Today's Medication Safety Risks, Tomorrow's Solutions

Carley Warren, PharmD, BCPS, CPPS

Medication Safety Manager, Preceptor

Diana Hoot, PharmD

PGY2 Medication Use Safety Resident

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Conflict of Interest Disclosure Statement

Neither speaker has relevant financial interest to disclose for self or spouse/partner from within the last 12 months.

None of the planners for this educational activity have relevant financial relationships to disclose with ineligible companies whose primary business is producing, marketing, selling, re-selling or distributing healthcare products used by or on patients.

Objectives

By the end of this presentation, the participants should be able to:

Pharmacists

- Identify current risks in medication management.
- Recall strategies to evaluate health system risks related to medication management.
- Recognize an action plan to address identified risks in medication management.

Technicians

- Identify current risks in medication management.
- Recall strategies to evaluate health system risks related to medication management.
- Recognize an action plan to address identified risks in medication management.

Current Risks in Medication Management

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Current Risks in Medication Management

- Drug Shortages
- Injudicious Use of Alerts
- Breakdowns in Transitions of Care
- Inconsistencies in Technology

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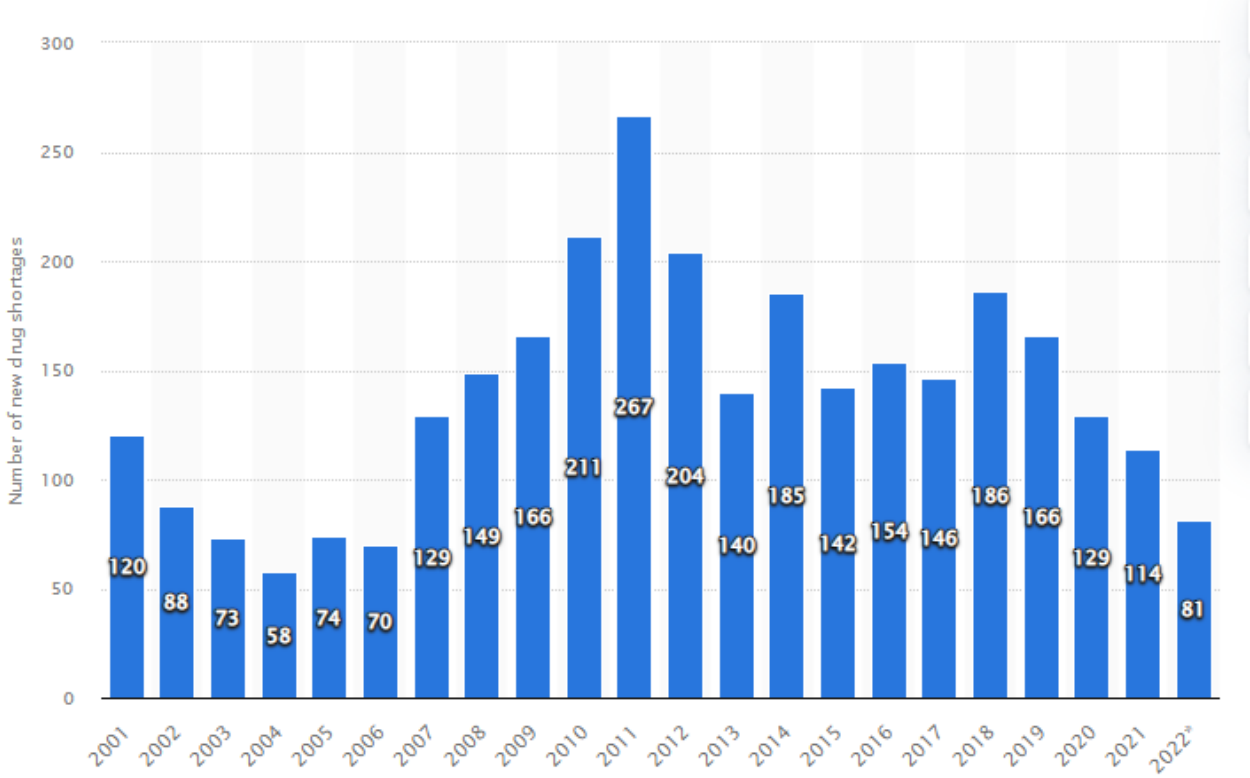
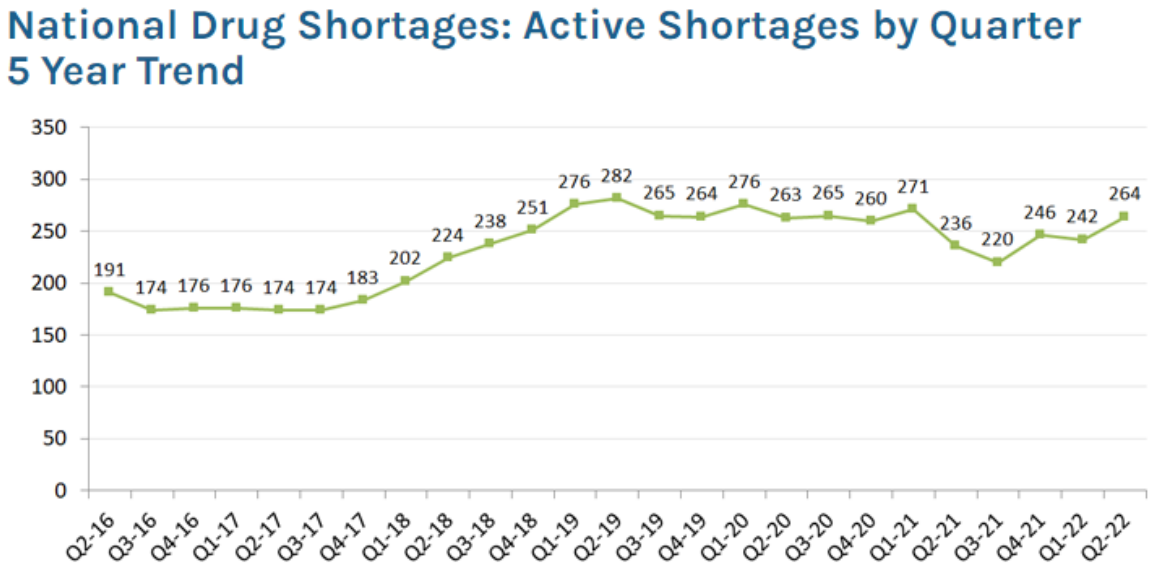
Drug Shortages

