Validating Controlled Substances

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Objectives

- Discuss drug diversion and medication abuse/misuse
- Analyze pharmacist's responsibility and judgment in determining appropriateness of controlled substance
- Examine the use of E-FORCSE® in validating prescriptions
- Review DEA number verification
- Compare medical use of controlled substances

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Disclosure

No financial interest with manufacturers or any commercial products mentioned

All E-FORCSE® material was retrieved from a training manual in the Florida Department of Health website. This presentation is not sponsored.

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Controlled Substance Prescription

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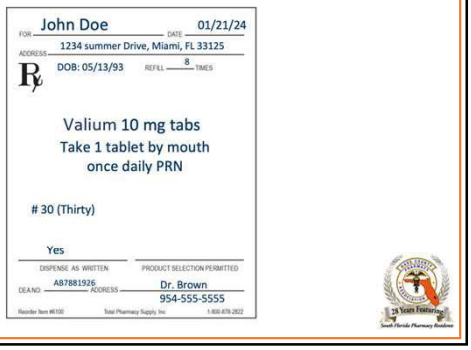

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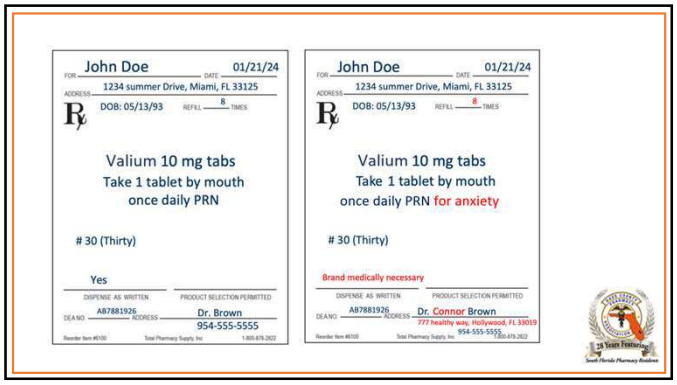

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Drug Diversion

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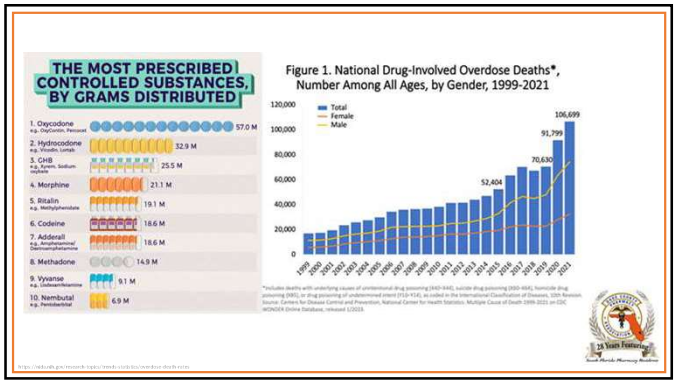

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Prescription Drug Type	Annual Abusers	% Among Rx Abusers	% Among Americans*
Painkillers	9.7 million	59.5%	3.43%
Opioids Alone	9.3 million	57.1%	3.29%
Sedatives	5.9 million	36.2%	2.08%
Stimulants	4.9 million	30.1%	1.73%
Benzodiazepine Alone	4.8 million	29.4%	1.70%
All Prescription Drugs	16.3 million	100%	5.76%

Aged 12 and older. Note multiple overlaps among prescription types and users.

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Case Study

- SH is a Miami native, who was known as a loving grandmother and a successful business-woman. She was the owner of Knoxville Pain Clinic in East Tennessee. In December 2020, the FBI received tips of inappropriate prescribing of opioids in this facility and the clinic was raided
- SH was found to be operating with a Florida group called "the Italians" profiting at least $21 million in a four-year period, producing more than 11 million opioid prescriptions
- Reported as Tennessee's largest pill mill operation, SH has been charged with racketeering and money laundering, sentenced to 33 years in prison

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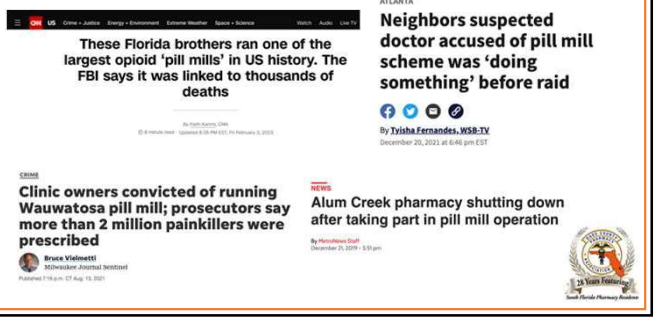

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Drug Diversion

- Medication abuse/misuse occurs for many reasons such as:
  - Self-medicating for pain, mood, and/or insomnia
  - Euphoric effects
  - Financial gain
- People abusing/misusing medications may exhibit behavior such as urgency to obtain medication, irritability, requesting specific medication and/or specific doses, requiring frequent dose increases
- Pharmacist duties
  - Assess pain symptoms, ask questions, speak with providers

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Pharmacist Responsibility and E-FORCSE®

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Clinical Judgement

- **Prescription "red flags"**
  - Prescription "cocktails" such as benzodiazepine, opioid and muscle relaxer
  - Polypharmacy
  - Filling multiple controlled substance prescriptions in different states or long distances
  - Invalid DEA number
  - Over-utilization or early fills
  - Unable to contact provider with questions/concerns
  - Diagnosis does not match need for prescription

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E-FORCSE®

Electronic-Florida Online Reporting of Controlled Substances Evaluation Program (E-FORCSE®) is a useful tool for validating prescriptions

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E-FORCSE®

- Created by the 2009 Florida Legislature in an initiative to encourage safer prescribing of controlled substances and to reduce drug abuse and diversion
- Dispensers of controlled substances are required to report to the PDMP each time a controlled substance are dispensed to a patient, as soon as possible but no later than close of business the day after the prescription is dispensed
- Each prescriber and dispenser has a duty to consult the PDMP system to review a patient's controlled substance dispensing history each time a controlled substance is prescribed or dispensed to a patient age 16 or older unless there is an exemption
- E-FORCE registration
  - https://florida.pmpaware.net/login

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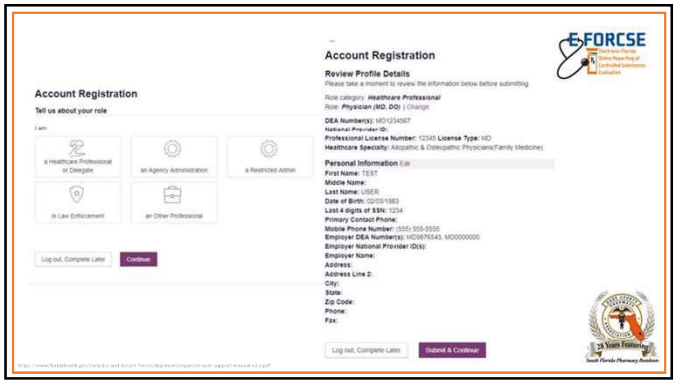

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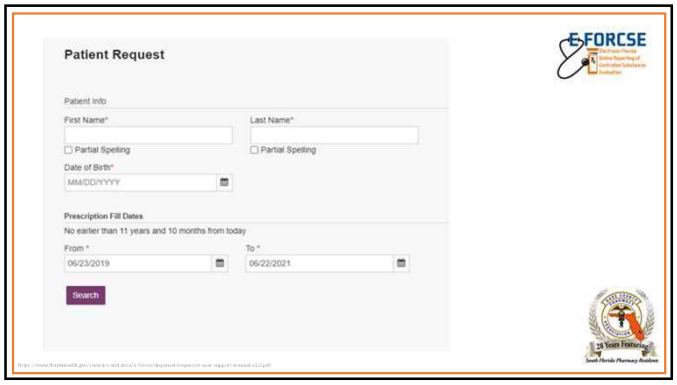
Patient Request
Patient Info
First Name*
Last Name*
Partial Spelling
Partial Spelling
Date of Birth*
MM/DD/YYYY
Prescription Fill Dates
No earlier than 11 years and 10 months from today
From *
To *
06/23/2019
06/22/2021
Search
E-FORCSE

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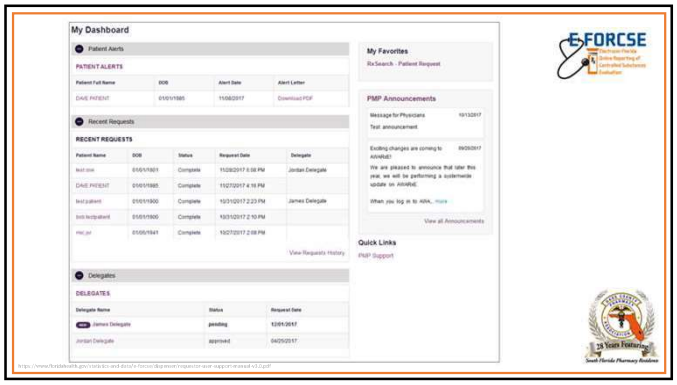
My Dashboard
Patient Alerts
PATIENT ALERTS
Recent Requests
RECENT REQUESTS
Delegates
DELEGATES
My Favorites
PMP Announcements
Quick Links
E-FORCSE

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Also Search
PMP Interconnect
RxCheck
None
To search in other states as well as your home state for patient information, select the states you wish to include in your search.
Search
E-FORCSE

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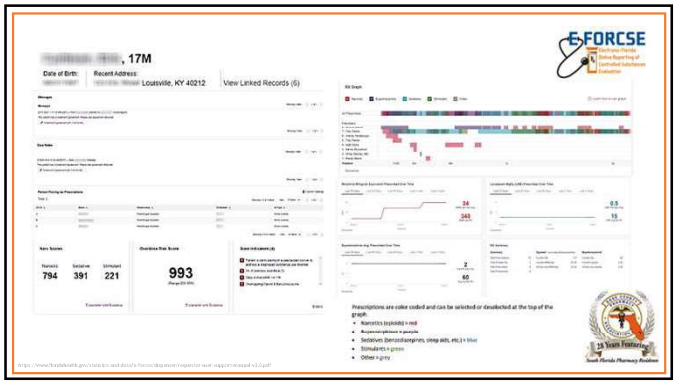

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E-FORCSE®

- **According to Florida Statute 893.055, prescription drug monitoring program (PDMP) reporting include**:
  - Name of prescriber
  - Prescriber's DEA number
  - Practitioner's National Provider Identification number (NPI)
  - Pharmacy information: permit number, DEA, and address
  - Date of prescription
  - Date filled
  - Method of payment
  - Name, address, telephone number, and date of birth of patient
  - Identify if prescription is a refill or an initial fill

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E-FORCSE®

- **Advantages**
  - Assist with prescription verification
  - Identify any possible misuse/abuse
  - Aid in record keeping with prescription fills
- **Limitations**
  - E-FORCE is specific to Florida, managed by Florida Department of Health
  - Limited to authorized personnel
  - Technological system failure preventing use of PDMP

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Checkpoint

According to Florida law, which of the following is **NOT** required for PDMP reporting?

a. Patient name, address, phone number, date of birth
b. Pharmacy permit number, DEA, and address
c. Practitioner's name, DEA number, NPI, office address, phone number
d. Date prescription was issued, filled, and method of payment

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Checkpoint

According to Florida law, which of the following is **NOT** required for PDMP reporting?

a. Patient name, address, phone number, date of birth
b. Pharmacy permit number, DEA, and address
c. Practitioner's name, DEA number, NPI, office address, phone number
d. Date prescription was issued, filled, and method of payment

All are required except for the practitioner's address and phone number. They should be included in a controlled substance prescription but not required for PDMP reporting

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DEA number

- **DEA number**
  - Unique identifier for any person and institution involved with manufacturing, distribution or dispensing controlled substances
  - Required to register with the DEA and must be renewed every 3 years
  - Each identifier starts with the letter "A", "B", "F", "M" or "G" and the second digit corresponds to the initial of provider's last name or first letter of the hospital name
  - The two letters are followed by 7 numbers

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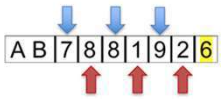
DEA number



- Step 1: Add digits 1, 3 and 5 — 7 + 8 + 9 = 24
- Step 2: Add digits 2, 4 and 6, then multiply by 2 — (8 + 1+ 2) x 2 = 22
- Step 3: Sum of both numbers — 24 + 22 = 46

A DEA number is valid IF the last digit in the sum of the numbers matches the last digit of the DEA number. Therefore, the DEA number above is valid

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True or False:

Dr. Jones writes a prescription for alprazolam. His DEA number is **JJ7980456**. The pharmacist should accept and dispense the prescription, as the DEA number is valid.

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True or False:

Dr. Jones writes a prescription for alprazolam. His DEA number is **JJ7980456**. The pharmacist should accept and dispense the prescription, as the DEA number is valid.

FALSE

Step 1: Add numbers 1, 3 and 5	7 + 8 + 4 = 19
Step 2: Add numbers 2, 4 and 6, then multiply by 2	(9 + 0 + 5) x 2 = 28
Step 3: Sum of both numbers	19 + 28 = 47

DEA number is invalid, as the last digit should be 6, not 7

This is considered a "red flag", as it is a problem that appears in many fraudulent scripts.

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Medical Use of Controlled Substances

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Medical use for controls

- **Schedule I** (C-I)
  - High potential of abuse and dependence
  - No accepted medical use in the US
  - Heroin, Dihydromorphine, Marijuana, Lysergic acid diethylamide (LSD), Peyote, Mescaline, Methaqualone
- **Schedule II** (C-II)
  - High potential of abuse and dependence
  - Accepted medical use in the US
  - Stimulants, opioids, cocaine, pentobarbital, secobarbital
- **Schedule III** (C-III)
  - Moderate potential for abuse and dependence, less than C-II
  - Anabolic steroids, ketamine, acetaminophen with codeine, butalbital, aspirin, and caffeine

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Medical use for controls

- Schedule IV (C-IV)
  - Lower potential for abuse and dependence compared to C-III
  - Benzodiazepines, stimulants (e.g. phentermine), tramadol, carisoprodol
- Schedule V (C-V)
  - Low potential for abuse and dependence
  - Pregabalin, antitussives with codeine, antidiarrheals containing opium

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Marijuana

- According to the FDA, marijuana is a C-I under controlled substances that have no medical use
- However, used in the following indications:
  - Multiple Sclerosis
  - Epilepsy
  - Glaucoma
  - Pain
  - Cancer
  - PTSD
  - Dementia
- Centers that sell/distribute medical marijuana are licensed by the FL Department of Health
- Federally, it is still restricted. Therefore, marijuana is still schedule I
- On August 29, 2023, the Department of Health and Human Services (HHS) recommended that the Drug Enforcement Administration (DEA) reschedule marijuana from Schedule I to Schedule III

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Cocaine

- Misconception between schedules, cocaine is a schedule II
- Considered a narcotic at the federal level, but medically, it is not a narcotic
- Cocaine acts as a central nervous system stimulant, creating euphoria with increased energy and motor activity and enhancing feelings of competence. It is used topically for its vasoconstrictive properties
- Indications
  - Topical local anesthetic for upper respiratory tract
  - Cocaine hydrochloride solution 4% and 10%
  - Reduce bleeding in mucous membranes
    - Mouth, throat, nasal cavities

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Gabapentin

- In 1993, the FDA approved gabapentin as a non-controlled substance, and it has remained so at the federal level
- Prescriptions for gabapentin more than doubled between 2004 and 2019 from about 18 million to about 45 million
  - In 2021, it was the 6th most frequently prescribed medication
- Gabapentin is misused for euphoric effects
  - Improved sociability, a marijuana-like 'high', relaxation, and sense of calm
  - US Centers for Disease Control and Prevention (CDC) found that between 2019 and 2020, coroners and medical examiners detected gabapentin in 5687 of the 58,362 (~10%) overdose deaths in 23 states
  - Officials ruled that gabapentin was a cause of death in almost 3000 of these cases

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Gabapentin

- States have petitioned to the FDA and DEA for schedule change. The FDA has assigned a docket number for the petition (FDA-2022-P-0149). However, there have not been any changes for this change as of yet
- As of September 2022, gabapentin was classified as a controlled substance in the a few states due to overdose related death. These states include:
  - Alabama
  - Kentucky
  - Michigan
  - North Dakota
  - Tennessee
  - Virginia
  - West Virginia

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Tramadol

- Mechanism of action: Inhibits serotonin and norepinephrine reuptake. Also, a weak mu-opioid receptor agonist
- Tramadol was approved as a non-controlled analgesic in 1995. However, DEA announced a change in classification to schedule IV on August 18, 2014, due to reports of drug abuse, misuse and criminal diversion
- It is still thought to be safer than other opioids, with lower risk of addiction
  - This is false, tramadol is still a narcotic!
  - Must use lowest dose for shortest duration

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Carisoprodol

- Skeletal muscle relaxer that is abused give the barbiturate-like properties at the γ-aminobutyric acid type A (GABA-A) receptor, leading to central nervous system depression and reinforcing effects
- Carisoprodol has a relatively short half-life, tolerance and dependence potential
  - Soma was classified as a controlled substance in several US states, and effective January 11, 2012, became a schedule IV-controlled substance at the US federal level
- Often used in combination with other substances such as codeine, alcohol, hydrocodone, and diazepam
  - Using carisoprodol and Vicodin thought to produce similar effect to those of heroin
- Given withdrawal and overdose risk, must be used with caution

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Checkpoint

Gabapentin **is** considered a schedule V controlled substance in which of the following states?

a. Arkansas
b. Florida
c. Ohio
d. Kentucky

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Checkpoint

Gabapentin **is** considered a schedule V controlled substance in which of the following states?

a. Arkansas
b. Florida
c. Ohio
d. Kentucky

Gabapentin is considered a controlled medication in Alabama, Kentucky, Michigan, North Dakota, Tennessee, Virginia and West Virginia

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QUESTIONS?

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Validating Controlled Substances

Legislation and Statutes

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Objectives

- Understand the pharmacist and pharmacy technician's responsibilities in validating controlled substances
- Understand the premise of emergency filling of controlled substances
- Review partial filling regulations of controlled substances
- Recognize appropriate methods of delivering controlled substances

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Pharmacist Responsibilities

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Pharmacist Responsibilities

- Ensuring Patient Safety
  - Controlled substances have a higher potential for abuse and addiction. Proper management ensures these medications are dispensed responsibly to minimize the risk of misuse or harm to patients

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Pharmacist Responsibilities: Misuse

Misuse

- Drug misuse is defined as the use of a substance for a purpose not consistent with legal or medical guidelines. It has a negative impact on health or functioning and may take the form of drug dependence, or be part of a wider spectrum of problematic or harmful behavior

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Pharmacist Responsibilities: Harm

Harm

- Harmful use: A pattern of psychoactive substance use that is causing damage to health. The damage may be physical (eg, hepatitis following injection of drugs) or mental (eg, depressive episodes secondary to heavy alcohol intake)
- Hazardous use: A pattern of substance use that increases the risk of harmful consequences for the user. Some would limit the consequences to physical and mental health (as in harmful use); some would also include social consequences. (In contrast to harmful use, hazardous use refers to patterns of use that are of public health significance despite the absence of any current disorder in the individual user.)

