

Medication Errors and Continuous Quality Improvement



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Disclosure

- Authors have no financial relationships to disclose with regards to this presentation



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Objectives

- Define medication errors and describe patient safety strategies that can decrease medication errors and improve the quality of pharmacy health care delivery
- Given a scenario, be able to categorize and/or report medication errors utilizing the National Coordination Council for Medication Error Reporting and Prevention (NCCMERP) scale
- Discuss basic error mitigation strategies utilized to reduce errors and improve patient safety
- Review methods to evaluate healthcare organizations to improve processes and prevent medication errors
- Explain how root cause analysis and failure mode & effects analysis can be utilized to determine the underlying cause of medication errors
- Identify strategies, the role of technology, and the importance of a non-punitive approach for handling medication errors after errors have occurred
- Use the CQI process to encourage a culture of safety and of providing feedback and assistance to effectively minimize patient risk
- Florida law stipulates requirements for a Continuous Quality Improvement plan: Outline steps required for a successful CQI Plan incorporating the State's requirements



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Objectives - Part I

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What is a Medication Error?



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Types of Medication Errors

1. Prescribing errors*	• Any error while selecting, writing, or transcribing a medication order
2. Omission errors	• Prescription medication is ordered or indicated but withheld
3. Wrong time error	• Medication administration time deviates from prescription order
4. Unauthorized drug errors	• Unlawful dispensation or administration of a drug
5. Improper dosage errors	• Drug administered at unintended or non-recommended dose, frequency, or duration
6. Wrong dosage form errors	• Dispensing/administering a drug in the wrong form (IV vs PO) or formulation (ER vs IR)

*Can lead to dispensing-related prescribing errors upon pharmacist verification



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Medication Errors: Annual Statistics



Medication errors account for:

- 5% - 41.3% of all hospital admissions
- 22% of all readmissions

Prevalence of medication errors:

- 30% higher when taking > 5 drugs
- 38% higher if age > 75 years

Dosing errors = most common type (21%):

- 41% of all fatal medication errors



Yoon KJ, Vailoff A, Yoon A, Schuster T. Medication dispensing errors and prevention. September, 2008. <https://www.nationalacademies.org/handbook/medication-dispensing-errors-and-prevention>

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In the News:

Medication mix-up blamed for death of a patient at Lexington hospital

As a nurse faces prison for a deadly error, her colleagues worry: Could I be next?

<https://www.wtix.com/news/lexington-hospital-medication-mix-up-blamed-for-death-of-a-patient-at-lexington-hospital>

MARCH 23, 2022 - 9:00 AM ET FROM: KFF Health News

Medication dispensing error nearly cost a woman her life. I-Team discovers it's not rare

By Lisa Fletcher | Thu, February 9th, 2023 at 5:58 PM Updated Tue, February 14th, 2023 at 11:55 AM

Lawsuit alleges medical mistake at AZ imaging center caused life-threatening overdose

Records show patient was accidentally given a sedative during MRI scan

<https://www.azcentral.com/story/news/health/2023/02/09/lawsuit-alleges-medical-mistake-at-az-imaging-center-caused-life-threatening-overdose/>



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Pharmacy Medication Errors in the News:

Mistakes at work happen. For pharmacists, it can end their career

By Nicole Gooding, CNN Updated 10:11 AM EST, Sun, December 27, 2020

<https://www.cnn.com/2020/12/27/health/pharmacy-errors/index.html>

Workers at chain pharmacies across the US have told CNN that increased demand for prescriptions, shots and other services without sufficient staff to fulfill those orders has made it nearly impossible for the workers to do their jobs properly and has created potentially unsafe conditions for customers.

Prescription for disaster: America's broken pharmacy system in revolt over burnout and errors

By Kaitlin Lee, CNN Updated 11:11 AM EST, Sun, December 27, 2020

<https://www.cnn.com/2020/12/27/health/pharmacy-errors/index.html>



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Pharmacy Medication Errors in the News:



https://www.youtube.com/watch?v=qgU_7d384



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Quality-Related Events

Quality-Related Event (QRE): Inappropriate dispensation or administration of a prescribed medication

Variations from the prescriber's order

- Incorrect drug
- Incorrect drug strength
- Incorrect dosage form
- Incorrect patient
- Incorrect or inadequate packaging, labeling, or directions

Failure to identify and manage

- Drug over- or under-utilization
- Therapeutic duplication
- Drug-disease, drug-drug, or drug-allergy interactions
- Incorrect dose or duration
- Clinical abuse/misuse



Florida Board of Pharmacy, 2015. Florida Administrative Code, 2015.

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Strategies to Minimize Errors

Minimize clutter

- Use basket system to separate each patient's prescriptions
- Clear away stock bottles from completed prescriptions
- Take phone calls in a quiet, distraction-free area



Confirm accuracy of verbal, telephone, & e-prescriptions

- **Write** and **repeat** telephone/verbal orders
 - Per ISMP, **spell** drug names during read back
- Review all details of e-prescriptions



Center for Medication Safety, 2015. ISMP, 2015. ISMP, Medication Safety to Reduce Medication Errors. Associated with Verbal Medication Orders and Prescriptions, 2015.

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Strategies to Minimize Errors

High-alert medications

- Greater risk for significant patient harm when errors occur
 - Anticoagulants, insulins, opioids, sedatives, chemotherapeutic agents, parenteral nutrition, neuromuscular blockers

Best practices for managing high-alert medications

- Standardize ordering, storage, preparation, and administration processes
- Use auxiliary labels (High-Alert; Hazardous; Pediatric Use Only)
- Employ clinical decision support and automated alerts
- Use redundancies like automated or independent double checks



Chen M, et al. Medication Errors, 2nd Edition. © 2017.

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Strategies to Minimize Errors

Implement technology

- **Computerized Provider Order Entry (CPOE)**
 - Standardizes orders and makes them legible
 - Speeds up ordering process and improves workflow
 - Integrated with electronic health records (EHRs)
- **Clinical Decision Support Systems (CDSS)**
 - Tailored recommendations, alerts, & guidelines at point of care
 - Often integrated with CPOE systems



Chen M, Vallbock A, Soria A, Schickel T. Medication dispensing errors and prevention. 10/20/11. 2011.

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Strategies to Minimize Errors

Involve the patient and/or caregivers

- Education and counseling
 - Teach-back
- Medication reconciliation
- Use of technology
 - Medication reminder apps
 - Patient portals
- Adverse event reporting



Chen M, Vallbock A, Soria A, Schickel T. Medication dispensing errors and prevention. 10/20/11. 2011.

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Strategies to Minimize Errors

Continuous quality improvement (CQI)

- An **ongoing, systematic, data-driven** approach to improve processes, systems, and outcomes
- **Steps for successful CQI :**
 1. Define problem
 2. Set SMART goal
 3. Analyze current process
 4. Develop solutions
 5. Implement a plan
 6. Measure outcomes
 7. Refine process
 8. Apply solution on larger scale



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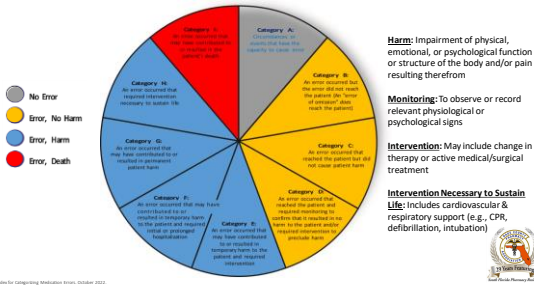
National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP)

- Independent organization dedicated to improving medication safety
- Composed of 27 national organizations including healthcare professionals, regulatory agencies, and consumer groups
- **Mission:** Maximize safe use of medications and increase awareness of medication errors



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NCC MERP Index for Categorizing Medication Errors



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NCC MERP Categories Explained

Category A
No Error,
No Harm

Definition: An incident with potential to cause error, but no error has occurred.

Example: A pharmacy technician places **bupropion** tablets in the **bupirone** bin while restocking. A pharmacist notices the error by chance and corrects it. No patients were affected.



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Failure Points

- **Human factors**
 - LASA drug confusion (bupropion vs buspirone)
 - Stress or multitasking
- **Environmental factors**
 - Misreading the bin label or medication label due to dim lighting
- **System/technology factors**
 - Lack of technology for barcode scanning during stocking
 - No audits of storage areas



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Categories Explained

Category B
Error,
No Harm

Definition: Error occurred but did not reach the patient.

Example: While talking on the phone, a pharmacist receives an order for metoprolol **tartrate** 25 mg but mistakenly selects **metoprolol succinate** during verification. The error is caught during a final check.



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Failure Points

- **Human factors leading to verification error**
 - LASA drug confusion
 - Pharmacist had a mental slip
 - Pharmacist was distracted due to multitasking
- **System/technology factors**
 - CPOE system did not automatically assign the correct product
 - Availability of both metoprolol forms in the product selection screen
 - Lack of CDS alert when selecting incorrect drug form



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Categories Explained

Category C
Error
No Harm

Definition: Error reached the patient but did not cause harm.

Example: A patient delivered a hand-written prescription for **losartan 25 mg** but received **50 mg** tablets. Patient realized error after three days of taking the wrong dose. No adverse effects occurred.



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Failure Points

- **Prescribing error**
 - Prescription was illegible or incorrectly written
- **Dispensing error**
 - Pharmacy staff did not clarify the prescription despite poor handwriting
 - Pharmacist failed to review patient's medication history
- **Environmental factor**
 - Pharmacy counter was cluttered, wrong losartan stock bottle was selected
- **System factor**
 - Pharmacist unable to confirm pill appearance against a reference image



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Categories Explained

Category D
Error, No Harm
Monitoring Required
(± intervention to prevent harm)

Definition: Error reaches patient and requires monitoring; may require intervention to prevent harm

Example: A provider calls the pharmacy to verbally order insulin. Patient receives **glargine** but should have received **lispro**—leading to blood sugar monitoring for potential hypoglycemia.



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Failure Points

- **Prescribing error**
 - Provider mistakenly said Lantus instead of lispro
- **Poor communication**
 - Pharmacist failed to confirm the order via read-back
- **System factor**
 - Storage of both insulin vials in close proximity
- **Administration error**
 - Failure to perform a double-check of high-risk medications



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Categories Explained

Category E
Error, Harm
Intervention Required

Definition: Results in temporary harm to the patient and requires intervention.

Example: An inpatient is overdosed on insulin **lispro**, leading to a hypoglycemic episode with altered mental status. The episode resolves after glucose administration.



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Failure Points

- **Prescribing error**
 - Dose miscalculation (e.g., incorrect sliding scale or weight-based)
 - Lack of consideration for patient-specific factors (e.g., renal function)
- **Monitoring errors**
 - Failure to adjust insulin dose based on glucose readings
- **Wrong drug preparation error**
 - Nurse draws more insulin from the vial than what was ordered
- **Administration error**
 - Administered without confirming meal timing or glucose level
 - Failure to perform a double-check of high-risk medications



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Categories Explained

Category F
Error, Harm
Hospitalization

Definition: Results in temporary harm to the patient and requires initial or prolonged hospitalization.

Example: Digoxin is prescribed and dispensed without considering a patient's impaired renal function, leading to digoxin toxicity and hospitalization for cardiac monitoring and management.



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Failure Points

- **Prescribing error**
 - Wrong dose ordered, recent labs may not have been reviewed
 - Knowledge gap, may not be fully aware of digoxin's narrow therapeutic index and its risks in patients with impaired renal function
 - Dispensing-related prescribing error if above bullets apply to pharmacist
- **Poor communication**
 - Pharmacist or prescriber did not counsel on toxic symptoms and risk factors like impaired renal function
- **Monitoring error**
 - Insufficient monitoring of serum digoxin levels and renal function during treatment



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Categories Explained

Category G
Error
Permanent Harm

Definition: Results in permanent harm to the patient.

Example: Upon transfer from a smaller hospital, a patient receives a high dose of vancomycin, causing permanent hearing loss due to ototoxicity.



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Failure Points

- **Prescribing error**
 - Dose miscalculation by provider; used pounds instead of kilograms
- **Dispensing error**
 - Dose miscalculation by pharmacist; did not confirm weight with nurse
- **Communication error**
 - Patient received vancomycin loading dose at previous facility; information was lost in transitions of care
 - Pharmacist unaware that patient was a transfer due to a lack of documentation



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Categories Explained

Category H
Error, Harm
Life-sustaining Intervention

Definition: Results in harm to the patient and requires intervention to sustain life.

Example: A patient is given potassium chloride IV push instead of diluted potassium infusion, resulting in cardiac arrest and requiring resuscitation.



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Failure Points

- **System factors leading to dispensing errors**
 - Lack of training or protocols regarding high-risk medications
 - Lack of CDS alerts when prescription was entered by provider, and again when verified by pharmacist
- **Communication errors**
 - Nurse ordered drug on behalf of provider without clear instructions; nurse failed to seek clarification and assumed IV push was safe
- **Administration error**
 - High-risk medication, failure to perform double-check



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Categories Explained

Category I
Error
Patient Death

Definition: Error results in patient death.

Example: A patient with a known severe allergy to penicillin is mistakenly administered piperacillin-tazobactam. Patient develops an anaphylactic reaction causing respiratory failure and death.



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Failure Points

- **Communication error due to poor documentation**
 - Patient stated the penicillin allergy, but it was not documented in EHR
 - Allergy was documented incorrectly (e.g., listed as a mild reaction)
 - Language barrier led to an incomplete patient history
- **System factors**
 - Inadequate medication reconciliation processes
 - CPOE system and/or verification system has excessive alerts, leading to alert fatigue among providers, pharmacists, and nurses
- **Patient-related factors**
 - Unable to provide medication and allergy history
 - Altered mental state, substance abuse, etc.



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Test Question #1

A nurse administers a dose of insulin to a patient with diabetes. However, the dose given is slightly higher than prescribed. The patient experiences no adverse effects because the error is caught early, and the patient's blood sugar levels are closely monitored and managed. According to the NCC MERP Index for Categorizing Medication Errors, which category does this error fall into?

- a. Category A
- b. Category B
- c. Category C
- d. Category D



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Test Question #1

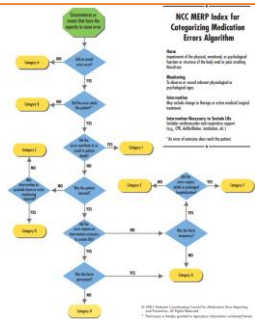
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- a. Category A
- b. Category B
- c. Category C
- d. **Category D**



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NCC MERP Index for Categorizing Medication Errors Algorithm



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Safe Medication Practices

- Institute for Safe Medication Practices (ISMP) is an independent, non-profit organization devoted to medication error prevention
- A cornerstone of ISMP on voluntary consumer or practitioner medication error reporting programs:
 - ISMP National Medication Errors Reporting Program (MERP)
 - ISMP National Vaccine Errors Reporting Program (VERP)
 - ISMP National Consumer Medication Errors Reporting Program (C-MERP)
- Medication errors can occur at any point of the medication use system
- Safe medication practices are crucial to ensure patient safety & error reduction



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Safe Medication Practices



ISMP guidelines on preventing medication errors in hospitals, January 2008



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Root Cause Analysis (RCA)

A **retrospective** investigation of an event (or close call) that has already occurred to uncover causes of the incident, failure or problem

Root

- Define the problem & areas of improvement

Cause

- Locate the "root" cause
- Use **Five Whys Strategy** or **Fishbone Diagram** to explore the cause-and-effect relationship underlying a particular problem

Analysis

- Find corrective & preventative solutions
- Create actionable strategies to implement solutions
- Monitor solution & analyze if it helps improve

NSRP guidelines on preventing medication errors in hospitals, January 2016

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RCA: Fishbone Diagram

NSRP guidelines on preventing medication errors in hospitals, January 2016

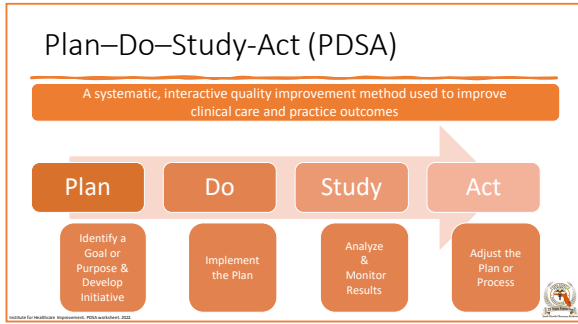
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Characteristics of a Successful RCA

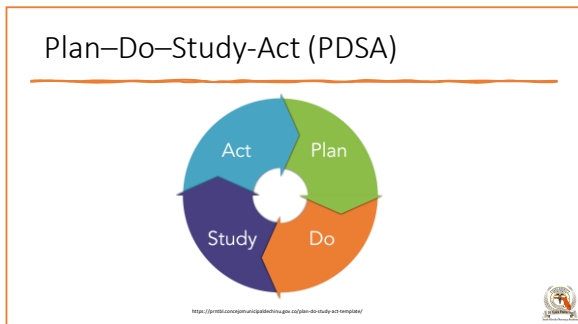
- Uses a thorough and systematic approach
 - Five Whys
 - Fishbone Diagram
- Focuses on system and process changes
 - Not on individual blame or performance
- Seeks actionable and preventative solutions
- Monitors outcomes continuously
- Promotes culture of safety and continuous improvement
 - Encourages **non-punitive** error reporting

NSRP guidelines on preventing medication errors in hospitals, January 2016

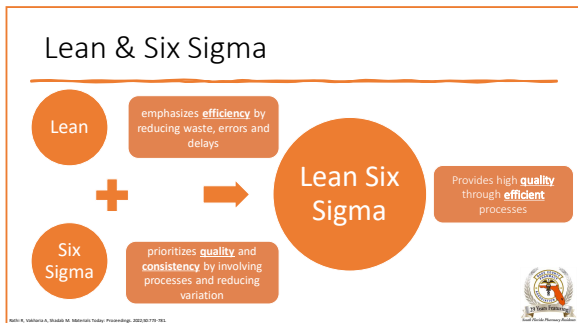
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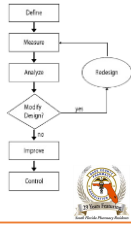
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DMAIC – 5 Phases of Six Sigma

- **DMAIC** is a problem-solving approach that drives Six Sigma. It is a **data-driven strategy to improve defects** with unknown causes.
 - Define the problem, current processes, and goal
 - Measure performance at baseline by collecting data
 - Analyze data to identify root cause
 - Improve process by developing & implementing solutions
 - Control and sustain improvements



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Test Question #2

Examples of Continuous Quality Improvement (CQI) programs include Lean and Six Sigma. Six Sigma focuses on reducing defects by using the DMAIC process. What does DMAIC stand for?