National Drug Shortages: Annual by Year



Active Shortages per Quarter



https://www.statista.com/statistics/288876/number-of-drug-shortages/

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Current Risks – Drug Shortages

- May require use of **alternative agents** that may be less effective
- **Limited familiarity** with alternatives may predispose to error
- **Compounding formulations** increases risk for error compared to ready-to-use formulations
- Medications may be **selected in error** when a specific formulation is unavailable

ISMP Featured Article. Drug Shortages Continue to Compromise Patient Care. Jan 11, 2018. ISMP.org.

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Current Risks – Drug Shortages

Examples of Errors Associated with Drug Shortages (ISMP):

Pharmacy had to compound EPINEPHrine with lidocaine, resulting in the wrong concentration

DOPamine 800 mg/250 mL bag was selected in error when the 400 mg/250 mL bags were unavailable

1 mL vials of morphine 10 mg were dispensed when the 2 mg vials were unavailable

ISMP Featured Article. Drug Shortages Continue to Compromise Patient Care. Jan 11, 2018. ISMP.org.

Current Risks – Care Transition Breakdowns

- Care transitions represent a threat to patient safety, often due to **inadequate communication** between care teams.
- Up to **50% of medication errors and 20% of ADRs** are estimated to be related to communication issues regarding patient medications at transitions of care.

Common breakdowns:

- Home medications stopped at hospital admission and not reordered upon discharge
- New medications started during hospitalization with limited communication between inpatient and outpatient providers
- Home medications changed while inpatient due to formulary restrictions or for clinical reasons and not restarted on discharge (or duplicated!)

Rozich JD, Resar RK. JCOM 2001;8(10):27-34.
The Joint Commission. Quick Safety Issue 26. April 2022.

Current Risks – Care Transition Breakdowns

Among hospitalized patients, more than half have at least one unintended medication discrepancy on admission, with up to 40% of these discrepancies having the potential to cause moderate to severe harm.