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Pharmacist Responsibilities

- Legal and Regulatory Compliance
  - Adherence to federal and state regulations regarding controlled substances is essential to avoid legal repercussions for pharmacists and healthcare institutions. Failure to comply can lead to severe penalties, including fines or license revocation

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Pharmacist Responsibilities: Fines

§775.083

- A person who has been convicted of a noncriminal violation may be sentenced to pay a fine. Fines for designated crimes and for noncriminal violations shall not exceed:
  - $15,000, when the conviction is of a life felony
  - $10,000, when the conviction is of a felony of the first or second degree
  - $5,000, when the conviction is of a felony of the third degree

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Pharmacist Responsibilities: Fines

§775.083

- $1,000, when the conviction is of a misdemeanor of the first degree
- $500, when the conviction is of a misdemeanor of the second degree or a noncriminal violation
- Any higher amount equal to double the pecuniary gain derived from the offense by the offender or double the pecuniary loss suffered by the victim
- Any higher amount specifically authorized by statute

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Pharmacist Responsibilities

- Preservation of Public Health
  - Effective management of controlled substances contributes to public health by preventing their illicit distribution and misuse. It helps in controlling the opioid crisis and other substance abuse issues prevalent in society
- Dispensing Responsibility
  - Pharmacists are entrusted with the ethical responsibility of ensuring these potent medications are dispensed and managed properly. This responsibility extends to safeguarding the community and patients from potential harm

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Ryan Haight Act

- In 2001, 18-year-old Ryan Haight consulted a physician through tele-health and was prescribed Vicodin, which he received in the mail. He tragically overdosed on the medication
- Investigators found that Ryan was purchasing medications online and had no patient relationship with this provider. His parents filed a lawsuit against the doctor and Main Street Pharmacy in Oklahoma

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Ryan Haight Act

Ryan Haight Online Pharmacy Consumer Protection Act of 2008

- The Act requires any practitioner issuing a prescription for a controlled substance to conduct an in-person medical evaluation prior to prescribing controlled substances and may prescribe via telemedicine thereafter
- The Act also describes special circumstances such as "covering practitioners" - "a practitioner who conducts a medical evaluation [by telemedicine] at the request of a practitioner who … has conducted at least 1 in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine within the previous 24 months"

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Ryan Haight Act

Current Status

- On October 6, 2023, DEA and HHS announced the second temporary extension of flexibilities around telemedicine prescribing of controlled substances from the COVID-19 public health emergency (PHE)
- The emergency flexibilities will be extended in full until **December 31, 2024**. These flexibilities include:
  - Patients can be prescribed schedules II-V controlled substances without a prior in-person examination as clinically appropriate and within normal scope of practice
  - DEA registration in one state allows prescription of controlled substances in any state

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Pharmacist Responsibilities

- Prevention of Drug Diversion
  - Controlled substances (CS) are frequently targeted for diversion, leading to their illegal distribution. By implementing strict management practices, pharmacists can play a crucial role in preventing diversion and safeguarding these medications

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Pharmacist Responsibilities: Diversion

- CS diversion in health systems is common and can be harmful for patients, diverters, and the organization
- Diversion is rarely discussed despite healthcare workers having rates of misuse and abuse similar to the general population
- CS diversion prevention program must be established with multiple factors in mind:
  - Support systems for the work force
  - Methods to monitor diversion prevention effectiveness
  - Patient safety considerations

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Pharmacist Responsibilities: Diversion

Procurement and Storage
- Purchase order and packing slip removed from records
- Unauthorized individual orders CS on stolen DEA 222 form
- Product container is compromised

Prescribing
- Prescription pads are diverted and forged to obtain CS
- Prescriber self-prescribes CS
- Verbal orders for CS created, but not verified by the prescriber
- Written prescriptions altered by patients

Preparation and Dispensing
- CS are replaced by product of similar appearance when prepackaging
- Removing volume from pre-mixed solutions
- Multi-dose vial overfill is diverted
- Prepared syringe contents replaced with saline solution

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Pharmacist Responsibilities: Diversion

Administration
- CS are withdrawn from an ADC on discharged or referred patient
- Medication is documented as given but not administered to patient
- Waste is not adequately witnessed and subsequently diverted
- Substitute drug is removed and administered while CS are diverted

Waste, Removal, and Destruction
- CS waste is removed from unsecure waste container
- CS waste in syringe is replaced with saline
- Expired CS are diverted from holding area

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Pharmacist Responsibilities: Diversion

Recommendations for preventing diversion

- Security measures (e.g. cameras)
- Badge reader/biometric access for Schedule 2 medications
- Auditing systems for inventory adjustments of CS
- Routine reports to identify discrepancies
- Chain of custody properly documented at every step

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Pharmacist Responsibilities: Diversion

Recommendations for preventing diversion

- Security measures (e.g. cameras)
- Badge reader/biometric access for Schedule 2 medications
- **Auditing systems for inventory adjustments of CS**
- **Routine reports to identify discrepancies**
- Chain of custody properly documented at every step

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Pharmacist Responsibilities: Diversion

Diversion risk point	Key process indicators
Procurement and inventory	Random inventory audits (to ensure the perpetual inventory count is correct) Inventory adjustment reasons and user Destocks Inventory statistics (amount dispensed, top movers, top issued medications, etc) Missing medication alerts
Preparation and dispensing	Overrides Quantity purchased vs. dispensed Discrepancies/time (day, month, etc) Discrepancy resolution by user Types of medications with top discrepancies Will-call audits (community-based prescriptions) Destock transactions Dispenses "off the clock" Dispensing consistent with pain scales Destock and null transactions Suspicious order monitoring Post-case reconciling Time between event and detection Time between event and resolution Dispenses post discharge or transfer from unit Temporary patient additions

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Pharmacist Responsibilities: Diversion

Prescribing	Verify active prescriber DEA license Only authorized prescribers are ordering CS (audit) Review and trend CS verbal orders that have not been cosigned Prescribing patterns trends compared to peers Suspicious order monitoring
Administration	Overrides User unlinked orders in relation to overrides Cancelation patterns/null transactions Returns Sole user (dispense, waste, return or issue) Out of area/unit dispensing/global list transactions Anesthesia post case reconciliation Anomalous user activity checks Gaps in documentation Delays in administration Delays in documentation Verbal read back or no cosign by location
Waste and removal	Waste patterns Waste witness patterns Time to document waste Delayed waste documentation from time of administration High waste products High waste procedures Full waste transactions

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Pharmacist Responsibilities: Diversion

Overall process integrity	Post-case reconciliation Tracer audits (from the last biennial to a random day) Control substance safety reporting Submission information for DEA 106 reports State control substance filings Outstanding discrepancies Time to resolve discrepancies DEA/significant loss reports Expired CS trends

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Pharmacist Responsibilities

- Documentation and Accountability
  - Proper management involves meticulous documentation of controlled substance transactions. Accurate records and accountability in dispensing ensure transparency and traceability of these medications throughout their lifecycle

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Pharmacist Responsibilities

- Patient-Centric Care
  - Effective management practices not only comply with regulations but also prioritize patient care. It ensures patients with legitimate needs have access to these medications while maintaining safety and compliance
- Professional Development and Trust
  - Pharmacists who excel in controlled substance management demonstrate a commitment to professional development, fostering trust among patients, healthcare providers, and regulatory bodies

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Pharmacy Technician Responsibilities

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Pharmacy Technician Responsibilities

- Documentation Review
  - Ensure all required documentation for controlled substances is complete and accurate, including verifying patient information, prescription details, and physician information
- Inventory Management
  - Participate in inventory control to prevent drug diversion, ensuring that quantities of controlled substances align with records and any discrepancies are reported promptly

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Pharmacy Technician Responsibilities

- Compliance Verification
  - Assist the pharmacist in complying with state and federal laws regarding controlled substances, including ensuring prescriptions meet legal requirements and monitoring refill restrictions
- Prescription Verification
  - Cross-check prescriptions for accuracy, verifying that the prescriber's information is valid and ensuring that the medication aligns with the prescription's details

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Pharmacy Technician Responsibilities

- Report and Record Keeping
  - Assist in maintaining accurate records and documentation as mandated by regulations, reporting any unusual patterns or concerns to supervisory personnel

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Responsibilities Summary

- Ultimately, pharmacy technicians assist pharmacists in all aspects of controlled substance management, ensuring compliance with regulations, maintaining proper documentation, and contributing to safe and responsible dispensing practices

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Emergency Filling

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Emergency Filling: Schedule II

- In the case of an emergency, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner, provided that:
  - The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the **emergency** period
  - Dispensing beyond the **emergency** period must be pursuant to a paper or electronic prescription signed by the prescribing individual practitioner

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Emergency Filling: Schedule II

- The pharmacist must promptly document the prescription in writing,
  - Including all necessary information
  - Except for the signature of the prescribing practitioner
- If the prescribing individual practitioner is not known to the pharmacist,
  - They must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner
  - May include a callback to the prescribing individual practitioner using his phone number as listed in the telephone directory and/or other good faith efforts to insure his identity

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Emergency Filling: Schedule II

- Within 7 days after authorizing an **emergency** oral prescription,
  - The prescribing individual practitioner shall cause a written prescription for the **emergency** quantity prescribed to be delivered to the dispensing pharmacist
  - In addition to conforming to the requirements of § 1306.05, the prescription shall have written on its face "Authorization for **Emergency** Dispensing," and the date of the oral order

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Emergency Filling: Schedule II

§ 1306.05 (a): Manner of issuance of prescriptions

- All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner

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Emergency Filling: Schedule II

The paper prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the 7-day period. Upon receipt, the dispensing pharmacist must attach this paper prescription to the oral **emergency** prescription that had earlier been reduced to writing

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Emergency Filling: Schedule II

Electronic Prescriptions

- The pharmacist must annotate the record of the electronic prescription with the original authorization and date of the oral order
- The pharmacist must notify the nearest office of the Administration if the prescribing individual practitioner fails to deliver a written prescription to them

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Emergency Filling: Florida Law

- Chapter 893 of the Florida Statutes—known as the **Florida Comprehensive Drug Abuse Prevention and Control Act**
- In Florida, possession of a controlled substance is a felony unless a doctor prescribed the medication to the person in possession
- Many charges for possession of a controlled substance involve prescription medications that are commonly abused, such as diazepam, alprazolam, oxycodone, and hydrocodone-acetaminophen

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Emergency Filling: Florida Law

Schedule II

- Chapter 893, § 893.04
  - Notwithstanding subsection (1), a pharmacist may dispense a one-time emergency refill of up to a 72-hour supply of the prescribed medication for any medicinal drug **other than a medicinal drug listed in Schedule II**, in compliance with s. 465.0275

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Emergency Filling: Florida Law

Schedule III-V

- In the event a pharmacist receives a request for a prescription refill and the pharmacist is unable to readily obtain refill authorization from the prescriber, the pharmacist may dispense:
  - A one-time emergency refill of up to a 72-hour supply of the prescribed medication

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Emergency Filling: Florida Law

Schedule III-V

- If the Governor issues an emergency order or proclamation of a state of emergency, the pharmacist may dispense up to a 30-day supply in the areas or counties affected by the order or proclamation, provided that:
  - The prescription is not for a medicinal drug listed in Schedule II appearing in chapter 893
  - The medication is essential to the maintenance of life or to the continuation of therapy in a chronic condition

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Emergency Filling: Chapter 893

SCHEDULE II.—A substance in Schedule II has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States, and abuse of the substance may lead to severe psychological or physical dependence

84

Emergency Filling: Chapter 893

The following substances are controlled in Schedule II:

- Opium and any salt, compound, derivative, or preparation of opium, except nalmefene or isoquinoline alkaloids of opium, including, but not limited to the following:
  - Raw opium
  - Opium extracts
  - Opium fluid extracts
  - Powdered opium
  - Granulated opium
  - Tincture of opium
  - Codeine
  - Dihydroetorphine
  - Ethylmorphine
  - Etorphine hydrochloride
  - Hydrocodone and hydrocodone combination products
  - Hydromorphone
  - Levo-alphacetylmethadol (LAAM)
  - Metopon (methyldihydromorphinone)
  - Morphine
  - Oripavine
  - Oxycodone
  - Oxymorphone
  - Thebaine

85

Emergency Filling: Chapter 893

The following substances are controlled in Schedule II:

- Any salt, compound, derivative, or preparation of a substance which is chemically equivalent to or identical with any of the substances previously referred, except that these substances shall not include the isoquinoline alkaloids of opium.
- Any part of the plant of the species Papaver somniferum, L.
- Cocaine or ecgonine, including any of their stereoisomers, and any salt, compound, derivative, or preparation of cocaine or ecgonine.

86

Emergency Filling: Chapter 893

Unless specifically excepted or unless listed in another schedule, any of the following substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation.

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Emergency Filling: Chapter 893

- Alfentanil
- Alphaprodine
- Anileridine
- Bezitramide
- Bulk propoxyphene
- Carfentanil
- Dihydrocodeine
- Diphenoxylate
- Fentanyl
- Isomethadone
- Levomethorphan
- Levorphanol
- Metazocine
- Methadone
- Methadone-Intermediate,4-cyano-2-dimethylamino-4,4-diphenylbutane
- Moramide-Intermediate,2-methyl-3-morpholoino-1,1-diphenylpropane-carboxylic acid
- Nabilone
- Pethidine (meperidine)
- Pethidine-Intermediate-A,4-cyano-1-methyl-4-phenylpiperidine
- Pethidine-Intermediate-B,ethyl-4-phenylpiperidine-4-carboxylate
- Pethidine-Intermediate-C,1-ethyl-4-phenylpiperidine-4-carboxylic acid
- Phenazocine
- Phencyclidine
- 1-Phenylcyclohexylamine
- Piminodine
- 1-Piperidinocyclohexanecarbonitrile
- Racemethorphan
- Racemorphan
- Remifentanil
- Sufentanil
- Tapentadol
- Thiafentanil

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Emergency Filling: Chapter 893

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- Thiafentanil

94

Emergency Filling: Schedule III-V

- The interruption of therapy might reasonably produce undesirable health consequences or may cause physical or mental discomfort
- The dispensing pharmacist creates a written order containing all of the prescription information required by this chapter and chapters 499 and 893 and signs that order
- The dispensing pharmacist notifies the prescriber of the emergency dispensing within a reasonable time after such dispensing

95

Emergency Filling

Pharmacist's Role and Responsibilities

Use professional judgment in assessing and responding to emergencies

- Assess the legitimacy and urgency of the emergency
- Verify patient need, identity, and prescription history if available
- Dispense an appropriate quantity to address the immediate need

96

Partial Filling

97

Partial Filling Regulations

- Definition: Dispensing less than the total quantity of a prescribed controlled substance.

98

Partial Filling

- Pharmacists can partially fill Schedule II controlled substance prescriptions if unable to supply the full quantity
- Supplied quantity must be noted on the prescription or in the electronic record
- The remaining portion must be filled within 72 hours
  - If not filled within this timeframe, the pharmacist must inform the prescribing practitioner
  - No additional quantity can be provided after 72 hours without a new prescription

99

Self Assessment Question

True or False: In regard to the general public, partial filling of controlled substances is not allowed

100

Self Assessment Question

False: In regard to the general public, partial filling of controlled substances **IS** allowed

101

Partial Filling: Schedule II

- Partial filling of a prescription for a schedule II controlled substance at the request of the prescribing practitioner or patient criteria:
  - General requirements
  - Time limitations
  - Practitioner request
  - Per patient/proxy request
  - Pharmacy documentation

102

Partial Filling: Schedule II

A prescription for a schedule II controlled substance may be partially filled if **ALL** the following conditions are satisfied

- It is not prohibited by State law
- The prescription is written and filled in accordance with chapter 2 and State law
- Requested by the patient, by one acting on behalf of the patient
  - Parent or legal guardian of a minor patient
  - Caregiver of an adult patient named in a medical power of attorney
  - Practitioner who wrote the prescription
- Total quantity dispensed in all partial fillings ≤ total quantity prescribed

103

Partial Filling: Schedule II

Time limitations on filling the remaining portions of a partially filled prescription for a schedule II controlled substance

- If all the conditions of the previous slide are met, and the prescription is partially filled
- Remaining portions, if filled, must be filled not later than 30 days after the date on which the prescription is written

104

Partial Filling: Schedule II

A practitioner may request partially filled prescriptions

- Practitioners prescribing schedule II controlled substances for partial filling must clearly specify the quantity for each partial fill
- This requirement applies to written, emergency oral, or electronic prescriptions

105

Partial Filling: Schedule II

A patient or one acting on a patient's behalf may request that a prescription for a schedule II controlled substance be partially filled

- A patient may request that his/her prescription be partially filled
- A caregiver named in an adult patient's medical power of attorney may request the adult patient's prescription be partially filled
- When a patient is a minor (under age 18), a parent or legal guardian of the minor may request the prescription be partially filled

106

Partial Filling: Schedule II

A pharmacy must record the partial filling of a prescription for a schedule II controlled substance

- Upon partially filling a prescription at the request of the prescribing practitioner, as requested when the prescriber issued the prescription, the pharmacist must make a notation of the quantity dispensed on the face of the written prescription or in the pharmacy's electronic records

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Partial Filling: Schedule II

Long term care facilities

- Prescriptions for Schedule II controlled substances in LTCFs or for terminally ill patients can be partially filled in individual doses
- If there is a question regarding the patient's terminal illness status, the pharmacist contacts the practitioner before partial filling
- Both the pharmacist and the prescriber ensure the controlled substance is for a terminally ill patient
- The pharmacist notes "terminally ill" or "LTCF patient" on the prescription

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Partial Filling: Florida Law

Schedule II

- Chapter 893, § 893.04
  - Notwithstanding subsection (1), a pharmacist may dispense a one-time emergency refill of up to a 72-hour supply of the prescribed medication for any medicinal drug other than a medicinal drug listed in Schedule II, in compliance with s. 465.0275

109

Self Assessment Question

True or False: In the case of a requested partial fill for a prescription, individuals such as the patient, parent or legal guardian (for a minor), or the caregiver named in a medical power of attorney are allowed to request a partial filling in an amount greater than specified by the practitioner

110

Self Assessment Question

False: In the case of a requested partial fill for a prescription, individuals such as the patient, parent or legal guardian (for a minor), or the caregiver named in a medical power of attorney are **NOT** allowed to request a partial filling in an amount **greater** than specified by the practitioner

111

Partial Filling: Schedule III-V

The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible, provided that:

- Each partial filling is recorded in the same manner as a refilling
- The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed
- No dispensing occurs after 6 months after the date on which the prescription was issued

112

Delivery

113

Delivery

- Central fill pharmacies are mandated to adhere to § 1301.74(e) guidelines when opting for private, common, or contract carriers for transporting filled prescriptions to a retail pharmacy, ensuring compliance with regulations
- In the event of in-transit losses, if a central fill pharmacy discovers such a loss, it becomes their responsibility to report it using a DEA Form 106

114

Delivery

§1301.74e

- When shipping controlled substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses
- When storing controlled substances in a public warehouse, a registrant is responsible for selecting a warehouseman which will provide adequate security to guard against storage losses; wherever possible, the registrant shall store controlled substances in a public warehouse which complies with the requirements set forth in § 1301.72
- In addition, the registrant shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or in-transit losses

115

Delivery: Schedules I and II

§1301.72

- Raw material, bulk materials awaiting further processing, finished products which are controlled substances listed in Schedule I or II and sealed mail-back packages, shall be stored in one of the following secured areas:
  - Where small quantities permit, a safe or steel cabinet
  - A vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system
  - A vault constructed after September 1, 1971

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Delivery: Schedules III-V

§1301.72

- Raw material, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedules III, IV, and V, and GHB when it is manufactured or distributed in accordance with an exemption under section 505(i) of the FFDCA, shall be stored in the following secure storage areas:

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Delivery: Schedules III-V

§1301.72

- A safe or steel cabinet as described in paragraph (a)(1) of this section
- A vault as described previously, equipped with an alarm system
- A building used for storage of Schedules III through V controlled substances with perimeter security which limits access during working hours and provides security after working hours
- A cage, located within a building on the premises

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Delivery: Schedules III-V

§1301.72

- A building or enclosure within a building which has been inspected and approved by DEA or its predecessor agency, BND, and continues to provide adequate security against the diversion of Schedule III through V controlled substances, of which fact written acknowledgment has been made by the Special Agent in Charge of DEA for the area in which such building or enclosure is situated

119

Self Assessment Question

True or False: Central fill pharmacies are not responsible for reporting in-transit losses when filled prescriptions are transported to a retail pharmacy by private, common, or contract carriers

120

Self Assessment Question

False: Central fill pharmacies **ARE** responsible for reporting in-transit losses when filled prescriptions are transported to a retail pharmacy by private, common, or contract carriers

121

Delivery to an Administering Practitioner

§ 829a. Delivery of a controlled substance by a pharmacy to an administering practitioner

A pharmacy may deliver a controlled substance to a practitioner in accordance with a prescription that meets the requirements of this subchapter and the regulations issued by the Attorney General under this subchapter, for the purpose of administering the controlled substance by the practitioner if:

(1) The controlled substance is delivered by the pharmacy to the prescribing practitioner or the practitioner administering the controlled substance, as applicable, at the location listed on the practitioner's certificate of registration

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Delivery to an Administering Practitioner

(2) The controlled substance is a narcotic drug in schedule III, IV, or V to be administered for the purpose of maintenance or detoxification treatment and is to be administered by injection or implantation

(3) The pharmacy and the practitioner are authorized to conduct the activities specified in this section under the law of the State in which such activities take place

(4) The prescription is not issued to supply any practitioner with a stock of controlled substances for the purpose of general dispensing to patients

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Delivery to an Administering Practitioner

(5) The controlled substance is to be administered only to the patient named on the prescription not later than 45 days after the date of receipt of the controlled substance by the practitioner

(6) The prescribing practitioner, and the practitioner administering the controlled substance, as applicable, maintain complete and accurate records of all controlled substances delivered, received, administered, or otherwise disposed of under this section, including the persons to whom controlled substances were delivered and such other information as may be required by regulations

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Thank You

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DADE COUNTY PHARMACY ASSOCIATION
28 Years Featuring
South Florida Pharmacy Residents

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Contraception: Which is the Best Option?