- Determine, Measure, Assess, Improve, Check
- Define, Measure, Analyze, Improve, Control
- Determine, Measure, Analyze, Improve, Control
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- Define, Measure, Assess, Improve, Check




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ISMP Hierarchy of Effectiveness of Risk-Reduction Strategies

Rank Order of Error Reduction Strategies:


- Forcing Functions
- Barriers & Fail Safes
- Automation & Computerization
- Standardization & Protocols
- Redundancies
- Warnings, Alerts, Reminders, & Checklists
- Rules & Policies
- Educational Programs
- Suggestions to "be more careful"



High Leverage
 (focus on system reliability)

Medium Leverage
 (focus on system, human vigilance and memory)

Low Leverage
 (focus on human reliability)



ISMP Medication Safety Alert: High-Risk Medication, March 11, 2025

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Safety Strategies: High Leverage

Forcing functions

- Smart infusion pumps
- System requires verification of patient weight when ordering high-risk drug

Barriers & fail Safes

- Automated dispensing cabinet (ADC) with restricted access (**barrier**) and ability to automatically log off after a certain period (**fail-safe**)

Automation & computerization

- ADC par levels that automatically prompt pharmacy to stock medications
- Using CPOE prescribing systems

ISMP Medication Safety Alert: High-Risk Medication, March 11, 2025

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Safety Strategies: Medium Leverage

Standardization & protocols

- Order Sets
- Protocols
 - IV to PO
 - Renal dose adjustment
 - Therapeutic interchange

Redundancies

- Independent double checks for high-risk medications
- BCMA plus smart IV pump to verify medication administration

Warnings, alerts, reminders, & checklists

- CDS alerts for allergies, interactions, or duplicate therapies

ISMP Medication Safety Alert: High-Risk Medication, March 11, 2025

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Safety Strategies: Low Leverage

Rules & policies

- High-Risk/High-Alert Medication Policy

Educational programs

- New employee and annual training
- Medication safety training
- Continuing education

Suggestions to be "more careful"

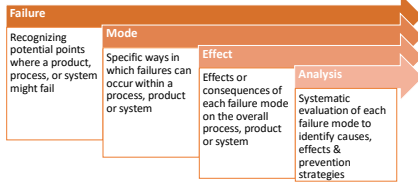
- Recommendations to improve



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Failure Mode and Effect Analysis (FMEA)

A **prospective** method for identifying potential failures that could occur in a product, process, or system, and their causes and anticipated effects



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FMEA Explained

- **"Failure Mode"** is the way (or mode) in which something might fail
 - Potential failures are prioritized according to:
 - **Severity**: Seriousness of the consequences
 - **Occurrence**: Frequency in which they can occur
 - **Detection**: How easily they can be detected
- **"Effects Analysis"** focuses on analyzing the impact of failures



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When to Use FMEA

- Designing or redesigning a module*
- Applying an existing module to a new environment
- Before developing control plans for a new or modified module
- Planning improvement goals for an existing module
- Investigating existing failures of a module
- Periodically while a module active

*Module = product, process, or system



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Steps to Conduct FMEA

- ✓ **Step 1.** Identify a high-risk pharmacy process
 - Map the process (process flowchart)
- ✓ **Step 2.** Assemble multidisciplinary team
- ✓ **Step 3.** Identify failure modes—causes & effects
- ✓ **Step 4.** Rate each failure mode based on:
 - Severity (1-10)
 - Occurrence (1-10)
 - Detection (1-10)
- ✓ **Step 5.** Calculate risk priority number (RPN)
 - $RPN = S \times O \times D$
- ✓ **Step 6.** Rank RPNs → focus on high RPN first
- ✓ **Step 7.** Develop & implement solution
- ✓ **Step 8.** Monitor & reassess



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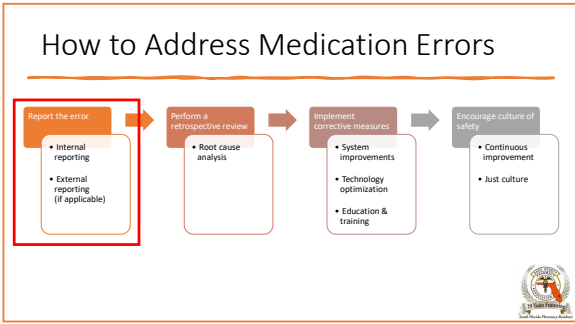
The Leapfrog Group



- **Nonprofit** organization dedicated to improving healthcare quality and safety in the United States
- Assigns letter grades to hospitals based on their performance in preventing **medication errors**, injuries, accidents and infections
- Conduct the Leapfrog Hospital Survey to evaluate hospitals on **safety**, quality and resource use



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Report the Error

Internal Reporting

- ☐ Institution's incident reporting system
- ☐ Be detailed and objective:
 - What led to the error?
 - Consequences

External Reporting

- ☐ Depending on the type/severity of error, may report to:
 - FDA (MedWatch)
 - FDA/CDC (VAERS)
 - ISMP (MERP, VERP, C-MERP)

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Where to Report Medication Errors

Report Medication Errors

ISMP Medication Error Reporting Program (MERP)
 1-800-224-7787
 1201 Third Street, NE, Atlanta, GA 30309
 1-800-PCA-1088

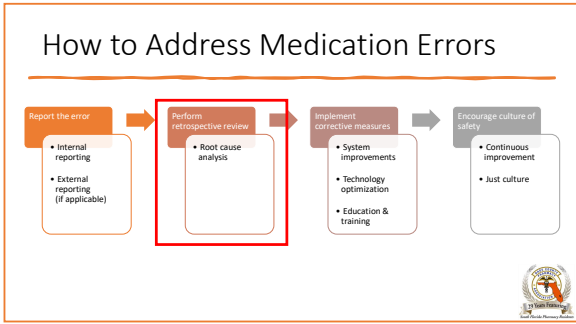
1 ISMP Report An Error

Medication errors and adverse events affect millions and billions of U.S. patients each year. Reporting medication errors and adverse events promptly can help prevent future errors and improve patient safety. Reporting errors and adverse events can also help improve the quality of patient care and the safety of the medication supply.

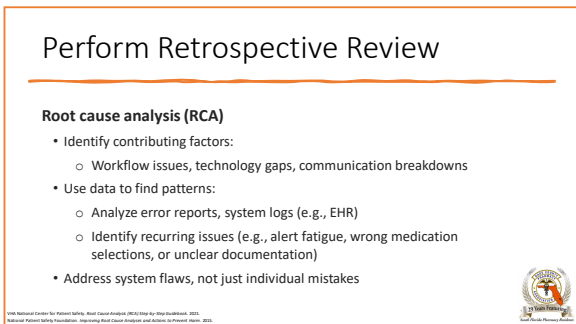
2 MedWatch Online Voluntary Reporting Form

MedWatch is a voluntary reporting system for reporting adverse events, medication errors, and quality concerns. It is a free, confidential, and secure online reporting system. Reporting errors and adverse events can help prevent future errors and improve patient safety. Reporting errors and adverse events can also help improve the quality of patient care and the safety of the medication supply.

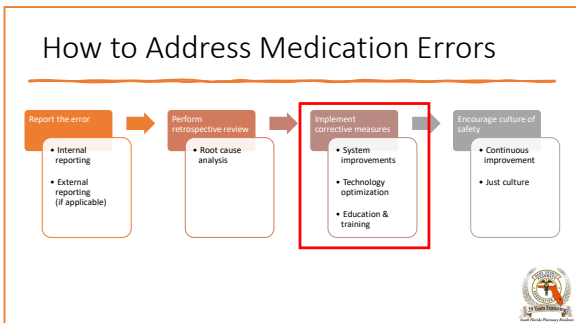
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Implement Corrective Measures

- **System improvements (High Leverage, Medium Leverage)**
 - Based on the RCA, develop and implement solutions to prevent similar errors, such as revising protocols, improving alert systems, or adding redundancies like double checks
- **Technology optimization (High Leverage)**
 - Implement medication management technologies that support automation and interoperability
 - Modify decision support systems, clinical alerts, or EHR configurations to prevent medication errors
- **Education and training (Low Leverage)**
 - Reinforce education for staff about the correct procedures, potential error-prone areas, and safety precautions



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Technology Optimization

- Pharmacy Management Software
- Medication Dispensing Devices
- Workflow Management Software
- Barcode Technology
- IV Smart Pump Interoperability
- Pharmacy Clinical Surveillance Tools



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Pharmacy Management Software


	Hospital	Retail	
 	<ul style="list-style-type: none"> • Cerner, Epic • Advantages: <ul style="list-style-type: none"> ○ EHR system ○ CPOE ○ CDSS <ul style="list-style-type: none"> ▪ Order sets ▪ Alerts 	<ul style="list-style-type: none"> • Enterprise, Newleaf • Advantages: <ul style="list-style-type: none"> ○ E-prescriptions ○ Organized and efficient workflow ○ Drug utilization review alerts 	 




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Medication Dispensing Devices

Automated Dispensing Cabinets	Medication-filling Robot
<ul style="list-style-type: none"> Pyxis, Omnicell <ul style="list-style-type: none"> Hospitals Advantages: <ul style="list-style-type: none"> Drug dispensing near point of care Dispenses right drug for right patient Automates drug tracking 	<ul style="list-style-type: none"> Yuyama, Kirbi Lester <ul style="list-style-type: none"> Community pharmacies Advantages: <ul style="list-style-type: none"> Automates dispensing Reduces human error Frees staff time to focus on other activities



Pyxis




Kirbi Lester


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Workflow Management Software

IV Verification/Tracking Software	Prescription Verification Software
<ul style="list-style-type: none"> DoseEdge, Medkeeper <ul style="list-style-type: none"> Used in hospitals Advantages: <ul style="list-style-type: none"> Comprehensive evaluation of the accuracy of a dose Remote compounding verification 	<ul style="list-style-type: none"> Parata <ul style="list-style-type: none"> Used in community pharmacies Advantages: <ul style="list-style-type: none"> High-speed, high-accuracy visual inspection system Safe and efficient verification



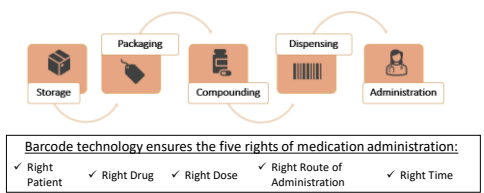
DoseEdge



Parata

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Barcode Technology



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IV Smart Pump Interoperability

2020 - 2021 ISMP Targeted Medication Safety Best Practices for Hospitals

- ❑ All IV medications should be administered through programmable IV smart pumps using dose error reduction software (DERS)

Most hospitals and health systems are compliant

- ❑ Institutions should implement smart pumps with bidirectional interoperability* to EHRs
 - *Two-way, real-time, continuous communication between smart pump & EHR which includes:
 - ✓ Auto-programming: EHR with ability to transfer medication orders & infusion parameters directly to smart pump
 - ✓ Auto-documentation: Smart pump with ability to transfer infusion-related data to EHR

Implementation lagging in many hospitals and health systems



2020-2021 ISMP Targeted Medication Safety Best Practices for Hospitals, 2020



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IV Smart Pump Interoperability



Center for Outpatient Patient Safety Through RRF and Infusion Integration (COPSI). YouTube. Published November 9, 2014. Accessed November 10, 2014. <https://www.youtube.com/watch?v=U0T0gq8e>



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Pharmacy Clinical Surveillance Tools

	Clinical Action	Impact	
Examples: • Senti7 • Vigilanz Common clinical uses	IV to oral conversion Alerts pharmacist to a patient on IV medication who is a candidate for conversion to oral medication	• Reduced exposure to nosocomial pathogens via intravenous access site • Reduced risk of phlebitis • Increased patient mobility • Improved patient comfort and convenience • Potential decreased length of stay • Lowered direct and indirect costs	Impact on patient care
	Renal dose adjustment Alerts pharmacist to a patient on a medication that needs to be evaluated for appropriateness of dose and/or frequency	• Optimized medication benefits • Reduced risk of serious adverse effects	
	Antimicrobial stewardship Alerts pharmacist to a patient with specific combinations of culture and sensitivity results and antimicrobial therapy (de-escalation or therapy optimization opportunity)	• De-escalated or optimized medication regimen • Decreased antimicrobial resistance and multi-drug resistant organisms • Reduced waste • Avoided harm	
	Anticoagulation monitoring Alerts pharmacist to patients on anticoagulant(s) to ensure appropriate use and monitoring of high-risk medications	• Improved appropriate use of anticoagulant medications • Enhanced monitoring and management of anticoagulant therapy in accordance with evidence-based guidelines, regulatory requirements, and national patient safety goals	

Wagner, L. et al. HCL Healthcare. Journal of Infection. 2011;63:1



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Test Question #3

The Institute for Safe Medication Practices (ISMP) created the hierarchy of effectiveness for risk-reducing strategies, which of the following is considered a medium leverage strategy?

- a. Having an in-service event on how to properly document rate changes on intravenous infusion
- b. Using technology with advanced analytics that identifies unusual behavior and flags individuals when it comes to dispensing and administration of controlled substances
- c. System requiring an independent double check when administering a paralytic to a critically ill patient
- d. A system wide protocol on how to dose and monitor patients on vancomycin



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Test Question #3

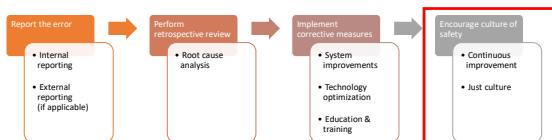
The Institute for Safe Medication Practices (ISMP) created the hierarchy of effectiveness for risk-reducing strategies, which of the following is considered a medium leverage strategy?

- a. Having an in-service event on how to properly document rate changes on intravenous infusion
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- c. System requiring an independent double check when administering a paralytic to a critically ill patient
- d. A system wide protocol on how to dose and monitor patients on vancomycin



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How to Address Medication Errors



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Encourage Culture of Safety: Continuous Quality Improvement

Continuous Quality Improvement:

- Proactive, systematic, data-driven approach to improve specific processes, systems, and patient outcomes in healthcare
- Pharmacies in Florida must have a CQI program to identify, document, and review QREs for improving patient safety
 - **64B16-27.300 Standards of Practice - Continuous Quality Improvement Program**



Florida Rule 64B16-27.001, Florida Administrative Code, 2024

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Encourage Culture of Safety: Continuous Quality Improvement

64B16-27.300 Standards of Practice - Continuous Quality Improvement Program

Definition of QRE:

- Variations from prescription orders
- Failures in identifying & managing issues

Pharmacy requirements:

- Create a **CQI Program** that must be detailed in policies and procedures
- Form **CQI Committee** that may include pharmacists, interns, techs, other necessary personnel
- Committee must **review QREs at least quarterly**
 - Pharmacy must have procedure in place for reviewing QREs
- Implement **system to record, measure, assess, & improve** patient care based on QRE findings
- Take **corrective action** after a QRE to resolve patient's issue
- Review staffing, workflow, & technology** to see if they contribute to errors



Florida Rule 64B16-27.001, Florida Administrative Code, 2024

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Encourage Culture of Safety: Continuous Quality Improvement

64B16-27.300 Standards of Practice - Continuous Quality Improvement Program

Documentation Requirements:

- Every QRE must be documented the same day it is reported to the pharmacist
- Records must include details of the event to allow for analysis
- Pharmacies must keep QRE documentation for at least 4 years

Confidentiality and Legal Protection:

- QRE records are confidential under HIPAA and protected from legal discovery in lawsuits
- The Department of Health may review policies, procedures, and summaries of QREs to ensure compliance, but patient and employee names must be excluded



Florida Rule 64B16-27.001, Florida Administrative Code, 2024

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Encourage Culture of Safety: Just Culture

Just Culture

- Emphasizes **accountability & learning over punishment** in response to errors and near-miss events
 - **Non-punitive environment**
- Establishes **environment where staff feel safe to report mistakes** and system vulnerabilities
 - **Promotes culture of trust and continuous improvement**
- Recognizes that most **human errors arise from system flaws**, not individual negligence
 - **Separates events resulting from flawed system design or unintentional human error from those caused by reckless behavior**



Shelton, et al. ASHP Section of Hospital Care Practitioners Advisory Group on Medication Safety, 2015.

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Encourage Culture of Safety: Just Culture

Human Error	At-Risk Behavior	Reckless Behavior
Inadvertent action (slip, lapse, mistake) <i>"I forgot to enter a patient's amikacin dose"</i>	Choice or action that increases risk (shortcuts, workarounds) <i>"I dosed a patient's amikacin using a historical weight from 2011"</i>	Conscious disregard of a substantial & unjustifiable risk <i>"I purposely avoided dosing a patient's amikacin because it was hard and time-consuming"</i>
Manage through changes in: <ul style="list-style-type: none"> Processes Procedures Training Design Environment 	Manage by: <ul style="list-style-type: none"> Removing incentives for at-risk behaviors Creating incentives for healthy behaviors Increasing situational awareness 	Manage through: <ul style="list-style-type: none"> Remedial action Disciplinary action
CONSOLE	TRAIN & COACH	DISCIPLINE



Shelton, et al. ASHP Section of Hospital Care Practitioners Advisory Group on Medication Safety, 2015.

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Encourage Culture of Safety: Just Culture

Second Victims

Healthcare providers who become traumatized after an unanticipated adverse patient event, medical error and/or a patient-related incident, and become victims of their own emotions

- May feel personally responsible as if they failed their patients, second-guessing their clinical skills and knowledge base
- Can be overcome by feelings of guilt, depression, sleep disturbances, anxiety, suicidal ideation, burnout/turnover, PTSD, distraction, or lack of confidence
 - **May affect medical judgment and lead to further medical errors**



Shelton, et al. ASHP Section of Hospital Care Practitioners Advisory Group on Medication Safety, 2015.

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Thank You!



