MEDICATION SAFETY BOOTCAMP

102: Application of Medication Safety Basics

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Supplemental Packet

Yellow file folder located on the bottom right side indicates additional information available within supplement packet

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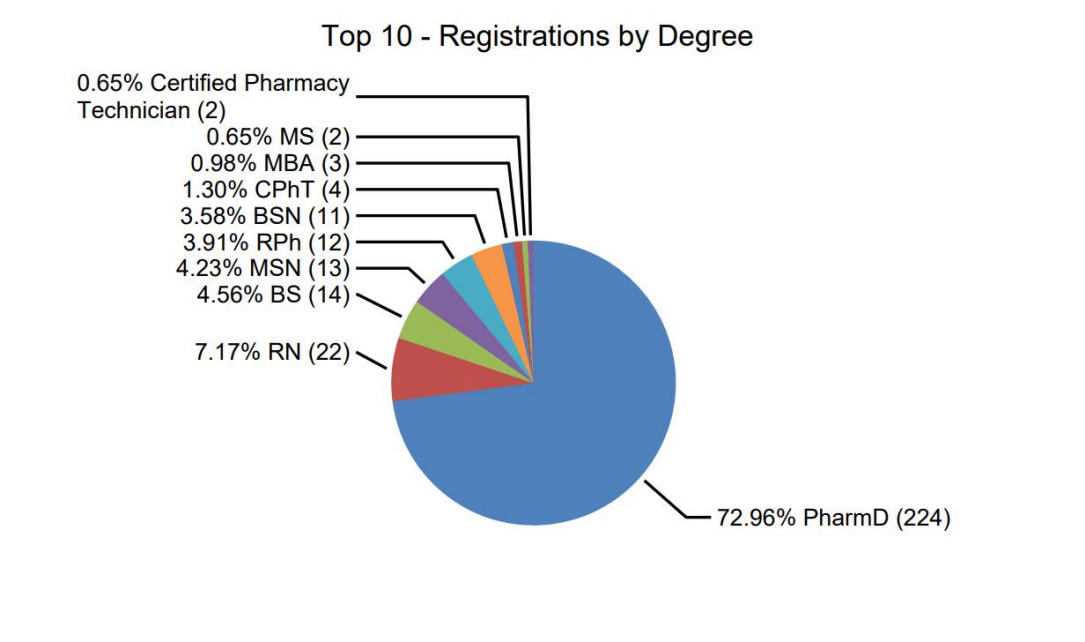
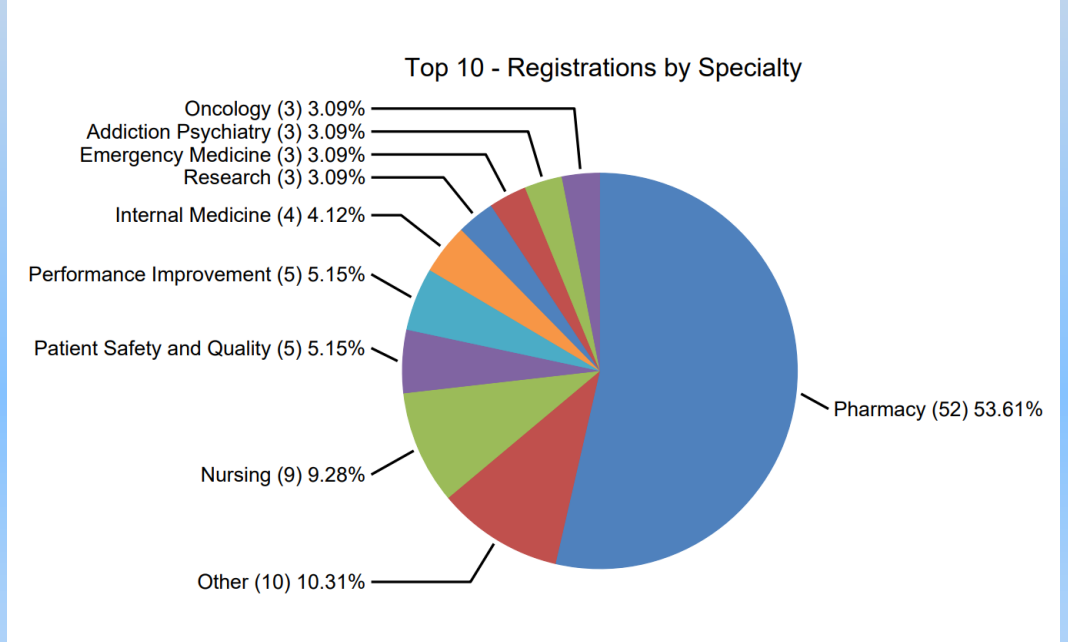
Who is participating today?