Common barriers to complete medication histories:

- Workflow time-constraints
- Limited training in completing med histories
- Inexperience with certain medications
- Gaps in information technology
- Patient-related factors, such as poor health literacy, complex illnesses, and forgetfulness
- Diffusion of responsibility

Belzile M, et al. JAMA Intern Med. 2021;181(4):540–541.

Current Risks – Injudicious Use of Alerts

- **Alert fatigue is a major, unintended consequence of computerization and automation of medication management.**
- "False alarms," or clinically insignificant alerts, can dilute the message of important alerts.
- A 2020 retrospective review of 16,000 provider-facing alerts found that 95.7% of all alerts were overridden, including 87.3% of high-severity DDIs.
  - Rates of ADEs were higher with inappropriate vs appropriate overrides.
    - 9.4% vs 4.3%; P = .038

Edrees H. *Am Med Inform Assoc*. 2020;27(6):893-900.
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Current Risks – Inconsistencies in Technology

- Automated Dispensing Cabinets:
  - Variable levels of training among end-users
  - Inconsistent locations of available stock
  - Possibility for workarounds, such as inappropriate overrides
  - Potential for human error while stocking the machine

https://www.bd.com/en-uk/products/medication-management/point-of-care/pyxis-medstation-es-system

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Current Risks – Inconsistencies in Technology

https://www.bd.com/en-ca/offerings/capabilities/infusion-therapy/infusion-system-devices/alaris-pump-module

- Smart IV Infusion Pumps:
  - Requires current library to be installed
  - Possibility for end-user to bypass the library and manually input the rate
  - Currently incapable of communicating with the electronic health record (interoperability)
  - Can contribute to alert fatigue
  - Numerous differences between vendors which make it challenging for new staff to translate their previous experience

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Assessment Question #1:

Which of the following is a current risk in the medication use system?

A. Smart IV infusion pump interoperability

B. Pharmacist-led medication reconciliation

C. Communication breakdowns in transitions of care

D. None of the above

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Tools Utilized to Evaluate Health System Risks

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Tools Utilized to Evaluate Health System Risks

Failure Mode & Effects Analysis

(FMEA)

Strengths, Weaknesses, Opportunities, Threats

(SWOT)

Probability & Impact Matrix

(PIM)

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Failure Mode & Effects Analysis (FMEA)

- *"Problem-solving tool used to analyze a process or system to identify possible modes of failure, and potential consequences of those failures."*

- Framework to conduct a proactive analysis of any process with potential for failure or harm

Failure Mode

- Ways (or "modes") in which something might fail
- Errors or defects that are potential or actual

Effects Analysis

- Studying the consequences of those failures

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FMEA

- Systematic, proactive method to evaluate a process and identify how it might fail

- **When should this be used?**
  - Designing a new process
  - Changing an existing process
  - Creating improvement goals
  - Introducing new technology
  - Periodically throughout the lifespan of a process

Assemble a multidisciplinary team

Define the specific focus of the FMEA

Process Flow Diagram

- Identify & map all sub-processes

Hazard Analysis

- List possible failure modes under the sub-processes and possible root causes
- Determine possibility, severity, and ability to detect failure modes

Take Action

- Determine root causes that can be eliminated, controlled, or accepted
- Assign responsibility for completing each action

Follow-Up

- Develop measurable indicators for the new process

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FMEA Example – Drug Shortages & Alternative Agents

	Potential Failure Mode as it Relates to Steps in the Product Use Process	Yes	No	Methods of Avoidance
Selection & Procurement	Have specific errors associated with this product been reported in the literature (e.g. Sentinel Event Alerts, ISMP newsletters)?			
	Is the product a high-alert drug?			
	Does the product have an approved REMS?			
Prescribing and Ordering	Is it likely that a calculation error could occur during prescribing, ordering, or processing?			
	Does the procured product contain latex?			
	Are there policies and procedures that need to be rewritten or amended before the product is approved for formulary use?			
Preparation & Dispensing	Is it likely there would be multiple steps in product preparation?			
	Are there any handling precautions associated with this product?			
	Does the preparation of this product require an independent double-check?			
Administration	Does the product require administration over a given amount of time that if not adhered to may cause harm?			
	Is there a specific skill necessary for nursing to achieve before administration?			
	Is it likely this product could be inadvertently administered by an alternative route?			

https://www.ismp.org/resources/weathering-storm-managing-drug-shortage-crisis
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Strengths, Weaknesses, Opportunities, Threats (SWOT)

- “Big picture” tool for strategic planning that identifies internal and external factors

Strengths: What you do well?