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Medication Errors and Continuous Quality Improvement




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**Not Really Covered:
Insured but
Medically Indigent**

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1


Learning Objectives

Define the medically indigent in population health and pharmacy practice and explain the health disparities they face despite being insured

Identify the social determinants of health that exacerbate challenges for medically indigent populations


Describe the pharmacist's role in addressing the needs of insured but medically indigent patients and identify strategies to support them effectively

Examine case studies where pharmacy interventions successfully improved care for medically indigent patients



2


Define the medically indigent in population health and pharmacy practice and explain the health disparities they face despite being insured



3

Medically Indigent



- **Definition:** Insured individual unable to afford healthcare costs such as:
 - Copays
 - Deductibles, or
 - Medications
- These individuals often fall into the gap
- Highlight their unique challenges compared to uninsured populations



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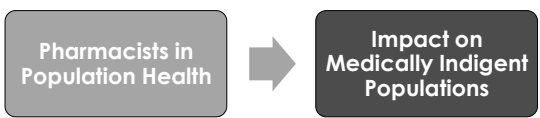
Medically Indigent in Population Health

- Importance in population health
- Impact on chronic disease management and preventative care
- Contributes to systemic inefficiencies in healthcare delivery



5


Medically Indigent in Pharmacy Practice



6

Demographics of the Medically Indigent Population


Age Income Conditions



7

Health Disparities in Medically Indigent


Financial
Healthcare Access
Chronic Conditions
Social Determinants



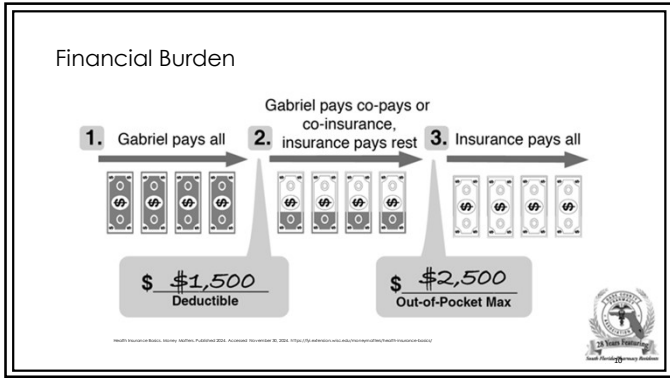
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Health Insurance Paradox

- **The Paradox:**
 - Being insured does not equate to affordable or accessible care
 - High-deductibles and co-pays as barriers
- **Example:**
 - Insured patients skipping medications due to cost



9



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Disparities to Access to Care

- **Care gap:**
 - Limited network providers
 - Financial barriers to accessing specialized treatments
- **Impact:**
 - Delays in diagnosis and treatment

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Role of Social Support Systems


- **Importance of support:**
 - Community programs
 - Assistance with transportation, childcare, etc.
- **Opportunities for Pharmacists:**
 - Partner with local organizations to provide holistic care solutions

Social Support Network

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Pharmacist-Led Interventions

- Medication therapy management (MTM)
- Patient education programs
- Further initiatives:
 - Promote the inclusion of pharmacist in primary care teams to address social determinants of health barriers



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Role of Policy in Addressing Disparities



- **Policy Interventions**
 - Medicaid expansion
 - Caps on out-of-pocket expenses
- **Advocacy Role:**
 - Encourage healthcare providers to advocate for policy reforms supporting underinsured populations



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Collaborative Approaches

- **Multidisciplinary Teams:**
 - Integration of pharmacist, social workers, and providers
- **Benefit:**
 - Comprehensive care reduces disparities




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Assessment #1

• **Question:** What are some key characteristics of medically indigent populations?

- a) Uninsured individuals with no access to care
- b) Insured individuals with high deductibles and limited resources**
- c) Wealthy individuals with chronic conditions
- d) Individuals with free access to specialty care




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Assessment #2

• **Question:** Why do medically indigent populations face health disparities despite being insured?

- a) High out-of-pocket costs prevent access to care**
- b) Insurance policies fully cover all medical needs
- c) They have no chronic disease burden
- d) They only utilize preventive services

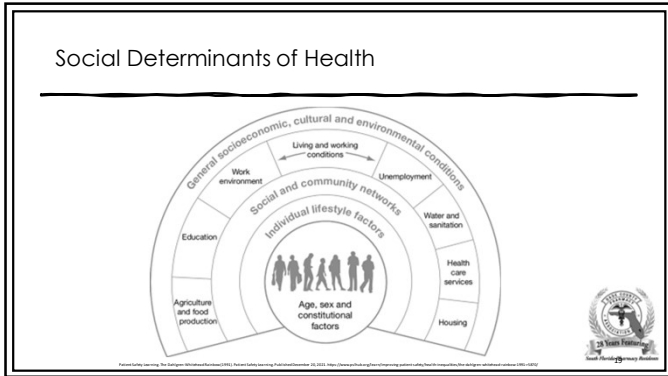


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Identify the social determinants of health that exacerbate challenges for medically indigent populations





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Economic Stability


- **Impact on medically indigent populations:**
 - Low wages and financial instability
 - Difficulty affording care despite insurance
- **Examples:** Patients skipping care to pay for rent or food

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Education and Health Literacy

- **Role of Education:**
 - Limited understanding of health insurance policies
 - Low health literacy leading to poor decision-making
- **Solution:** Tailored education programs for underserved populations
- **Examples:** Literacy programs and simplified insurance guides



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Social and Community Context

Social Isolation:

- Lack of family or community support

Cultural Barriers:


- Language and mistrust in healthcare systems

Impact:

- Reduced ability to navigate complex healthcare systems

Potential interventions:


- Community health worker programs to bridge cultural gaps



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Access to Healthcare


- **Challenges:**
 - Limited provider networks
 - Long wait times for appointments
- **Pharmacy-Specific Issues:**
 - Pharmacies not accepting certain insurance plans
- **Potential Solutions:** Expansion of telehealth and mobile pharmacy units



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Neighborhood and Built Environment

- **Environmental Factors:**
 - Lack of transportation to pharmacies or clinics
 - Unsafe neighborhoods deterring care-seeking behavior
- **Solutions:** Mobile health units, telehealth expansion
- **Example:** Mobile clinics improving rural health access




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Interventions to Address SDOH

Community-Based Solutions



Pharmacy Role



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Policy Solutions for SDOH

- **Policy interventions:**
 - Subsidized healthcare programs that cover essential needs
 - Expansion of Medicaid and social safety nets
- **Impact:**
 - Policies aimed at alleviating financial barriers improve health outcomes and reduce disparities



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Pharmacists as a Change Agent


- **Role of Pharmacists:**
 - Identify SDOH barriers during consultations and suggest resources
 - Partner with local organizations to support food security and access to care



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Collaborative Communitive Efforts


- **Collaborations:**
 - Public-private partnerships to fund healthcare initiatives
 - Cross-disciplinary teams integrating pharmacists, case managers, and social workers
- **Example:**
 - Community clinics that provide free screenings and follow-up care, reducing ER visits



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Challenges in Addressing SDOH


Barriers to Change:	Strategies:
<ul style="list-style-type: none">• Limited funding• Resistance from stakeholders	<ul style="list-style-type: none">• Building awareness• Leveraging data• Empowering grassroots advocacy



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Assessment #1


- **Question:** Which of the following is an example of a social determinant of health impacting medically indigent populations?
 - a) Limited education and health literacy
 - b) Having high financial wealth
 - c) Access to luxury healthcare
 - d) Living in a high-resource neighborhood



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Assessment #2

- Question: What is a key barrier faced by medically indigent populations related to economic stability?
 - a) High income levels making care accessible
 - b) Low wages and financial instability preventing affordable care**
 - c) Access to all specialty care services
 - d) Free transportation to medical appointments.



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Describe the pharmacist's role in addressing the needs of insured but medically indigent patients and identify strategies to support them effectively



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Pharmacist's Role in Supporting Medically Indigent Patients



33

Pharmacy's Role in Identifying Medically Indigent Patients

Assessment:

- Reviewing medication histories and identifying non-adherence
- Asking about financial barriers to obtaining medications or treatment
- Identifying patients with multiple chronic conditions who may need extra support

Collaboration:

- Work with other healthcare providers to create a comprehensive care plan



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Medication Access and Affordability

Actions:

- Recommend cost-effective generics or therapeutic alternatives
- Enroll patients in Patient Assistance Programs (PAPs)
- Provide multi-month fills to reduce co-pay frequency



35

Medication Therapy Management

Purpose of MTM:


- Identify and resolve medication barriers (cost, adherence, or side effects)
- Ensure patients receive optimal, affordable therapy



36

Educating Patients

- **Key Areas of Education:**
 - How to navigate insurance benefits and formularies
 - Proper medication use and adherence
 - Managing chronic conditions on a budget



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Insurance Navigation Support

- **Helping Patients Understand Their Insurance:**
 - Many patients face challenges in understanding their health insurance benefits and formulary
- **Insurance Appeals:**
 - Insurance companies may deny coverage for certain medications or services, even if they are clinically necessary




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Identifying Financial Support Programs

Charity Pharmacies

Public Assistance Programs



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Helping Patients Access PАПs: A Pharmacist's Example

• **Scenario:**

"A patient in Florida with diabetes is struggling to afford their insulin despite having insurance with a high deductible. The pharmacist steps in to help."



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Helping Patients Access PАПs: A Pharmacist's Example

• **Steps Taken by the Pharmacist:**

1. **Identify the Need:**
 - o The patient reports skipping doses due to cost
2. **Research PАП Options:**
 - o The pharmacist uses resources such as:
 - NeedyMeds.org – A database of PАПs for medications
 - RxAssist.org – A resource for drug-specific assistance programs
 - Manufacturer Websites – For patient savings cards and co-pay support (e.g., Lilly Cares for insulin)
3. **Provide Guidance:**
 - o The pharmacist explains eligibility requirements and assists the patient with the application process, such as:
 - Proof of income
 - Recent prescription details
4. **Follow-Up:**
 - o Ensures the patient successfully enrolls in the PАП and receives their medication at little or no cost



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Leveraging Technology



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Community Outreach Programs


- **Pharmacy-Led Initiatives:**
 - Host free health screenings for chronic diseases
 - Provide immunizations to underserved populations
 - Organize workshops on medication adherence

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Collaboration with Healthcare Teams


- **Collaborative Efforts:**
 - Work with physicians, social workers, and nurses to address financial and healthcare barriers
 - Contribute expertise on medication management and cost-saving strategies.



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Advocacy for Systemic Change



- **Advocacy Goals:**
 - Support drug pricing transparency initiatives
 - Push for expanded Medicaid and affordable healthcare policies
 - Advocate for pharmacist reimbursement in patient care services



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Measuring Impact and Outcomes


- **Metrics to Track:**
 - Improved medication adherence rates
 - Reduced ER visits and hospitalizations
 - Increased patient satisfaction and health literacy

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Call to Action


"Pharmacists are essential in improving access and outcomes for medically indigent patients. Take action to advocate, educate, and innovate."



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Assessment Question #1

- **Question:**
 - What is one of the primary roles of a pharmacist in supporting medically indigent patients?
 - a) Prescribing medications without a doctor's approval
 - b) Recommending generic alternatives to reduce medication costs**
 - c) Waiving insurance co-pays for patients
 - d) Providing free medical consultations to all uninsured patients




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Assessment Question #2

• **Question:**

- Which of the following strategies can pharmacists use to improve medication adherence in medically indigent patients?

- a) Providing telepharmacy services
- b) Assisting patients with Patient Assistance Programs (PAPs)
- c) Educating patients on proper medication use
- d) All the above



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Examine case studies where pharmacy interventions successfully improved care for medically indigent patients



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Case study 1: Chronic Illness

- **Background:**
 - Emily is a 38-year-old single mother working full-time as a receptionist. She has employer-provided health insurance with a high deductible plan (\$4,000 annually). Emily was recently diagnosed with multiple sclerosis (MS).
- **Challenges:**
 - Emily's insurance covers 70% of her treatment costs after she meets her deductible.
 - Her monthly out-of-pocket expenses for MS medications, physical therapy, and doctor visits amount to \$1,200—nearly half her monthly income.
 - She skips physical therapy sessions and delays purchasing medication to cover rent and utilities.



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Case study 1: Chronic Illness

- **Intervention:**
 - Emily's healthcare provider referred her to a nonprofit organization that assists with medication costs.
 - She also qualified for a hospital financial assistance program to reduce her out-of-pocket expenses.
- **Outcome:**
 - With reduced medication costs and assistance from the program, Emily was able to afford both her treatment and essential living expenses, improving her quality of life.



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Case Study 2: Emergency Surgery

- **Background:**
 - Carlos, a 45-year-old construction worker, has employer-sponsored insurance with a \$6,000 deductible. He suffered a workplace injury requiring emergency surgery for a torn ligament.
- **Challenges:**
 - Despite having insurance, Carlos was billed \$7,500 for the surgery, anesthesia, and follow-up care because he hadn't met his deductible.
 - Unable to pay the bill in full, he fell behind on rent and utilities, leading to eviction.
 - His recovery was hindered by stress and limited access to physical therapy



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Case Study 2: Emergency Surgery


- **Intervention:**
 - Carlos worked with a hospital financial counselor, who helped him negotiate a reduced bill and set up a manageable payment plan.
 - He was also referred to a local nonprofit that provided temporary housing during his recovery.
- **Outcome:**
 - Carlos resumed physical therapy through a sliding-scale clinic and returned to work after his recovery, avoiding long-term financial ruin.



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Case Study 3: Cancer Treatment


- **Background:**
 - Maria, a 62-year-old retired teacher, has Medicare but no supplemental insurance. She was diagnosed with breast cancer and requires surgery, chemotherapy, and radiation.
- **Challenges:**
 - Medicare covers 80% of her treatment costs, but Maria is responsible for the remaining 20%, amounting to over \$15,000 for the year.
 - Maria depleted her savings and struggled to pay for basic needs, including groceries and transportation to medical appointments.



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Case Study 3: Cancer Treatment



- **Background:**
 - Maria, a 62-year-old retired teacher, has Medicare but no supplemental insurance. She was diagnosed with breast cancer and requires surgery, chemotherapy, and radiation.
- **Challenges:**
 - Medicare covers 80% of her treatment costs, but Maria is responsible for the remaining 20%, amounting to over \$15,000 for the year.
 - Maria depleted her savings and struggled to pay for basic needs, including groceries and transportation to medical appointments.



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Case Study 4: An Insured Patient's Struggles

- **Case Study:** Sarah, a 45-year-old woman with diabetes, has insurance through her employer but faces high out-of-pocket costs for her insulin
 - **Sarah's Challenges:**
 - High deductible means she pays a significant portion of her insulin cost
 - Cannot afford a nutritionist to help manage her condition
 - Experiences complications due to inadequate diabetes control
- **Outcome:** Despite insurance, Sarah's health outcomes deteriorate due to financial barriers

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Key takeaways

Pharmacists are key to improving access:

- Our role is critical in ensuring that indigent patients receive medications

Medication Assistance Programs (MAPs):

- Effective in improving adherence and reducing healthcare costs

Policy change is essential:

- Advocating for reforms that reduce financial burdens is necessary to create lasting impact



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Thank You



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Not Really Covered:
Insured but
Medically Indigent



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Artificial Intelligence and its Impacts on Clinical Care and Management

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January 25th, 2025



1

Objectives

1. Describe the basic concepts of artificial intelligence.
2. List and explain current applications of artificial intelligence in health systems.
3. Evaluate the ways artificial intelligence influences clinical decision-making and improves patient outcomes.
4. Identify potential limitations of artificial intelligence in the healthcare setting.
5. Discuss key ethical and practical considerations when implementing artificial intelligence.



2

What is artificial intelligence?

- **Artificial Intelligence (AI)** is an umbrella term for computer software that simulates human intelligence in order to perform complex tasks and learn from them.
- **Weak AI (Narrow AI):** perform a specific task or limited range of tasks. Makes decisions based on programmed algorithms and training data.
- **Strong AI (Generalized AI):** can understand, learn, and apply knowledge across a wide range of tasks. Acquires new skills and adapts to new situations autonomously.
- **Super AI (Conscious AI):** human-level consciousness that requires self-awareness. Most advanced form of AI.




Artificial Intelligence (AI) Terms: A to Z Glossary, Artificial Intelligence Terms: A to Z Glossary, December 16, 2024. <https://courses.org/news/6271265f93a10a481456889351e60c>

3

Types of AI

Diagnostic	Assesses correctness of behavior by analyzing historical data to understand what happened and why.
Predictive	Forecasts future outcomes based on historical and current data. Predicting customer behavior, market trends
Prescriptive	Analyzes data to determine and recommend best course of action
Generative	Mimics human creativity and cognitive processes to produces various types of content
Reactive	Responds to specific inputs with predetermined responses. No memory or learning capabilities
Limited Memory	Uses past experiences to inform current decisions. Has learning abilities.
Theory of Mind	Aims to understand human emotions, beliefs, and intentions.
Self-Aware	Has own consciousness and self-awareness. Understands and reacts to its own emotions and states. Most advanced form of AI.

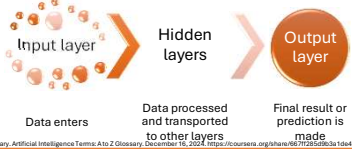
Future of Health: The emerging landscape of augmented February 26, 2024. <https://www.ama-assn.org/system/files/future-health-augmented-intelligence-health-care.pdf>




4

How does AI work?

- **Machine Learning (ML):** The core concept of AI where computers use algorithms to learn from data to perform a variety of complex tasks and to improve their performance on tasks without being explicitly programmed.
- **Deep Learning:** A method that trains computers to process information in a way that mimics human neural processes. Uses several layers to perform tasks without any human intervention.




Artificial Intelligence (AI) terms: A to Z glossary, Artificial Intelligence Terms: A to Z Glossary, December 16, 2024. <https://courses.org/share/60712255893a1d4481455889351e00>




5

Can AI really “learn?”

- **Supervised Learning:**
 - The algorithm is trained with labeled data (the correct answer is provided for each input)
- **Unsupervised Learning:**
 - The algorithm finds patterns in unlabeled data (without being given the correct answers)
- **Reinforcement Learning:**
 - Learning by trial and error, receiving rewards for positive actions and penalties for negative ones.



Artificial Intelligence (AI) terms: A to Z glossary, Artificial Intelligence Terms: A to Z Glossary, December 16, 2024. <https://courses.org/share/60712255893a1d4481455889351e00>



6

Question 1

Machine learning is defined by which of the following?