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January 20, 2024

1

Objectives

- Discuss the different contraceptive methods and their advantages and disadvantages
- Recommend contraceptive products based on individual characteristics
- Formulate proper patient education for hormonal contraceptive products

2

Introduction

- In 2019, estimated 5.5 million pregnancies in the US
- 35.7% of those pregnancies were unintended
  - Teens aged 15-19 years old
  - Hispanic and African-American/Black women
- Unintended pregnancy
  - Unwanted, unplanned or mistimed at the time of conception
  - Most common cause is not using a contraceptive, not using it consistently or correctly

3

Contraception

- Contraception is using a method or device to prevent pregnancy
  - Inhibiting the sperm from coming in contact with a mature ovum (egg)
  - Preventing implantation of the fertilized egg

4

Pharmacist's Role

- The goal for conception is for pregnancies to be planned and wanted
- Can be achieved through education and counseling
- Educate on the use and effectiveness of contraceptive methods
- Some states have passed laws allowing pharmacist to initiate contraceptive therapy
  - This is not allowed in Florida

5

Considerations When Choosing a Contraceptive

- Patient's lifestyle
  - Cost
  - Ease of use
  - Reversibility
- Adverse effects
- Adherence
- Contraindication

6

Contraceptive Methods

- Nonpharmacological
  - Spermicides
  - Barriers
- Hormonal
  - Combined hormonal
  - Progestin
- Non-hormonal
  - Intrauterine device

7

Non-Pharmacologic Therapy

- Condoms (Female or Male)
  - Advantages:
    - Inexpensive
    - STI/STD protection
  - Disadvantages:
    - High user failure rate
    - Breakage issues
    - Allergic reaction to latex

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Non-Pharmacologic Therapy

- Diaphragm with spermicide
  - Advantages:
    - Inexpensive
  - Disadvantages:
    - High user failure rate
    - Increase risk of UTI and yeast infection
    - Efficacy decreases as usage increases

9

Non-Pharmacologic Therapy

- Spermicide
  - Advantage:
    - Inexpensive
  - Disadvantage:
    - High user fail rate
    - No STD/STI or HIV protection
    - Must be used right before intercourse

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Non-Pharmacologic Therapy

- Sponge
  - Advantage:
    - Inexpensive
  - Disadvantage:
    - High user fail rate
    - No STD/STI or HIV protection
    - Can not be used during menses

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Combined Hormonal Contraceptive (CHC)

- CHC contains estrogen and progestin
  - Estrogen: stabilizes endometrial lining to control bleeding and provide cycle control
  - Progestin: inhibits ovulation by blocking luteinizing hormone (LH) surge
- Formulations
  - Patch (transdermal)
  - Ring (intra-vaginal)
  - Pills (oral)

12

Combined Oral Contraceptive (COC)

- Regimen
  - Traditional: 28-day regimen; 21 days active and 7 days placebo
  - Extended cycle: 91-day regimen; 84 days active and 7 days placebo
  - Continuous: 365 days active

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Combined Oral Contraceptive (COC)

	Regimen	Estrogen	Progestin	Common Brand Names
Monophasic	Fixed dose of Estrogen and Progestin for 21 days	Ethinyl Estradiol	• Norethindrone • Drospirenone	• Lo Loestrin 24 Fe • Microgestin Fe • Sprintec • Yaz
Biphasic	• Estrogen fixed dose for 21 days • Progestin at low dose for 10 days and increase dose for 11 days	Ethinyl Estradiol	Norethindrone	Necon
Triphasic	Increasing amount of Estrogen and Progestin	Ethinyl Estradiol	Norethindrone	Ortho Tri-Cyclen
Quadriphasic	Changing amount of estrogen and progestin	Ethinyl Valerate	Dienogest	Natazia

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Combined Oral Contraceptive (COC)

	Regimen	Estrogen	Progestin	Common Brand Names
Extended Cycle	Fixed dose of Estrogen and Progestin for 84 days	Ethinyl Estradiol	Levonorgestrel	• Jolessa • Seasonique
Continuous Cycle	Fixed dose of Estrogen and Progestin for 365 days	Ethinyl Estradiol	Levonorgestrel	Amethyst

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Combined Oral Contraceptive (COC)

When to Start

- First Day
  - Start within 5 days of menstrual cycle
    - Back-up method not needed
- Sunday Start
  - Start on the Sunday after menstrual cycle
    - Back-up method needed
- Quick Start
  - Start when prescription given
    - Back-up method needed

Missed Dose

- One Dose
  - Take missed dose as soon as possible and take next pill at regular scheduled time
    - Back-up method not needed
- Two or more doses
  - Take recent missed pill as soon as possible
    - Discard any other missed pill
  - Continue pills at regular scheduled time
    - Back-up method needed until active pill has been taken consecutively for 7 days

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Combined Oral Contraceptive (COC)

Advantages

- Efficacy rate 99%
- Improves menstrual symptoms
- Decreases risk of
  - Endometrial and ovarian cancer
  - Ovarian cysts

Disadvantages

- Increases risk
  - Thromboembolism
  - Stroke
  - MI
- Drug interactions
  - Anticonvulsants
  - Antibiotics
  - Natural products
  - Protease inhibitors
- Breakthrough bleeding

17

Question

A patient with an untreated active DVT may be started on a combined oral contraceptive?

a. True

b. False

18

Answer

False

It is contraindicated to be on combine hormonal contraceptive (estrogen and progestin containing products) with any active DVT unless being treated with anticoagulation

19

Combined Transdermal Contraceptive

- Medication:
  - Xulane® Patch (35mcg of ethinyl estradiol and 150mcg norelgestromin)
- Recommended for patients < 90 kg (200 lbs.)
  - Over 90 kg or a BMI over 30 kg/m^2 has decreased efficacy
- Side effects
  - Increased risk of thromboembolism
  - Application site reactions
  - Breast discomfort, headaches, nausea

20

Combined Transdermal Contraceptive

When to Start

- Once weekly patch for 3 weeks of active followed by 1 week patch free
  - Applied on abdomen, buttocks, upper torso, or upper arm
- Apply on the 1st day of menstrual cycle and changed weekly on the same day

Missed Dose

- Detached for less than 24 hours
  - Detached patch or missed patch can be reapplied
    - Back-up method not needed
- Detached for more than 24 hours or forget to change patch on time
  - Start a new patch and that will be the new patch day
    - Back-up method needed until patch worn consecutively for 7 days

21

Combined Vaginal Ring Contraceptive

- Medication:
  - NuvaRing® (15 mcg of ethinyl estradiol and 120 mcg etonogestrol)
  - Annovera® (13 mcg of ethinyl estradiol and 150 mcg segesterone)
    - One-year reusable ring
- Inserted vaginally for 21 day, and removed for 7 days
  - Discard ring after the 21 days (NuvaRing®)
  - Store ring after the 21 days (Annovera®)
- Side effects
  - Breast discomfort, headaches, and nausea
  - Vaginal symptoms
  - Device expulsion
  - Discomfort

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Combined Vaginal Ring Contraceptive

NuvaRing®

- Apply on the 1st day or before 5th day of menstrual cycle
- Missed doses
  - If displaced less than 3 hours
    - Reinsert vaginal ring
    - No back-up method needed
  - If displaced more than 3 hours
    - Reinsert vaginal ring
    - Back-up method needed for 7 days

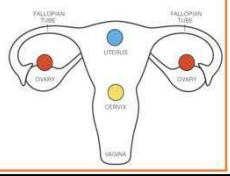
Annovera®

- Apply on the 2nd day or 5th day of menstrual cycle
- Missed doses
  - If displaced less than 2 hours
    - Reinsert vaginal ring
    - No back-up method needed
  - If displaced more than 2 hours
    - Reinsert vaginal ring
    - Back-up method needed for 7 days

23

Progestin-Only Contraceptive

- Progestin
  - Inhibits ovulation by blocking luteinizing hormone surge
  - Thins the endometrium reducing chances of implantation
  - Thickens cervical mucous creating a barrier for sperm penetration
- Formulations
  - Pills (oral)
  - Long- acting injection (intramuscular)
  - Long-acting reversible implant (subdermal)



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Progestin-Only Oral Contraceptive

- Medication
  - Camila®, Errin® (35mg of norethindrone)
    - 28 days of active pill and no placebo
  - Slynd® (4 mg of drospirenone)
    - 24 days of active pill and 4 days of placebo
- Side effects
  - Irregular menstrual cycle
  - Acne
  - Headache, nausea, and libido change
  - Hyperkalemia and bone loss (drospirenone)

25

Progestin-Only Oral Contraceptive

When to Start

- Start 1st day of menstrual cycle
  - Back-up method not needed
- If taken later in the menstrual cycle
  - Back-up method needed for 48 hours
- Take at the same time every day
  - Less strict timing with drospirenone

Missed Dose

- One dose or less than 3 hours late
  - Take missed dose as soon as possible and take next pill at regular scheduled time
    - Back-up method needed for 48 hours
- Two or more doses
  - Take recent missed pill as soon as possible
    - Discard another missed pill
  - Continue pills as regular scheduled time
    - Back-up method needed

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Progestin-Only Contraceptive

Advantages

- No estrogen
  - No estrogen side effects
- Used in
  - Lactating women
  - Cardiovascular diseases
    - HTN
    - Current DVT
    - CVA
  - Smokers

Disadvantages

- Less effective than COC
- Adherence issues
  - Must be taken every day at the same time
- Menstrual irregularities

27

Question

With progestin-only contraceptives, you can take it whenever you want as long as it is taken daily?

a. True

b. False

28

Answer

False

The progestin-only contraceptives should be taken at this same time every day and if taken 3 hours outside usual schedule dose time it is considered a missed dose

29

Progestin-Only Injection Contraceptive

- Medication
  - Depo-Provera® (150mg of medroxyprogesterone)
    - Given intramuscularly
  - Depo-SubQ Provera 104® (104mg of medroxyprogesterone)
    - Given subcutaneously
- Administered every 3 months between day 1-7 of cycle
  - If administered after 7th day of cycle, back- up method needed for 3 weeks
- Side effects
  - Irregular menstrual cycle
  - Weight gain
  - Breast tenderness
  - Depression

30

Progestin-Only Injection Contraceptive

- Contraindications
  - Active breast cancer
- Precaution
  - Past medical history
    - Lupus
    - Cardiovascular disease
    - Breast cancer

31

Progestin-Only Injection Contraceptive

Advantage	Disadvantage

• Adherence
  • Given every 3 months
• No increased risk of thromboembolism
• Low failure rate
• Decreased menstrual cramping or no menstrual flow
	• Weight gain
	• Requires medical office visit
	• Decreased
	  • Bone density
	  • HDL
	• Breakthrough bleeding
	• Fertility may be delayed

32

Question

The Depo-Provera shot is administered every month?

a. True
b. False

33

Answer

False

The Depo-Provera shot is given every three months for the prevention of pregnancy

34

Progestin-Only Implant Contraceptive

- Medication
  - Nexplanon® (68 mg of etonogestrol)
    - Releases 60-75 mcg daily for 5-6 weeks then, 30 mcg for 3 years
- Subdermal implant under the skin of the upper arm
  - Administered anytime
  - Preferably between day 1 and 5 of menstrual cycle
  - Back-up method for 7 days
- Side effects
  - Infrequent bleeding
- Contraindication
  - Active breast cancer

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Progestin-Only Implant Contraceptive

Advantage

- Adherence
  - Implanted every 3 years
- No increased risk of thromboembolism
- Low failure rate
- Decreased menstrual cramping or no menstrual flow
- Used while breast-feeding
- Return to fertility in 30 days

Disadvantage

- Infrequent bleeding
- Requires medical office visit

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Intrauterine Devices

- Medication:
  - Copper
    - Paragard® used for 10 years
  - Progestin-releasing (levonorgestrol)
    - Mirena® used for 5 years
    - Skyla® used for 3 years
    - Kyleena® used for 5 years
    - Liletta® used for 3 years
- Contraindication
  - Pregnancy
  - Uterine abnormalities
  - Uterine, cervical, or endometrial cancer

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Intrauterine Devices

Advantage	Disadvantage
• No adherence issues	• Infrequent bleeding
• No increased risk of thromboembolism	• Requires medical office visit
• Low failure rate	• Pelvic infection
• Decreased menstrual cramping or no menstrual flow	• Ectopic pregnancy
• Used while breast-feeding	
• Return to fertility in 30 days	

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Emergency Contraceptives

- This decreases the risk of pregnancy after unprotected sexual intercourse has occurred
  - Unprotected sex
  - Usage failure of barrier methods
  - Incorrect usage of contraception
- Medication
  - Ulipristal acetate 30mg
    - Ella®
  - Levonorgestrel 1.5mg
    - Plan B One Step®
    - MyWay®
  - Copper IUD
    - Paragard®

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Emergency Contraceptives

- Timing of use:
  - Within 5 days
    - Ulipristal acetate, copper IUD
  - Within 3 days
    - Levonorgestrel 1.5mg
- Side effects
  - Headache
  - Nausea
  - Abdominal pain

40

Question

Emergency contraceptive pill must be taken within 24 hours of unprotected sexual intercourse

a. True
b. False

41

Answer

False

You have up to five days to take the emergency contraceptive pill but the sooner it is taken the most effective it would be

42

Review

Patient Factors	Preferred Contraception Options
Acne	COC with drospirenone (Yaz, Yasmin)
Breastfeeding	Progestin only contraceptive, copper IUD
Estrogen contraindication	Progestin only contraceptive, copper IUD
Migraine with aura or hypertension (>160/100 mmHg)	Progestin only contraceptive, copper IUD
Overweight	Avoid CHC Patch and Depo-Provera injection
Avoid monthly cycle	Extended or continuous COC
Hormone contraindication	Non-hormonal: copper IUD or non-pharmacological methods

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THANKS!

Do you have any questions?

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Postpartum Depression

A Review of Pharmacological Treatment Approaches

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PGY-1 NSU Community Pharmacy Resident
Fort Lauderdale, FL
January 20, 2024

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South Florida Pharmacy Residents

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Objectives

1. Define Postpartum Depression
2. Identify Key Signs and Symptoms
3. Review Pharmacological Treatments

2

Acronyms

PPD	Postpartum Depression	SSRI	Selective Serotonin Re-Uptake Inhibitors
DSM-5	Diagnostic and Statistical Manual of Mental Disorder, Fifth Edition	SNRI	Serotonin-Norepinephrine Re-Uptake Inhibitors
ACOG	American College of Obstetricians and Gynecologist	TCA	Tricyclic Antidepressants
CDC	Center for Disease Control and Prevention	REMS	Risk Evaluation and Mitigation Strategy
PHQ-9	Patient Health Questionnaire	CNS	Central Nervous System
EPDS	Edinburgh Postnatal Depression Scale		

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INTRODUCTION

Definition
Epidemiology
Pathophysiology
Risk Factors

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Introduction

- Childbirth is an extremely delicate time for both parent and baby
- The body goes through many **hormonal, physical, psychological and emotional changes** throughout pregnancy and postpartum
- Emotions postpartum can range from happiness to periods of sadness, which usually resolve after 2 weeks **("baby-blues")**
- Alternatively, they can be prolonged and classified as **PPD or perinatal depression**
- Treatment for PPD is patient specific and requires healthcare practitioners to identify symptoms early and treat accordingly based on severity

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Post-Partum Depression Definition

Per the DSM-5, PPD or peripartum depression is defined as a **major depressive episode starting during pregnancy or within 4 weeks of delivery**

ACOG defines PPD as **a depressive episode that occurs during pregnancy or within a year of giving birth.**

Table 1. DSM-5 Diagnostic Criteria for Major Depressive Disorder[a]

For a diagnosis of major depressive disorder, 5 or more of the following symptoms must be present nearly every day for at least a 2-week period (at least one of the symptoms is either depressed mood or anhedonia). Symptoms must impair functioning and cannot be secondary to another drug or illness.

- Depressed mood most of the time and on most days (e.g., feels sad, appears tearful)
- Anhedonia (e.g., decreased interest or pleasure in activities)
- Significant change in weight (e.g., weight loss, weight gain)
- Sleep disturbances (e.g., insomnia, hypersomnia)
- Psychomotor fluctuations (e.g., psychomotor agitation or retardation)
- Changes in energy levels (e.g., fatigue, loss of energy)
- Excessive guilt or feelings of worthlessness
- Difficulties concentrating
- Recurrent thoughts of death or suicidal thoughts (e.g., active or passive suicidal ideation with or without a plan)

Peripartum onset specifier: Onset of symptoms occurs during pregnancy or within 4 weeks after childbirth. Episodes can present with psychotic features.

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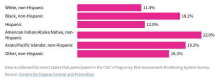
Epidemiology

Among women in the CDC survey, postpartum depression rates were highest among American Indian/Alaska Native women in 2018.

Prevalence of postpartum depression symptoms by race/ethnicity among 31 survey sites, 2018



Data is collected for select states that participated in the CDC's Pregnancy Risk Assessment Monitoring System Survey. Source: Centers for Disease Control and Prevention

According to the CDC **1 in 8 women** experience symptoms of postpartum depression

A recent CDC analysis showed that rates of depression diagnosis at delivery are increasing, **7 times higher** in 2015 compared to 2000

Up to **20% of postpartum deaths were due to suicide**

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Pathophysiology

The Pathogenesis of PPD is currently unknown, but it has been suggested that **genetics, hormones, psychological, and social life stressors** play a role in the development of PPD.

Genetics	Hormones	Psychological
A national registry study of sisters found that the relative contribution of genetic factors to postnatal depression was 40 percent	Fluctuations in estradiol, progesterone, oxytocin and prolactin following delivery	Previous history of major depressive episodes and anxiety have been shown as risk factors

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Risk Factors

Depression during pregnancy	Breastfeeding issues
History of depression	History of trauma or abuse
Stressful life events	Unintended/unwanted pregnancy
Poor social and financial support	Fear of childbirth
History of anxiety symptoms or disorders	Poor physical health during pregnancy
Young age (<25 years old)	History of premenstrual syndrome
Multiple births	Childcare stress
First time motherhood	Family history of PPD or other psychiatric disorders

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SIGNS & SYMPTOMS

Diagnosis
Severity
Timeline

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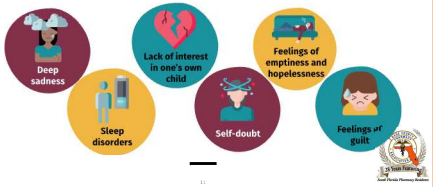
Signs and Symptoms



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Diagnosis

Table 1 DSM-5 Diagnostic Criteria for Major Depressive Disorder[a]

For a diagnosis of major depressive disorder, 5 or more of the following symptoms must be present nearly every day for at least a 2-week period (at least one of the symptoms is either depressed mood or anhedonia). Symptoms must impair functioning and cannot be secondary to another drug or illness.

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- Changes in energy levels (e.g., fatigue, loss of energy)
- Excessive guilt or feelings of worthlessness
- Difficulties concentrating
- Recurrent thoughts of death or suicidal thoughts (e.g., active or passive suicidal ideation with or without a plan)

Peripartum onset specifier: Onset of symptoms occurs during pregnancy or within 4 weeks after childbirth. Episodes can present with psychotic features.

Tools

10-item Edinburgh Postnatal Depression Scale (EPDS)
Maximum score of 30

Patient Health Questionnaire (PHQ-9)
Maximum score of 27

Hamilton Depression Rating Scale (HAM-D)
Maximum score of 52

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Severity and Timeline

Mild to Moderate	Severe
Characterized by five or six depressive symptoms • Score < 20 on PHQ-9 • Score of 11-15 on EPDS	Characterized by seven to nine depressive symptoms • Score ≥ 20 on PHQ-9 • Average score of 20 on EPDS

The duration of PPD is variable. Most cases resolve within a few months with treatment, but 24% of women diagnosed with PPD are still depressed one year after giving birth and 13% after two years. Untreated PPD is likely to recur as depressive episodes, resulting in ongoing problems for mother, child, and family.

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TREATMENT

Non-Pharmacologic
Pharmacologic
FDA Approved Agents

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Treatment Options

Non-Pharmacological
- Lifestyle modifications, Psychotherapy

Pharmacological
- Antidepressants

FDA Approved Therapy
- brexanolone, zuranonlone

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Non-Pharmacological Options

Lifestyle Modifications	Psychotherapy
Exercise Social/peer support Parenting education Couples/family therapy	Cognitive behavioral therapy Behavioral activation Interpersonal psychotherapy Nondirective counseling Psychodynamic psychotherapy

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Efficacy: Psychotherapy

- A meta-analysis of six randomized trials compared psychotherapy (either CBT or interpersonal psychotherapy) with treatment as usual in patients with perinatal depression (n >1300; primarily postpartum depression): Remission was greater in patients who received psychotherapy than patients treated as usual (relative risk 2.1, 95% CI 1.7-2.6)
- A meta-analysis of 17 trials (n >1200 postpartum patients) compared psychotherapy with control conditions (eg, usual care or waiting list): Improvement was greater with psychotherapy, and the clinical benefit was moderate to large
- A meta-analysis of six randomized trials (n = 516 primary care patients) compared psychotherapy with usual care at follow-up assessments that occurred a median of six months after study completion: Improvement was superior among patients treated with psychotherapy

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Pharmacological

Treatment approach is based on several factors:

History of Antidepressant Use	Breastfeeding Status	Treatment Timeline

Antidepressants are first-line therapy

SSRIs are the most widely studied antidepressant used for PPD

If the patient has used an antidepressant in the past with success, that agent should be selected

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SSRIs

Zoloft (sertraline)
Paxil (paroxetine)
Prozac (fluoxetine)
Luvox (fluvoxamine)
Celexa (citalopram)
Lexapro (escitalopram)

- Used as initial treatment in patients
- SSRIs have been used and more widely studied in breastfeeding patients than other antidepressant classes
- A retrospective study of women (n = 459) who were treated for postpartum depression with antidepressants found that SSRIs were used in 90 percent

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Efficacy: SSRIs

- A meta-analysis of three trials lasting six or eight weeks compared paroxetine (10 to 40 mg/day) or sertraline (50 to 200 mg/day) with placebo in 146 patients with postpartum unipolar major depression, some of whom were breastfeeding. Remission occurred in more patients who were treated with SSRIs than placebo (relative risk 1.8, 95% CI 1.1-3.0), and in each of the studies, the incidence of adverse effects was comparable for active drug and placebo.
- A four-week trial compared antidepressants (primarily SSRIs) with usual care (nondirective counseling) in 254 patients with postpartum unipolar major depression (n = 254). More than 40 percent of the patients were breastfeeding their infants. Improvement (Edinburgh Postnatal Depression Scale occurred in more patients who received antidepressants than usual care (45 versus 20 percent).
- A 16-week trial (n = 109 patients, including 29 who breastfed) compared sertraline (50 to 200 mg/day) with nortriptyline (25 to 150 mg/day) and found that improvement was comparable

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Alternative Antidepressants

SNRI	TCA	Atypical
Cymbalta (duloxetine)	Pamelor (nortriptyline)	Remeron (mirtazapine)
Effexor (venlafaxine)		Wellbutrin (bupropion)
Pristiq (desvenlafaxine)		

Patients resistant to initial treatment and show minimal response (improvement <25 percent), It is recommended to switch antidepressants rather than augmentation with a second drug

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Safety Profile: Antidepressants

Side Effects

Sexual dysfunction
Sleep disturbances
Weight changes
Anxiety
Dizziness
Xerostomia
Headache
Gastrointestinal distress
QTc Prolongation

Lactation

All psychotropic medications are transferred to breast milk in varying amounts

Infant serum concentrations appear to be lower in antidepressants with shorter half lives

- BBW: Increased risk of suicidality among pediatric and young adult (up to age 25) populations
- Antidepressant effects seen in 4-6 weeks

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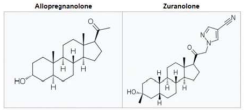
FDA Approved Agents

Zulresso (brexanolone)	Zurzuvae (zuranolone)

Neuroactive steroid $GABA_A$ receptor positive allosteric modulator
FDA approved for treatment of PPD in adults

Allopregnanolone



Zuranolone

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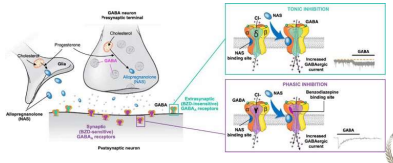
Mechanism of Action



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Zulresso (brexanolone)

- FDA approved in 2019
- 60 hr IV infusion
- Ages 15 and older
- Schedule IV
- Available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS)
- **Boxed Warning** for excessive sedation and sudden loss of consciousness
- 100 mg/20 mL (per mL): $447.00

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Zulresso (brexanolone)

Warnings	Adverse Reactions	Renal/Hepatic
• Excessive sedation and sudden loss of consciousness • Possible cause suicidal thoughts and behaviors • Concomitant use with CNS depressants and antidepressants increasing the risk of sedation	Presyncope Sedation Somnolence Vertigo Xerostomia Diarrhea Dyspepsia Hot Flashes Loss of consciousness	• Avoid use in eGFR <15ml/min due to accumulation • Extensively metabolized by non-CYP based pathways via three main routes - keto-reduction, glucuronidation, and sulfation
Animal studies have shown fetal harm in pregnancy patients, with additional data supporting there is low levels in breastmilk		