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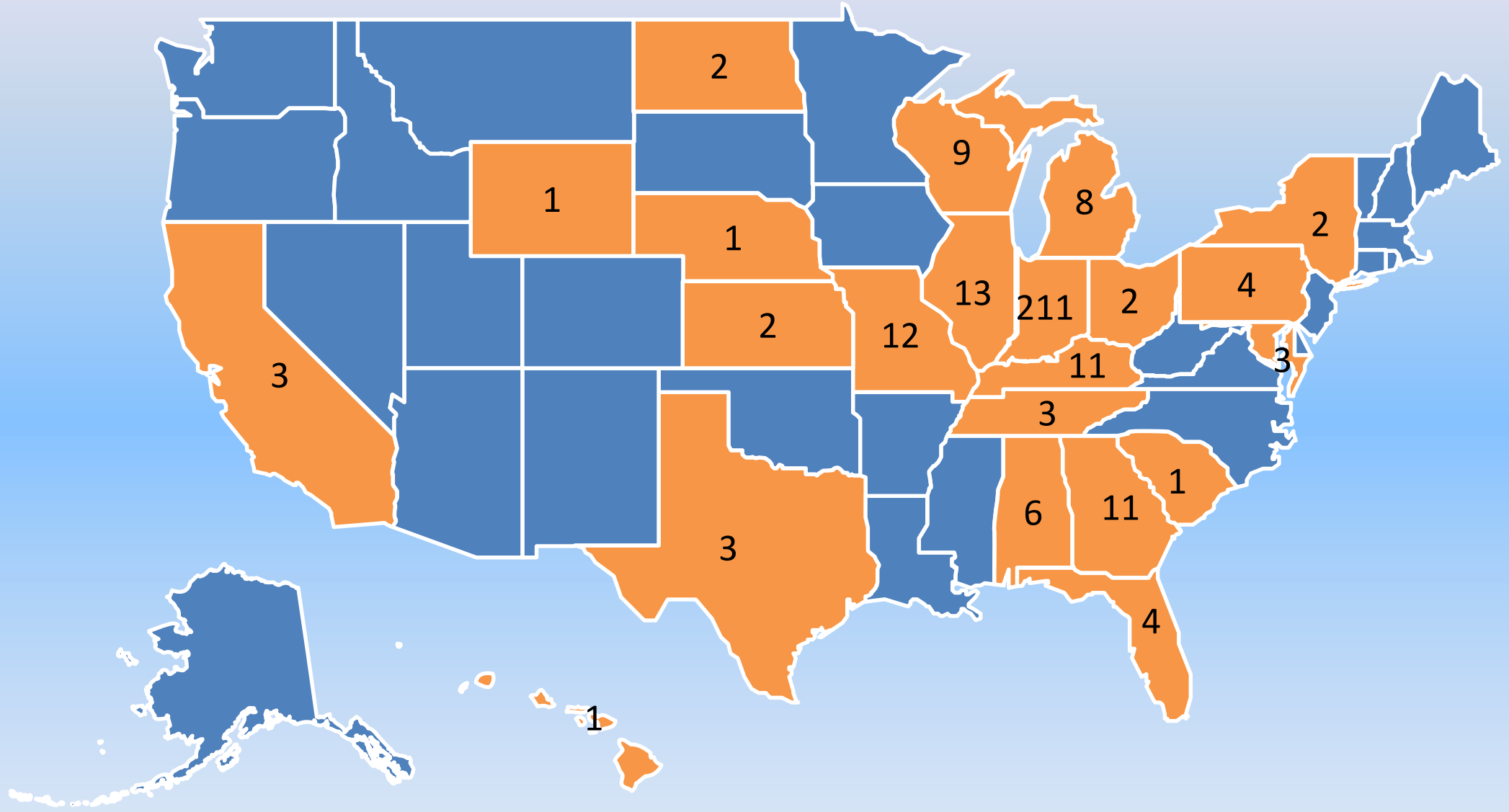
Where is everyone from?



In the chat bar, please answer the following question:

What do you hope to gain/learn from this afternoon?