- a. An umbrella term for computer software that simulates human intelligence in order to perform complex tasks and learn from them.
- b. A method that trains computers to process information in a way that mimics human neural processes and uses several layers to perform tasks without any human intervention.
- c. The core concept of AI where computers use algorithms to learn from data to perform a variety of complex tasks and to improve their performance on tasks without being explicitly programmed.
- d. A system that mimics human creativity and cognitive processes to produces various types of content.

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Uses of AI

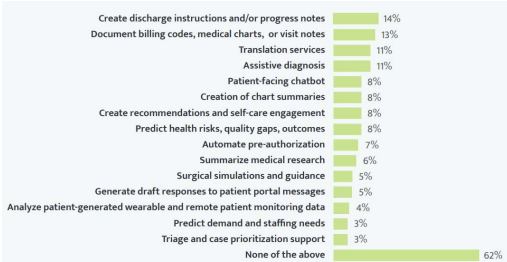
- Identifying objects, patterns, and/or characteristics within data (often images).
 - Medical imaging studies
- Translating data inputs into another data type or data format (often between modalities or languages), often using natural language processing.
 - Converting complex medical terminology to "plain language" for patients
- Summarizing data inputs into shorter and more accessible outputs.
 - Chart/ patient notes summary
- Predicting or forecasting future events based on historical data and patterns.
 - Hospital readmission rates
- Providing recommendations, guidance or advice. In some systems, suggestion automatically lead to a specific downstream action.
 - Insulin correction based on glucose readings

Futures of Health: The emerging landscape of augmented. February 26, 2024. <https://www.ama-assn.org/system/files/futures-health-augmented-intelligence-health-care.pdf>



8

AMA 2023 AI Physician Survey: Current use cases across specialties



Futures of Health: The emerging landscape of augmented. February 26, 2024. <https://www.ama-assn.org/system/files/futures-health-augmented-intelligence-health-care.pdf>




9

AI in current practice: Examples

All specialties	Cardiology
<ul style="list-style-type: none"> Real-time clinical transcription. Answer routine patient questions via chatbots. Draft personalized patient education materials based on patient history and chart review. Predict adverse clinical outcomes based on vitals and/or other markers. 	<ul style="list-style-type: none"> Detect arrhythmias, ischemia and other heart abnormalities through electrocardiogram (ECG) analysis. Predict fractional flow reserve (FFR) from computed tomography (CT) images to aid in assessment of coronary artery disease. Use guidance during echo image analysis to optimize views and enable upskilling of practitioners.

Future of Health: The emerging landscape of augmented. February 26, 2024. <https://www.ama-assn.org/system/files/future-health-augmented-intelligence-health-care.pdf>




10

AI in current practice: Examples

Emergency medicine	Family medicine	Pathology
<ul style="list-style-type: none"> Monitor patient vital signs and predict decompensation based on vital-sign trends. Augment triage of patients based on review of current patient clinical condition and medical history. Analyze images to accelerate time to treatment (e.g., identification of patients with suspected critical findings admitted to the ED for acute stroke). 	<ul style="list-style-type: none"> Monitor blood pressure via connected devices and alert patient's care team when deviations occur. Support patient engagement and education through AI-driven chatbots and symptom checkers that answer foundational questions about health. 	<ul style="list-style-type: none"> Identify biomarkers (e.g., cancer detection through tissue sample analysis) and suggest diagnosis. Conduct quality control on pathology laboratory processes (e.g., identify staining artifacts)

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11

Mandy

Mandy

Please give me a brief description of your feeling.

I have cough and fever recently. And I was in my usual state of health until 7 days ago when a cough developed. Two days ago I saw a grade four (G4) diverticulitis, which pointed to 38.6 F yesterday. Besides that, my system is yellow.

Do you have chest pain?

No

Do you have crossed nerve palsy?

Control nerve palsy: Injury to any of the cranial nerves or chest muscles in the brain resulting in muscle weakness.

No

Send

Patient Report


Name: Mr. W
 Gender: male
 Age: 56

The patient has these symptoms: chest pain.

The patient doesnot have these symptoms: hypotension, abdominal pain, shortness of breath, dysphagia, cough, cardiac arrest.

The initial hypothesis of possible results are:
 Gastroesophageal reflux, Myocardial infarction, Pneumonia or Ischaemic heart disease.

Chief Health: Meet Mandy - an Intelligent and Interactive Medicine System: Meet Mandy - An Intelligent and Interactive Medicine System. July 26, 2023. <https://www.ama-assn.org/system/files/ama-assn-org-interactive-medicine-system-2023-07-26.pdf>



12

Opportunities for implementation

All Specialties	Cardiology
<ul style="list-style-type: none"> • Draft responses to patient in-basket communications. • Convert open-ended clinical notes and data (e.g., dictation, long-form text) into an electronic health record (EHR) format and codify medical information into standardized terminology. • Support patient triage based on severity of symptoms. 	<ul style="list-style-type: none"> • Triage data from imaging and electronic health record (EHR) system for early diagnosis and referral. • Utilize ECG to assess progression of valvular disease. • Assess personalized risk factors most strongly influencing cardiovascular outcomes for modification

Future of Health: The emerging landscape of augmented. February 26, 2024. <https://www.ashp.org/system/files/future-health-augmented-intelligence-health-care.pdf>

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Opportunities for implementation

Emergency medicine	Family medicine	Pathology
<ul style="list-style-type: none"> • New capabilities for facilitating the performance and interpretation of point of care (POC) ultrasound. • Automate real-time prediction of optimal therapy for individual patients. 	<ul style="list-style-type: none"> • Support medication adherence by monitoring patients and sending alerts to both patients and providers. • Develop novel remote physiologic monitoring capabilities that provide passive and real-time remote sensing of disease onset or progression. 	<ul style="list-style-type: none"> • Assist in sample (e.g., blood smear) diagnosis. • Standardize quantification tasks (e.g., tumor protein expression quantification and treatment recommendation).

Future of Health: The emerging landscape of augmented. February 26, 2024. <https://www.ashp.org/system/files/future-health-augmented-intelligence-health-care.pdf>

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Question 2

What are some examples of current uses of artificial intelligence (AI) in health systems?

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Clinical benefits of AI in pharmacy

- Patient Safety
 - Pharmacovigilance
 - Adverse drug reactions
 - Clinical decision support systems (CDSS)
 - High risk drug dosing
 - Potentially inappropriate medications (PIMs)
 - Patient chart analysis
 - Readmission rates

ASHP Statement on the Use of Artificial Intelligence in Pharmacy, ASHP
<https://doi.org/10.1093/ajhp/azx228>
 Daveygoni T, Kalakota R. The potential for artificial intelligence in healthcare. *Future Healthc J*. 2019;6(2):94-98. doi:10.7861/futurehosp.6-2-94
<https://doi.org/10.1093/ajhp/azx228>
 NICE Medicines 9 - The role of AI in pharmacy practice: progress, benefits and challenges. *Pharmacy*. 2024; 3(4):24-30.

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Clinical benefits of AI in pharmacy

Bisher, Hamrah & Braun, *Medicine*. (2022). Diffused responsibility: attributions of responsibility in the use of AI-driven clinical decision support systems. *AI and Ethics*. 3-10. 1007/s43681-022-00125-4.

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Readmission Rates

AI-Powered Predictive Analysis: Revolutionizing Clinical Practice

Alomay, Shuang, et al. (2023). Revolutionizing healthcare: the role of artificial intelligence in clinical practice. *BMJ Medical Education*. 73, 10.1136/bmj-2023-049992.


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Clinical benefits of AI in pharmacy

Patient engagement and adherence

- Patient education
- Treatment plans
- Mobile applications
- Electronic pillboxes
- Ingestible sensors

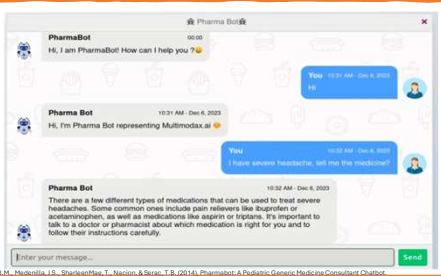
- Blister pack technology
- Electronic medication management systems
- Patient self-report-based technology
- Video-based technology
- Motion sensor technology




• ASHP Statement on the Use of Artificial Intelligence in Pharmacy, ASHP
<https://doi.org/10.1093/ajhp/zrzd08>
 • Davignon T, Kalkanis R. The potential for artificial intelligence in healthcare. *Future Healthc J*. 2019;6(2):94-98. doi:10.7861/futurehosp.6-2-94
<https://doi.org/10.1093/ajhp/zrzd08>
 • *Next Millennium: The Role of AI in Pharmacy Practice Programs, Courses, and Collaborations. Pharmacist*. 2019;24:2019

19

PharmaBot

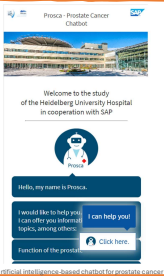


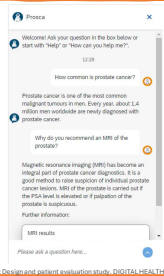


• Comandeur B.E., Francisco D.M., Medvedev J.S., Shakhshobiz T., Neeson & Scott, T.R. (2014). Pharmabot: A Customized Generic Medicine Consultation Chatbot.

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PROSCA







• Oltay H, Baumgaertel P, Schmidt T, et al. An artificial intelligence-based chatbot for prostate cancer education: Design and patient evaluation study. *DIGITAL HEALTH*. 2023;9:202301172023

21

Clinical benefits of AI in pharmacy

- Workflow
 - Robotic dispensing systems
 - Automated dispensing systems
 - Dosage recommendation system
 - Clinical documentation
 - Clinical protocol development



• ASHP Statement on the Use of Artificial Intelligence in Pharmacy - ASHP
<https://doi.org/10.1093/ajhp/ajz028>
 • Daverport T, Kalakota R. The potential for artificial intelligence in healthcare. *Future Healthc J*. 2019;6(2):94-98. doi:10.7861/futurehosp.6-2-94
<https://doi.org/10.1093/ajhp/ajz018>
 • Wolk M, Minkovich P. The use of AI in pharmacy practice: economic benefits and challenges. *Pharmacy Times*. 2019;34:3074

22

Robotic Dispensing System



<https://youtu.be/h6h6b6K5A8k>
 Robot dispensing, hospital, mail-order and community pharmacy - with CONSIGN robotic systems

23

Question 3

- What are some ways artificial intelligence can contribute to patient safety?
- Identifying drug-drug interactions
 - Clinical decision support systems (CDSS)
 - Assisting with high-risk drug dosing
 - Identifying potentially inappropriate medications (PIMs)
 - All of the above




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Limitations of AI

Bias	Explainability	Transparency
Hallucinations	Liability	Privacy and Security
Regulation and Oversight		



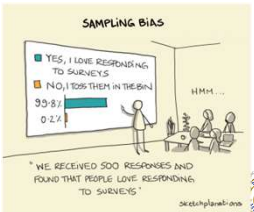
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 • <https://www.ashp.org/system/files/2024-02/02-future-of-health-augmented-intelligence-health-care.pdf>


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Bias

- Data Bias: Prejudices or unconscious biases incorporated in training datasets that inform AI output
- Sample bias, measurement bias, and algorithm bias among others have potential to produce inaccurate or potentially discriminatory results.

SAMPLING BIAS







• Future of Health: The emerging landscape of augmented. February 26, 2024. <https://www.ashp.org/system/files/2024-02/02-future-of-health-augmented-intelligence-health-care.pdf>
 • <https://www.ashp.org/system/files/2024-02/02-future-of-health-augmented-intelligence-health-care.pdf>

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Explainability

- Explainability refers to an end-user's ability to explain how an AI model's output was generated from inputs
- Some models are so large and complex it is difficult to understand and predict output





• Future of Health: The emerging landscape of augmented. February 26, 2024. <https://www.ashp.org/system/files/2024-02/02-future-of-health-augmented-intelligence-health-care.pdf>
 • <https://www.ashp.org/system/files/2024-02/02-future-of-health-augmented-intelligence-health-care.pdf>

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Transparency

- Transparency refers to the ability to access information about an AI model's training data and model details
- Can patient data be accessed? Are reliable sources used? Is training data internal or external? Is the model private, proprietary information?



• Future of Health: The emerging landscape of augmented. February 26, 2024. <https://www.ama-assn.org/system/files/future-health-augmented-intelligence-health-care.pdf>

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Hallucinations

- Hallucinations, or confabulations, refer to when a generative artificial intelligence algorithm creates outputs that are either nonsensical or appear credible but are factually inaccurate.
- Should AI models be discontinued if evidence of hallucinations are found?



• Future of Health: The emerging landscape of augmented. February 26, 2024. <https://www.ama-assn.org/system/files/future-health-augmented-intelligence-health-care.pdf>

• Anolis F. 2023. AI is creating synthetic: The AI videos that shaped the future of content creation. LinkedIn. December 14, 2024. <https://www.linkedin.com/feed/update/urn:li:activity:7154916416416416416>

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Liability

- Hallucinations, or confabulations, refer to when a generative artificial intelligence algorithm creates outputs that are either nonsensical or appear credible but are factually inaccurate.
- Who is ultimately account for errors? Clinician? Developers?




• Future of Health: The emerging landscape of augmented. February 26, 2024. <https://www.ama-assn.org/system/files/future-health-augmented-intelligence-health-care.pdf>

30

What do you think?

What are some factors that should be considered prior to implementing artificial intelligence (AI) in your practice?

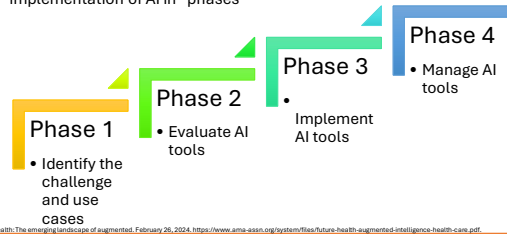
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Implementing AI into practice

- The American Medical Association (AMA) recommends considering implementation of AI in "phases"




Phase 1
• Identify the challenge and use cases

Phase 2
• Evaluate AI tools

Phase 3
• Implement AI tools

Phase 4
• Manage AI tools

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Phase 1: Identify the challenge and use cases

- Understands what problems you are trying to solve with AI.
- How can AI successfully address this problem?
- Do AI tools exist that address the problem?
- What are the potential risks and liability to your practice?


Patient Safety

Pharmacovigilance

Administrative duties

Workflow enhancements

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Phase 2: Evaluate AI tools

- What data will be used to train AI?
- Is there evidence of reliable performance?
- Does your practice have the appropriate technology and infrastructure?
- How much will the AI cost to integrate?
- What is the potential financial incentive?


Reduction in posttreatment expenditures

Early diagnosis

Enhanced clinical trials

Supply chain management

Forecasting medication demand



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Phase 2: Evaluate AI tools

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Reduction in posttreatment expenditures

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Phase 3: Implement AI tools


- How will staff, patients, or other end-users be trained to use the AI tool?
- How will the AI be integrated into workflow?
- How will issues or errors be reported?
- How can product owners ensure the consistent examination of AI tools to identify and rectify biases, preventing unintended consequences that may disproportionately affect marginalized groups?

Electronic health record (HER)

Mobile app

Technology infrastructure

Collaborative care



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Phase 4: Manage AI tools


- How will the AI tool be maintained?
- How will the clinical environment be monitored for impact of AI tool?
- What is the return on investment?
- How are risks and biases assessed and monitored?

Software updates

Malware

Performance measures

Impact




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Key Points

- Key AI techniques include Machine Learning, Deep Learning, and learning types like supervised, unsupervised, and reinforcement learning.
- AI supports several clinical processes such as patient education, automated dispensing systems, and clinical decision support systems (CDSS).
- AI can enhance patient safety, encourage adherence, and improve workflows with automation.
- Limitations of AI include data bias, lack of explainability, hallucinations, and privacy concerns. AI Requires oversight for ethical and unbiased application.
- AI should be implemented in phases to identifying challenges, evaluate tools, train users, and perform ongoing monitoring.



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Thank you!



42


Questions?



43

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46

Artificial Intelligence and its Impacts on Clinical Care and Management

Stephanie Rivera-Correa, PharmD, MBA
 Walgreens-Nova Southeastern University
 Miami, FL
 January 25th, 2025



47

Artificial Intelligence and Impacts on the Pharmacy Profession & Jobs

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January 25th, 2024



1

Relevant Financial Relationship Disclosure

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2

Learning Objectives

- 01** Define AI and discuss currently available technologies.
- 02** Analyze AI-exposure and AI-vulnerability of pharmacy.
- 03** Describe the professional impacts of AI in the hospital setting.
- 04** Describe the professional impacts of AI in the community setting.
- 05** Describe the professional impacts of AI in the industry setting.
- 06** Describe the professional impacts of AI in the academia setting.