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Zulresso (brexanolone)

27

Zurzuvae (zuranolone)

- First oral capsule FDA approved for PPD (2023)
- Approved for adults
- Schedule IV
- Boxed Warning for driving impairment due CNS depressant effects
- 20 mg and 25 mg (per each): $681.43
- 30 mg (per each): $1,362.86

Administer with fat-containing food

Recommended dosage is 50 mg orally once daily in the evening for 14 days

Dosage may be reduced to 40 mg once daily if CNS depressant effects occur

Can be used alone or as an adjunct to oral antidepressant therapy

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Zurzuvae (zuranolone)

Warnings	Adverse Reactions	Renal/Hepatic
• Driving impairment due CNS depressant effects • CNS depressant effects such as somnolence and confusion. • May cause fetal harm in pregnancy, but data not available to establish risk • Possible cause suicidal thoughts and behavior	Somnolence Dizziness Fatigue Diarrhea Urinary Tract Infection Memory Impairment Abdominal Pain Tremor Myalgia	• The dosage in patients with moderate and severe renal impairment is lower • The recommended dosage in patients with severe hepatic impairment is 30 mg orally once daily in the evening for 14 days
Animal studies have shown fetal harm in pregnancy patients, with additional data supporting there is low levels in breastmilk		

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Zurzuvae (zuranolone)

Strong CYP3A4 Inhibitors	
Clinical Impact	Concomitant use with a strong CYP3A4 inhibitor increases the exposure of zuranolone
Management	Reduce zuranolone dosage when used with a strong CYP3A4 inhibitor
CYP3A4 Inducers	
Clinical Impact	Concomitant use with a CYP3A4 inducer decreases the exposure of zuranolone
Management	Avoid with concomitant use of zuranolone

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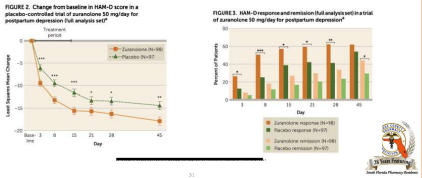
Zurzuvae (zuranolone)



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Place in Therapy

Zulresso (brexanolone)	Zurzuvae (zuranolone)
• Rapid symptom relief (60hr infusion) • High rate of remission (70%) • Efficacy established in PPD patients	• 14-day treatment with symptom relief • Oral administration • Efficacy established in PPD patients

Antidepressant treatment naïve patients may go through several agents before finding symptom relief

Pharmacogenomic testing with antidepressants may present an opportunity for streamline use of these agents

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Summary

- PPD can severely impact the mental and physical health of both parent and child
- Identifying patients' experiencing symptoms early and beginning treatment is important to preventing long term health issues
- Antidepressants have been used as the primary treatment in the past
- New FDA approved medications (brexanolone and zuranolone) can provide rapid symptom relief compared to treatment with antidepressants

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Question 1

First time motherhood is a risk factor for developing postpartum depression.

a) True
b) False

36

36

Question 1

First time motherhood is a risk factor for developing postpartum depression.

a) **True**
b) False

37

Question 2

There are two FDA approved oral treatments for postpartum depression.

a) True
b) False

38

Question 2

There are two FDA approved oral treatments for postpartum depression.

a) True
b) **False**

39

Question 3

Zuranolone is an allosteric modulator of the $GABA_a$ receptor.

a) True
b) False

40

Question 3

Zuranolone is an allosteric modulator of the $GABA_a$ receptor.

a) **True**
b) False

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Postpartum Depression

A Review of Pharmacological Treatment Approaches

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January 20, 2024

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Men's Health: A Cause for Concern

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Miami VA Healthcare System
01/20/2024

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Objectives

- Discuss common and under-represented conditions that pose a risk to men's health
- Review lifestyle adjustments, considerations, and guideline recommendations to improve men's health outcomes
- Explore resources available to support men's health

2

Disclosures

- I have no financial disclosure or conflict of interest relative to the contents of this presentation

3

Current Status of Men's Health

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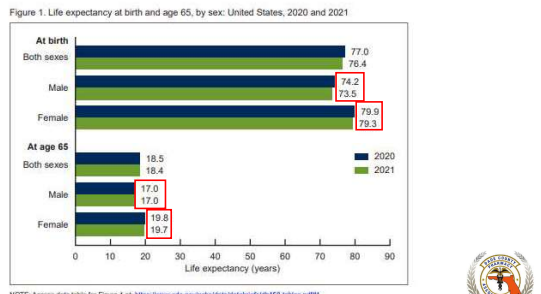

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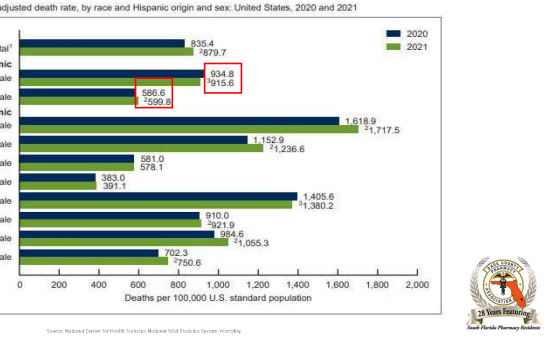

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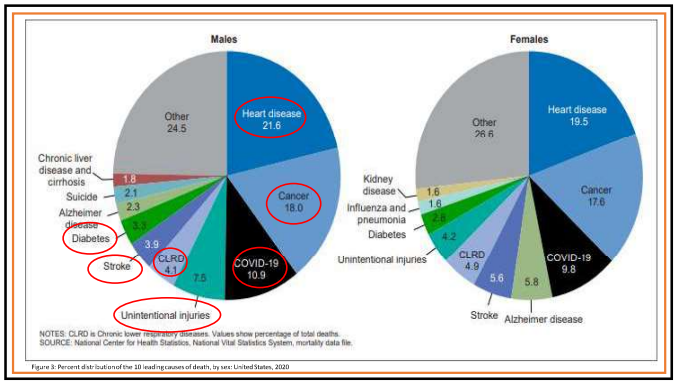

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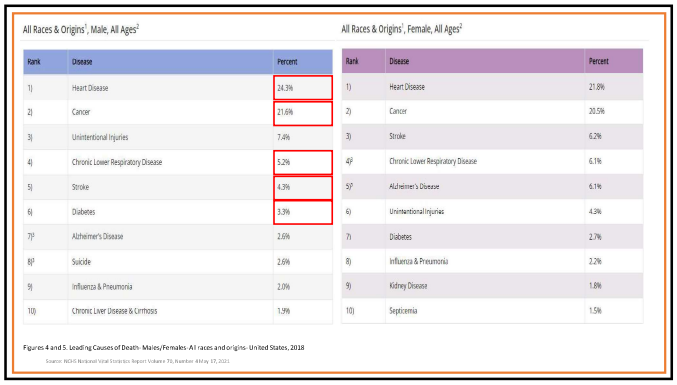


All Races & Origins[1], Male, All Ages[2]

Rank	Disease	Percent
1)	Heart Disease	24.3%
2)	Cancer	21.6%
3)	Unintentional Injuries	7.4%
4)	Chronic Lower Respiratory Disease	5.2%
5)	Stroke	4.3%
6)	Diabetes	3.3%
7)[3]	Alzheimer's Disease	2.6%
8)[3]	Suicide	2.6%
9)	Influenza & Pneumonia	2.0%
10)	Chronic Liver Disease & Cirrhosis	1.9%

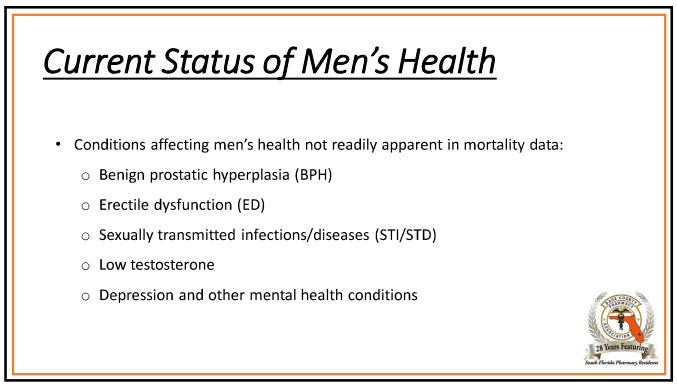
All Races & Origins[1], Female, All Ages[2]

Rank	Disease	Percent
1)	Heart Disease	21.8%
2)	Cancer	20.5%
3)	Stroke	6.2%
4)[3]	Chronic Lower Respiratory Disease	6.1%
5)[3]	Alzheimer's Disease	6.1%
6)	Unintentional Injuries	4.3%
7)	Diabetes	2.7%
8)	Influenza & Pneumonia	2.2%
9)	Kidney Disease	1.8%
10)	Septicemia	1.5%

Figures 4 and 5. Leading Causes of Death- Males/Females- All races and origins- United States, 2018

Source: NCHS National Vital Statistics Report Volume 70, Number 4 May 17, 2021

8



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Conditions Affecting Men's Health

10

Heart Disease

- Range of conditions affecting the heart and related blood vessels
  - Myocardial infarction , coronary artery disease, heart failure, arrythmias, and heart valve problems
- Leading cause of death for men in the United States
  - ~ 1 in every 4 male deaths

11

Heart Disease

Risk factors

- Hypertension
- Diabetes
- Overweight and obesity
- Unhealthy diet
- Physical inactivity
- Excessive alcohol use

12

Heart Disease

- Resources for information on recommendations and treatment of heart disease
  - American Heart Association
  - National Heart, Lung, and Blood Institute
  - Center for Disease Control and Prevention

13

Stroke

- Disruption of blood flow to an area of the brain
  - Hemorrhagic stroke
  - Ischemic stroke
- Leading cause of death and long-term disability for men in the United States

14

15

Stroke

Risk factors

- Hypertension
- Diabetes
- Overweight and obesity
- Physical inactivity
- Excessive alcohol use
- Smoking

16

Stroke

- Resources for information on recommendations and treatment of stroke
  - American Stroke Association
  - National Heart, Lung and Blood Institute
  - National Institute of Neurological Disorders and Stroke

American Stroke Association. Together to End Stroke

NIH National Heart, Lung, and Blood Institute

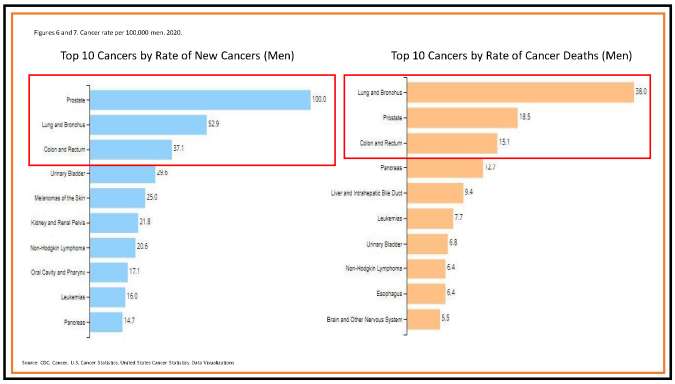
NIH National Institute of Neurological Disorders and Stroke

17

Cancer

- 814,545 new cases of cancer reported in the US in 2020
  - 317,730 deaths
- Second leading cause of death among men
  - 1 in every 5 deaths
- Prostate cancer is the most common cancer in men in the US
- Lung cancer is the most fatal cancer in men in the US

18



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Cancer

Risk factors

- Age
- Smoking
- UV light exposure from sun, or artificial sources
  - Tanning beds, booths, sun lamps (specifically for skin cancer)
- Alcohol consumption
  - Increases risk for developing 5 kinds of cancer (liver and colorectal)
- Overweight and obesity
  - Associated with roughly 40% of all cancers

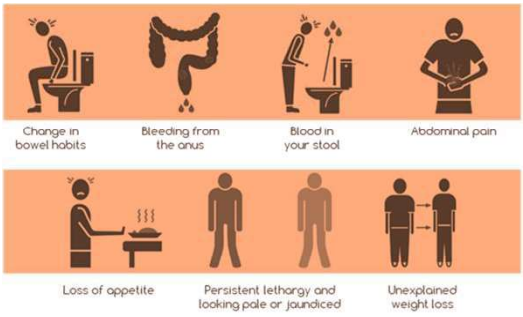
20

Cancer

Colorectal cancer screening

- Recommended in all adults ages 45-75 years
- Certain adults aged 76 to 85 years
- Frequency of examination dependent on type of screening test (i.e., colonoscopy every 10 years)

21



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Cancer

Types of colorectal cancer screenings

- Fecal Immunochemical test (FIT)
- Sigmoidoscopy
- Colonoscopy
- Virtual colonoscopy
- DNA stool test

23

Cancer

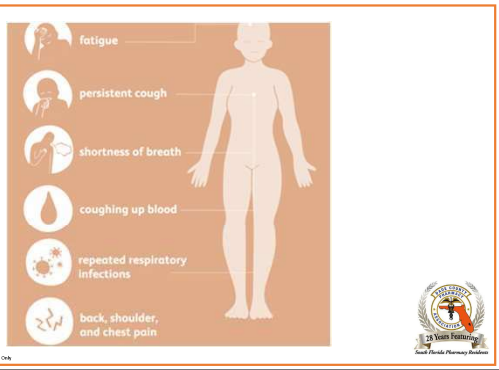
Lung cancer screening

- Recommended for all adults 50-80 years
  - Current smoker
  - Former heavy smokers (≥20 pack-year smoking history)
  - Quit within the past 15 years

Types of lung cancer screening

- Low dose computer tomography (LDCT) scan

24



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Cancer

Prostate cancer screening

- Men who are 55 to 69 years old
  - Should make individual decisions about being screened
- Men ≥ 70 years should not be screened routinely
- Prostate specific antigen (PSA) test

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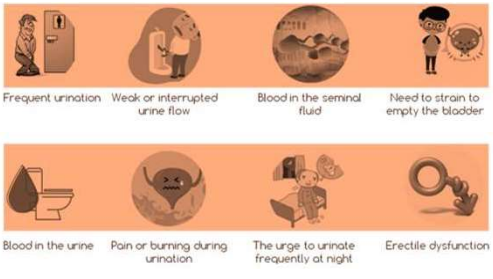

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Cancer

- Resources for information on recommendations and treatment of cancer
  - National Cancer Institute
  - National Comprehensive Cancer Network
  - Center for Disease Control and Prevention

NCI Comprehensive Cancer Center
A Cancer Center Designated by the National Cancer Institute

NCCN National Comprehensive Cancer Network®

CDC Centers for Disease Control and Prevention

28

Chronic Lower Respiratory Diseases

- Range of conditions affecting the lungs
  - Asthma, chronic obstructive pulmonary disease (COPD), bronchitis, emphysema
- One of leading cause of death for men in the United States
  - ~ 5% of total male deaths in 2018

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Chronic Lower Respiratory Diseases

Risk factors

- History of respiratory infections/conditions
- Smoke/pollutants exposure
- Obesity/ overweight
- Age
- Allergy history

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Chronic Lower Respiratory Diseases

- Resources for information on recommendations and treatment of CLRD
  - National Heart, Lung, and Blood Institute
  - American Lung Association
  - American Thoracic Society
  - Centers for Disease Control and Prevention

31

Diabetes

- Divided into 3 subtypes:
  - Type 1 diabetes mellitus (T1DM), type 2 diabetes mellitus (T2DM) and gestational diabetes
  - T2DM accounting for about 90-95% of cases
- 38.4 million Americans (~ 11.6% of the population) have been diagnosed
- Diabetes affects ~ 12.6% of all American men
- 8th leading cause of death in the US
  - 399,401 deaths listed as underlying or contributing factor in 2021
  - 103,294 death certificates listed diabetes as the underlying cause

32

Diabetes

Risk factors

- Family history
- Race or ethnic background
  - African-Americans, Asian-American, Latino/Hispanic-American, Native American, or Pacific-Islander decent have a higher risk for developing diabetes
- Age
- Weight, physical activity, and diet
- Smoking and alcohol consumption
- Stress and lack of sleep

33

Diabetes

- Resources for information on recommendations and treatment of cancer
  - American Diabetes Association
  - Center for Disease Control and Prevention

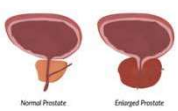
34

Other Conditions Affecting Men's Health

35

Benign Prostatic Hyperplasia (BPH)

- Non-cancerous enlargement of prostate
- Most common prostate problem for older than age 50
- Affects
  - 50% of men > age of 50
  - 90% of men > age of 80



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Benign Prostatic Hyperplasia (BPH)

Risk factors

- Age 40 years and older
- Family history of BPH
- Medical conditions
  - Obesity, T2DM, and cardiovascular diseases
- Lack of physical activity

37

Benign Prostatic Hyperplasia (BPH)

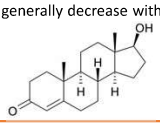
- Resources for information on recommendations and treatment of BPH
  - American Urological Association

American Urological Association

38

Testosterone Deficiency

- Testosterone is the primary sex hormone and androgen in males
- Key role in development of male reproductive tissues and secondary sexual characteristics
- Significant role in mood, cognition, social and sexual behavior
- Insufficient levels can lead to health abnormalities
  - Testosterone levels generally decrease with age



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Testosterone Deficiency

Risk Factors

- Aging
- Obesity
- Metabolic syndrome
- Medication use (antidepressants and narcotics)
- Health conditions (Klinefelter syndrome, HIV/AIDS, etc.)

40

Testosterone Deficiency

- Resources for information on recommendations and treatment of low testosterone
  - American Urological Association

American Urological Association

41

Erectile Dysfunction (ED)

- Inability to maintain penile erection that is sufficient for sexual performance
- Source of emotional stress to both patient and partner
- Usually caused by other conditions
  - Heart disease, diabetes, medications, and stress
- 30 million Americans suffer from ED

42

Erectile Dysfunction (ED)

Risk factors

- Age
- Obesity
- Stress and anxiety
- Heart disease
- Hypertension
- Diabetes

43

Erectile Dysfunction (ED)

- Resources for information on recommendations and treatment of sexual health
  - American Urological Association

American Urological Association

44

Sexual Health

Sexually transmitted infections/diseases (STI/STD)

- STI refers to a virus, bacteria, fungus, or parasite transmitted through sexual contact
- STD develops because of an STI and implies the infection has led to some symptom of disease
- Examples include syphilis, gonorrhea, and chlamydia

45

Sexual Health

Risk factors

- Age
- Sexuality
- Unprotected sex
- History of STI's
- Multiple partners
- Alcohol/drug use

46

Sexual Health

- Resources for information on recommendations and treatment of sexual health
  - Center for disease control and prevention
  - Infectious Disease Society of America
  - HIV.gov

IDSA Infectious Diseases Society of America

HIV gov

CDC Centers for Disease Control and Prevention

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Mental Health

- Mental disorders affect both men and women
- Prevalence of multiple mental disorders
  - Women > Men
  - Men are more likely to die by suicide
- Over 6 million men in the US suffered from depression in the last year
  - Often undiagnosed
- > 3 million men in the in the US have a panic disorder, agoraphobia, or any other phobia
- Men are less likely to receive mental health treatment

48

Mental Health

Risk factors

- Trauma
- Experiences with chronic mental conditions
- Biological factors
- Use of alcohol/drugs
- Feelings of loneliness or isolation

49

Mental Health

- Resources for information on recommendations and treatment of mental health
  - American Mental Wellness Association
  - American Psychiatric Association
  - Centers for Disease Control and Prevention

AMERICAN MENTAL WELLNESS ASSOCIATION

AMERICAN PSYCHIATRIC ASSOCIATION
Medical leadership for mind, brain and body.

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

50

Factors Contributing to Poor Men's Health Outcomes

51

Factors Contributing to Poor Men's Health Outcomes

- Men have a shorter life span and worse health outcomes compared to women
- Some of the difference may be explained by
  - Biological factors
  - Social factors

52

Factors Contributing to Poor Men's Health Outcomes

- ***Biological factors***
  - Genetic disorders
  - Sex hormones (testosterone/estrogen)
  - Immune system
  - High-density lipoprotein
  - Adipose tissue distribution

53

Factors Contributing to Poor Men's Health Outcomes

- ***Social factors***
  - Work-related stress and occupational hazards
  - Unhealthy behaviors
  - Risk-seeking behaviors

54

Factors Contributing to Poor Men's Health Outcomes

- Men are less likely to visit a doctor or other healthcare professional
  - Often choosing to wait as long as possible
- Common reasons given by men for not attending regular doctor visits include
  - Work
  - Lack of time
  - Lack of heath insurance
  - Choosing to "tough it out"
  - Believing they are healthy, and do not need to see a doctor

55

Figure 8. Share of adults 18-64 years without health insurance in the United States from 2015 to 2022, by gender

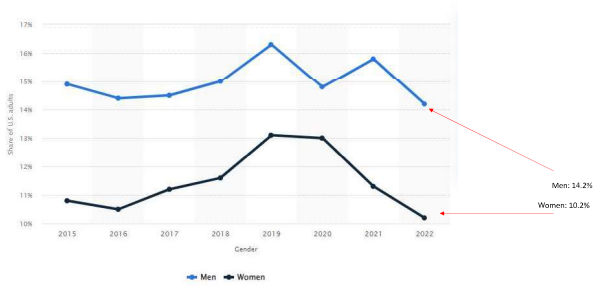

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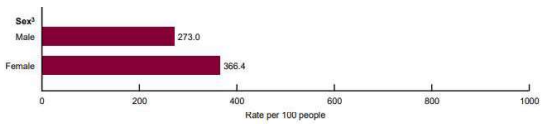
Figure 9. Office-based physician visit rates, by sex: United States, 2019



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Keys to Better Outcomes: Prevention!