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Agenda

Time	Item
10 mins	• Introductions • Housekeeping • Pre-Assessment

45 mins	• Overview/Introduction
	  • History, Literature, Data
	  • Just Culture/High Reliability

30 mins	• Section 1 • How do I obtain medication safety information/data?
5 mins	**BREAK**

Time	Item
25 mins	• Section 2 • What do I do now that I have data? How do I organize it and strategize solutions?
30 mins	• Section 3 • How do I implement process improvements?
30 mins	• Question/Answer • Group Therapy: Audience sharing and group problem solving
5 mins	• Wrap-up • Housekeeping • Post-assessment

Objectives

- Explain medication safety terminology and methodology for frontline staff, students, new and established practitioners as well as direct and non-direct patient caregivers.
- Recognize the importance and be able to incorporate an interdisciplinary approach to medication safety.
- Review opportunities to improve medication safety through the use of technology, process improvement, and implementing innovative or evidence based best practices.

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Acronyms

Common acronyms utilized throughout this session include:

ACPE: Accreditation Council for Pharmacy Education

ADC: Automated Dispensing Cabinet

ADE: Adverse Drug Event

AHRQ: Agency for Healthcare Research and Quality

ASHP: American Society of Health-System Pharmacists

COS: Culture of Safety

ECRI: Emergency Care Research Institute

FDA: Food and Drug Administration

HAM: High Alert Medication

HEAT: Hypoglycemia Evaluation Analysis Tool

HRO: High Reliability Organization

ICPS: Indianapolis Coalition for Patient Safety

IHI: Institute for Healthcare Improvement

ISMP: Institute for Safe Medication Practices

ME: Medication Error

MSO: Medication Safety Officer

NPSG: National Patient Safety Goal

PSO: Patient Safety Organization

SLAMS: St. Louis Area Medication Safety

TJC: The Joint Commission

USP: United States Pharmacopeia

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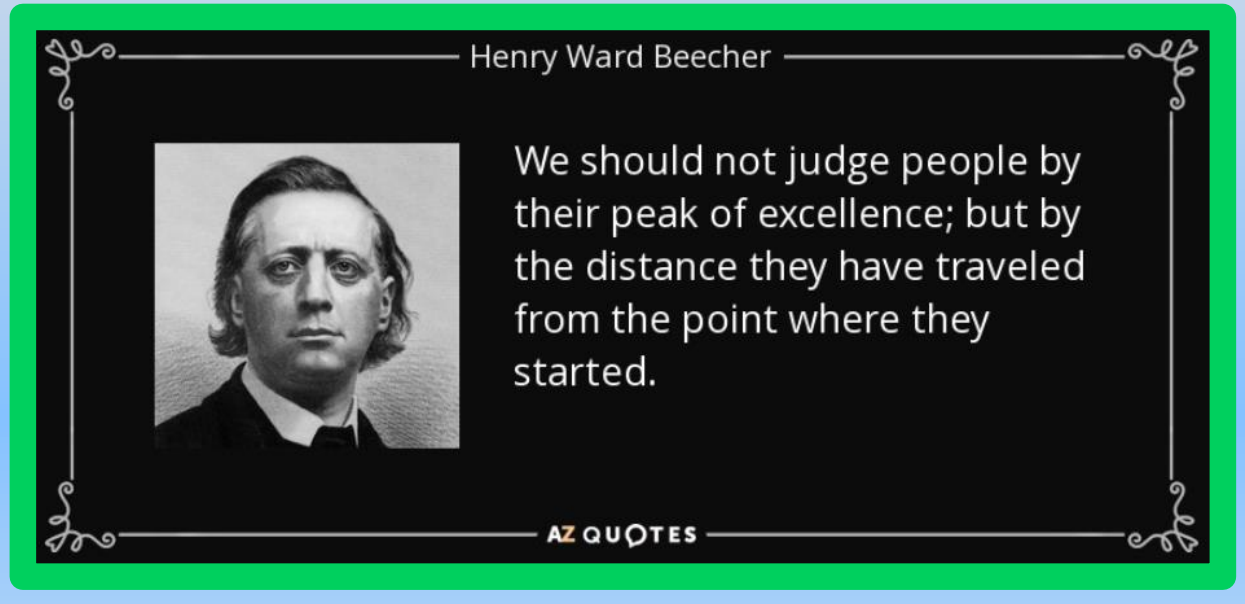
Overview/Introduction