3


Abbreviations

- ADR → Adverse Drug Reaction
- AI → Artificial Intelligence
- CDS → Clinical Decision Support
- DDI → Drug-Drug Interaction
- EHR → Electronic Health Record
- LLM → Large Language Models
- ML → Machine Learning
- MTM → Medication Therapy Management
- NLP → Natural Language Processing



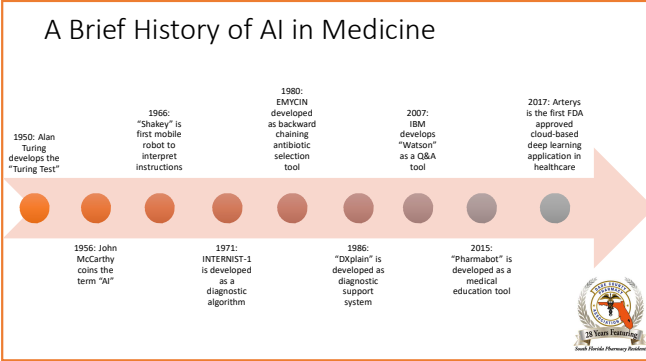
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Overview of AI and Currently Available Technology



5

A Brief History of AI in Medicine



1950: Alan Turing develops the "Turing Test"

1956: John McCarthy coins the term "AI"

1966: "Shakey" is first mobile robot to interpret instructions

1971: INTERNIST-1 is developed as a diagnostic algorithm


1980: EMYCIN developed as backward chaining antibiotic selection tool

1986: "DXplain" is developed as diagnostic support system

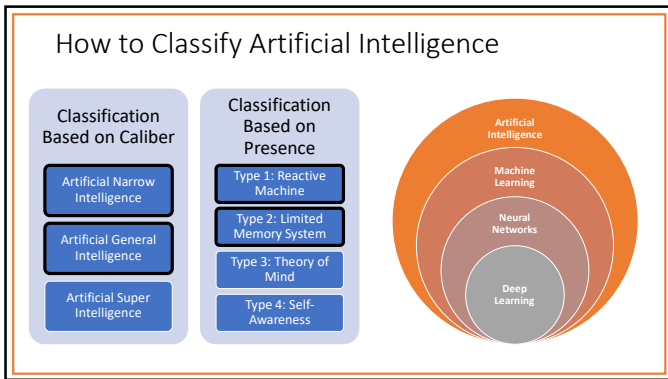
2007: IBM develops "Watson" as a Q&A tool

2015: "Pharmabot" is developed as a medical education tool

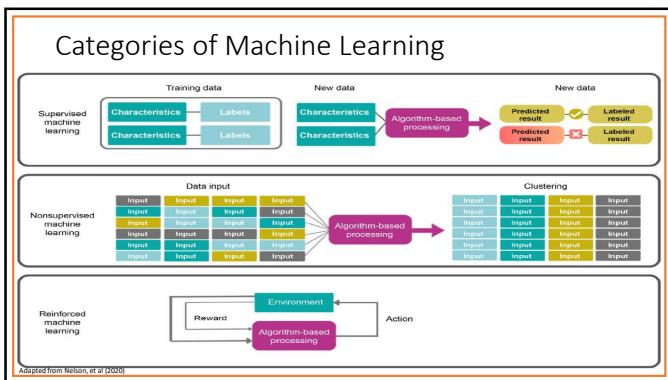
2017: Arterys is the first FDA approved cloud-based deep learning application in healthcare



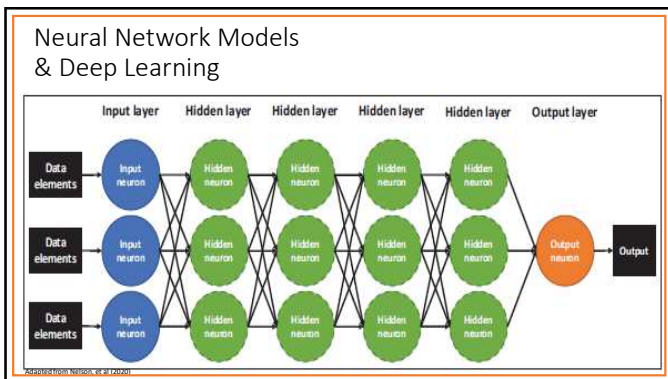
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9

Check-In Question #1

Which of these machine learning categories is unethical to use in the patient care setting?

- A) Supervised Learning
- B) Unsupervised Learning
- C) Reinforced Learning
- D) Repeated Learning



10

Check-In Question #1

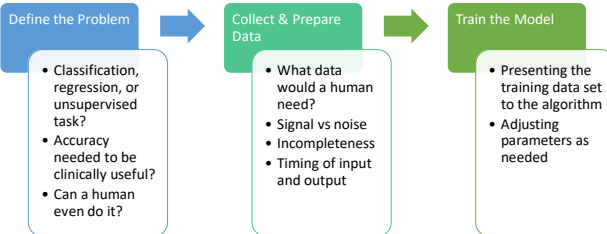
Which of these machine learning categories is unethical to use in the patient care setting?

- A) Supervised Learning
- B) Unsupervised Learning
- C) **Reinforced Learning → Since this methods requires the machine to make mistakes to learn, it is unethical to utilize this type of machine learning in patient care.**
- D) Repeated Learning

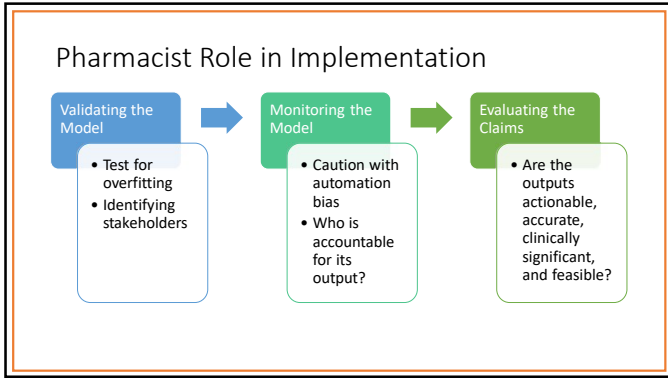


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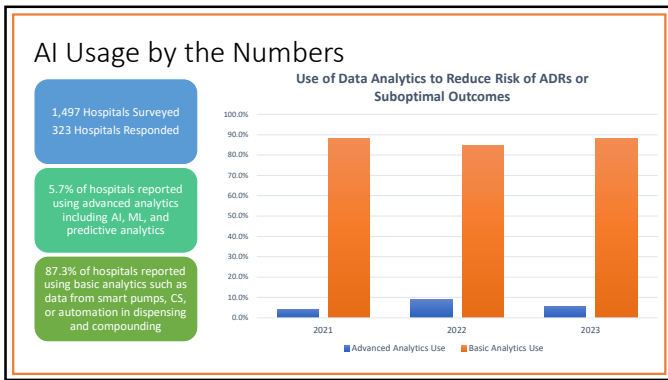
Pharmacist Role in Development



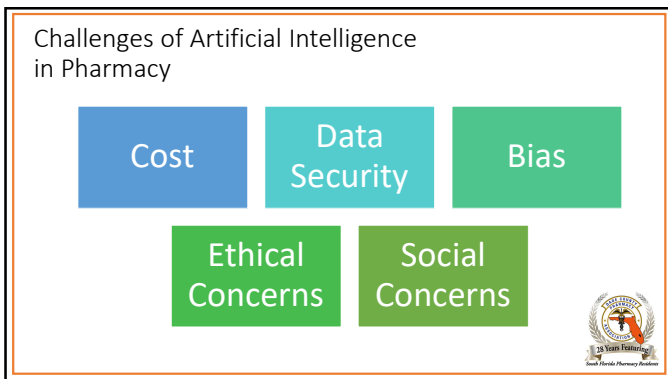
12



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AI Exposure & Vulnerability of Pharmacy



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AI Exposure and Vulnerability

JULY 10, 2024

Potential Labor Market Impacts of Artificial Intelligence: An Empirical Analysis

Council of Economic Affairs (2024)

High Exposure Activities

Activities where the use of AI is the most feasible given current and expected AI abilities.

High Exposure Occupations


High exposure activities are of higher importance to the occupation than all other activities

AI-Related Performance

The degree of complexity to which each activity must be performed to satisfactorily perform the job.

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Panel A. AI Exposed Work Activities		Panel B. All Other Work Activities	
Activity ID	Activity Name	Activity ID	Activity Name
4.A.1.a.1	Getting Information	4.A.1.b.1	Identifying Objects, Actions, and Events
4.A.1.a.2	Monitoring Processes, Materials, or Surroundings	4.A.1.b.2	Inspecting Equipment, Structures, or Materials
4.A.2.a.2	Processing Information	4.A.1.b.3	Estimating the Quantifiable Characteristics of Products, Events, or Information
4.A.2.a.3	Evaluating Information to Determine Compliance with Standards	4.A.2.a.1	Judging the Qualities of Objects, Services, or People
4.A.2.a.4	Analyzing Data or Information	4.A.2.b.3	Updating and Using Relevant Knowledge
4.A.2.b.1	Making Decisions and Solving Problems	4.A.2.b.4	Developing Objectives and Strategies
4.A.2.b.2	Thinking Creatively	4.A.2.b.6	Organizing, Planning, and Prioritizing Work
4.A.2.b.5	Scheduling Work and Activities	4.A.3.a.1	Performing General Physical Activities
4.A.3.a.3	Controlling Machines and Processes	4.A.3.a.2	Handling and Moving Objects
4.A.3.a.4	Operating Vehicles, Mechanized Devices, or Equipment	4.A.3.b.4	Repairing and Maintaining Mechanical Equipment
4.A.3.b.1	Working with Computers	4.A.3.b.5	Repairing and Maintaining Electronic Equipment
4.A.3.b.2	Drafting, Laying Out, and Specifying Technical Devices, Parts, and Equipment	4.A.4.a.1	Interpreting the Meaning of Information for Others
4.A.3.b.6	Documenting/Recording Information	4.A.4.a.2	Communicating with Supervisors, Peers, or Subordinates
4.A.4.a.8	Performing for or Working Directly with the Public	4.A.4.a.3	Communicating with People Outside the Organization
4.A.4.c.1	Performing Administrative Activities	4.A.4.a.4	Establishing and Maintaining Interpersonal Relationships
4.A.4.c.3	Monitoring and Controlling Resources	4.A.4.a.5	Assisting and Caring for Others
		4.A.4.a.6	Selling or Influencing Others
		4.A.4.a.7	Resolving Conflicts and Negotiating with Others
		4.A.4.b.1	Coordinating the Work and Activities of Others
		4.A.4.b.2	Developing and Building Teams
		4.A.4.b.3	Training and Teaching Others
		4.A.4.b.4	Guiding, Directing, and Motivating Subordinates
		4.A.4.b.5	Coaching and Developing Others
		4.A.4.b.6	Providing Consultation and Advice to Others
		4.A.4.c.2	Staffing Organizational Units



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Occupation Categories

AI-Exposed w/ High AI-Related Performance	AI-Exposed w/ Low AI-Related Performance	Not Highly AI-Exposed
<ul style="list-style-type: none"> • Mostly abstract, cognitive activities • AI not likely to replace, more likely to complement 	<ul style="list-style-type: none"> • More routine, less cognitive activities • Most vulnerable to replacement by AI 	<ul style="list-style-type: none"> • AI-exposed activities are not crucial to the occupation's performance • Not vulnerable to AI replacement or complement

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How Does Healthcare Stack Up?

Healthcare AI-Exposure	Healthcare AI-Related Performance
-0.05	0.52
Medical Transcriptionists High Risk for Replacement w/ AI	Human Resource Managers Low Risk for Replacement w/ AI
<ul style="list-style-type: none"> • AI-Exposure High • 0.81 • AI-Related Performance Low • -0.73 	<ul style="list-style-type: none"> • AI-Exposure Low • -0.67 • AI-Related Performance High • 0.60




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Check-In Question #2

Into which of these occupational categories does **pharmacy** best fit?

- A) Not AI-Exposed
- B) AI-Exposed w/ Low AI-Performance
- C) AI-Exposed w/ Medium AI-Performance
- D) AI-Exposed w/ High AI-Performance



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Check-In Question #2

Into which of these occupational categories does **pharmacy** best fit?

- A) Not AI-Exposed
- B) AI-Exposed w/ Low AI-Performance
- C) AI-Exposed w/ Medium AI-Performance
- D) **AI-Exposed w/ High AI-Performance → Pharmacist jobs utilize activities that AI cannot perform, and those it can perform must be at a high complexity.**



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AI Impacts to the Hospital Setting



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Current Use of Artificial Intelligence in Hospital Pharmacy

ADR & DDI Detection	CDS	Chatbots	Dose Recommendations
NLP in EHR	High Risk Drug Identification	Medication Adherence	Medication Error Identification

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Job Quantity

- Streamlined operations may decrease demand for operational tasks, allowing technicians and pharmacists to further specialize.
- Unclear if there would be a net increase or decrease in job quantity

Job Quality

- Increased accuracy and safety improves the mental and physical health of both patients and pharmacy staff.
- Upskilling can lead to more rewarding and mobile skill sets within pharmacy.

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Emerging Job Types

- **AI Workflow Managers:** Pharmacists who oversee and integrate AI tools into hospital workflows.
- **Clinical Decision Support Specialists:** Professionals who guide the application of AI in personalized treatment planning.

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AI Impacts to the Community Setting



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Job Quantity

- AI-powered robotic dispensing systems can fill prescriptions more accurately and quickly than humans, potentially reducing the demand for pharmacy technicians and some pharmacist roles in retail settings.
- Pharmacists may be increasingly required to focus on patient counseling, MTM, and vaccination services, as dispensing tasks become more automated.

Job Quality

- Increased Focus on Patient-Centric Roles: With repetitive tasks automated, pharmacists can devote more time to improving patient outcomes, which may increase job satisfaction for those who prefer clinical over technical roles.
- Workforce Reduction Risk: AI could reduce the number of entry-level jobs, particularly for pharmacy technicians, leading to job displacement.

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Emerging Job Types

- **Interoperations Specialist:** Specialists in leveraging EHRs from multiple sources to determine appropriate outpatient therapies.
- **ChatBot Designers:** Pharmacists focused on training ChatBots to accurately, empathetically, and ethically communicate with patients regarding their medications.

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AI Impacts to the Industry Setting



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Job Quantity

- Accelerated Drug Development: AI can rapidly analyze massive datasets to identify drug candidates, potentially reducing the need for some traditional research positions.
- Expanded Job Opportunities: Growth in AI-driven drug discovery companies could create new positions requiring expertise in both pharmacy and data science.

Job Quality

- Shift from Bench Work to Data Analysis: Many pharmacy researchers may transition from traditional wet-lab roles to computational and AI-supported roles.
- Collaborative Roles: Interdisciplinary collaboration (e.g., with data scientists and bioinformaticians) could enhance job diversity but may require additional skills.

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Emerging Job Types

- **Ethics & Regulation:** Pharmacists can play an important role in determining the ethical use of patient data for AI model training.
- **Pharmacy Data Analysts:** New roles may emerge to analyze AI-generated insights on consumer behavior and optimize marketing methods

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AI Impacts to the Academia Setting



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OpenEvidence
 An AI system to aggregate, synthesize, and visualize clinically relevant evidence in understandable, accessible formats that can be used to make more evidence-based decisions and improve patient outcomes.

ChatGPT Versus OpenEvidence AI: Per Step

Step	ChatGPT	OpenEvidence AI
USMLE Step 1	55.8	95.7
USMLE Step 2 CK	59.1	86.2
USMLE Step 3	61.2	90.2

Directly comparable results between ChatGPT (per King et al., 2023) and OpenEvidence AI.

Practice Guideline
 What is the preferred treatment for African Americans with hypertension?
 Expanded question: What is the preferred treatment for African Americans with hypertension?

The preferred treatment for African Americans with hypertension, according to the 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APHA/ASPC/ASNC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults, is **thiazide diuretics or calcium channel blockers (CCBs)**. The American College of Cardiology and the American Heart Association recommended these classes of medications because they have been shown to be more effective in lowering blood pressure and reducing cardiovascular events in this population compared to renin-angiotensin system (RAS) inhibitors or beta blockers.¹⁰

Thiazide diuretics, such as chlorthalidone, are particularly effective and should be administered at a dose of 12.5 to 25 mg/day (or 25-50 mg/day for hydrochlorothiazide) for optimal endpoint protection. CCBs, such as amlodipine, are also effective and have been shown to reduce blood pressure, cardiovascular disease, and stroke events more effectively than ACE inhibitors in African Americans.¹⁰

For African Americans with hypertension and comorbid conditions like diabetes mellitus with nephropathy, RAS inhibitors may be considered, but they do not offer an advantage over thiazide diuretics or CCBs in those without nephropathy or heart failure.¹⁰

American College of Cardiology
 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APHA/ASPC/ASNC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines
 Published October 2018

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Precepting Students

- Starting Point vs Final Product Creation
- Catching AI-Generated Work
- Official Stances of Local Pharmacy Schools/ACPE

Letter Writing


- Be specific the words you use to describe the student.
- Provide the AI with as much detail as possible.

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Check-In Question #3

In which step of AI tool development should pharmacists be involved?

- A) Designing training data collection
- B) Engaging stakeholders to improve user interface
- C) Validating model and identifying bias
- D) All of the above!



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Check-In Question #3

In which step of AI tool development should pharmacists be involved?

- A) Designing training data collection
- B) Engaging stakeholders to improve user interface
- C) Validating model and identifying bias
- D) **All of the above!**



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Key Takeaways

- 1 Job Evolution, Not Elimination
- 2 Upskilling & Adaptability
- 3 New Ethical & Regulatory Roles
- 4 Impact on Workforce Composition

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“AI won’t replace humans—
But humans with AI
will replace humans without AI”
~Karim R. Lakhani

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Questions?

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Artificial Intelligence and Impacts on the Pharmacy Profession & Jobs

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Transforming Care: Pharmacists Path to Provider Status



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January 25, 2025
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Financial Relationship Disclosure

- No one in control of the content of this activity has a relevant financial relationship (RFR) with an ineligible company
- As defined by the Standards of Integrity and Independence in Accredited Continuing Education definition of an ineligible company. All relevant financial relationships have been mitigated prior to the CPE activity



Objectives



Understand pharmacist responsibilities



Analyze how pharmacist training equips us to prescribe medications safely and effectively



Assess the impact of pharmacist on access to care, hospital admission prevention, wait times, and medication adherence in underserved areas



Review the benefits and barriers of pharmacist provider status



Abbreviations

- ADE – Adverse Drug Event
- AIDS – Acquired Immunodeficiency Syndrome
- COPD – Chronic Obstructive Pulmonary Disease
- CDTM – Collaborative Drug Therapy Management
- CMS – Centers for Medicare & Medicaid Services
- CRA – Certified Public Accountant
- CPT – Current Procedural Terminology
- FBG – Fasting Blood Glucose
- HbA1c – Hemoglobin A1C
- HIV – Human Immunodeficiency Virus
- LDL – Low-Density Lipoprotein
- MG – Milligram
- MTM – Medication Therapy Management
- NPI – National Provider Identifier
- PEP – Ple-Ethoposure Propylates
- PT – Patient
- T2DM – Type 2 Diabetes Mellitus
- US – United States
- MMCL – Millimole



Defining Provider Status

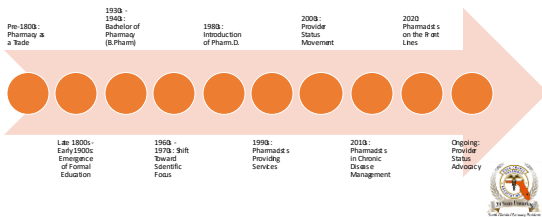
Provider Status Definition: Legal recognition of healthcare professionals eligible for Medicare Part B service reimbursement

Current Recognized Providers

- Physicians
- Physician assistants
- Nurse practitioners
- Certified nurse midwives
- Nurse anesthetists
- Clinical psychologists
- Physical and occupational therapists
- Dietitians
- Social workers



The Evolution of the Pharmacy Profession



Pharmacists' Role Today

- Immunizations
- Patient Education
- Emergency Dispensing
- Prescription Drug Monitoring
- MTM
- Chronic Disease Management



Medications and Services Pharmacists Can Prescribe without Provider Status

- Emergency Contraceptives
- Hormonal Contraceptives
- Immunizations
- Nicotine Replacement Therapy
- PrEP for HIV



Pharmacists Role During the COVID-19 Pandemic

- Expanded Role:** Pharmacists administered COVID-19 tests, vaccines, and prescribed antiviral treatments (Paxlovid, Molnupiravir) under collaborative agreements.
- Legislation:** The PREP Act allowed pharmacists to provide vaccines and prescribe treatments via Emergency Use Authorization.
- State Laws:** Many states authorized pharmacists to prescribe COVID-19 treatments and offer testing services.
- Impact:** Increased access to care, supporting the healthcare system during the pandemic surge.
- Paxlovid (nirmatrelvir/ritonavir):** Pharmacists in Florida prescribed Paxlovid for eligible patients with mild to moderate COVID-19 at risk of severe disease.
- Molnupiravir (Lagevrio):** Pharmacists prescribed Molnupiravir for patients unable to take Paxlovid due to contraindications.