Weaknesses: What could be improved?

Opportunities: What are you not doing yet?

Threats: What could harm the process?

Internal	Strengths	Weaknesses
External	Opportunities	Threats

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	Strengths	Weaknesses
Internal	Strengths should be leveraged. Do more of what you are good at!	Weaknesses should be minimized. Utilize action plans and interdisciplinary teams.
	Opportunities	**Threats**
External	Opportunities should be exploited. What areas of possibility haven't been tapped into yet?	Threats should be mitigated. What challenges and obstacles do your weaknesses expose you to?

SWOT Example – Incomplete Medication Histories

	Strengths	Weaknesses
Internal	Understanding of the importance of accurate medication histories Stakeholder buy-in among the pharmacy department	Limited nursing experience Limited pharmacy involvement in current process
	Opportunities	**Threats**
External	Dedicated "Transitions of Care" pharmacist (or technician) position Implement pharmacy-led medication reconciliation	Limited nursing time Inconsistent patient health literacy Complicated medication regimens Limited financial resources

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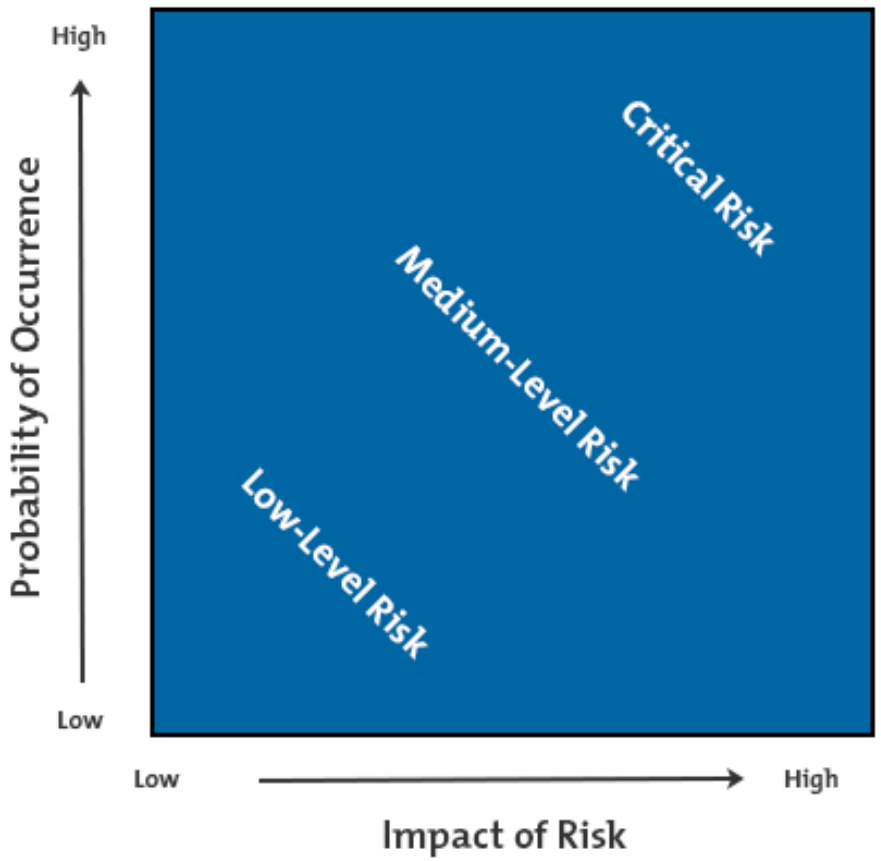
Probability and Impact Matrix (PIM)

- Two-dimensional representation of risk; can range from simple (pictured) to relatively complex
- **Probability:** the chances of a potential risk occurring
- **Impact:** the negative impact if the risk were to occur



https://www.mindtools.com/pages/article/newPPM_78.htm

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Probability and Impact Matrix (PIM)

Benefits:

- Identify areas with potential for risk reduction
- Provide a visual representation of risk
- Gauge and prioritize levels of risk
- Can be tailored in complexity

			Impact			
			0 Acceptable	1 Tolerable	2 Unacceptable	3 Intolerable
			Little or No Effect	Effects are Felt but Not Critical	Serious Impact to Course of Action and Outcome	Could Result in Disasters
Likelihood	Improbable	Risk Unlikely to Occur				
	Possible	Risk Will Likely Occur				
	Probable	Risk Will Occur				

In medication safety, unlikely risks with severe impact still matter – such as a medication error resulting in a patient death.