History, Literature, Data
Safety Culture/High Reliability

History[1,2]



- "Safety" and "inherited human limitations" are not new ideas
  - Hippocratic Oath
- Focused work began in 1975
  - 45 years or less
  - Many safety concepts integrated within practice have been recently established

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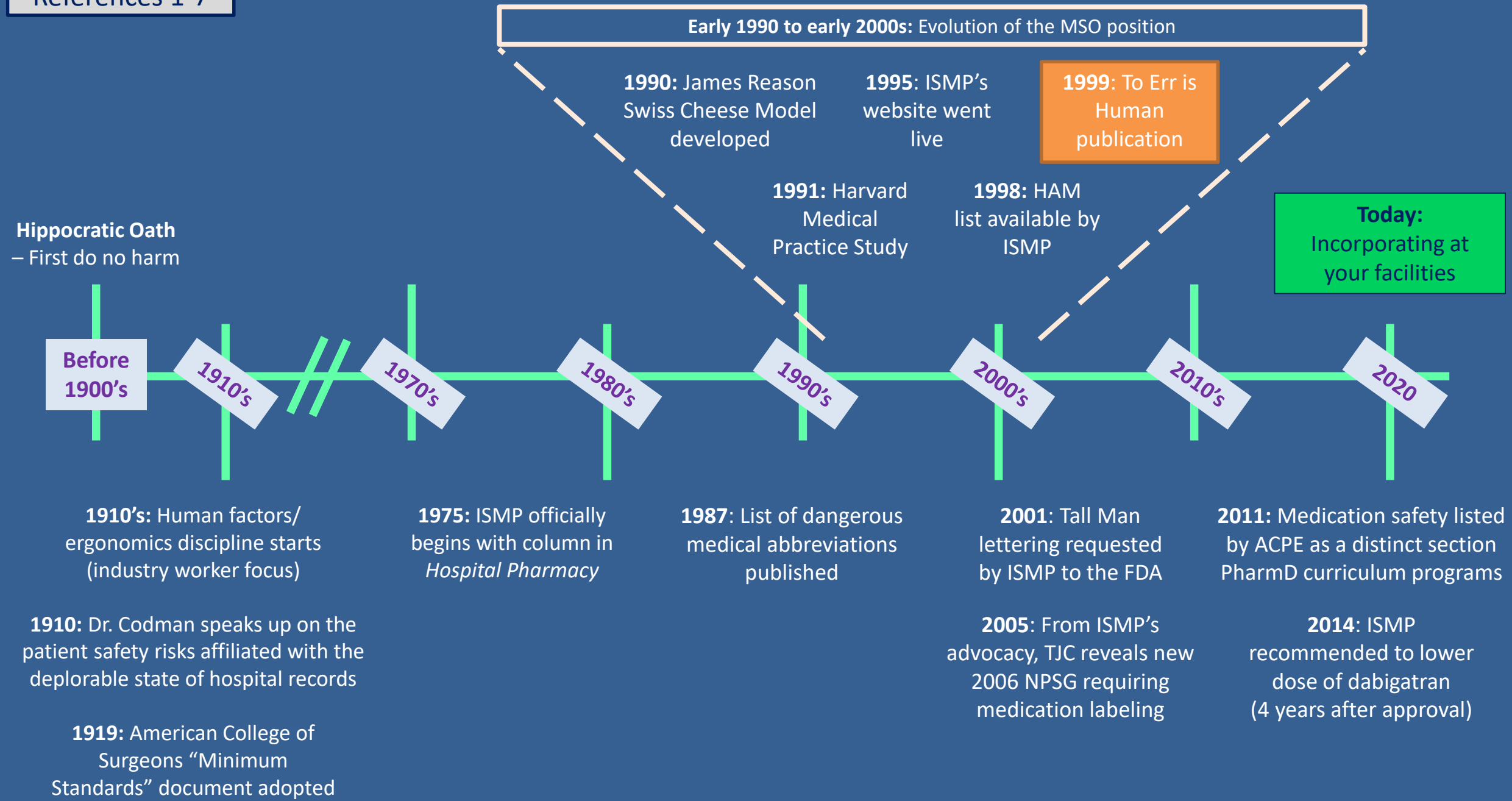
References 1-7



The Minimum Standard

1. That physicians and surgeons privileged to practice in the hospital be organized as a definite group or staff. Such organization has nothing to do with the question as to whether the hospital is "open" or "closed," nor need it affect the various existing types of staff organization. The word STAFF is here defined as the group of doctors who practice in the hospital inclusive of all groups such as the "regular staff," "the visiting staff," and the "associate staff."