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Pharmacists Role During the COVID-19 Pandemic

Authors	Study Description	Key Contributions	Conclusion
Stephanie L. Schondelmeyer, Kimberly A. Ranta, et al.	The role of pharmacist's expanded during the COVID-19 pandemic, with many moving beyond traditional dispensing duties to becoming frontline healthcare providers. Providing patient care services such as medication therapy management, COVID-19 testing, vaccination administration, and supporting telehealth initiatives.	<p>Expanded Practice: Pharmacists provided patient care, including COVID-19 testing and treatment.</p> <p>Testing & Vaccination: Administered COVID-19 tests and vaccines.</p> <p>Telepharmacy: Offered remote consultations and follow-up.</p> <p>Team Collaboration: Worked with health care teams to manage treatment and optimize medication use.</p>	<p>Increasing recognition of pharmacists as health care providers, particularly during public health emergencies like the COVID-19 pandemic.</p> <p>We should further empower pharmacists to practice at the top of their education and training, thus enhancing healthcare access and quality.</p>



Expanding Pharmacy Practice



Expanding Pharmacy Practice: Florida House Bill 389



Collaborative Pharmacy Practice Agreements:

Pharmacists can initiate, modify or discontinue drug therapy for select conditions.



Prescribing Criteria:

- Active pharmacist license in good standing
- PharmD and 15+ years of experience
- Complete a 20-hour training course
- License renewal every 2 years with 8-hour continuing education
- Maintain professional liability insurance and patient records



Expanding Pharmacy Practice – Florida House Bill 389 Con't.



Minor Conditions:

Requires approval from supervising physician and pharmacy owner

- Influenza
- Strep
- Lice
- Skin conditions (e.g., ringworm)
- Minor infections



Chronic Conditions

Under supervising physician through CPA

- Arthritis
- Asthma
- COPD
- Type 2 Diabetes
- HIV/AIDS
- Obesity



Florida House Bill 599

Consultant Pharmacists' Role:

- MTM
- Collaborative Practice
- Patient Education
- Medication Regimen Review



Florida House Bill 599

Requirements for Consultant Pharmacists in Florida:

- **Licensure:** Active Florida pharmacist license
- **Certification:** Complete a 12-hour consultant pharmacist course
- **Experience:** 1,500 hours of pharmacy practice or an internship
- **CE:** 30 hours of continuing education every 2 years
- **Background Check:** Fingerprinting and criminal background check
- **Exam:** Pass a consultant pharmacist exam



Expanding Pharmacy Practice: Florida House Bill 389 & 599 Cont

Feature	House Bill 389 (CRA)	House Bill 599 (Consultant Pharmacist)
Primary Focus	Expanding role of pharmacist in managing patients through collaboration with health care providers	Defining role and possibilities of consultant pharmacist in various settings
Pharmacist Role	Authorizes pharmacist to initiate, modify, or discontinue appropriate partnership with healthcare providers	Provides oversight and management of medication use in long-term care, hospitals, or other facilities
Patient Care	Focus on providing better patient outcomes through direct collaboration in therapeutic drug management	Focus on improving medication safety and optimizing therapeutic outcomes in institutional settings
Setting	Community pharmacies, clinics, and other outpatient settings where pharmacist can work directly with patient and provider	Long-term care, hospitals, or other health care facilities
Responsibilities	Adjusting medication doses, monitoring therapy, and ordering laboratory tests based on agreed protocol	Review medication regimens, monitor adverse effects, and consult with health care teams

Florida House Bill 389 and 599, House Bill 389, 2018 Florida Legislature



Incident-to Billing and CPT Code Levels for Pharmacists

Level	History	Physical Exam	Med Decision Making	Time	Estimated Reimbursement
99210 (level 1) Minimal	Minimal	Minimal	None	9 minutes	\$23.07
99212 (level 2) Problem Focused	CC, HPI	1-5 Elements	Straight forward	10 minutes	\$45.77
99213 (level 3) Expanded Problem Focused	CC, HPI, RCS	6 or more elements	Low Complexity	15 minutes	\$75.38
99214 (level 4) Detailed	CC, HPI, RCS, PF, SH	12 elements	Moderate Complexity	25 minutes	\$110.28
99215 (level 5) Comprehensive	CC, HPI, RCS, PF, SH	All elements	High Complexity	40 minutes	\$147.76

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Example of Incident-to Billing Case

Patient BR presents to your pharmacotherapy clinic for blood pressure management. Her blood pressure today is 170/80 and her current blood pressure medication is enalapril 10 mg daily. You decide to increase her enalapril to 20 mg daily and see her back in 2 weeks. The total visit time with documentation is 15 minutes.

What level of service could be billed by the provider?

- **Answer: Level 99212**
- Why - History = HPI
- Physical exam = 1 element = blood pressure
- Medical decision making = straightforward (1 medication change)

◦ Although time was greater than 10 minutes, the remaining elements would not justify a level 3 billing

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States With Pharmacist Provider Status

- California
- North Carolina
- Montana
- New Mexico
- Nevada
- Utah
- Idaho
- Colorado
- Tennessee



- These states have passed legislation to allow pharmacists to bill for services like medication therapy management, immunizations, and chronic disease management, enhancing their role in patient care.
- <https://www.fda.gov/oc/2014/05/2014-05-20-pharmacist-prescribes-only-authorization> provides a link to the FDA's guidance on pharmacist prescribes only.

Assessment Question 1

- Which state has granted pharmacists provider status to prescribe medications?
- A) California
 - B) New York
 - C) Florida
 - D) Ohio



Assessment Question 1

- Which state has granted pharmacists provider status to prescribe medications?
- A) California
 - B) New York
 - C) Florida
 - D) Ohio
- Answer: A



Florida Pharmacist Requirements

Pharmacy License: Active, valid Florida pharmacy license

Pharm.D.: Doctor of Pharmacy degree from an accredited school

Internship: 1,500 hours of internship experience

Exams: Pass NAPLEX and Florida Pharmacy Law Exam

Continuing Education: 30 hours every two years

Background Check: Clear criminal background check

Florida Pharmacist Requirements Con't

Hospital Pharmacist:

Hospital Experience: Clinical experience in an inpatient setting

Residency: PGY1 or PGY2 residency preferred

Certification: Board Certified Pharmacotherapy Specialist

Retail Pharmacist:

Retail Experience: Experience in a community or retail pharmacy

Immunization Certification: Required for vaccine administration

OTC Knowledge: Expertise in over-the-counter medications

Ambulatory Care Pharmacist:

Ambulatory Care Training: Experience in outpatient settings

Residency: PGY1 and PGY2 ambulatory care residency

Certification: Board Certified Ambulatory Care Pharmacist

OPA: Ability to work under collaborative practice agreements

Given the qualifications and training required for pharmacists, do you believe we should be granted provider status?



APhA Survey



83% of voters agree that pharmacists have both the education and the training to do more than fill prescriptions

66% say that they already think of pharmacists as health care providers

95% of pharmacists say that provider status is important to them

Benefits of Pharmacists Provider Status

Better Integration into Healthcare Teams

Expanded Services

Better Patient Outcomes

Improved Access to Care

Professional Standing



States With Pharmacist Provider Status

- California
- North Carolina
- Montana
- New Mexico
- Nevada
- Utah
- Idaho
- Colorado
- Tennessee



A map of states that allow pharmacists to autonomously prescribe (A) contraceptive products, (B) naloxone, and (C) tobacco cessation products.^{1,18-20,24}

• These states have passed legislation to allow pharmacists to bill for services like medication therapy management, immunizations, and chronic disease management, enhancing their role in patient care.

Assessment Question 2

True or False: Expanding Florida's pharmacist's role to include prescribing would improve patient access to medications and healthcare services.



Assessment Question 2

True or False: Expanding Florida's pharmacist's role to include prescribing would improve patient access to medications and healthcare services.

Answer: True



Barriers to Provider Status



Addressing Barriers to Provider Status

Advocate for Legislative Change

Expand Training and Education

Collaborate with Healthcare Providers

Increase Public Awareness

Streamline Administrative Processes

Focus on Outcome-Based Reimbursement



Assessment Question 3

What barrier do you see that currently limits pharmacists from providing greater patient care in your community? Select all the above.

- A) Lack of pharmacist interest
- B) Limited funding or resources
- C) Insufficient training or education on patient care
- D) Regulatory restrictions



Assessment Question 3

What barrier do you see that currently limits pharmacists from providing greater patient care in your community?

- A) Lack of pharmacist interest
- B) Limited funding or resources
- C) Insufficient training or education on patient care
- D) Regulatory restrictions

Answer: B, C, and D.




Transition to Value Based Care




Enhancing Healthcare Quality: The Role of Pharmacists in HEDIS Measures and Outcomes

Measure Name	Abbreviation	Measure Description
Effectiveness of Care: Persistence of Beta-Blocker Treatment After a Myocardial Infarction	PBH	The percentage of members 18 years of age and older diagnosed with a myocardial infarction who were prescribed and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of AHA/ACC-defined persistent beta-blocker treatment for 180 days following discharge.
Statins Therapy for Patients with Cardiovascular Disease	SFC	The percentage of males 21-75 years of age and females 40-75 years of age diagnosed the measurement year who were identified as having clinical atherosclerotic cardiovascular disease (ASCVD) and met the following criteria: The following criteria are reported: 1. Received statin in the study. Members who were dispensed at least one high-intensity or moderate-intensity statin medication during the measurement year. 2. Statin adherence 80%.
Glycemic Status Assessment for Patients with Diabetes	GSD	The percentage of members 18-75 years of age with diabetes (types 1 and 2) whose most recent glycemic status (hemoglobin A1c [HbA1c]) or glucose management (fasting or (GMI)) was within the following levels during the measurement year: Glycemic Status <6.0%, Glycemic Status >6.0%, None. Organizations must use the same data collection method (administered or reported) to report these indicators.




Enhancing Healthcare Quality: The Role of Pharmacists in HEDIS 2025 Measures

- **HEDIS 2025:** A set of updated performance measures to enhance healthcare quality reflecting clinical best practices.
- **New Measures:**
 - **Documentation of Assessment After Mammogram:** BI-RADS assessments for women 40-74, documented within 34 days.
 - **Follow-Up After Abnormal Breast Cancer Assessment:** Follow-up within 30 days for high-risk BI-RADS results.
 - **Blood Pressure Control for Hypertension:** Includes pharmacy data and is stratified by race/ethnicity.
- **Changes:**
 - **Eye Exam for Diabetes:** Now reported using the Administrative Method.
 - **Mental Health Follow-Up:** Expanded follow-up criteria for mental health.
 - **High-Risk Medications in Older Adults:** Updated per new Beers Criteria.
- **Expanded & COM-D-19 Related Changes:**
 - **Well-Care Visits:** Removal of telehealth visits.
 - **Acute Hospital Utilization:** Now includes Medical members age 18-64.
 - **Adult Immunization:** Added hepatitis B for adults 19-59.
- **Why Pharmacists Should Get Provider Status:**
 - **Medication Management:** Critical for conditions like hypertension and diabetes.
 - **Timely Interventions:** Ensure follow-up care, improving outcomes.
 - **Expanded Access:** Provide services, preventive services, improving HEDIS scores.




Let's Look at the Studies!




Provider Status Preparedness: The Importance of Clinical Pharmacists in Improving Blood Glucose and Lipid Levels in Patients with Diabetes and Myocardial Infarction

Authors	Study Description	Primary Endpoints	Secondary Endpoints	Results	Conclusion
Shi, E-H., Yu, B. B., Shen, L, et al.	Interventional (Randomized Controlled Trial) or Cohort Study 128 patients 47 in intervention 81 in usual care group	Blood Glucose Levels: Changes in fasting glucose or HbA1c. Lipid levels: Changes in LDL total cholesterol, and HDL.	Patient satisfaction with pharmacist-led care Medication adherence improvements	Significant improvements were seen in blood glucose (HbA1c: 9.0 to 8.3, FBS: 11.3 to 7.1, P&S: 17.9 to 12.1, p<0.001) and lipid levels (TC: 4.9 to 3.5, LDL-C: 3.0 to 1.8, p<0.001). The intervention group showed better HbA1c (p<0.05). Subgroup analysis showed improvements.	Clinical pharmacists improve glucose and lipid control in patients with diabetes and myocardial infarction



Provider Status Preparedness: Impact of Pharmacist-Led Chronic Disease Management in a Federally Qualified Health Center

Authors	Study Description	Primary Endpoints	Secondary Endpoints	Results	Conclusion
McCarthy C. & Bateman Jr, M. T.	Interventional Study: A randomized controlled trial 300 enrolled, 199 included	Improvement in chronic disease markers (e.g., blood pressure, blood glucose, cholesterol levels) Reduction in healthcare utilization (e.g., hospital visits, emergency room visits)	Patient satisfaction with pharmacist-led care Medication adherence improvements	Primary endpoint for T2DM (n=96, A1C change -2.1%, p<0.001), hypertension (n=32, SBP change -9.7 mmHg, p<0.001), anxiety (n=25, GAD-7 change -7, p<0.001), and depression (n=22, PHQ-9 change -11.1, p<0.001). Patient satisfaction improved	Positive impact of pharmacist-led management on chronic disease outcomes Enhanced patient care and satisfaction in a Federally Qualified Health Center setting Reduction in healthcare costs due to fewer hospitalizations and emergency visits



Provider Status Preparedness: Impact of Ambulatory Care Pharmacist-Led Diabetes Mellitus Management on Hemoglobin A1C Values Among Patients with Diabetes in a Primary Care Clinic Over Two Years

Authors	Study Description	Primary Endpoints	Secondary Endpoints	Results	Conclusion
Hagedorn, S. M., Stone, K. L., Manser, et al.	Interventional Study (retrospective chart review)	Change in Hemoglobin A1c (HbA1c) Level: Measurement of the change in HbA1c values over two years in patients receiving pharmacist-led diabetes management	Secondary Endpoints: Blood Glucose Control: Medication management in fasting glucose or HbA1c Medication Adherence: Assessment of adherence to diabetes medications	The mean HbA1c decreased from 8.8% at baseline to 7.8% after two years (p<0.001). The percent age of patient with HbA1c <7% improved from 12.9% (n=15) pre-intervention to 42.2% (n=49) post-intervention (p<0.001). Mean HbA1c improved from 8.8% to 8.2% (p<0.001).	Pharmacist-led diabetes management effectively reduces HbA1c values in patients. Improved blood glucose control and medication adherence due to pharmacist involvement in primary care.



Provider Status Preparedness: A Randomized Trial of a Community-Based Approach to Dyslipidemia Management

Authors	Study Description	Primary Endpoints	Secondary Endpoints	Results	Conclusion
Tavakoli, R., Rosenthal, M., Pearson, G.	Randomized controlled trial in 14 community pharmacies in 99 adults with uncontrolled dyslipidemia	The proportion of participants achieving target LDL-cholesterol (LDL-C) levels at 6 months, defined as: Target LDL-C <2 mmol/L or a 50% reduction in LDL-C from baseline.	The adjusted mean difference in LDL-C levels between the intervention group (pharmacist prescribing and the control group (usual care)). This endpoint assesses the change in LDL-C levels from baseline to 6 months, comparing the two groups.	49% of the intervention group reached target LDL-C levels vs 18% in the control group (p = 0.007), a statistically significant difference. The intervention group had a significantly greater reduction in LDL-C (1.22 mmol/L vs 0.42 mmol/L, p < 0.001).	Pharmacist prescribing significantly improved LDL-C target achievement, suggesting a major public health impact.



Provider Status Preparedness: Effect of Pharmacist-Led Intervention in Elderly Patients through a Comprehensive Medication Reconciliation: A Randomized Clinical Trial

Authors	Study Description	Primary Endpoints	Results	Conclusion
Lee, S., Mi, Y., Han, E., et al.	Prospective, open-label, randomized clinical trial with post-discharge follow-up within 6 months	Difference in adverse drug events (ADEs) during hospitalization and 30 days after discharge.	No ADEs reported in the intervention group vs 5 ADEs in the control group at the 30-day follow-up (p = 0.039). This difference was statistically significant, indicating that the intervention was effective in reducing ADEs.	Pharmacist-led interventions using comprehensive medication reconciliation significantly reduced ADEs at 30-day follow-up, highlighting the potential benefits for elderly patients in managing medications post-discharge.



Improving Medicare Part C & D Star Ratings Through Pharmacist Provider Status



Overview of Medicare Part D Star Ratings:

- A quality measurement system for Medicare Part D prescription drug plans.
- Ratings range from 1 to 5, with 5 being the highest.

Factors Affecting Star Ratings:

- Medication adherence (e.g., diabetes, hypertension)
- Proper medication use and patient satisfaction
- Reducing errors and hospital readmissions

Pharmacists' Role in Improving Star Ratings:

- **MTM Services:** Optimize therapy, improve adherence, and educate.
- **Medication Synchronization & Counseling:** Help with refills and medication understanding.
- **Chronic Disease Management:** Support patients for better outcomes.