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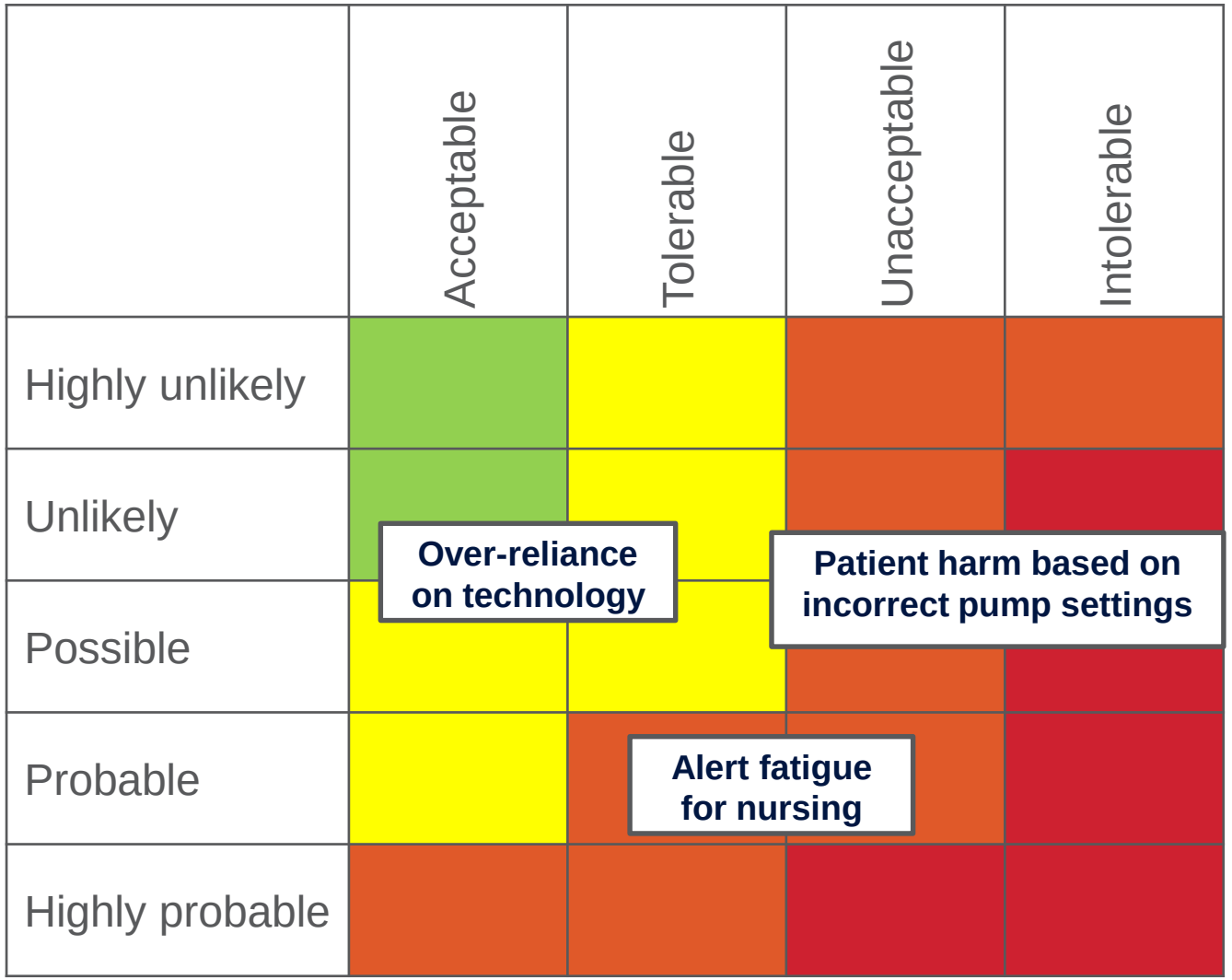
PIM Example - Technology

- Smart pump-EHR integration has been approved and financed for your facility. Your team is working on planning and implementation and wants to complete a PIM to identify critical risks.