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Prevention

- Recommend regular annual healthcare visits and exams
- Routinely monitor and screen for common conditions
  - Blood pressure
  - Fasting blood glucose and A1c
  - Cholesterol
  - PSA levels

59

Prevention

Exercise

- Physical inactivity is a major risk factor in a variety of diseases
- Patients should aim to get at least 150 minutes of moderate intensity aerobic activity per week
  - Walks (2.5 miles/hour)
  - Water exercises
  - Dancing
  - Gardening

60

Prevention

- Alternatively, can aim for 75 minutes per week of vigorous aerobic activity
  - Running
  - Swimming laps
  - Jump rope
  - Heavy yardwork
- Include resistance training sessions at least 2 days per week
  - Weights, resistance bands
- Spend less time sitting

61

Prevention

Diet/Nutrition

- Contributes to maintaining a healthy weight and proper intake of vitamins and minerals

62

Prevention

According to dietary guidelines for Americans, a healthy eating plan should include the following

- Emphasis on fruits, vegetables, whole grains, and fat-free or low-fat dairy products (milk, yogurt, etc.)
- Variety of protein foods such as seafood, lean meats, poultry, eggs, legumes (beans and peas), soy products, nuts and seeds
- Diet low in added sugars, sodium, saturated fats, trans fats, and cholesterol
- Stay within daily caloric needs

63

Knowledge Check

64

Question 1

True or False: Men have a lower life expectancy across the globe regardless of race, geography, or ethnicity

65

Question 1

True or False: Men have a lower life expectancy across the globe regardless of race, geography, or ethnicity

66

Question 2

True or False: Closing the gap between male and female health outcomes only benefits men

67

Question 2

True or False: Closing the gap between male and female health outcomes only benefits men

68

Question 3

Multiple Choice: Men are at a higher risk of morbidity and mortality from which of the following conditions

A. Heart disease
B. Hypertension
C. Diabetes
D. Cancer
E. All the above

69

Question 3

Multiple Choice: Men are at a higher risk of morbidity and mortality from which of the following conditions

A.Heart disease
B.Hypertension
C.Diabetes
D.Cancer
E.All the above

70

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Sweet New Ways to Manage Type 2

Updates in Diabetes Treatment and Technology

Jeremy Espeut, Pharm.D., MBA
Corporate Pharmacy & Administration Leadership PGY1/2
Baptist Hospital of Miami
January 20th, 2024

28 Years Featuring
South Florida Pharmacy Residents

1

Abbreviations

- ADA: American Diabetes Association
- T2DM: type 2 diabetes mellitus
- Hx: history
- SQ: subcutaneously
- PO: by mouth
- BID: twice daily
- Wt: weight
- SBP: systolic blood pressure
- DBP: diastolic blood pressure
- CKD: chronic kidney disease
- LDL: low-density lipoprotein
- PCSK9i: proprotein convertase subtilisin/kexin type 9 inhibitor
- FBG: fasting blood glucose
- 2 hr-PPG: 2-hour post-prandial glucose
- HFrEF: heart failure with reduced ejection fraction
- HFpEF: heart failure with preserved ejection fraction
- HF: heart failure
- ASCVD: atherosclerotic cardiovascular disease
- MOA: mechanism of action
- CGM: continuous glucose monitor
- TIR: time in range
- GLP-1 RA: glucagon-like peptide receptor agonists
- SGLT2i: sodium-glucose cotransporter-2
- DPP-4i: dipeptidyl peptidase 4 inhibitor
- GIP: glucose-dependent insulinotropic polypeptide
- SUSTAIN-6: semaglutide and cardiovascular outcomes in patients with type 2 diabetes
- CANVAS: canagliflozin and cardiovascular and renal events in type 2 diabetes
- DECLARE-TIMI 58: dapagliflozin and cardiovascular outcomes in type 2 diabetes
- REWIND: dulaglutide and cardiovascular outcomes in type 2 diabetes
- SURPASS-2: Tirzepatide versus Semaglutide Once Weekly in Patients with Type 2 Diabetes
- EMPA-REG OUTCOME: Empagliflozin, Cardiovascular Outcomes, and Mortality in Type 2 Diabetes

2

Objectives

- Review current American Diabetes Association guidelines and updates
- Understand medical therapy for the management of type 2 diabetes
- Identify technology used in the management of type 2 diabetes

3

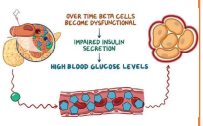
Type 2 Diabetes Mellitus: **A Brief Overview**

Pathophysiology

- Pancreatic beta cell dysfunction
  - ➢Insulin production decreases, therefore, glucose levels are elevated

Risk Factors

- ➢Family hx
- ➢Age 45 years or older
- ➢Prediabetes
- ➢Black, Hispanic/Latino, American Indian, Asian American, or Pacific Islander
- ➢Lifestyle choices



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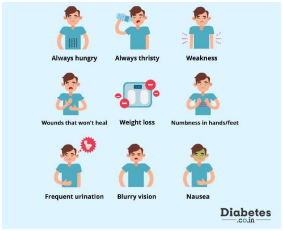
Symptoms



Complications

- Macrovascular
  - ➢ASCVD
- Microvascular
  - ➢Neuropathy
  - ➢Retinopathy
  - ➢Nephropathy

5

Diagnosis

Criteria for diagnosis:	
	HbA_{1c} ≥6.5% or
	FPG ≥7.0 mmol/L (126 mg/dL) or
	2-h plasma glucose ≥11.1 mmol/L (200 mg/dL) during an OGTT or
	In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥11.1 mmol/L (200 mg/dL)

*If any one of the above criteria is met, confirmation is necessary to establish the diagnosis (repeating either glucose or HbA_{1c})

Diabetes Care 2023;47(Suppl. 1):S14-S321

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Glycemic Goals

A1c	< 7% for most patients
FBG	80-130 mg/dL
2-hour PPG	< 180 mg/dL

Diabetes Care 2023;47(Suppl. 1):S314-S321

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2024 ADA Guidelines: **Overview**

- Obesity and weight management for the prevention and treatment of T2DM
- Consideration of social determinants of health
- Medications used for diabetes management based on other comorbidities
- Diabetes technology
- Blood pressure diagnosis
- LDL goal adjustments for patients who have diabetes and ASCVD
- Facilitating positive behaviors and well-being to improve health outcomes

8

ADA Evidence Grading System

A	B	C	E
Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered	Supportive evidence from well-conducted cohort studies	Supportive evidence from poorly controlled or uncontrolled studies	Expert consensus or clinical experience

9

Obesity and Weight Management

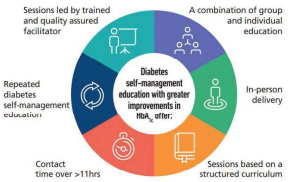
Emphasis was placed on supporting larger weight losses (up to 15%) based on efficacy and access of newer medications

Evidence: A

All people with diabetes should participate in diabetes self-management education and support (DSMES) to facilitate the knowledge, decision-making, and skills mastery for diabetes self-care

Evidence: C

- Associated with improved diabetes knowledge, lower A1C, lower self-reported weight and improved quality of life



Diabetes Care 2023;47:S11-S19

10

Consideration of Social Determinants of Health

Consider the involvement of community health workers to support the management of diabetes and cardiovascular risk factors, in underserved communities and health care systems

Evidence: C

- **SDOH:** economic, environmental, political, and social conditions in which people live and are responsible for a major part of health inequality worldwide
- Health inequities related to diabetes and its complications heavily influenced by SDOH
- Among people with chronic illness, two-thirds of those who reported not taking medications as prescribed due to cost-related barriers never shared this with their physician

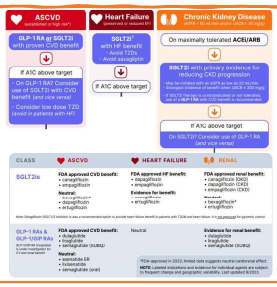
Diabetes Care 2023;47:S77-S110

11

Medications Based on Other Comorbidities

Recommendation added to recommend treatment with an SGLT2 inhibitor in individuals with T2DM and established HF

Evidence: A



12

Diabetes Technology

People with diabetes should be offered any type of diabetes device (e.g., insulin pens, connected pens, glucose meters, and CGM or AID systems)

Evidence: A

Recommendation added to emphasize that health care professionals should acquire sufficient knowledge for the use and application of diabetes technology for people with diabetes

Evidence: E

The importance of "preference" for diabetic devices was added in all recommendations

Evidence: E

- Type(s) and selection of devices should be individualized based on a person's specific needs, preferences, and skill level

People with diabetes who have been using CGM should have continued access across third-party payers, regardless of age or A1C levels

Evidence: E

Diabetes Care 2023;47:S126-S144

13

Blood Pressure Diagnosis

Updated definitions of HTN to align with current definition according to the American College of Cardiology and American Heart Association

People with diabetes and hypertension qualify for antihypertensive drug therapy when the blood pressure is persistently elevated ≥ 130/80 mmHg

Evidence: B

Blood Pressure Categories

BLOOD PRESSURE CATEGORY	SYSTOLIC mm Hg (upper number)		DIASTOLIC mm Hg (lower number)
NORMAL	LESS THAN 120	and	LESS THAN 80
ELEVATED	120 – 129	and	LESS THAN 80
HIGH BLOOD PRESSURE (HYPERTENSION) STAGE 1	130 – 139	or	80 – 89
HIGH BLOOD PRESSURE (HYPERTENSION) STAGE 2	140 OR HIGHER	or	90 OR HIGHER
HYPERTENSIVE CRISIS (consult your doctor immediately)	HIGHER THAN 180	and/or	HIGHER THAN 120

Diabetes Care 2023;47:S179–S218

14

Diabetes and ASCVD

Use of high-intensity statin therapy in individuals with diabetes aged 40-75 years at higher risk, to reduce the LDL cholesterol by ≥50% of baseline and to target an LDL cholesterol goal of <70 mg/dL

Evidence: B

- Recommended to consider adding treatment with ezetimibe or a PCSK9 inhibitor to maximum tolerated statin therapy in these individuals

15

Facilitating Positive Health Behaviors and Well-being

Recommendations adjusted to place focus on guiding the behavior of health care professionals rather than people with diabetes

Recommendation updated to reflect five critical times to evaluate the need DSMES
Evidence: E

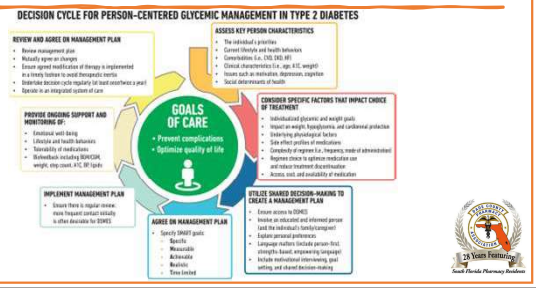
- At diagnosis, when not meeting treatment goals, annually, when complicating factors develop, and when transitions in life and care occur

Recommendation updated to include a broader integration of cultural sensitivity in the context of person-centered care
Evidence: E

Recommendation added to recommend practicing sleep-promoting routines and habits
Evidence: A

16

Selecting Treatment



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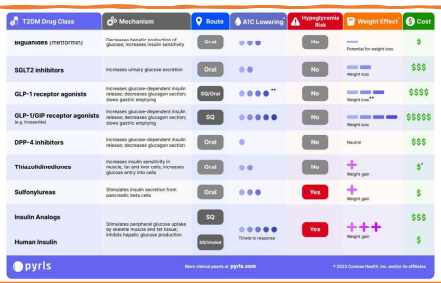
Type 2 Diabetes Pharmacotherapy

- Biguanides
- SGLT2 inhibitors
- GLP-1 receptor agonists
- GLP-1/GIP receptor agonists
- DPP-4 inhibitors
- Thiazolidinediones
- Sulfonylureas
- Insulin analogs
- Human insulin

18

Type 2 Diabetes Drug Class Comparison



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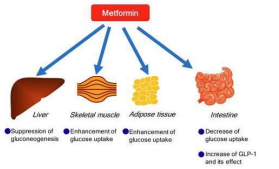
Biguanides

MOA

- Decreases hepatic glucose production, decreases intestinal absorption of glucose and improves insulin sensitivity

Clinical pearls:

- Take with food to avoid GI side effects
- Patients who have had GI side effects with regular metformin can be rechallenged with the extended-release formulation



20

Metformin

Brand	Indication	Dosing	Side Effects	Monitoring Parameters
Glucophage (PO)	T2DM	**Initial:** 500 mg PO daily to BID **Max:** 2550 mg PO daily *Titrate every 1 to 2 weeks	• Diarrhea • Flatulence • N/V • Weight loss • **Lactic acidosis (Black Box Warning)**	• A1C at baseline, every 3 months if uncontrolled, then every 6 months once controlled • CMP (renal function) • Vitamin B-12 serum concentration yearly • CBC for megaloblastic anemia

21

Sodium-Glucose Cotransporter-2 Inhibitors

22

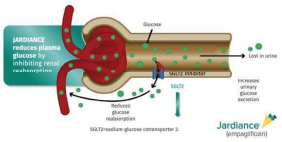
SGLT2i: Overview

MOA

- Blocks the reabsorption of glucose in the proximal tubules and increases excretion of glucose in urine

Clinical Pearls

- Patients should be educated on risk of UTI/mycotic genital infections and how to prevent
- Caution with use in patients who are bed-ridden, who utilize adult diapers, and/or have urinary incontinence
- Causes mild increase in serum creatinine after initiation, however, should return to normal



23

SGLT2i: Empagliflozin

Brand	Indication	Dosing	Side Effects	Monitoring Parameters
Jardiance (PO)	T2DM	**Initial:** 10 mg PO daily **Max:** 25 mg PO daily *titrated 4 to 12 weeks after initiation Renal dosing: eGFR < 25 if on Jardiance already: 10 mg PO daily	• Increased urination • UTI	• A1C at baseline, every 3 months if uncontrolled, then every 6 months once controlled • CMP (renal function) • S/Sx of UTI/mycotic infections
	HFrEF/HFpEF	10 mg PO daily Renal dosing: Studied in HF patients with eGFR ≥ 20		

24

Empagliflozin, Cardiovascular Outcomes, and Mortality in Type 2 Diabetes

Study	Design	Intervention	Outcome(s)
EMPA-REG OUTCOME (2015)	Double-blinded, placebo controlled RCT N=7020 • Empagliflozin n=4687 • Placebo n=2333 Inclusions: • eGFR > 30 • Established CVD	Empagliflozin 10 mg or 25 mg PO daily vs. placebo PO daily	Primary: • Composite of CV death, nonfatal myocardial infarction, or nonfatal stroke: • 12.1% (placebo) vs 10.5% (empagliflozin) • HR 0.86; 95% CI 0.74 to 0.99; P = 0.04 (superiority) Secondary: • Death from CV causes: • 38% relative risk reduction in empagliflozin group; HR 0.62 (0.49-0.77) • Hospitalizations for HF: • 35% relative risk reduction in empagliflozin group; HR 0.65 (0.50-0.85) • Death from any cause: • 32% relative risk reduction in empagliflozin group; HR 0.68 (0.57-0.82) Safety: Increased rate of genital infection in empagliflozin group

25

SGLT2i: Dapagliflozin

Brand	Indication	Dosing	Side Effects	Monitoring Parameters
Farxiga (PO)	T2DM	**Initial**: 5 mg PO daily **Max:** 10 mg PO daily *Titrated 4 to 12 weeks after initiation **Renal dosing**: •eGFR < 25: do not recommend use	• Increased urination • UTI	• A1C at baseline, every 3 months if uncontrolled, then every 6 months once controlled • CMP (renal function) • S/Sx of UTI/mycotic infections
	Diabetic kidney disease	10 mg PO daily **Renal dosing:** • eGFR <25: do not initiate, however can continue with 10 mg if already on		
	HFrEF	10 mg PO daily **Renal dosing:** eGFR <25: do not initiate, however can continue with 10 mg if already on		

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SGLT2i: Canagliflozin

Brand	Indication	Dosing	Renal Dosing	Side Effects	Monitoring Parameters
Invokana (PO)	T2DM	**Initial**: 100 mg PO daily **Max**: 300 mg PO daily *Titrated 4 to 12 weeks after initiation	eGFR 30 to < 60: 100 mg PO daily eGFR < 30: •Urinary albumin > 300 mg/day: do not initiate, however can continue with 100 mg if already on •Urinary albumin ≤ 300 mg/day: do not initiate	•Increased urination •UTI •Lower limb amputations (toe)	•A1c at baseline, every 3 months if uncontrolled, and then every 6 months once controlled •CMP •S/Sx of UTI/mycotic infections
	Diabetic kidney disease	100 mg PO daily if urinary albumin > 300 mg/day			
	ASCVD + T2DM	100 or 300 mg PO daily			

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Canagliflozin and Cardiovascular and Renal Events in Type 2 Diabetes

Study	Design	Intervention	Outcome(s)
CANVAS 2017	Double-blinded, placebo controlled RCT N= 10142 • canagliflozin n= 5795 • placebo n= 4347 Inclusion: • eGFR > 30 • 30 yrs old or older with history of symptomatic atherosclerotic CVD OR 50 yrs old or older with 2 or more risk factors for CVD	canagliflozin 100 mg or 300 mg PO daily vs placebo PO daily	Primary: • Composite of CV death, nonfatal myocardial infarction, or nonfatal stroke: • 31.5 participants per 1000 patient years (placebo) vs 26.9 participants per 1000 patient years (canagliflozin) • HR 0.86 (0.75 to 0.97); P = 0.02 (superiority); P < 0.001 (noninferiority) Secondary: • Death from any cause: HR 0.87 (0.74-1.01) • Death from CV causes: HR 0.87 (0.72-1.06) • Progression of albuminuria: HR 0.73 (0.67-0.79) • Sustained 40% reduction in eGFR, need for RRT, or death from renal causes • HR 0.60 (0.47-0.77) • Composite of CV death and hospitalization for HF: HR 0.78 (0.67-0.91) Safety: increased risk of amputation (toe or metatarsal)

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SGLT2i: Bexagliflozin

Brand	Indication	Dosing	Side Effects	Monitoring Parameters
Brenzavvy (PO)	T2DM	**Initial:** 20 mg PO daily in the AM **Max:** 20 mg PO daily in the AM **Renal dosing:** • eGFR < 30: do not recommend use	• Increased urination • UTI • LDL increase	• A1C at baseline, every 3 months if uncontrolled, then every 6 months once controlled • CMP (renal function) • S/Sx of UTI/mycotic infections

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Safety and Effectiveness of Bexagliflozin in Patients with T2DM and CKD

Study	Design	Intervention	Outcome(s)

Safety and Effectiveness of Bexagliflozin in Patients with T2DM and Stage 3a/3b CKD
 	
2019
	Phase 3, double-blind, placebo-controlled, multicenter, multinational, randomized trial
	
	N = 312
	
	Inclusion:
	• eGFR > 30
	• 30 yrs old or older with history of symptomatic atherosclerotic CVD OR 50 yrs old or older with 2 or more risk factors for CVD
		Bexagliflozin 20 mg daily vs. placebo for 24 weeks	Primary:
			• Change in percent hemoglobin A_{1c} from baseline to week 24:
			  • Bexagliflozin lowered hemoglobin A1c levels by 0.37%
			  • (95% CI, 0.20%-0.54%); P<0.001 compared to placebo
			Secondary:
			• Changes in body weight: decreased body weight (1.61kg; P<0.001)
			• Changes in systolic blood pressure: decreased systolic blood pressure (3.8mm Hg; P=0.02)
			• Hemoglobin A1c level stratified by CKD stage: Patients with CKD stages 3a (eGFR, 45-<60mL/min/1.73m2) and 3b (eGFR, 30-<45mL/min/1.73m2) experienced reductions in hemoglobin A1c levels of 0.31% (P=0.007) and 0.43% (P=0.002), respectively

30

SGLT2i: Ertugliflozin

Brand	Indication	Dosing	Side Effects	Monitoring Parameters
Steglatro (PO)	T2DM	**Initial**: 5 mg once daily **Max**: 15 mg PO once daily *May increase to 15 mg once daily after 4 to 12 weeks **Renal dosing:** • eGFR < 45: do not recommend use	• Increased urination • UTI • LDL increase	• A1C at baseline, every 3 months if uncontrolled, then every 6 months once controlled • CMP (renal function) • S/Sx of UTI/mycotic infections

31

Glucagon-Like Peptide 1 Receptor Agonists

32

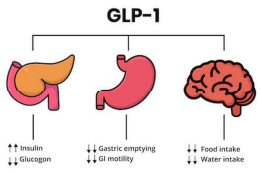
GLP-1 RA: An Overview

MOA

- Increases glucose-dependent insulin secretion, decreases inappropriate glucagon secretion, slows gastric emptying
- Acts in areas of the brain involved in regulation of appetite and caloric intake

Clinical pearls:

- Starting doses for each GLP-1 RA and GLP-1/GIP RA is to establish GI tolerance and will have little effect on glycemic control
- Avoid greasy foods
- Eat smaller & more frequent meals
- Hold therapy for at least 1 month prior to bariatric surgery, if applicable
- Avoid in patients with hx of acute pancreatitis or patients with a family or personal history of thyroid C-cell tumors **(Black Box Warning)**



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GLP-1 RA: Semaglutide

Brand	Indication	Dosing	Side Effects	Monitoring Parameters
Ozempic (SQ)	T2DM *FDA-approved for patients who are at high risk for ASCVD and/or would benefit from weight loss	**Initial**: 0.25 mg SQ weekly **Max**: 2 mg SQ weekly *Titrate every 4 weeks	• N/V • Pancreatitis • Weight loss	•A1c at baseline, every 3 months if uncontrolled, and then every 6 months once controlled •S/Sx of thyroid cancer •S/Sx of pancreatitis
Rybelsus (PO)	T2DM	**Initial**: 3 mg PO daily **Max**: 14 mg PO daily *Titrate every 4 weeks *Must be taken with a small amount of water 30 minutes prior to any food or other medications		

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Question #1

Which of the following is a primary mechanism of action for the diabetes medication semaglutide?

A. Inhibiting the absorption of dietary carbohydrates in the small intestine

B. Stimulating insulin production in the pancreas

C. stimulating insulin secretion, lowering glucagon secretion, and delaying gastric emptying

D. Promoting weight loss and reducing appetite

35

Question #1

Which of the following is a primary mechanism of action for the diabetes medication semaglutide?