2. That membership upon the staff be restricted to physicians and surgeons who are (a) full graduates of medicine in good standing and legally licensed to practice in their respective states or provinces; (b) competent in their respective fields and (c) worthy in character and in matters of professional ethics; that in this latter connection the practice of the division of fees, under any guise whatever, be prohibited.

3. That the staff initiate and, with the approval of the governing board of the hospital, adopt rules, regulations, and policies governing the professional work of the hospital; that these rules, regulations, and policies specifically provide:

(a) That staff meetings be held at least once each month. (In large hospitals the departments may choose to meet separately.)

(b) That the staff review and analyze at regular intervals their clinical experience in the various departments of the hospital, such as medicine, surgery, obstetrics, and the other specialties; the clinical records of patients, free and pay, to be the basis for such review and analyses.

4. That accurate and complete records be written for all patients and filed in an accessible manner in the hospital—a complete case record being one which includes identification data; complaint; personal and family history; history of present illness; physical examination; special examinations, such as consultations, clinical laboratory, X-ray and other examinations; provisional or working diagnosis; medical or surgical treatment; gross and microscopical pathological findings; progress notes; final diagnosis; condition on discharge; follow-up and, in case of death, autopsy findings.

5. That diagnostic and therapeutic facilities under competent supervision be available for the study, diagnosis, and treatment of patients, these to include, at least (a) a clinical laboratory providing chemical, bacteriological, serological, and pathological services; (b) an X-ray department providing radiographic and fluoroscopic services.

Literature[8]

We all know medication safety is important, but why are we in the beginning of this journey?

- Difficult to assess problem scope
  - Death certificates can only include ICD 10 codes as the reason the patient expired
  - Medical error is not one of these items
- Several methods exist to help estimate impact of medication errors
  - Lack of document standardization provides difficultly to fully understand the magnitude and impact
  - Wide variety of data noted within publications