- What risks come with this new process?
- What is their probability of occurring?
- What is the impact of occurrence?



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Assessment Question #2:

A failure mode effects analysis can be used to:

A. Assess the impact of risk occurrence

B. Evaluate a process and identify how it might fail

C. Identify external and internal factors in strategic planning

D. None of the above

Assessment Question #2:

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Creating an Effective Action Plan

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SMART Goals

Specific – What exactly are you setting out to do?

Measurable – How will you evaluate this goal?

Attainable – Can this be accomplished in the timeframe?

Relevant – Does this goal align with current priorities and values?

Time-Based – When should this be achieved?

Which goal is a SMART goal?

1. We want our pharmacists to complete more medication reconciliations.

S – Not specific

M – “more” is not an appropriate way to measure

A – Easily attainable as written, but not at all challenging

R – Minimizes transitions of care gap

T – Doesn’t identify a goal timeframe

2. In one month, each clinical pharmacist on our team will complete 10 admission medication reconciliations.

S – Provides the who, what, when

M – Can measure how many med recs were completed

A – Attainable within the time frame

R – Minimizes transitions of care gap

T – One month

Key Leader Buy-In

Because of the interdisciplinary nature of the action plan, it is essential that key stakeholders and leaders are involved in the creation and execution.

Consider use of RACI

Who needs to be involved in this action plan?

What does each member of the team contribute?

Responsible: people leading the work

Accountable: leaders over the care area

Consulted: people who the process affects

Informed: leadership

Steps to Create an Action Plan

1. Define your end goal using the SMART framework
2. List key steps and tasks to be completed to attain the goal
3. Prioritize the tasks and determine specific deadlines
4. Delegate tasks to define team roles and responsibilities
5. Determine deadlines and milestones
6. Assess and improve your plan

Evidence of Improvement

- One key aspect of creating an action plan is determining how you will measure its success
- Developing SMART goals before steps and tasks ensures that improvements can be measured
- Evidence of improvement should be clearly defined within the action plan

What element will be used to measure success?

How often will this be assessed?

Whose responsibility is it to measure and report evidence of improvement?

Action Plan Template
Goal: Remove promethazine from formulary
Anticipated Completion Date: 9/30

Date	Action/ Description	Responsible Person(s)	Resources Required	Predicted Barriers	Strategies to Overcome	Status Date & Update	Outcome
9/1/22	Prepare evidence review	Sam – Clinical Pharmacist	2 hours	n/a	n/a	9/3 Done	Information sent to Mgr.
9/1/22	Present findings to hospitalists	Julie – Clinical Mgr	20 min of time	Getting the audience together	Use medical staff meeting 9/15	9/3 Not started	
9/1/22	Lead conversation at P&T	Director of Pharmacy & Hospitalist Leader	P&T Meeting time 9/30	n/a	n/a	9/3 Not started	

Assessment Question #3:

Once the team has identified a specific risk in the process, which is the most appropriate order of steps?

A. Identify and prioritize key steps; Define the SMART goal; Determine deadlines; Delegate tasks; Assess and improve

B. Define the SMART goal; Identify and prioritize key steps; Determine deadlines; Delegate tasks; Assess and improve

C. Identify and prioritize key steps; Define the SMART goal; Delegate tasks; Determine deadlines; Assess and improve

D. Define the SMART goal; Identify and prioritize key steps; Delegate tasks; Determine deadlines; Assess and improve

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D. Define the SMART goal; Identify and prioritize key steps; Delegate tasks; Determine deadlines; Assess and improve

Summary

Call to Action:
Identify unique risks within the medication management system and use the tools discussed to develop and implement action plans with your interdisciplinary teams.

Current Risks

- Drug Shortages
- Injudicious Use of Alerts
- Breakdowns in Transitions of Care
- Inconsistent Technology

Tools

- FMEA
- SWOT Analysis
- PIM

Action Plan

- Key Leader/ Stakeholder Involvement
- SMART Goals
- Evidence of Improvement

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Thank you!

Carley Warren: carley.castelein@hcahealthcare.com
Diana Hoot: diana.hoot@hcahealthcare.com

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