A. Inhibiting the absorption of dietary carbohydrates in the small intestine

B. Stimulating insulin production in the pancreas

C. stimulating insulin secretion, lowering glucagon secretion, and delaying gastric emptying

D. Promoting weight loss and reducing appetite

36

GLP-1 RA: Dulaglutide

Brand	Indication	Dosing	Side Effects	Monitoring Parameters
Trulicity (SQ)	T2DM *FDA-approved for patients who are at high risk for ASCVD	**Initial:** 0.75 mg SQ weekly **Max:** 4.5 mg SQ weekly *Titrate every 4 weeks	• N/V • Pancreatitis • Weight loss	• A1c at baseline, every 3 months if uncontrolled, and then every 6 months once controlled • S/Sx of thyroid cancer • S/Sx of pancreatitis

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GLP-1/GIP RA: Tirzepatide

Brand	Indication	Dosing	Side Effects	Monitoring Parameters
Mounjaro (SQ) Zepbound (SQ)	T2DM Weight management, chronic	**Initial:** 2.5 mg SQ weekly **Max:** 15 mg SQ weekly *Titrate every 4 weeks	• N/V • Pancreatitis • Weight loss	• A1c at baseline, every 3 months if uncontrolled, and then every 6 months once controlled • S/Sx of thyroid cancer • S/Sx of pancreatitis

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Tirzepatide versus Semaglutide Once Weekly in Patients with Type 2 Diabetes

Study	Design	Intervention	Outcome(s)

SURPASS-2
 	
2021
	Double-blinded, placebo controlled RCT
	
	N= 1879
	• tirzepatide n= 1409
	• 5 mg n = 470
	• 10 mg n = 469
	• 15 mg n = 470
	• semaglutide n= 469
	
	Inclusion:
	• Inadequately controlled on metformin 1500 mg daily
		tirzepatide 5 mg, 10 mg, or 15 mg SQ weekly vs semaglutide 1 mg SQ weekly	Primary:
			• Change in glycated hemoglobin level from baseline to week 40
			  • tirzepatide 5 mg: -2.01; P = 0.02
			  • tirzepatide 10 mg: -2.24; P < 0.001
			  • tirzepatide 15 mg: -2.30; P < 0.001
			  • semaglutide 1 mg: -1.86
			Secondary:
			• Change in body weight from baseline to week 40
			  • tirzepatide 5 mg: -7.6 kg; -1.9 kg (CI -2.8 to -1.0)
			  • tirzepatide 10 mg: -9.3 kg; -3.6 kg (CI -4.5 to -2.7)
			  • tirzepatide 15 mg: -11.2 kg; -5.5 kg (CI -6.4 to -4.6)
			  • semaglutide 1 mg: -5.7 kg
			• Attainment of glycated hemoglobin level targets of less than 7.0% and less than 5.7%
			• < 7%: 82-86% in tirzepatide vs 79% Semaglutide
			• < 5.7%: 27-46% in tirzepatide vs 19% semaglutide
			Safety: adverse events were similar in both groups

39

Question #2

Which of the following statements about the diabetes medication tirzepatide is accurate?

A. Tirzepatide is primarily used to treat type 1 diabetes.

B. Tirzepatide is administered through intravenous (IV) infusion.

C. Tirzepatide is a GLP-1 receptor agonist with additional action on the GIP receptor.

D. Tirzepatide is available as a once-daily oral tablet.

40

Question #2

Which of the following statements about the diabetes medication tirzepatide is accurate?

A. Tirzepatide is primarily used to treat type 1 diabetes.

B. Tirzepatide is administered through intravenous (IV) infusion.

C. Tirzepatide is a GLP-1 receptor agonist with additional action on the GIP receptor.

D. Tirzepatide is available as a once-daily oral tablet.

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Dipeptidyl Peptidase 4 Inhibitors

42

DPP-4i: Overview

MOA

- Inhibits DPP-4 enzyme, which prolongs active incretin levels
  - Leads to increasing insulin synthesis and release, and decrease glucagon secretion from alpha cells, which leads to decreased hepatic glucose production

Clinical pearls:

- Costly and not as effective as GLP-1 RA or SGLT2i
  - None have shown ASCVD or weight loss benefit in clinical studies
- Can be used if patient had GI intolerance to GLP-1 RA therapy
- Avoid use of saxagliptin (Onglyza) in patients with HF
- **Avoid use of DPP-4i and GLP-1 RAs together**

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DPP-4i

Brand/Generic	Indication	Dosing	Side Effects	Monitoring Parameters
Januvia (sitagliptin)	T2DM	100 mg PO daily **Renal dosing:** • eGFR ≥ 30 < 45: 50 mg PO daily • eGFR < 30: 25 mg PO daily	• Nausea • Diarrhea • Pancreatitis • Headache • Hypoglycemia • Nasopharyngitis • Hospitalization risk for HF* • Increased uric acid**	• A1c at baseline, every 3 months if uncontrolled, and then every 6 months once controlled • S/Sx HF
Nesina (alogliptin)		25 mg PO daily **Renal dosing:** • eGFR ≥ 30 < 60: 12.5 mg PO daily • eGFR < 30: 6.25 mg PO daily		
Onglyza* (saxagliptin)		2.5 to 5 mg PO daily **Renal dosing:** • eGFR < 45: 2.5 mg PO daily		
Tradjenta** (linagliptin)		5 mg PO daily **Renal dosing:** none		

44

Sulfonylureas

45

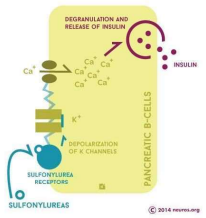
Sulfonylureas: An Overview

MOA

- Directly stimulate release of insulin from pancreatic beta cells

Clinical pearls:

- Can cause marked hypoglycemia
  - Caution in elderly populations
- Cost effective
- Long clinical experience



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Sulfonylureas

Brand/Generic	Indication	Dosing	Side Effects	Monitoring Parameters
Glucotrol, Glucotrol XL (glipizide)	T2DM	**Immediate-release:** 2.5-40 mg once or twice daily • Doses >15 mg/day should be divided and given before meals • Max 40 mg/day **Extended-release:** 2.5-20 mg/day	• Nausea • Diarrhea • Hypoglycemia • Weight gain • Skin reactions • Dark-colored urine	• A1c at baseline, every 3 months if uncontrolled, and then every 6 months once controlled • S/Sx of hypoglycemia
Amaryl (glimepiride)		1-8 mg once daily		
Diabeta, Micronase, Glynase PresTab (glyburide)		**Tablet:** 1.25-20 mg once or twice daily **Micronized tablet:** 0.75-12 mg once or twice daily		

47

Thiazolidinediones

48

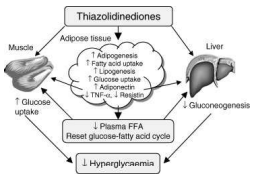
TZDs: An Overview

MOA

- Increase insulin sensitivity by acting on adipose, muscle and the liver to increase glucose utilization and decrease glucose production

Clinical pearls:

- Use cautiously in patients with HF
- Reduces bone mineral density



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TZDs

Brand/Generic	Indication	Dosing	Side Effects	Monitoring Parameters
Actos (pioglitazone)	T2DM	Recommended starting dose is 15-30 mg once daily • Titrate in 15 mg increments up to 45 mg once daily as determined by glycemic response	• Fractures • Edema and CHF • Weight gain • Bladder cancer • Hepatotoxicity	• A1c at baseline, every 3 months if uncontrolled, and then every 6 months once controlled • S/Sx of HF
Rosiglitazone (Avandia)		• Recommended starting dose is 4 mg once daily or in divided doses • If response is inadequate after 8-12 weeks, may increase to 8 mg/day		

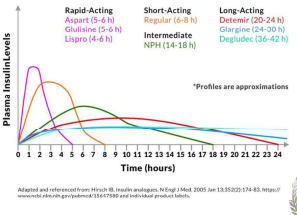
50

Insulin Therapy

51

Insulin Therapy: Clinical Pearls

- Titrate low and slow
- Be cautious to avoid overbasalization:
  - Max daily basal dose = 0.5 x wt. (kg)
  - Decreases risk of hypoglycemia
- Decrease dose by 10-20% if hypoglycemia occurs
- If patient is on insulin, consider CGM for better BG monitoring



Adapted and referenced from: Hirsch IB. Insulin analogues. N Engl J Med. 2005 Jan 13;352(2):174-83. https://www.ncbi.nlm.nih.gov/pubmed/15647580 and individual product labels.

52

Diabetes Devices & Technology

53

Smart Insulin Pen

- Reusable injector pen with an intuitive smartphone app
- Calculates and tracks doses, provides helpful reminders, alerts, and reports
- Can come in the form of an add-on to your current insulin pen or a reusable form which uses prefilled cartridges instead of vials or disposable pens
- Insulin cartridges dispensed separately
- Covered by most insurances

54

NovoPen®6 & NovoPen Echo® Plus

- Records insulin dosing information
- Intended for patients who have been prescribed Tresiba® or Fiasp®
- NovoPen®6: 60-unit maximum dose in 1-unit increments
- NovoPen Echo® Plus: 30-unit maximum dose in 0.5-unit dose increments

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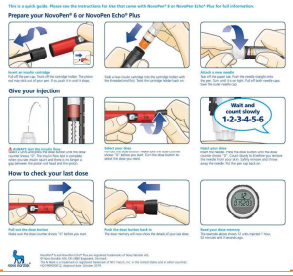
NovoPen®6 & NovoPen Echo® Plus



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NovoPen®6 & NovoPen Echo® Plus

Personal injection log:

- If you have a smartphone, tablet, personal computer, glucose monitor or another device that supports Near Field Communication (NFC), you can transfer your insulin dosing information from your smart pen to your device
- Insulin dosing information can be transferred to patients preferred diabetes app

glooko® FreeStyle LibreLink mySugr® dexcom DOSE CHECK

Hold the dose memory of the pen straight against the NFC spot on your device. Wait while your injection details are automatically transferred to a compatible app on your device.

The NFC spot may vary depending on the phone model.

57

Medtronic InPen®

- Intended for patients who have been prescribed Humalog®, Novolog®, or Fiasp®
- Compatible with 3 mL cartridges
- Dose range 0.5 to 30 units in 0.5-unit increments
- Comes in 3 colors and two different models
  - ➢InPen Humalog® or InPen Novolog®/Fiasp®

58

Continuous Glucose Monitoring (CGM)

- Reports blood glucose levels in real time
- Works through a sensor placed on your skin
- Beneficial in patients who have trouble reaching and maintaining target blood glucose

59

CGM & Time in Range

- Time in range: amount of time you spend in the target blood glucose range
  - Between 70 and 180 mg/dL for most people
- Works with CMS's data by looking at the amount of time blood glucose has been in target range and times of hypo and hyperglycemia
- Most people with diabetes should aim for a time in range of at least 70% of readings

60

Time in Range vs. A1C

A1C: measure of your average blood glucose for the previous three months

- Doesn't document the daily highs and lows people may have

Who should use time in range?

- People who use insulin and have tight blood glucose goals
- Barrier to the widespread use of time in range for diabetes management is the limited number of people who use a CGM

61

Abbott Freestyle Libre 14®, Freestyle Libre 2®, & Freestyle Libre 3®

- Measures glucose every minute and records glucose level every 15 minutes
- Approved for ages ≥ 2 yrs
- Placement: back of upper arm
- Sensor life: 14 days
- Interactions: Vitamin C (> 500 mg per day)
- Differences: Libre 2® & Libre 3® has improved Bluetooth connectivity

62

Dexcom G6® & Dexcom G7®

- Glucose readings sent to receiver/smart device every 5 minutes
- Approved for ages ≥ 2 yrs
- Placement: G6: abdomen or back of upper arm (upper buttocks for patients 2-17 yrs), G7: back of upper arm
- Sensor life: 10 days
- Interactions: Hydroxyurea and high dose acetaminophen (> 1 g every 6 hours in adults)

NEW Dexcom G6 Receiver

63

Medtronic Guardian Connect®

- Glucose readings sent to smart device every 5 minutes
- Approved for ages 14-75 yrs
- Placement: abdomen or back of upper arm
  Sensor life: 7 days
- Calibration: after initialization and at least every 12 hours
- Interactions: acetaminophen

64

Senseonics Eversense®

- Glucose readings sent to smart device every 5 minutes
- Approved for ≥ 18 yrs
- Placement: back of upper arm (surgically)
- Sensor life: up to 180 days
- Calibration: after initialization and twice per day 10-14 hours apart
- Interactions: tetracycline antibiotics

65

Question #3

Which CGM has an interaction with vitamin C?

A. Senseonics Eversense®

B. Medtronic Guardian Connect®

C. Dexcom G6® & Dexcom G7®

D. Abbott Freestyle Libre®

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Question #3

Which CGM has an interaction with vitamin C?

A. Senseonics Eversense®

B. Medtronic Guardian Connect®

C. Dexcom G6® & Dexcom G7®

D. Abbott Freestyle Libre®

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How to Pick a CGM

Things to consider:

- Ease of use
- Cost and insurance coverage
- Information retrieval
- flexibility

68

Insulin Pumps

Small, computerized devices that deliver insulin in two ways:

- In a steady measured and continuous dose (basal insulin)
- As a surge (bolus) dose, at your direction, around mealtime
- Delivery mimics the body's normal release of insulin

Beneficial for people who:

- Have frequent low blood sugar reactions
- Have gastroparesis
- Are active

Doesn't take away the need to check blood glucose

Can be costly

69

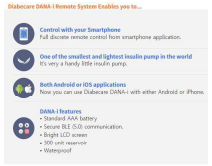
Omnipod 5® & Omnipod DASH®

- Tubeless
- **Basal range:** 0.05 to 30 units per hour in 0.05-unit increments
- **Bolus range:** From 0.05 to 30 units.
- Increments of 0.05, 0.1, 0.5, or 1 unit. Insulin-to-carb ratio in whole units only
- Pod is changed every 72 hours (or after delivering 200 units of insulin)
- Remote personal diabetes manager (PDM) controls the pod's functions and has a built-in blood glucose meter (DASH® doesn't have built in meter)
- Pod must be within 5 feet of the PDM to deliver bolus doses

70

Diabecare DANA-i®

- **Basal range:** 0.04 to 16 units per hour in 0.01- or 0.1-unit increments
- **Bolus range:** From 0.1 to 80 units increments of 0.1, 0.5-, or 1-unit Insulin-to-carb ratio in whole units only
- 300-unit reservoir
- Indicated for use with U-100 insulin
- Can control with your smartphone



71

Combination CGM & Insulin Pumps

72

Medtronic MiniMed 630G® & 670G®

- **Basal range:** 0.025 to 35 units per hour in 0.025-unit increments
- **Bolus range:** 0.025 to 25 units in increments of 0.025 units, insulin-to-carb ratio allows for fractions of grams
- 300-unit reservoir
- SmartGuard® technology to stop insulin delivery for up to 2 hours if the glucose level reaches a preset low limit
- Works with Contour Next Link 2.4® meter

73

Tandem T-Slim X2®

- **Basal range:** 0.1 to 15 units per hour in 0.001-unit increments
- **Bolus range:** 0.05 to 25 units in increments of 0.01 units
- 300-unit reservoir
- Basal-IQ® technology predicts glucose levels and stops insulin delivery if glucose is expected to drop below 80 mg/dL in the next 30 minutes
- Control-IQ® technology allows the system to automatically deliver correction bolus of approx. 60% of normal correction dose
- For use with Dexcom G6 CGM

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Summary

- Field of diabetes care is rapidly changing as new research, technology, and treatments that can improve the health and well-being of people with diabetes continue to emerge
- Diabetes care and management is patient-centric
- Even with CGM, patients should still utilize BGM
- Pharmacists have a key role in the advocacy for diabetes management

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Sweet New Ways to Manage Type 2

Updates in Diabetes Treatment and Technology

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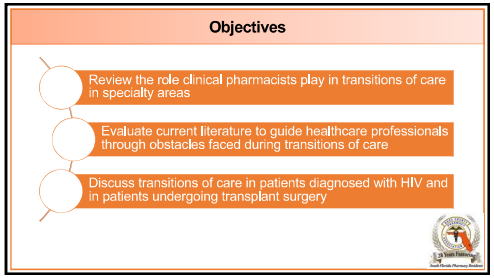
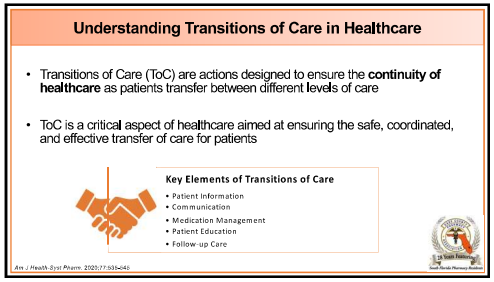
Transitioning Through the Healthcare System
Mireille Mitchell, PharmD
Jackson Memorial Hospital
Miami, FL
Saturday, January 20th 2023
28 Years Featuring
South Florida Pharmacy Residents

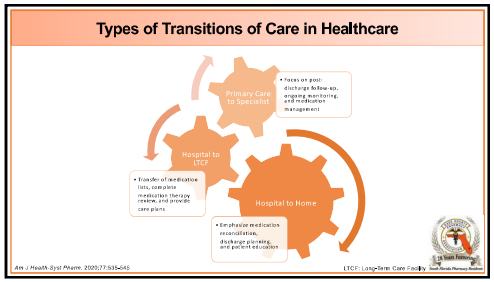
1


Objectives
Review the role clinical pharmacists play in transitions of care in specialty areas
Evaluate current literature to guide healthcare professionals through obstacles faced during transitions of care
Discuss transitions of care in patients diagnosed with HIV and in patients undergoing transplant surgery

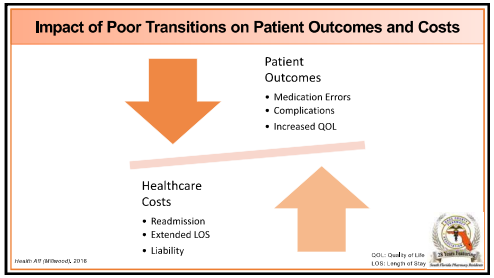
2


Understanding Transitions of Care in Healthcare
• Transitions of Care (ToC) are actions designed to ensure the continuity of healthcare as patients transfer between different levels of care
• ToC is a critical aspect of healthcare aimed at ensuring the safe, coordinated, and effective transfer of care for patients
Key Elements of Transitions of Care
• Patient Information
• Communication
• Medication Management
• Patient Education
• Follow-up Care

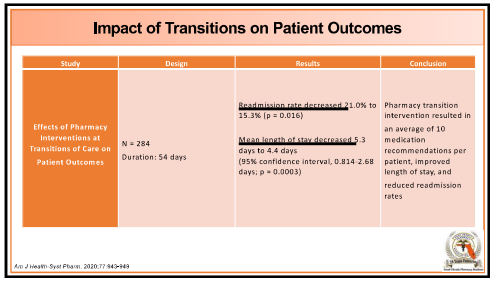
3


Types of Transitions of Care in Healthcare
Primary Care to Specialist
• focus on post-discharge follow-up, ongoing monitoring, and medication management
Hospital to LTCF
• Transfer of medication lists, complete medication therapy review, and provide care plans
Hospital to Home
• Emphasize medication reconciliation, discharge planning, and patient education
Am J Health-Syst Pharm. 2020;77:535–546
LTCF: Long-Term Care Facility

4


Impact of Poor Transitions on Patient Outcomes and Costs
Patient Outcomes
• Medication Errors
• Complications
• Increased QOL
Healthcare Costs
• Readmission
• Extended LOS
• Liability
Health Aff (Millwood). 2016
QOL: Quality of Life
LOS: Length of Stay

5


Impact of Transitions on Patient Outcomes
Study
Design
Results
Conclusion
Effects of Pharmacy Interventions at Transitions of Care on Patient Outcomes
N = 284
Duration: 54 days
Readmission rate decreased 21.0% to 15.3% (p = 0.016)
Mean length of stay decreased 5.3 days to 4.4 days (95% confidence interval, 0.814-2.68 days; p = 0.0003)
Pharmacy transition intervention resulted in an average of 10 medication recommendations per patient, improved length of stay, and reduced readmission rates
Am J Health-Syst Pharm. 2020;77:943–949

6

Impact of Transitions on Healthcare Costs

Study / Design / Time	Endpoints	Results
Weiyi N, et al. (2018) Observational cohort 2016	-Compare cost outcomes in a group of patients discharged and referred to an ambulatory care pharmacy-based ToC program versus usual care -30-day/180-day inpatient, outpatient, prescription, emergency room and total costs	-Among 830 patients referred to the ToC program, total health-care costs at 180 days after discharge were an average of $2139 lower versus 1005 control group patients (savings $1.8 million for managed care plan)

- Data for the study was retrieved from the Medicaid managed care health plan **paid claims database** (inpatient records, ER visits, prescription medications, etc.)
- Over the 30 days after discharge, pharmacists collaborated with outpatient providers to resolve medication-related problems for adult patients at high-risk for readmission
  - Inappropriate medication selection, dosage adjustments, drug-drug interactions, duplicates, etc

Am J Health-Syst Pharm. 2018; 75:613-21

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Knowledge Check

What is the primary impact of effective transitions of care on patient outcomes?

a) It primarily affects healthcare costs but not patient outcomes
b) It improves patient safety, quality of care, and outcomes
c) It leads to increased complications and readmissions
d) It involves multiple healthcare providers disrupting continuity of care

8

Knowledge Check

What is the primary impact of effective transitions of care on patient outcomes?

a) It primarily affects healthcare costs but not patient outcomes
b) It improves patient safety, quality of care, and outcomes
c) It leads to increased complications and readmissions
d) It involves multiple healthcare providers disrupting continuity of care

9

Hospital Readmission Reduction Program (HRRP)

- Affordable Care Act of 2010
  - Section 3025: Hospital Readmissions Reduction Program
- Medicare value-based purchasing program → Improves communication + care coordination → **Reduces avoidable admissions**
  - Social Security Act (Section 1886q): Reduce payments to hospitals for excess readmissions beginning October 1st, 2012
  - 21st Century Cures Act: Assesses performance relative to other hospital's with a similar proportion of beneficiaries beginning in fiscal year 2019
    - To maintain budget neutrality under peer grouping v non-peer grouping methodology

Hospital readmissions reduction program (HRRP). CMS.gov. CMS: Centers for Medicare & Medicaid Services

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Hospital Readmission Reduction Program (HRRP)

Acute Myocardial Infarction | Chronic Obstructive Pulmonary Disease | Heart Failure | Pneumonia | Coronary Artery Bypass Graft | Elective Total Hip/Knee Arthroplasty

- CMS calculates payment reduction + component results for each hospital based on its performance during a rolling performance period
  - Payment adjustment factor: Utilized by CMS to reduce hospital payments
    - Applied to Medicare fee-for-service base operating diagnosis-related group payments
    - Payment reduction capped at 3% (adjustment factor: 0.97)

Hospital readmissions reduction program (HRRP). CMS.gov.