Impact of Provider Status:

- Allows pharmacists to bill for services and provide comprehensive care.
- Improves medication outcomes, boosting Star Ratings.

Conclusion: Provider status enables pharmacists to improve patient care and Medicare Part D Star Ratings.



Improving Medicare Part C & D Star Ratings Through Pharmacist Provider Status

Measure	2022 MA-PD Average Star	2023 MA-PD Average Star	2024 MA-PD Average Star	2025 MA-PD Average Star
Medication Adherence for Diabetes Medications	3.7	3.0	3.3	3.2
Medication Adherence for Cholesterol Statins	3.6	3.1	3.2	3.3
Statins Use in Persons with Diabetes (SUDP)	3.4	3.1	2.7	2.8



Key Takeaway Points



- **Roles and Responsibilities:** Pharmacists manage medications, provide education, immunize, assist in chronic disease management, and collaborate in healthcare teams.
- **Path to Recognition:** Achieve provider status through advocacy, legislation, service expansion, training, and healthcare collaboration.
- **Advantages:** Provider status improves access to care, increases revenue, enhances patient outcomes, elevates the profession, and fosters integration in healthcare teams.
- **Challenges:** Barriers include legislative issues, public understanding, reimbursement, scope-of-practice limits, and resistance from other providers.
- **Strategies:** Overcome barriers through advocacy, public education, evidence building, interprofessional collaboration, and advanced training.



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- Lee, S., Mi, Y., Han, E., et al. Effect of pharmacist-led intervention in elderly patients through a comprehensive medication reconciliation: A randomized clinical trial. *JAM Geniatr Soc*.



Questions?



Transforming Care: Pharmacists Path to Provider Status

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Is it Worth the "Weight:" GLP Guidelines for Use

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January 26, 2025



Objectives

- Explain the pharmacokinetics and pharmacodynamics of glucagon-like peptide 1 (GLP-1) receptor agonists
- Review the current guidelines on the use of GLP-1 agonists
- Assess the utilization of GLP-1 agonists in obesity and weight loss
- Discuss the concerns of compounding GLP-1 agonists

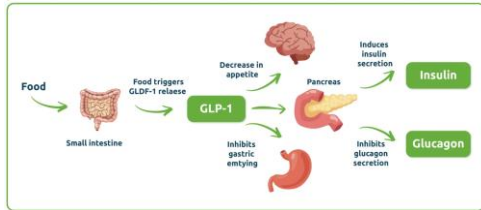


Background

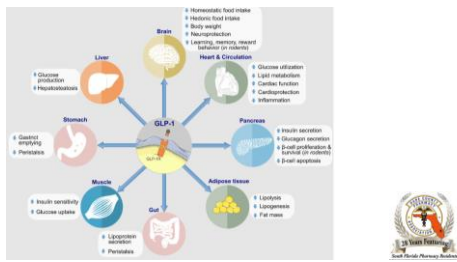


- Over the past two decades, therapies based on incretin hormones, spearheaded by glucagon-like peptide 1 (GLP1) receptor agonists, have become the treatment of choice for obesity and type 2 diabetes mellitus (T2DM)
- Incretins are natural hormones released from the gut in response to nutrient intake that help to regulate appetite and metabolism by stimulating pancreatic hormone secretion
- There are two known incretins:
 - o Glucose-dependent insulinotropic polypeptide (GIP) are produced by the K cells of an upper gut
 - o GLP-1 are produced by the L cells of a lower gut
- GLP-1 agonists are a class of medications originally approved for type 2 diabetes but have been shown to be safe and effective for obesity and cardiovascular disease

Glucagon like peptide-1 (GLP-1)



Glucagon like peptide-1 (GLP-1)- Effects



GLP-1 receptor agonists

- Glucagon-like peptide 1 receptor agonists affect glucose control through several mechanisms including:
 - Enhancing glucose-dependent insulin secretion
 - Slowing gastric emptying
 - Reducing postprandial glucagon and food intake
- Structurally, these agents fall into 2 broad categories: human GLP-1 backbone agents and exendin-4 backbone agents

Categories	Medications
Human GLP-1 backbone	Dulaglutide (Trulicity®) Liraglutide (Victoza®, Saxenda®) Semaglutide (Ozempic®, Wegovy®)
Exendin-4 backbone	Exenatide (Byetta®, 2 formulations) Tirzepatide (Mounsjuro®, Zepbound®)



Pharmacokinetics

Absorption

- Rapid absorption and achieving peak concentrations within 3 hours

Distribution

- Low volume of distribution, predominantly remaining in the bloodstream

Half Life

- Exenatide = 3 hours
- Semaglutide = 7 days
- Liraglutide = 12.5 hours
- Dulaglutide = 4.5 days
- Tirzepatide = 5 days

Excretion

- Renal elimination



Adverse Effects

- Most frequent adverse reactions include:
 - Nausea
 - Vomiting
 - Diarrhea
 - Could lead to an acute kidney injury due to volume contraction
 - Dizziness
 - Injection-site pruritus and erythema

More severe adverse reactions include: pancreatitis, medullary thyroid carcinoma, gallbladder disease, acute kidney injury, and diabetic retinopathy



Warnings

Contraindications

- Hypersensitivity and pregnancy/breastfeeding
 - Some formulations of contraception are recommended with GLP-1 agonists in women of childbearing age
- Gastroparesis and inflammatory bowel disease
- Personal or family history medullary thyroid cancer
- Patients with MEN2 syndrome

Black Boxed Warnings

- Risk of thyroid C-cell tumors

Warnings

Suicidal Thoughts

- The FDA has been evaluating reports of suicidal thoughts or actions in patients treated with glucagon-like peptide-1 receptor agonists (GLP-1 RA)
- A preliminary evaluation has not found evidence that the use of these medicines causes suicidal thoughts or actions, but the FDA is continuing to investigate this issue
- Health care providers should monitor for and advise patients using GLP-1 RAs to report new or worsening depression, suicidal thoughts, or any unusual changes in mood or behavior

Surgical Procedures

- American Society of Anesthesiologists has suggested **holding** GLP-1 agonists prior to planned procedures requiring general anesthesia
- Use of GLP-1 agonists has been associated with elevated residual gastric contents, which may increase the risk for adverse events during anesthesia and deep sedation (including aspiration)

Monitoring Parameters



- Plasma glucose
- GI adverse reactions (eg, nausea, vomiting, diarrhea)
- Weight loss
- Kidney function (at baseline and following dose increases in patients with kidney impairment reporting severe GI adverse reactions)
- Signs/symptoms of pancreatitis
- HbA1c:
 - Monitor every 6 months in patients who have stable glycemic control and are meeting treatment goals
 - Monitor every 3 months in patients in whom treatment goals have not been met

GLP-1 RA Comparison

FBG: fasting blood glucose
PPBG: postprandial blood glucose

Specific Agent	Glucose Effect	Hypoglycemia	Weight Effect	CV Reduction	Availability	Renal Cutoffs
Exenatide IR (Byetta®)	↓	Low	↓	X	Pre-filled, multi-dose pen	CrCl < 30
Lixisenatide (Adlyxin®)	PPBG (short-acting)	Low	↓	X	Pre-filled, multi-dose pen	eGFR < 15
Liraglutide (Victoza®, Saxenda®)	↓	Low	↓↓	Yes	Pre-filled, multi-dose pen	None
Dulaglutide (Trulicity®)	↓	Low	↓↓	Yes	Single-dose pen	None
Semaglutide (Ozempic®, Wegovy®, Rybelsus®)	FBG (and PPBG; long acting)	Low	↓↓↓	Yes	Pre-filled, multi-dose pen	None
Tirzepatide (Mounjaro®, Zepbound®)	↓	Low	↓↓↓	X	Pre-filled, multi-dose pen	None

Source: FDA, AACE. Pharmacologic treatment of type 2 diabetes mellitus. Update of USPSTF Recommendation. JAMA. 2019;321(10):1000-1012.

Dosing Considerations- *Obesity Agents*

Medication	Dosing Titration
Dulaglutide (Trulicity®)	Initial: 0.75 mg once weekly; may increase to 1.5 mg once weekly after 4 to 8 weeks (maximum of 4.5 mg once weekly)
Liraglutide (Saxenda®)	Initial: 0.6 mg once daily for 1 week; increase by 0.6 mg/day at weekly intervals to a target dose of 3 mg once daily
Semaglutide (Wegovy®)	SQ; Initial: 0.25 mg once weekly for 4 weeks, then increase to 0.5 mg once weekly. May increase to 1 mg once weekly after 4 weeks on the 0.5 mg/week dose if needed to achieve glycemic goals; may increase further to 2 mg once weekly (maximum: 2 mg/week)
Tirzepatide (Zepbound®)	Initial: 2.5 mg once weekly for 4 weeks, then increase to 5 mg once weekly. May increase dose in 2.5 mg/week increments every 4 weeks if needed to achieve glycemic goals (Maximum: 15 mg/week)

Knowledge Check #1

Which GLP-1 receptor agonist is available as an oral formulation?

- A. Semaglutide
- B. Tirzepatide
- C. Liraglutide
- D. Exenatide



Knowledge Check #1

Which GLP-1 receptor agonist is available as an oral formulation?

- A. **Semaglutide**
- B. Tirzepatide
- C. Liraglutide
- D. Exenatide



Knowledge Check #2

True or False: GLP-1 agonists can be used in patients with a history of thyroid cancer without any concerns



Knowledge Check #2

False: GLP-1 agonists can be used in patients with a history of thyroid cancer without any concerns



Tackling Obesity: The Power of GLP-1 Agonists

Background

- Obesity rates have reached epidemic dimensions globally and obesity ranks as one of the leading preventable causes of death, second only to smoking.
- Obesity is a chronic disease with high prevalence and associated comorbidities, making it a growing global concern
- Randomized controlled trials and real world evidence have consistently shown that GLP-1 receptor agonists are effective and acceptably safe for the treatment of type 2 diabetes and obesity
- As of 2024, the GLP-1 agonists that are FDA approved for chronic weight management include :
 - Semaglutide
 - Liraglutide
 - Tirzepatide



Key Facts on Obesity

- In 2022, 1 in 8 people in the world were living with obesity.
- Worldwide adult obesity has more than doubled since 1990, and adolescent obesity has quadrupled.
- In 2022, 2.5 billion adults (18 years and older) were overweight. Of these, 890 million were living with obesity.
- In 2022, 43% of adults aged 18 years and over were overweight and 16% were living with obesity.
- In 2022, 37 million children under the age of 5 were overweight.
- Over 390 million children and adolescents aged 5–19 years were overweight in 2022, including 160 million who were living with obesity.

WHO. Obesity fact sheet. March 1, 2024. www.who.int/news-room/fact-sheets/detail/obesity-and-overweight

Guidelines for Obesity Management

- AHA/ACC/TOS Guidelines (2013): Management of Overweight and Obesity in Adults
- AACE/ACE Guidelines (2016): Clinical Practice Guidelines For Medical Care of Patients with Obesity
- Canadian Guidelines (2020): Obesity in adults: a clinical practice guideline - PMC
- VA-DoD Guidelines (2020): VA/DoD Clinical Practice Guideline for the Management of Adult Overweight and Obesity
- AGA (2022): Clinical Practice Guideline on Pharmacological Interventions for Adults with Obesity
- ADA (2024): Standards of Care in Diabetes—2024

American Heart Association (AHA)
American College of Cardiology (ACC)
The Obesity Society (TOS)
American Association of Clinical Endocrinology (AACE)
American Association of Endocrine Surgeons (AAES)
American Association of Dietitians (ADA)
American Association of Endocrine Surgeons (AAES)
American Diabetes Association (ADA)

What Do The Guidelines Say?

- Weight loss of 3–7% of baseline weight improves glycemia and other intermediate CV risk factors
- Sustained loss of >10% of body weight usually confers greater benefits, including disease-modifying effects and possible remission of T2D, and may improve long-term CV outcomes and mortality

In people with diabetes and overweight or obesity, the preferred pharmacotherapy should be a GLP-1 RA or GIP/GLP-1 RA with greater weight loss efficacy (i.e., semaglutide or tirzepatide)

Wright KS, et al. R. Shetty and weight management for the prevention and treatment of type 2 diabetes. *Diabetes Care*. 2022;45(12):2100-2110.

AACE Care for Persons with Overweight/Obesity



	BMI < 25	BMI > 25-27	BMI > 27-35	BMI > 35
Nutrition	Maintain or achieve optimal weight	Intentional caloric reduction	Structured diet with meal replacements	
Physical Activity	Aerobic exercise >150 minutes/week + resistance training 2-3 sessions/week	Structured exercise program with overweight and accountability		
Sleep	6-8 hours/night	Screen for sleep disturbances	Refer for formal sleep study	
Medications	Not recommended	Consider weight loss meds	Add weight loss meds	
Interventions	Screen high-risk groups for complications	Screen and manage complications	Consider bariatric surgical options	Refer for bariatric surgical options

American Association of Clinical Endocrinology (AACE)

Weight Loss Medications



Drug	Class	Weight Loss
Phentermine (Adipex-P®)	Sympathomimetic	3%
Phentermine/topiramate-ER (Qsymia®)	Sympathomimetic amine/gabamnergic	9-10%
Naltrexone-ER/Bupropion-ER (Contrave®)	Opioid-receptor antagonist/dopamine-norepinephrine reuptake inhibitor	4-6%
Orlistat (Xenical®)	GI lipase inhibitor	4%
Liraglutide	GLP-1 RA	5-6%
Semaglutide	GLP-1 RA	18%
Tirzepatide	GIP/GLP-1 RA	18%

AGA Guidelines(2022)

Recommendation	Strength of Recommendation	Quality of Evidence
In adults with obesity or overweight with weight-related complications, who have had an inadequate response to lifestyle interventions, the AGA recommends adding pharmacological agents to lifestyle interventions over continuing lifestyle interventions alone	Strong	Moderate
In adults with obesity or overweight with weight-related complications, the AGA suggests using semaglutide 2.4 mg with lifestyle modifications, compared with lifestyle modifications alone Given the magnitude of net benefit, semaglutide 2.4 mg may be prioritized over other approved AOMs for the long-term treatment of obesity for most patients.	Conditional	Moderate
In adults with obesity or overweight with weight-related complications, the AGA suggests using liraglutide 3.0 mg with lifestyle modifications, compared with lifestyle modifications alone	Conditional	Moderate

American Gastroenterological Association (AGA)

AGA Indian Clinical Practice Guidelines for Management of Obesity/Overweight Based on Evidence 2022

ADA Guidelines (2024)



- Summary of Recommendations:
 - For patients with T2D and CVD or high cardiovascular risk, GLP-1 RAs are preferred as part of the treatment regimen after metformin
 - For weight management, GLP-1 RAs like semaglutide (Wegovy) are effective in helping patients with obesity and T2D achieve significant weight loss.
 - Close monitoring for side effects, especially gastrointestinal issues, is necessary.

2024 ADA Guidelines strongly endorse GLP-1 receptor agonists as an integral part of treatment for type 2 diabetes and obesity

Weight Management- Efficacy



Very High	High	Low
Semaglutide Tirzepatide	Dulaglutide Liraglutide	Exenatide Lixisenatide

GLP-1 Receptor Agonists (GLP-1 RAs) and Tirzepatide (Tirzepatide) are recommended as first-line treatment for type 2 diabetes (T2D) and obesity. GLP-1 RAs are recommended for T2D and obesity. Tirzepatide is recommended for obesity. Tirzepatide is recommended for obesity. Tirzepatide is recommended for obesity.

Let's Meet Our Patient

JD is a 52 year old male with Type 2 Diabetes (T2DM), Hypertension (HTN), Dyslipidemia, Obesity, and recently diagnosed with Obstructive Sleep Apnea (OSA)

JD presents for a routine follow-up visit with his primary care physician. He reports difficulty managing his blood glucose levels despite being on metformin and following dietary recommendations. He has a sedentary lifestyle and has gained approximately 10 pounds over the past 6 months. He mentions occasional episodes of increased thirst and frequent urination but has not noticed significant changes in vision.



Vitals/Lab Results

Vital Signs	Pertinent Labs
BP: 130/82 mmHg HR: 72 bpm Respiratory Rate: 16 breaths/min Temperature: 98.6°F Weight: 235 lbs Height: 5'10" BMI: 33.8 kg/m ²	HbA1c: 8.2% (target < 7.0%) Fasting blood glucose: 160 mg/dL Lipid panel: Total Cholesterol: 180 mg/dL LDL: 95 mg/dL HDL: 45 mg/dL Triglycerides: 120 mg/dL Creatinine: 0.9 mg/dL eGFR: 90 mL/min/1.73m ²



Step 1: Diagnosis
<p>Does the patient have the following conditions?</p> <p>Obesity: BMI ≥ 30 kg/m² (or ≥ 27 kg/m² with comorbidities like T2D, hypertension, or dyslipidemia)</p> <p>Type 2 Diabetes (T2D): Diagnosed with T2D and HbA1c ≥ 6.5% or fasting glucose ≥ 126 mg/dL</p> <p>Other Comorbidities: Assess for cardiovascular disease, hypertension, and other metabolic risk factors</p>
Step 2: Lifestyle Modifications
<p>Initiate lifestyle interventions including calorie-reduced diet, increased physical activity (≥150 minutes per week), and behavioral therapy. Encourage psychosocial support for long-term weight management.</p>
Step 3: Evaluate Need for Pharmacotherapy
<p>Obesity Treatment Criteria:</p> <p>Consider pharmacotherapy (BMI ≥ 30 kg/m² or BMI ≥ 27 kg/m² with obesity-related comorbidities (e.g., T2D, CVD). Consider GLP-1 agonists for weight loss when lifestyle changes alone are insufficient.</p> <p>T2D Treatment Criteria:</p> <p>Consider GLP-1 agonists if HbA1c remains high after lifestyle modifications and metformin therapy, consider if there is cardiovascular risk (e.g., history of stroke, heart disease)</p>
Step 4: Start GLP-1 Agonist Therapy
<p>Choose GLP-1 agonist:</p> <ul style="list-style-type: none"> • Semaglutide (Ozempic, Wegovy) • Tirzepatide (Mounjaro, Zepbound)
Step 5: Additional Considerations and Adjustments
<p>Combination Therapy:</p> <ul style="list-style-type: none"> • For patients with T2D and obesity, combine GLP-1 agonists with SGLT2 inhibitors or insulin if needed for better glycemic control. <p>Discontinuation:</p> <ul style="list-style-type: none"> • Discontinue GLP-1 agonist therapy if the patient does not achieve at least 5% weight loss within 6 months, as per treatment guidelines. <p>Long-Term Maintenance:</p> <ul style="list-style-type: none"> • Continue lifestyle modifications and re-assess the need for ongoing pharmacotherapy • GLP-1 agonists may be continued long-term in patients who maintain weight loss and glycemic control

Our Patient

JD is a 52 year old male with Type 2 Diabetes (T2DM), Hypertension (HTN), Dyslipidemia, Obesity, and recently diagnosed with Obstructive Sleep Apnea (OSA)

JD presents for a routine follow-up visit with his primary care physician. He reports **difficulty managing his blood glucose levels despite being on metformin** and following dietary recommendations. He has a sedentary lifestyle and has **gained approximately 10 pounds over the past 6 months**. He mentions occasional episodes of increased thirst and frequent urination but has not noticed significant changes in vision.

