct answer is C.**
Rationale: Using the CKD-EPI creatinine equation and the given information about Sally results in an estimated GFR of 44 mL/min/1.73m^2.

4. **The correct answer is C.**
Rationale: With a GFR of 44 mL/min/1.73m^2, Sally would fall into Stage 3b, moderately reduced GFR (30–44 mL/min/1.73 m^2).

5. **The correct answer is D.**
Rationale: Lisinopril, an ACE inhibitor, has been shown to decrease the risk of long- term dialysis and mortality.

6. **The correct answer is B.**
Rationale: To reduce cardiovascular risk in patients with chronic kidney disease, treatment with a statin or statin plus ezetimibe for adults aged 50 years and older with an estimated GFR of less than 60 mL/min/1.73m2 who are not on long-term dialysis is recommended.

7. **The correct answer is D.**
Rationale: Paricalcitol, doxercalciferol, and calcitriol appear to have comparable efficacy in reducing parathyroid hormone levels, and studies have not shown a preference for one agent over the others.

Final Examination Questions

Select the best answer for each question and then proceed to **EliteLearning.com/Book** to complete your final examination.

106. The National Kidney Foundation recommends using _____ to estimate GFR.
   a. CKD-EPI creatinine equation.
   b. Cockroft–Gault Equation.
   c. 24-hour urine collection.
   d. Jelliffe equation.

107. The Kidney Disease: Improving Global Outcomes (KDIGO) Work Group defines chronic kidney disease as abnormalities of kidney structure or function, present for greater than _____, with implications for health.
   a. Three days.
   b. Three months.
   c. Ttwo weeks.
   d. 30 days.

108. Which of the following accurately describes stage 4 CKD?
   a. Markers of kidney damage found, but GFR is normal or increased (>90 mL/min/1.73 m^2).
   b. Mildly reduced GFR (60–89 mL/min/1.73 m^2).
   c. Severely reduced GFR (15–29 mL/min/1.73 m^2).
   d. Kidney failure (GFR <15 mL/min/1.73 m^2 or dialysis).

109. The KDIGO Work Group recommends restricting dietary sodium to _____ per day in all adult CKD patients unless contraindicated.
   a. Less than 4 grams.
   b. Less than 2 grams.
   c. Greater than 2 grams.
   d. Less than 1 gram.

110. The KDOQI Work Group suggests a target systolic blood pressure of _____ in CKD patients.
   a. Less than 120 mmHg.
   b. Less than 130 mmHg.
   c. Less than 135 mmHg.
   d. Less than 140 mmHg

111. If an increase in serum creatinine of more than _____ occurs within four weeks of starting or increasing the dose of an ACE inhibitor or ARB, the medication should be stopped.
   a. 10%.
   b. 20%.
   c. 30%.
   d. 40%.

112. _____ is a rare earth element that has effectiveness in reducing phosphate levels in chronic kidney disease patients.
   a. Lanthanum.
   b. Calcium carbonate.
   c. Doxercalciferol.
   d. Cinacalcet.

113. _____ is an iron-based chewable phosphate binder sold under the name Velphoro.
   a. Sevelamer.
   b. Sucroferric oxyhydroxide.
   c. Lanthanum.
   d. Calcium acetate.

114. _____ is the activated form of vitamin D.
   a. Calcitriol.
   b. Doxercalciferol.
   c. Paricalcitol.
   d. Calcium acetate.

115. Unlike vitamin D analogs, calcimimetics can be administered in patients with:
   a. Hyperphosphatemia.
   b. Hypoparathyroidism.
   c. Hypertension.
   d. Hyperlipidemia.

Course Code: RPUS02CK