11

Hospital Readmission Reduction Program (HRRP)

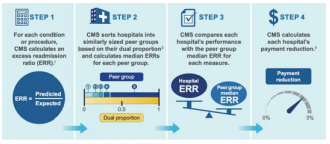
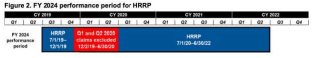


Figure 2. FY 2024 performance period for HRRP



Hospital readmissions reduction program (HRRP). CMS.gov.

12

Hospital Readmission Reduction Program (HRRP)

Changes in HRRP from FY 2013 to FY 2024

Program year	Readmission measures	Maximum payment reduction	Payment reduction methodology
FY 2013	AMI HF Pneumonia	Up to 1 percent	Non-peer grouping methodology
FY 2014	No change in measures	Up to 2 percent	Non-peer grouping methodology
FY 2015	AMI HF Pneumonia COPD (added) THA/TKA (added)	Up to 3 percent	Non-peer grouping methodology
FY 2016	No change in measures	Up to 3 percent	Non-peer grouping methodology
FY 2017	AMI HF Pneumonia (expanded cohort) COPD THA/TKA CABG (added)	Up to 3 percent	Non-peer grouping methodology
FY 2018	No change in measures	Up to 3 percent	Non-peer grouping methodology
FY 2019 to FY 2022	No change in measures[a]	Up to 3 percent	**Peer grouping methodology**[a,c]
FY 2023	Pneumonia paused[a,d]	Up to 3 percent	Peer grouping methodology
FY 2024	Pneumonia resumed[a,d]	Up to 3 percent	Peer grouping methodology

[a] Hospital readmissions reduction program (HRRP), CMS.gov.

13

Knowledge Check

Which of the following is not a CMS core measure?

a) Acute myocardial infarction
b) Coronary artery bypass graft surgery
c) Diabetes
d) Elective primary total hip arthroplasty

14

Knowledge Check

Which of the following is not a CMS core measure?

a) Acute myocardial infarction
b) Coronary artery bypass graft surgery
c) Diabetes
d) Elective primary total hip arthroplasty

15

Transitional Care Management (TCM) Services

- Medicare may cover transitional care services during a **30-day period** beginning from physician discharge at an inpatient stay
  - Services include **supporting a patient's transition to a community setting**, healthcare professionals taking responsibility for a patient's care, etc.

From: Inpatient Setting
- Acute Care Hospital
- Psychiatric Hospital
- Rehab Facility
- Long-Term Care Hospital
- Skilled Nursing Facility
- Hospital Outpatient Observation

To: Community Setting
- Home
- Domiciliary (Group Home)
- Nursing Facility
- Assisted Living Facility

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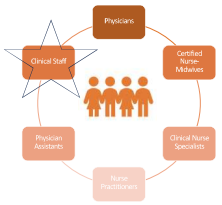
TCM Contributing Team Members



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The Critical Role of Collaboration in ToC

18

TCM Interactive Contact Details

- **Interactive Contact**: Must contact the patient via phone, email, or face-to-face within 2 business days after discharge
  - May report service after 2+ unsuccessful separate contact attempts in a timely manner
  - Continue trying to contact patient until successful
  - Must be done by physician, qualified non-physician provider, or "clinical staff"
    - Can address patient status and needs beyond scheduling
- **Non-face-to-face Services**: Auxiliary personnel (pharmacists) may provide the following TCM services under general supervision:
  - Communicate with the patient
  - Communicate with agencies and community service providers
  - Educate patient/caregiver to support self-management and independent living
  - Assess and support treatment adherence (medication management)
  - Identify available community + health resources
  - Help patient to access needed care services

CMS MLN909928, July 2019, Available: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/pfs-Care-Management

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The Critical Role of Collaboration in ToC

Study	Design	Results	Conclusion
Evaluating the Effects of a Multidisciplinary Transition Care Management Program on Hospital Readmissions	N = 492 Retrospective Cohort September 2015 – July 2016	30-day All-cause Readmissions: 9% intervention v 15% control (1.82; 95% CI,1.15-2.89;p= 0.0108) 14-day Primary Care Visits: 59% intervention patients (n = 288) v 62% of control (n = 235) (OR, 1.92; 95% CI, 0.75 1.91; p = 0.46)	A pharmacist initiated TOC program was effective at reducing 30-day all-cause hospital readmissions, regardless of primary care follow-up after discharge.

- **Objective**: Measure effects of a pharmacist-initiated, multidisciplinary ToC program on:
  - 30-day all cause readmissions
  - 14-day post-discharge primary care visits

Am J Health-Syst Pharm. 2020;77:935-937

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Healthcare Effective Data and Information Set (HEDIS)

- **Objective**: Tool used by more than 90% of U.S. health plans to measure performance on care and service
  - National Committee for Quality Assurance (NCQA) collects HEDIS survey results directly from health plans and determines metrics annually
- **HEIDS Transitions of Care (TRC) Measures:**
  - Notification of Inpatient Admission
  - Receipt of Discharge Information
  - Patient Engagement After Inpatient Discharge
  - Medication Reconciliation Post-Discharge
- **Who is included in the TRC Measure?**
  - Medicare patients > 18 years of age after discharge from an inpatient facility

NCQA, https://www.ncqa.org/hedis/measures/transitions-of-care/.

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Healthcare Effective Data and Information Set (HEDIS)

Codes for medication reconciliation

99483	Assessment of and care planning for a patient with cognitive impairment, requiring an independent historian, in the office or other outpatient, home or domiciliary or rest home, with all of the following required elements: • Cognition-focused evaluation including a pertinent history and examination • Medical decision-making of moderate or high complexity • Functional assessment (e.g., basic and instrumental activities of daily living), including decision-making capacity • Use of standardized instruments for staging of dementia (e.g., functional assessment staging test [FAST], clinical dementia rating [CDR]) • Medication reconciliation and review for high-risk medications • Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized screening instrument(s) • Evaluation of safety (e.g., home), including motor vehicle operation • Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports and the willingness of caregiver to take on caregiving tasks • Development, updating or revision, or review of an advance care plan • Creation of a written care plan, including initial plans to address any neuropsychiatric symptoms, neuro-cognitive symptoms, functional limitations, and referral to community resources as needed (e.g., rehabilitation services, adult day programs, support groups) shared with the patient and/or caregiver with initial education and support. Typically, 50 minutes are spent face-to-face with the patient and/or family or caregiver.

99496 (Med T-T post-discharge)	Transitional care management services with the following required elements: • Communication (direct contact, telephone, electronic) with the patient and/or caregiver within two business days of discharge • Medical decision-making of high complexity during the service period • Face-to-face visit within seven calendar days of discharge
99495 (Med B-M post-discharge)	Transitional care management services with the following required elements: • Communication (direct contact, telephone, electronic) with the patient and/or caregiver within two business days of discharge • Medical decision-making of at least moderate complexity during the service period • Face-to-face visit within 14 calendar days of discharge
1111F (within 30 days post-discharge*)	• Discharge medications reconciled with the current medication list in outpatient medical record *The 30-day limit relates to the measure specifications; not to a time-limit on when the code can be used.

NCQA, https://www.ncqa.org/hedis/measures/transitions-of-care/.

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Knowledge Check

True/False: The Healthcare Effective Data and Information Set (HEDIS) metrics determine Medicare reimbursement rates

a) True
b) False

23

Knowledge Check

True/False: The Healthcare Effective Data and Information Set (HEDIS) metrics determine Medicare reimbursement rates

a) True
b) False

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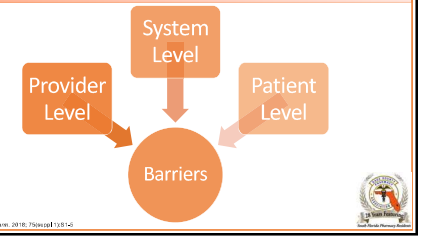
Common Barriers to Successful Transitions of Care



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Common Barriers to Successful Transitions of Care

Study / Design / Time	Endpoints	Results
Virapongse A, et al. (2018) Literature Review 1960 – 2016	-Determine social determinants of Health during Transitions of Care in the Medically Underserved	-When reclassified into themes, access failures and social fragility were most commonly represented

- Healthcare Access
- Cost of Care
- Housing Instability
- Mental Illness
- Transportation
- Medication Adherence
- Insurance Status
- Health Literacy

- Coordination of timely access to publicly funded safety-net clinics
- Patient Assistance Programs
- Telemedicine services/Home health visits
- Transportation vouchers
- Meds-to-Beds
- Patient Education

J Gen Intern Med. 2018 Nov; 33(11): 1950–1957

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Common Barriers to Successful Transitions of Care

Study / Design / Time	Measures	Conclusion
Nijhawan A, et al. (2018) Semi-structured interviews in HIV-positive patients readmitted within 30 days of a previous admission 2018 N=86	1. Stakeholder's perceptions of 30-day readmissions as a quality metric in patients with HIV and in safety net hospitals 2. Preventability of readmission in patient's with HIV 3. Strategies to reduce readmission	1. 30-day readmissions is a reasonable metric (promotes care optimization for vulnerable populations) but was inappropriate for patients with AIDS- illnesses (due to the severity and unpredictability of their disease) 2. Participants disagreed about preventability, especially regarding patient-level factors 3. Various stakeholders proposed readmission reduction strategies that spanned the inpatient to outpatient care continuum

- **Objective**: Determine factors contributing to readmission among patients with HIV admitted to safety net hospitals to help refine readmission metrics
  - Qualitative study to solicit perspectives towards readmission + prevention strategies to improve outcomes in HIV-positive individuals

J Int Assoc Provid AIDS Care. 2019 Jan-Dec;18:2325958218822615.

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Common Barriers to Successful Transitions of Care

Insufficient Community Resources
- Safety net populations require more than medical intervention at discharge, need for "social solution"

Insufficient System Capacity
- Providers overburdened in the outpatient system, leading to more emergency department visits and admissions

System Factors
- Delays in inpatient diagnostic workups, interruptions in medications at discharge, and limited ability to transfer patients to other facilities

Provider-Provider Communication
- Inadequate communication among providers at various transitions during the patient's admission

Provider-Patient Communication
- Ineffective education about prognosis, medications, and post-discharge self-care tasks

Patient-Level Factors
- Medication adherence, substance use, social circumstances (lack of housing/transportation), denial of disease, etc.

J Int Assoc Provid AIDS Care, 2019 Jan Dec;18:2325958219827615.

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Common Barriers to Successful Transitions of Care

During Admission	At Discharge	Postdischarge	General System Changes
REALLOCATION OF EXISTING RESOURCES			
• **Intensive patient education during admission**, not just at discharge: ○ Motivational interviewing/counseling to promote self-care ○ In-depth assessment of barriers to medication and appointment adherence ○ Set up medication app on smartphone	• **Intensive patient education by staff trained in care of patients with HIV**, including: ○ Teach-back discharge instructions for medications and appointments ○ Emphasize prognosis currently and if HIV is well controlled ○ Give all medications in hand, pill box ○ Confirm readiness of medication app	• Document plans for support services for paints with newly diagnosed HIV and patients with AIDS	• **Exempt patients with AIDS from 30-day metric** • **Shorten time to primary care provider (PCP) appointments for patients at highest risk of readmission** ○ Offer virtual outpatient visits to well-controlled patients with HIV • Allow well-controlled HIV-positive patients to be seen by non-HIV specialist PCP
ENHANCED COORDINATION OF SERVICES			
• **Identify patients at high risk of readmission using medical and social risk algorithm** • **Multidisciplinary teams with specialized training for HIV-positive patients** • **EHR/technological improvements** ○ Improve quality of report of all admitted patients with HIV ○ Providers use tablets at bedside to streamline documentation and orders • Establish "buddy" from community HIV orgnization for support at dischrge	• Reduce number of services provided only at discharge—too overwhelming	• **Require proactive, ongoing transitional care management** for patients newly diagnosed with HIV and patients with AIDS (eg, follow-up calls, assessments of symptoms, assessment of barriers and needs) • **Provide phone access to HIV case manager or staff familiar with recent hospitalization** • Confirm medication continuity through pharmacy	• **Embed mental health services in primary care clinics** ○ **EHR/technological improvements** ○ Flag 30-day readmission patients ○ Flag high-readmission risk points ○ Merge EHR and HIV case management database ○ Revise billing system to reflect clinical severity and complexity ○ Improve health information exchange with other institutions • **Educate hospitalists and ED providers** ○ Available outpatient services for patients with HIV ○ What constitutes an appropriate admission versus ED management versus outpatient management

J Int Assoc Provid AIDS Care, 2019 Jan Dec;18:2325958219827615.

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Knowledge Check

What is a common barrier to successful transitions of care in healthcare settings?

a) Optimized electronic health record systems
b) Active patient engagement in care decisions
c) Interprofessional collaboration among healthcare teams
d) Poor medication reconciliation and management

30

Knowledge Check

What is a common barrier to successful transitions of care in healthcare settings?

a) Optimized electronic health record systems
b) Active patient engagement in care decisions
c) Interprofessional collaboration among healthcare teams
d) Poor medication reconciliation and management

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Successful Transitions of Care

During Admission	At Discharge	Post-Discharge

• Disease-state education by trained staff
  • "Teach-back" strategies
  • Motivational interviewing
  • Delivered in patient's native language
• Assessment of individual barriers
	• Medication education by trained staff
	• Delivery of medications bedside before leaving the floor
	  • Providing pill boxes
	  • Medication management apps
	• Phone number to case manager
		• Follow-up team dedicated to high-risk patients
		  • Review symptoms
		  • Ensure receipt of medications
		  • Appointment reminders
		  • Identify obstacles to outpatient care

J Int Assoc Provid AIDS Care. 2019 Jan-Dec;18:2325958219877815.

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Successful Transitions of Care

- **Medication Reconciliation:**
  - History: Formal process of obtaining a complete and accurate list of each patient's pre-admission medication
  - Reconciliation: Determination of an appropriate and safe medication regimen at times of admission, transfer, and discharge
- **The Joint Commission: National Patient Safety Goal (NPSG)**

Develop List of Current Medication → Develop List of Medications to be Prescribed → Compare Medications on Both Lists → Make Clinical Decision Based on Comparison → Communicate List to Caregivers and Patient

Agency for Healthcare Research and Quality (US) 2008 Apx. Chapter 28.

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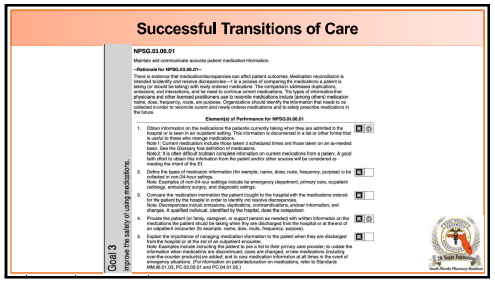
Successful Transitions of Care



NPSG.03.06.01

Maintain and communicate accurate patient medication information.

Rationale for NPSG.03.06.01

There is evidence that medication discrepancies can affect patient outcomes. Medication reconciliation is the process of identifying the most accurate list of all medications that the patient is taking—including what is taking (or should be taking) with newly ordered medications. The comparison addresses duplications, omissions, and interactions, and be need to continue ordered medications. The types of information that physicians and other licensed practitioners use to reconcile medications include (among others) medication name, dose, frequency, route, are purpose. Organizations should identify the information that needs to be collected in order to reconcile current and newly ordered medications and to safely prescribe medications in the future.

Element(s) of Performance for NPSG.03.06.01

1. Obtain information on the medications the patient is currently taking when they are admitted to the hospital or is seen in an outpatient setting. This information is documented in a list or other format that is used for the purpose of reconciliation.
   Note 1: Current medications include those taken a scheduled times and those taken on an as-needed basis. See the Glossary box definition of medications.
   Note2: It is often difficult to obtain complete information on current medications from a patient. A good faith effort to obtain this information from the patient and/or other sources will be considered as compliance with this EP.
2. Defines the types of medication information (for example, name, dose, route, frequency, purpose) is to be collected in hose inf-hour settings.
   Note: Examples of non-24-our settings include be emergency cleadment, primary care, ouputient radiology, ambulatory surgery, and diagnostic settings.
3. Compares the medication inormation the patient brought to the hospital with the medications ordered for the patient by the hospital in order to identify and resolve discrepancies.
   Note: Examples of discrepancies include omissions, duplications, contraindications, unclear information, and changes. A qualified individual, identified by the hospital, does the comparison.
4. Provides the patient (or family, caregiver, or support person as needed) with written information on the medications the patient should be taking when they are discharged from the hospital or at the end of an outpatient encounter (for example, name, dose, route, frequency, purpose).
5. Provides a complete medication information to the patient when they are discharged from the hospital or at the end of an outpatient encounter.
   Note: Examples include instructing the patient to ive a list to their primary care provider; to update the information when medications are discontinued, cases are changed, or new medications (including over-the-counter products) are added; and to carry medication information at all times in the event of unexpected hospitalization. For more information on medication on medications, refer to Standards MM.06.01.03, PC.02.03.01 and PC.04.01.05.)

Goal 3
Improve the safety of using medications.

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Successful Transitions of Care

- **Key Current/Future Pharmacy Technician Roles:**
  - Assist with medication histories
  - Coordinate with pharmacists, social work, physicians, and nurses to identify medication needs of discharging patient
  - Identify prescription payment source at time of discharge
    - Insurance, co-payments, patient assistance, etc.
  - Expedite data entry + filling prescriptions inpatient prescribed at discharge
  - Utilize medication delivery of prescriptions to bedside

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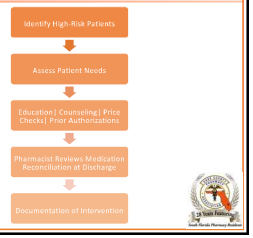
Successful Transitions of Care

Key Pharmacist Roles:

- Medication Reconciliation
- Medication Management
- Patient Education
- Care Coordination
- Prescription Services
- Comprehensive Discharge Planning



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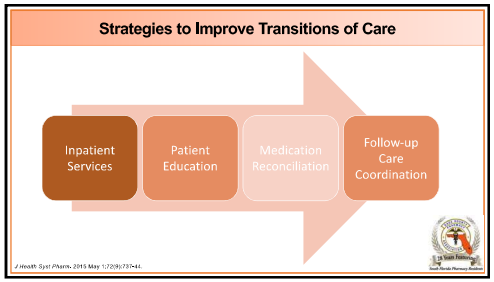
Strategies to Improve Transitions of Care
Inpatient Services
Patient Education
Medication Reconciliation
Follow-up Care Coordination

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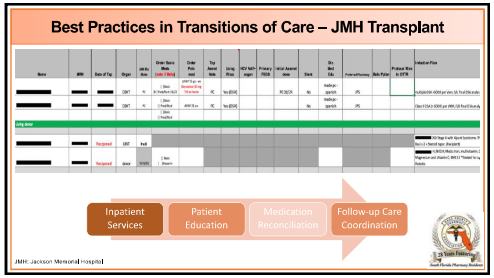
Best Practices in Transitions of Care – JMH Transplant
Inpatient Services
Patient Education
Medication Reconciliation
Follow-up Care Coordination
JMH: Jackson Memorial Hospital

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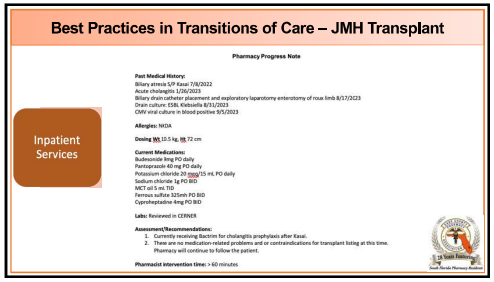
Best Practices in Transitions of Care – JMH Transplant
Pharmacy Progress Note
Inpatient Services

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Best Practices in Transitions of Care – JMH Transplant

Inpatient Services

Drug (for 70 kg patient)	Drug Unit	Cost per unit	High IS Induction			
			Level 1 Cost (no IVIG)	Level 2 Cost (2 g/kg IVIG)	Level 3 Cost (0.3 g/kg IVIG)	Level 4 Cost (0.5 g/kg IVIG)
Thymoglobulin 75 mg x 3 doses	25 mg/Vial	$635	$4,815	$4,815	$4,815	$4,815
Basiliximab 20 mg x 2 doses	20 mg/vial	$3,992	$7,984	$7,984	$7,984	$7,984
IVIG 2.1-140 g/kg total dose	10 g	$715	$0			
Rituximab 750 mg x 1 dose	500 mg/vial	$2,476	$3,466	$3,466	$3,466	$3,466
TOTAL DRUG COST			$16,265	$16,265	$16,265	$16,265

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Best Practices in Transitions of Care – JMH Transplant

Inpatient Services

Jackson Memorial Hospital Kidney and Pancreas Clinical Pharmacist Collaborative Agreement with Miami Transplant Institute

Authority and Purpose

Authorization of therapy continuation and therapeutic interchange by kidney and pancreas clinical transplant pharmacist at Jackson Memorial Hospital for kidney and pancreas transplant patients.

Definitions

Authorization of refills

In this service, the prescriber authorizes the pharmacist to extend refills based on the pharmacist's assessment (of electronic medical record, including but not limited to last notes and lab results from: CERNER, OTTR and Telos) of the patient. Under these terms, a pharmacist is permitted to extend refills of a patient's medications for treating chronic conditions related to the transplanted organ, thereby removing delays in therapy and administrative barriers and potentially increasing medication adherence.

Therapeutic interchange

Here the prescriber authorizes the pharmacist, under a CPA, to substitute another drug in the same drug class.