Do you believe our patient qualifies for weight loss pharmacotherapy?



Let's Dive Into the Literature

SCALE Maintenance Trial

#	N	Population	Duration	Outcomes (% Weight Loss)
1	422	Adults with obesity or overweight (with comorbidities), without T2D who lost ≥5% of initial weight during a low-calorie diet run-in	56 weeks	Liraglutide 3.0 mg: -6.2% Placebo: -0.2%

Conclusion: 3.0 mg of liraglutide, as an adjunct to diet and exercise, was associated with reduced body weight and improved metabolic control

Bottom Line: A total of 63.2% of the patients in the liraglutide group as compared with 27.1% in the placebo group lost at least 5% of their body weight (P<0.001), and 33.1% and 10.6%, respectively, lost more than 10% of their body weight (P<0.001)

Shah RR, Luchini L, Shor R, et al. Obesity (2018) 24(12):2277-83.

STEP Trials- Obesity

#	N	Population	Duration	Outcomes (% Weight Loss)
1	1961	Adults with at least 1 unsuccessful weight loss attempt, BMI>30 or >27 with at least 1 weight related condition without diabetes	68 weeks	Semaglutide 2.4mg: -16% Placebo: -5.7%
2	1210	Adults with at least 1 unsuccessful weight loss attempt, BMI>27 +T2D	68 weeks	Semaglutide 1mg: -6.9% Semaglutide 2.4mg: -9.6% Placebo: -3.4%
3	611	Adults with at least 1 unsuccessful weight loss attempt, BMI>30 or >27 with at least 1 weight related condition without diabetes	68 weeks	Semaglutide 2.4mg: -16% Placebo: -5.7%
4	801	Adults with at least 1 unsuccessful weight loss attempt, BMI>30 or >27 with at least 1 weight related condition without diabetes	20 weeks semaglutide open-label, then 48 weeks placebo vs semaglutide	20 weeks Semaglutide 2.4mg: -10.6% 20-68 weeks Semaglutide 2.4mg: -7.9% Placebo: -6.9%

Conclusion: The change in body weight from baseline to week 68 was -15.3 kg in the semaglutide group as compared with -2.6 kg in the placebo group (estimated treatment difference, -12.7 kg; 95% CI, -13.7 to -11.7).

Bottom Line: In patients who are overweight or obese, 2.4 mg of semaglutide once weekly plus lifestyle intervention was associated with sustained, clinically relevant reduction in body weight

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How Does Tirzepatide Stand Out From Other GLP-1 Receptor Agonists?

Background



- Tirzepatide has a dual action mechanism which targets both glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist
- Addition of GIP receptor agonism allows tirzepatide to further enhance insulin secretion, improve fat metabolism, and increase energy expenditure
- By combining the effects of GLP-1 and GIP receptor agonism, tirzepatide offers a more comprehensive and effective approach to managing Type 2 diabetes and obesity

This dual action results in greater weight loss and improved glucose control compared to GLP-1 receptor agonism alone

GLP-1/GIP Receptor Agonist

	GLP-1	GIP
Brain	<ul style="list-style-type: none"> Decrease appetite Decrease food intake Increase nausea 	<ul style="list-style-type: none"> Decrease appetite Decrease food intake Decrease nausea
Pancreas	<ul style="list-style-type: none"> Increase insulin secretion Decrease glucagon 	<ul style="list-style-type: none"> Increase insulin secretion Increase glucagon
Stomach	<ul style="list-style-type: none"> Decrease gastric emptying 	<ul style="list-style-type: none"> Decrease gastric acid secretion
Adipose Tissue	<ul style="list-style-type: none"> Lipolysis 	<ul style="list-style-type: none"> Increase lipogenesis Increase lipid buffering capacity
Bone		<ul style="list-style-type: none"> Decrease bone resorption
Heart	<ul style="list-style-type: none"> Cardioprotective 	
Kidney	<ul style="list-style-type: none"> Increase diuresis 	

Ref: Med. 913, 923, 92134

SURMOUNT 1 and 2 Trials- Obesity

SURMOUNT Trial	Inclusion Criteria	Outcomes (% Weight Loss)
1	Adults with 1+ self-reported unsuccessful dietary efforts for weight loss and BMI ≥ 27 kg/m ² and a weight-related comorbidity OR BMI ≥ 30 kg/m ²	% change in body weight AND achievement of ≥ 5% weight loss from baseline to week 72
2	Adults with BMI ≥ 27 kg/m ² AND T2D	% change in body weight AND achievement of ≥ 5% weight loss from baseline to week 72

SURMOUNT 1 N Engl J Med 2022;386(12):1123-34. SURMOUNT 2 Lancet 2023;401(10305):1055-65

SURMOUNT 1 and 2 Trials- Obesity

Trial	Efficacy Outcomes	Safety Outcomes
1	Tirzepatide 5, 10, or 15 mg vs Placebo <ul style="list-style-type: none"> % change in body weight: -15.9, -19.5, -20.9 vs -3.1%(p<0.001) Achievement of ≥ 5% weight loss: 85%, 89%, 91% vs 35% (p<0.001) 	Tirzepatide 5, 10, or 15 mg vs Placebo <ul style="list-style-type: none"> Adverse events leading to discontinuation: 4.3%, 7.1%, 6.2% vs 2.6% Nausea: 24.6%, 33.3%, 31% vs 9.5% Diarrhea: 18.7%, 21.2%, 23% vs 7.3%
2	Tirzepatide 10 or 15 mg vs Placebo <ul style="list-style-type: none"> % change in body weight: -12.8, -14.7 vs -3.2% (p<0.0001) Achievement of ≥ 5% weight loss: 79.2%, 82.8% vs 32.5% (p<0.001) 	Tirzepatide 10 or 15 mg vs Placebo <ul style="list-style-type: none"> Adverse events leading to discontinuation: 4%, 7% vs 4% Gastrointestinal-related: 51%, 57% vs 18%

Conclusion: Most patients are able to have a 5% weight loss. At the 15 mg dose, tirzepatide leads to a nearly 21% reduction in body weight

Bottom Line: Among overweight or obese patients, tirzepatide leads to substantial weight loss as compared to placebo. Compared to other obesity pharmacotherapies and GLP-1 agonists, tirzepatide appears to have a larger mean reduction in body weight, although this needs to be studied in dedicated trials

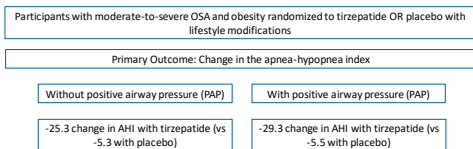
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SURMOUNT 3 Trial

Outcome (after randomization to tirzepatide 15 mg versus placebo after 12-week intensive lifestyle intervention)	Tirzepatide (n=287)	Placebo (n=292)	p-value
Change in Body Weight	-18.4%	+2.5%	<0.001
≥ 5% Weight Loss	87.5%	16.5%	<0.001
≥ 10% Weight Loss	76.7%	8.9%	<0.001
≥ 15% Weight Loss	65.4%	4.2%	<0.001
≥ 25% Weight Loss	28.7%	1.2%	Not Reported

NEJM 2023;389:974

SURMOUNT-OSA Trial



Bottom Line:

- 61.2 to 72.4% of those receiving tirzepatide had a ≥50% reduction in AHI events at week 52
- 17.7 to 19.6% weight reduction with tirzepatide

OSA = obstructive sleep apnea; AHI = apnea-hypopnea index

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Back To Our Patient

JD is a 52 year old male with **Type 2 Diabetes (T2DM)**, **Hypertension (HTN)**, Dyslipidemia, **Obesity**, and recently diagnosed with **Obstructive Sleep Apnea (OSA)**

JD presents for a routine follow-up visit with his primary care physician. He reports difficulty managing his blood glucose levels despite being on metformin and following dietary recommendations. He has a sedentary lifestyle and has gained approximately 10 pounds over the past 6 months. He mentions occasional episodes of increased thirst and frequent urination but has not noticed significant changes in vision.



Which GLP-1 agonist would be the best option for our patient considering his past medical history?

- A. Semaglutide 0.25 mg weekly
- B. Tirzepatide 2.5 mg once weekly
- C. Liraglutide 0.6 mg once daily
- D. Dulaglutide 0.75 mg once weekly



Which GLP-1 agonist would provide the most benefit for our patient considering his past medical history?

- A. Semaglutide 0.25 mg weekly
- B. Tirzepatide 2.5 mg once weekly**
- C. Liraglutide 0.6 mg once daily
- D. Dulaglutide 0.75 mg once weekly



Rising Threat of Counterfeit GLP-1 agonists

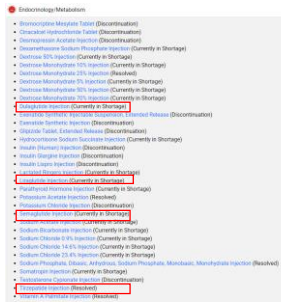
Background



- About 1 in 8 adults in the United States has used a GLP-1 drug like Ozempic or Mounjaro at some point in their life
- Public interest for GLP-1 agonists has grown exponentially from 2018-2024
- Novo Nordisk stated at least 25,000 people in the US are starting its drug Wegovy each week
- About 80% of patients stated they got the medication from a primary care doctor or a specialist
 - 11% got them from an online provider or website
 - 10% said they got them from a medical spa or aesthetic medical center



Shortages



- The supply of glucagon-like peptide-1 (GLP-1) receptor agonists is not expected to return to normal until at least the end of 2024
- Clinicians have been told not to prescribe GLP-1 agonists licensed for type 2 diabetes for off-label indications

Compounding GLP-1 agonists

- Trouble accessing glucagon-like peptide 1 (GLP-1) agonists has led some patients to turn to compounded versions
- FDA has received reports of adverse events, some requiring hospitalization, that may be related to overdoses due to dosing errors associated with compounded injectable products
- FDA has received reports that in some cases, compounders may be using salt forms of semaglutide, including semaglutide sodium and semaglutide acetate
 - The salt forms contain different active than the approved drug which contain the base form

FDA Stance on Compounding

- FDA reminds compounders of the legal restrictions on making copies of FDA-approved drugs
 - Compounded drugs must meet conditions to qualify and are not approved by the FDA
- Section 503A of the FD&C Act
 - Restricts compounding drugs that are essentially copies of a commercially available drug
 - When a drug shortage is resolved, FDA generally considers the drug to be commercially available
- Section 503B of the FD&C Act
 - Restricts outsourcing facilities from making compounded drugs that are essentially a copy of one or more FDA-approved drugs
 - Unless the approved drug is on FDA's drug shortage list.

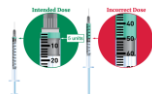
Dangers of Compounding

- In 2023, there were 352 cases of AEs associated with compounded semaglutide, with 268 classified as serious in nature
- According to Novo Nordisk, 84 cases required hospitalization and 5 involved deaths
- Some entities have been selling the compounded drug in combination with BPC-157, which the FDA has prohibited in compounding due to safety risks
 - Level of unknown impurities reaching 33%
 - Can lead to serious and life-threatening reactions, including anaphylaxis



Case Report 1

- A 50-year-old male with a history of type 2 diabetes incorrectly self-administered 50 units (0.5 mL) of semaglutide subcutaneously instead of 5 units (0.05 mL) as his first dose for weight loss.
- The patient contacted the regional poison center 8 hours after injection after having vomited throughout the night.
- The patient consistently vomited for 2 days and had ongoing nausea for 1 week. He never experienced diarrhea or abdominal pain. He tolerated small amounts of fluids orally throughout the entire week and slowly was able to increase his food intake. He never experienced dehydration and never required evaluation at a health care facility.
- The patient reported receiving his medication from a specialty compounding pharmacy although it is unclear whether this was a local pharmacy or a mail-order pharmacy.
 - The product was co-formulated with cyanocobalamin and was dosed in units and milliliters rather than milligrams.
 - The patient was unable to find a drug concentration.



Case Report 2

- A 37-year-old female with a history of obesity incorrectly self-administered 1 mL (2.5 mg) of semaglutide 2.5 mg/1 mL subcutaneously instead of 0.1 mL (0.25 mg) as her first dose for weight loss. The patient experienced frequent vomiting that resolved after 1 day.
- Over the next 3 days, the patient developed a persistent headache, decreased appetite, weakness, and fatigue.
- The entire duration of the patient's symptoms is unknown because the patient was lost to follow-up after 4 days. The patient tolerated small amounts of oral fluids and food and received an unknown over-the-counter anti-nausea medication that reportedly was beneficial. The patient never required evaluation at a health care facility.
- **The patient reported receiving her medication from a compounding pharmacy although it is unclear whether this was a local pharmacy or a mail-order pharmacy.**
 - The product was dispensed in a vial with syringes for self-administration and was co-formulated with cyanocobalamin
- **The patient reported never receiving counseling from a pharmacist on how to dose or administer the medication properly**

Mitigating Shortages of GLP-1 agonists

Selecting Therapeutic Equivalents

Agent	Dosing Route and Interval	Comparative Doses													
Exenatide	SC twice daily	5 µg	10 µg												
Lixisenatide	SC once daily	10 µg	20 µg												
Liraglutide	SC once daily	0.6 mg	1.2 mg	1.8 mg											
Exenatide XR	SC once weekly			2 mg											
Dulaglutide	SC once weekly		0.75 mg	1.5 mg	3 mg	4.5 mg									
Semaglutide	SC once weekly		0.25 mg	0.5 mg	1 mg	2 mg									
Semaglutide	PO once daily	3 mg	7 mg	14 mg											
Tirzepatide	SC once weekly			2.5 mg			5 mg	7.5 mg	10 mg	12.5 mg	15 mg				

Recommendations for Missed Doses

Agent	Dosing Interval	Manufacturer Recommendations for Missed Doses
Short-acting agents		
Lixisenatide	Once daily	If a dose is missed, administer within 1 hour prior to next meal.
Long-acting agents		
Dulaglutide	Once weekly	Administer as soon as possible if there are ≤ 3 days (72 hours) until next scheduled dose. If > 3 days before next scheduled dose, skip the missed dose and administer on the next scheduled day.
Liraglutide	Once daily	If dose is missed, resume with the next scheduled dose
Semaglutide (injectable)	Once weekly	Administer as soon as possible within 5 days after the missed dose. If >5 days have passed, skip the dose and administer on the next scheduled day.
Semaglutide (oral)	Once daily	If dose is missed, resume with the next scheduled dose.
Tirzepatide	Once weekly	Administer as soon as possible within 4 days (96 hours) after the missed dose. If >4 days have passed, skip the dose and administer on the next scheduled day.

Conclusion



- The alarming rise in counterfeit GLP-1 receptor agonists underscores a critical threat to public health and safety
- As demand for these medications surges, the risk of counterfeit drugs infiltrating the market grows, jeopardizing patient outcomes and eroding trust in healthcare systems
- To tackle this issue, we need to raise public awareness, enforce stricter regulations, and utilize technology like block chain to verify the authenticity of drugs

Back To Our Patient

It has been 2 months and our patient has been titrated to tirzepatide 5 mg/weekly. He reports having lost 10 lbs and reports some mild nausea on days after the injection. The pharmacy calls JD to let him know that tirzepatide is back on shortage and they will need to provide him with an alternative GLP-1 agonist.

What is an appropriate therapeutic equivalent to tirzepatide 5 mg/weekly?

- Switch to Semaglutide 2 mg SQ weekly
- Switch to Liraglutide 0.6 mg SQ daily
- Obtain the agent from a medical spa that compounds
- Switch to Dulaglutide 0.75 mg weekly



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Liraglutide	SC once daily	0.6 mg	1.2 mg	1.8 mg											
Exenatide XR	SC once weekly			2 mg											
Dulaglutide	SC once weekly		0.75 mg	1.5 mg	3 mg	4.5 mg									
Semaglutide	SC once weekly		0.25 mg	0.5 mg	1 mg	2 mg									
Semaglutide	PO once daily	3 mg	7 mg	14 mg											
Tirzepatide	SC once weekly			2.5 mg	5 mg	7.5 mg	10 mg	12.5 mg	15 mg						



Ultimately,
 the person with T2DM and comorbid conditions will make the decision about which treatment to choose, based on individual's needs and preferences. The person will consider other factors, such as lifestyle habits, budget/financial restraint, and health insurance coverage

Is It Worth the “Weight?”

Proven Effectiveness in Weight Loss

- Shown significant weight loss benefits (15-20% reduction in clinical trials)

Superior Glycemic Control

- Proven to reduce HbA1c by up to 1.5% or more

Cardiovascular Benefits

- Demonstrated reduction on MACE such as myocardial infarction or stroke

Long Term Safety Profile

- Favorable safety profile in long term use, with fewer side effects compared to other weight-loss or diabetes medications

GLP-1 agonists are breakthrough agents in managing weight loss and many other metabolic disorders. Their efficacy and long-term benefits make them a valuable choice worth waiting for in treatment plans

Future Incretins



- Semaglutide – oral high dose (50 mg daily)
- Orforglipron – oral GLP-1 RA
- Retatrutide – subcutaneous GLP-1/GIP/glucagon RA
- Survodutide – subcutaneous GLP-1/GIP agonist
- Cagrilintide + semaglutide (CagriSema) – subcutaneous
- GLP-1 RA/amylin analog
- Pemvidutide – subcutaneous GLP-1/glucagon RA

Chen, et al. • J Pharm Pract 2024;37(1):100-102

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Questions?

Is it Worth the "Weight:" GLP Guidelines for Use

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