Functions delegated to clinical transplant pharmacists by prescribers include

1.) Initiating, modifying or discontinuing medication therapy as listed below.
   a) refill authorizations (for medications listed in 'Covered Drugs')
   b) therapeutic interchange

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Best Practices in Transitions of Care – JMH Transplant

Patient Education

Medication Education Handout

Common Medicines after Kidney and Kidney/Pancreas Transplant

Congratulations on your new transplant! Understanding your medicaitons is a very important part of your transplant journey. Below is a list of common medications given after transplant. It includes how to take the medicines, including any specific food requirements and some common or severe side effects that may happen while on these medicines. Additional information may be found in your Pharmacy handouts and transplant journal. You will receive a complete list of medicines specific to you prior to leaving the hospital. This list will include old medications from before the transplant that you are to continue and any new medicaications the inpatient transplant team has prescribed. Medicines you are to stop taking will also be listed on your discharge medication list. New medications that you will continue after discharge may be sent to a specialty pharmacy, or other as deemed by your insurance.

3 general medication safety rules to remember:

- ✓ **Do not** start any **new medicines** (including over-the-counter) or take old medicines from **before the transplant** without talking with the transplant team
- ✓ **Avoid** taking nonsteroidal anti-inflammatory drugs (**NSAIDs**) eg., ibuprofen (Advil®), (Aleve®) as these could harm your kidneys.
- ✓ **Keep an updated list** of your medicines with you

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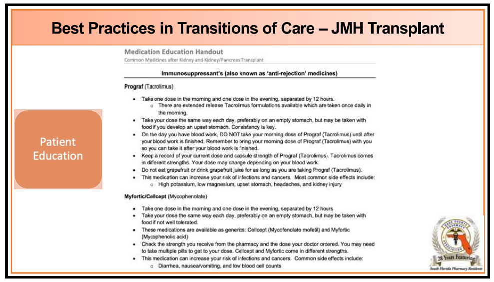
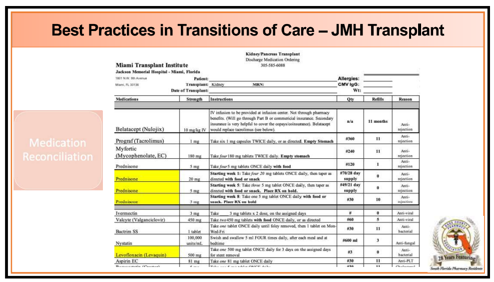

Best Practices in Transitions of Care – JMH Transplant
Patient Education
Medication Education Handout
Common Medicines after Kidney and Kidney/Pancreas Transplant
Immunosuppressant's (also known as 'anti-rejection' medicines)
Prograf (Tacrolimus)
Take one dose in the morning and one dose in the evening, separated by 12 hours.
There are extended release Tacrolimus formulations available which are taken once daily in the morning.
Take your dose the same way each day, preferably on an empty stomach, but may be taken with food if you develop an upset stomach. Consistency is key.
On the day you have blood work, DO NOT take your morning dose of Prograf (Tacrolimus) until after your blood work is finished. Remember to bring your morning dose of Prograf (Tacrolimus) with you so you can take it after your blood work is finished.
Keep a record of your current dose and capsule strength of Prograf (Tacrolimus). Tacrolimus comes in different strengths. Your dose may change depending on your blood work.
Do not eat grapefruit or drink grapefruit juice for as long as you are taking Prograf (Tacrolimus).
This medication can increase your risk of infections and cancers. Most common side effects include:
High potassium, low magnesium, upset stomach, headaches, and kidney injury
Myfortic/Cellcept (Mycophenolate)
Take one dose in the morning and one dose in the evening, separated by 12 hours
Take your dose the same way each day, preferably on an empty stomach, but may be taken with food if not well tolerated.
These medications are available as generics: Cellcept (Mycofenolate mofetil) and Myfortic (Mycophenolic acid)
Check the strength you receive from the pharmacy and the dose your doctor ordered. You may need to take multiple pills to get to your dose. Cellcept and Myfortic come in different strengths.
This medication can increase your risk of infections and cancers. Common side effects include:
Diarrhea, nausea/vomiting, and low blood cell counts

43


Best Practices in Transitions of Care – JMH Transplant
Medication Reconciliation
Kidney/Pancreas Transplant
Discharge Medication Ordering
305-585-6088
Miami Transplant Institute
Jackson Memorial Hospital - Miami, Florida
1801 N.W. 9th Avenue
Miami, FL 33136
Patient:
Transplant: Kidney MRN:
Date of Transplant:
Allergies:
CMV IgG:
Wt:
Medications | Strength | Instructions | Qty | Refills | Reason
Belatacept (Nulojix) | 10 mg/kg IV | IV infusion to be provided at infusion center. Not through pharmacy benefits. (Will go through Part B or commericial insurance. Secondary insurance is very helpful to cover the copays/coinsurance). Belatacept would replace tacrolimus (see below). | n/a | 11 months | Anti-rejection
Prograf (Tacrolimus) | 1 mg | Take six 1 mg capsules TWICE daily, or as directed. Empty Stomach | #360 | 11 | Anti-rejection
Myfortic (Mycophenolate, EC) | 180 mg | Take four 180 mg tablets TWICE daily. Empty stomach | #240 | 11 | Anti-rejection
Prednisone | 5 mg | Take four 5 mg tablets ONCE daily with food | #120 | 1 | Anti-rejection
Prednisone | 20 mg | Starting week 1: Take four 20 mg tablets ONCE daily, then taper as directed with food or snack | #70/28 day supply | 0 | Anti-rejection
Prednisone | 5 mg | Starting week 5: Take three 5 mg tablet ONCE daily, then taper as directed with food or snack. Place RX on hold. | #49/21 day supply | 0 | Anti-rejection
Prednisone | 5 mg | Starting week 8: Take one 5 mg tablet ONCE daily with food or snack. Place RX on hold | #30 | 10 | Anti-rejection
Ivermectin | 3 mg | Take ___ 3 mg tablets x 2 dose, on the assigned days | # | 0 | Anti-viral
Valcyte (Valganciclovir) | 450 mg | Take two 450 mg tablets with food ONCE daily, or as directed | #60 | 5 | Anti-viral
Bactrim SS | 1 tablet | Take one tablet ONCE daily until foley removed, then 1 tablet on Mon-Wed-Fri | #30 | 11 | Anti-bacterial
Nystatin | 100,000 units/mL | Swish and swallow 5 ml FOUR times daily, after each meal and at bedtime | #600 ml | 3 | Anti-fungal
Levofloxacin (Levaquin) | 500 mg | Take one 500 mg tablet ONCE daily for 3 days on the assigned days for stent removal | #3 | 0 | Anti-bacterial
Aspirin EC | 81 mg | Take one 81 mg tablet ONCE daily | #30 | 11 | Anti-PLT

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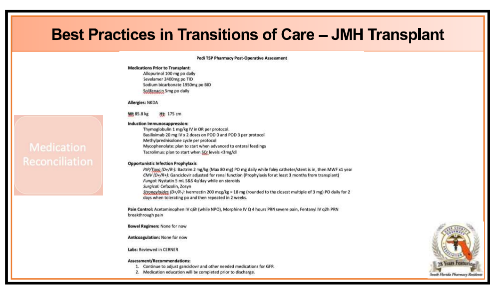
Best Practices in Transitions of Care – JMH Transplant
Medication Reconciliation
Pedi TSP Pharmacy Post-Operative Assessment
Medications Prior to Transplant:
Allopurinol 100 mg po daily
Sevelamer 2400mg po TID
Sodium bicarbonate 1950mg po BID
Solifenacin 5mg po daily
Allergies: NKDA
Wt 85.8 kg Ht: 175 cm
Induction Immunosuppression:
Thymoglobulin 1 mg/kg IV in OR per protocol.
Basiliximab 20 mg IV x 2 doses on POD 0 and POD 3 per protocol
Methylprednisolone cycle per protocol
Mycophenolate: plan to start when advanced to enteral feedings
Tacrolimus: plan to start when SCr levels <3mg/dl
Opportunistic Infection Prophylaxis
PJP/Toxo (D+/R-): Bactrim 2 mg/kg (Max 80 mg) PO mg daily while foley catheter/stent is in, then MWF x1 year
CMV (D+/R+): Ganciclovir adjusted for renal function (Prophylaxis for at least 3 months from transplant)
Fungal: Nystatin 5 mL S&S 4x/day while on steroids
Surgical: Cefazolin, Zosyn
Strongyloides (D+/R-): Ivermectin 200 mcg/kg = 18 mg (rounded to the closest multiple of 3 mg) PO daily for 2 days when tolerating po and then repeated in 2 weeks.
Pain Control: Acetaminophen IV q6h (while NPO), Morphine IV Q 4 hours PRN severe pain, Fentanyl IV q2h PRN breakthrough pain
Bowel Regimen: None for now
Anticoagulation: None for now
Labs: Reviewed in CERNER
Assessment/Recommendations:
1. Continue to adjust ganciclovir and other needed medications for GFR.
2. Medication education will be completed prior to discharge.

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Best Practices in Transitions of Care – JMH Transplant
Follow-up Care Coordination

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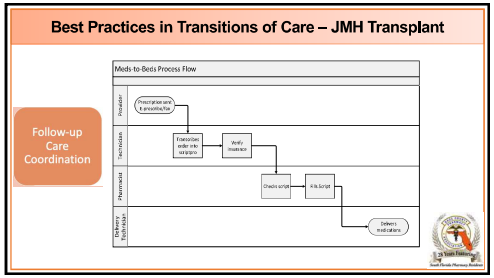
Best Practices in Transitions of Care – JMH Transplant
Meds-to-Beds Process Flow
Follow-up Care Coordination

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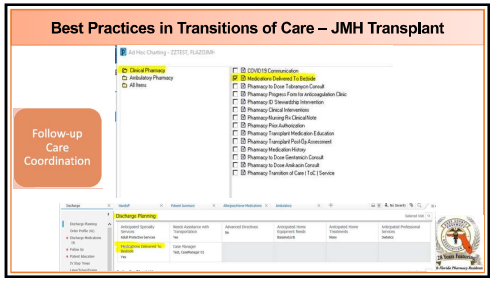
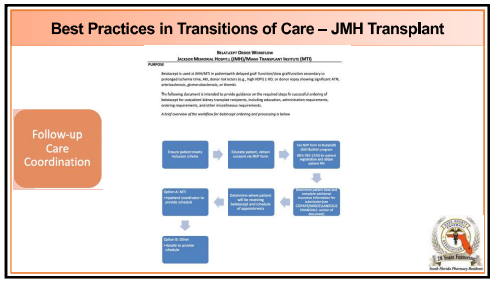
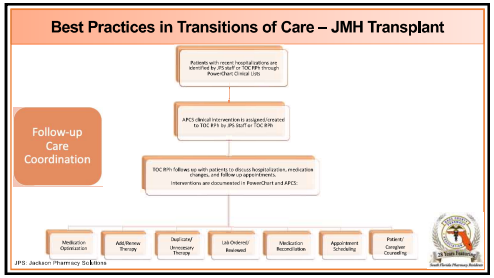

Best Practices in Transitions of Care – JMH Transplant
Follow-up Care Coordination

48


Best Practices in Transitions of Care – JMH Transplant
Follow-up Care Coordination

49


Best Practices in Transitions of Care – JMH Transplant
Follow-up Care Coordination
Patients with recent hospitalizations are identified by JPS staff or TOC RPh through PowerChart Clinical Lists
APCS clinical interventions is assigned/created to TOC RPh by JPS staff or TOC RPh
TOC RPh follows up with patients to discuss hospitalization, medication changes, and follow up appointments.
Interventions are documented in PowerChart and APCS.
Medication Optimization
Add/Renew Therapy
Dup/Unnecessary Therapy
Lab Ordered/ Reviewed
Medication Reconciliation
Appointment Scheduling
Patient/ Caregiver Counseling
JPS: Jackson Pharmacy Solutions

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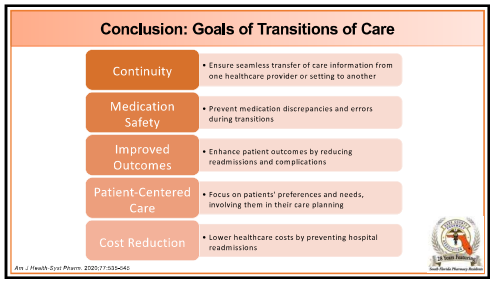
Conclusion: Goals of Transitions of Care
Continuity
• Ensure seamless transfer of care information from one healthcare provider or setting to another
Medication Safety
• Prevent medication discrepancies and errors during transitions
Improved Outcomes
• Enhance patient outcomes by reducing readmissions and complications
Patient-Centered Care
• Focus on patients' preferences and needs, involving them in their care planning
Cost Reduction
• Lower healthcare costs by preventing hospital readmissions
Am J Health Syst Pharm. 2020;77:535–540

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Knowledge Check

What are the key components of a medication reconciliation process in healthcare settings?

a) Diagnosis, treatment plans, and follow-up care
b) Medication list verification, patient counseling, and cultural competence
c) Standardized handoff protocols, electronic health records, and quality improvement initiatives
d) Medication list verification, dosage adjustment, and communication of changes

52

Knowledge Check

What are the key components of a medication reconciliation process in healthcare settings?

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53

References

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- Virapongse A, Misky GJ. Self-Identified Social Determinants of Health during Transitions of Care in the Medically Underserved: a Narrative Review. *J Gen Intern Med.* 2018 Nov;33(11):1959-1967
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Transitioning Through
the Healthcare System
Mireille Mitchell, PharmD
Jackson Memorial Hospital
Miami, FL
Saturday, January 20th 2023
28 Years Featuring
South Florida Pharmacy Residents

55

Drug Selection in the Inpatient Management of Alcohol Withdrawal

Dr. Christian Grillo, Pharm.D.
NSU Pharmacy PGY-1 Community-Based Pharmacy Practice
3200 S University Drive
Davie, FL, 33328
January 20th, 2024

1

Objectives

1. Provide an overview of the risk factors and pathophysiology of alcohol dependence, alcohol addiction, and alcohol withdrawal

2. Elaborate on current treatment guidelines for drug selection in patients undergoing alcohol withdrawal in different patient populations

3. Discuss prophylaxis, alternative agents in contraindicated patients, and patient education

2

Overview of Alcohol Use Disorder, Dependence, and Withdrawal

3

The Scope of Alcohol Dependence

- ICD-10 criteria defines alcohol use disorder (AUD) as three of the following:
  - Tolerance, withdrawal, difficulties controlling drinking, neglect of activities, time spent drinking, craving, and drinking despite physical/psychological issues
- A 2022 survey showcased that over 29.5 million people had AUD in the past year
- A third of U.S. adults experience alcohol use disorders within their lifetime

4

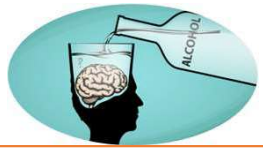
Risk Factors for Alcohol Dependence

- The DSM-5 denotes the following risk factors for AUD:
  - Family history of alcoholism, male sex, impulsivity, absence of alcohol-related skin flush, psychiatric illness, and low response to alcohol
- Those with higher frequency of different risk factors (male sex + alcoholic relatives + impulsivity) have the highest rate of binging

5

Neurobiology/Pathophysiology of Alcohol Addiction

- Ethanol interactions with dopamine function within the mesolimbic reward pathway
- The reward effects incentivize craving and relapse



6

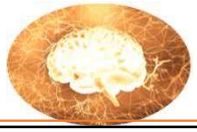
What Is Alcohol Withdrawal?

- Physical reaction after an abrupt reduction or stop of alcohol consumption AFTER prolonged drinking
- Diagnosis based on the DSM-5 requires:
  - Cessation of alcohol use that has been heavy or prolonged
  - And 2 of the following: autonomic hyperactivity, insomnia, nausea, transient hallucinations, psychomotor agitation, anxiety, generalized tonic-clonic seizures
- Delirium tremens

7

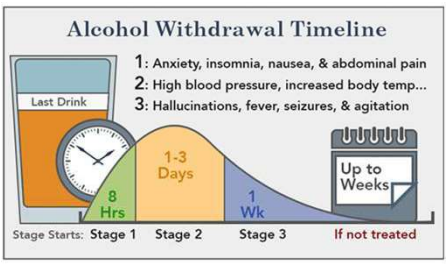
Neurobiology/Pathophysiology of Alcohol Withdrawal

- Brain adaptation due to alcohol enhance the effects of GABA
- Upon abrupt cessation of alcohol, reduced GABAergic inhibition contributes to anxiety, tremors, and seizures
- Conversely, increased glutamatergic activity leads to irritability and hallucinations



8

Withdrawal Symptom Timeline



9

Current Treatment Guidelines for Alcohol Withdrawal

10

Supportive Care

- Adherence to facility guidelines is imperative
  - Restraints for delirium tremens?
  - Lighting and noise
- Ensure volume defects are properly managed
- Nutritional support patent to patients chronic, heavy alcohol use

11

Supportive Care and Management

- Management of the following metabolic derangements:
  1. Hypovolemia
  2. Metabolic acidosis
  3. Hypokalemia
  4. Hypomagnesemia
  5. Hypophosphatemia

12

Supportive Care and Management (Cont.)

- Management of the following metabolic derangements:
  1. Infusion of NS or lactated ringers
  2. Fluids, sodium bicarbonate, etc.
  3. Potassium replacement
  4. Magnesium replacement
  5. Phosphate replacement

13

Pharmacotherapy for Alcohol Withdrawal

- Symptom specific
- Benzodiazepines (BDZs): prevent withdrawal symptoms from worsening, along with psychomotor agitation
  - Ex: diazepam, lorazepam, chlordiazepoxide
- Long-acting BZDs are preferred due to smoother clinical course

14

Symptom-Triggered Approach

- Recommended for most patients; treatment given when patient has symptoms
- Assessment, such as CIWA-Ar, based with frequent evaluations
- If score is elevated, additional medication is provided

15

Symptom-Triggered Approach (Cont.)

- Elevated score dosing:
  - Acute withdrawal: diazepam 5-10mg IV, or lorazepam 2-4mg IV (severe liver disease), or chlordiazepoxide 25-100mg PO, or oxazepam 10-30mg PO (severe liver disease)
- For truly severe patients, sedation scale (RASS) is used

16

Front-Loading Approach

- Higher initial doses to prevent/achieve rapid control of symptoms
- Dosing:
  - Diazepam 5-10mg IV every 5-10 minutes or lorazepam 2-4mg IV every 15-20 minutes
    - Doses may exceed >500mg diazepam initially and >2000mg diazepam over the following 48 hours

17

Refractory Delirium Tremens

- If symptoms of severe withdrawal are not controlled after IV administration of >50mg of diazepam or 10mg of lorazepam during the first hour of treatment
- If symptoms of severe withdrawal are not controlled after IV administration of 200mg of diazepam or 40mg of lorazepam during the initial three to four hours of treatment

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Refractory Delirium Tremens (Cont.)

- Alternative treatment therapy:
  - Barbiturates: 130 to 260 mg IV, repeated every 15 to 20 minutes, until symptoms are controlled, not exceeding cumulative doses of 15mg/kg in the first 24 hours
  - Propofol: Case series
  - Dexmedetomidine: preliminary evidence

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Medications to Avoid

- May mask hemodynamic signs of withdrawal
  - Ethanol: difficult to titrate, adverse events, inferior to BZDs
  - Antipsychotics: may lower seizure threshold
    - Only appropriate if decompensated thought disorder is present

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Medications to Avoid (Cont.)

  - Anticonvulsants: Seizures are self-limiting (no treatment required)
    - Carbamazepine, gabapentin, and VPA can be used for MILD outpatient withdrawal
  - Centrally acting alpha-2-agonists: Not recommended for severe alcohol withdrawal
  - Beta blockers: Do not prevent seizures or DT
  - Baclofen: Unproven to control symptoms

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Alternate Agents in the Critically Ill, Patient Education

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Symptomatic Care Alternate Agents

- Chlordiazepoxide 25-100mg every 6 hours for one day followed by 25-50mg every 6 hours for an additional two days
- Oxazepam 10-30mg (similar regimen if severe liver disease is present)
- Propofol (sedation if needed)
- Baclofen is NOT recommended
- Dexmedetomidine is NOT recommended
- If withdrawal appears, BZD IV standard treatment

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Asymptomatic Care Alternate Agents

- Chlordiazepoxide 25-50mg every hour as needed when a CIWA-Ar score of 8 or higher
- Oxazepam 10mg every hour as needed when a CIWA-Ar score of 8 or higher
- Baclofen is NOT recommended
- If withdrawal appears, BZD IV standard treatment

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Critical Illness or Mechanical Ventilation

- Mechanical ventilation at risk for severe withdrawal:
  - IV sedation with benzodiazepines (GABA-A allosteric modulator) or propofol (GABA agonist)
  - Dexmedetomidine not recommended due to lack of evidence
  - If withdrawal manifested, standard IV benzodiazepine treatment initiated

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Critical Illness or Mechanical Ventilation

- Mechanical ventilation without sedation at risk:
  - Standard prophylaxis with oral chlordiazepoxide or oxazepam
  - Potential risk of inducing ICU delirium should be weighed

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Patient Education

- Recognize symptoms
- Seek medical attention and treatment
- Antabuse? Acamprosate?
- Support groups

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GLP-1 Agonists?!

- Semaglutide and cousins for addiction?
- Patients on Ozempic also stop smoking, gambling, and drinking?
- Trials

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Questions

1. Anticonvulsants are first-line drugs of choice for the treatment of moderate-to-severe alcohol withdrawal symptoms.

a. True

b. False

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Questions

2. Dosing of benzodiazepines used for alcohol withdrawal symptoms is done using BMI.

a. True

b. False

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Questions

3. Supportive care includes infusions of vitamins, frequent vital sign assessments, and environmental controls.

a. True

b. False

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Summary

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Conclusion

- Alcohol use disorder prevalence and diagnosis
- AUD risk factors
- AUD Pathophysiology
- Alcohol withdrawal symptoms
- Alcohol withdrawal pathophysiology

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Conclusion (Cont).

- Initial treatment and stabilization
- Delirium tremens and refractory delirium tremens management
- Critical care patients
- Supportive care

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Thank You 

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Any Questions?
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