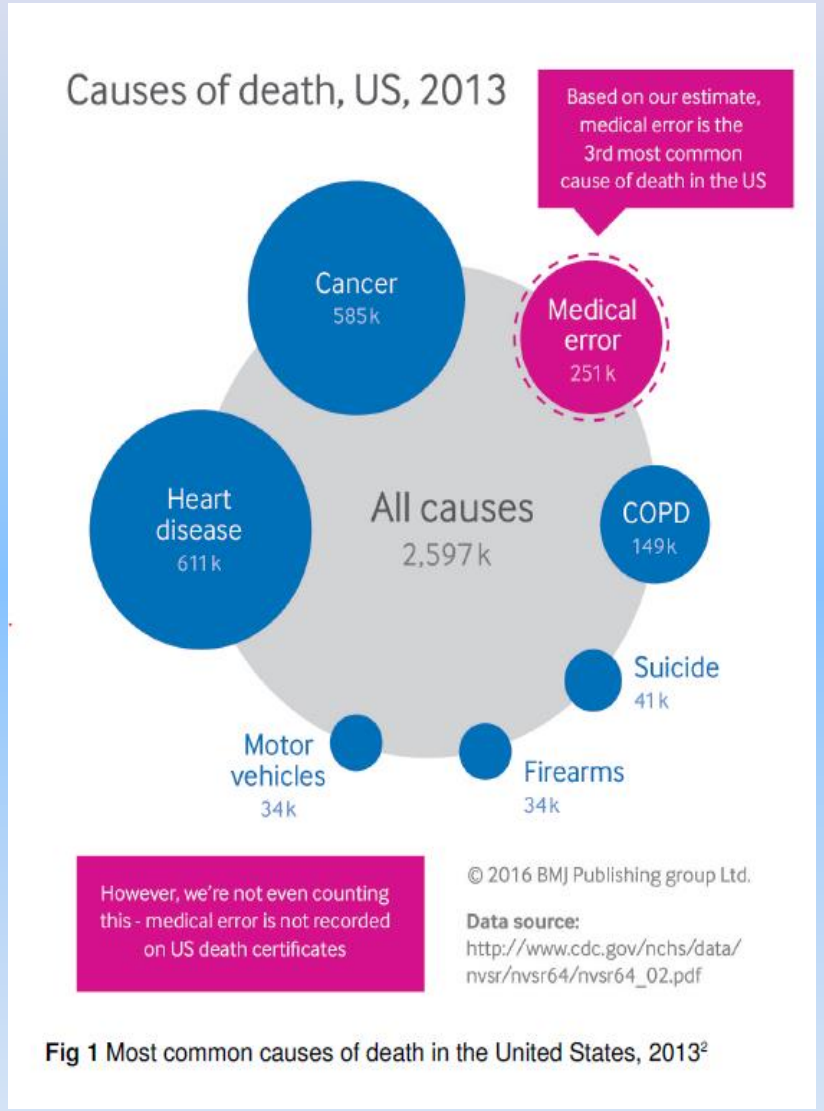


Fig 1 Most common causes of death in the United States, 2013[2]

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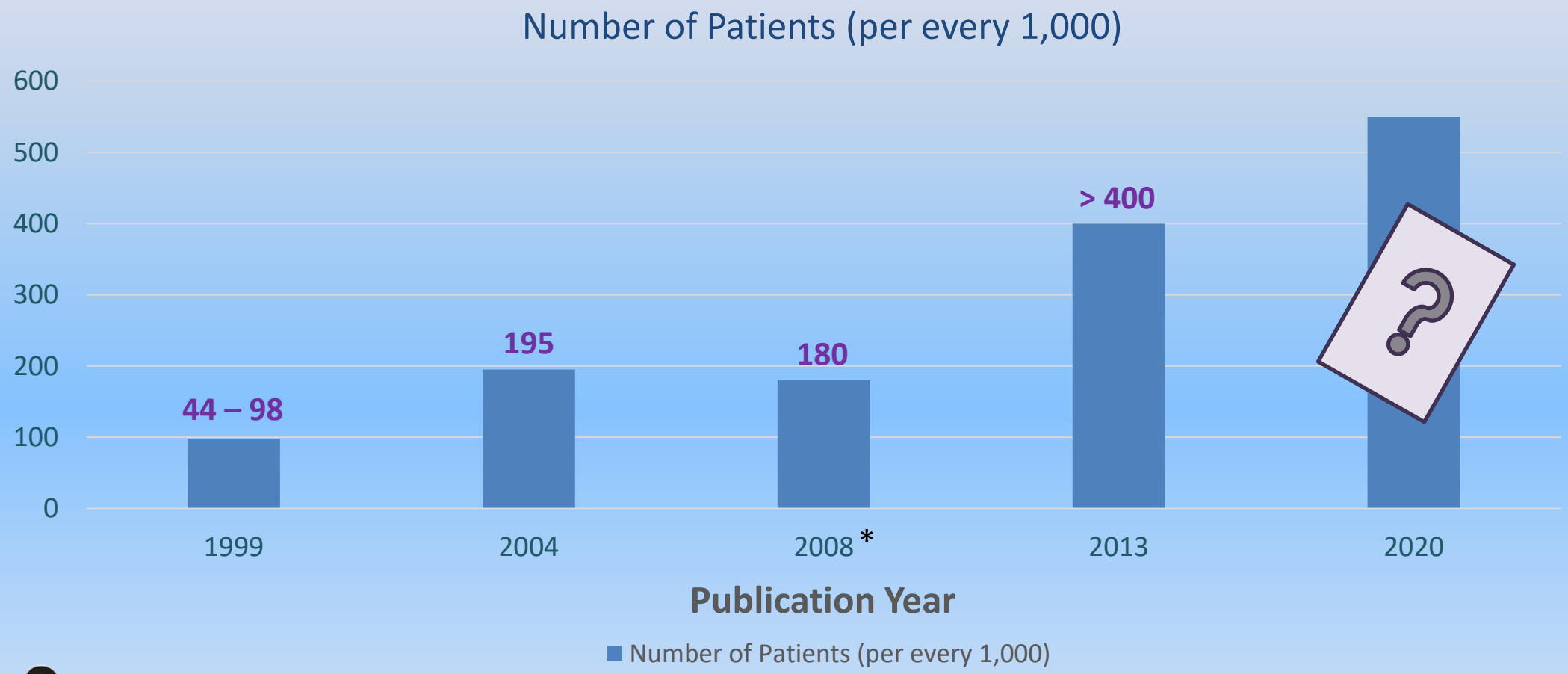
Estimations Published[8]



*Medicare Beneficiaries only

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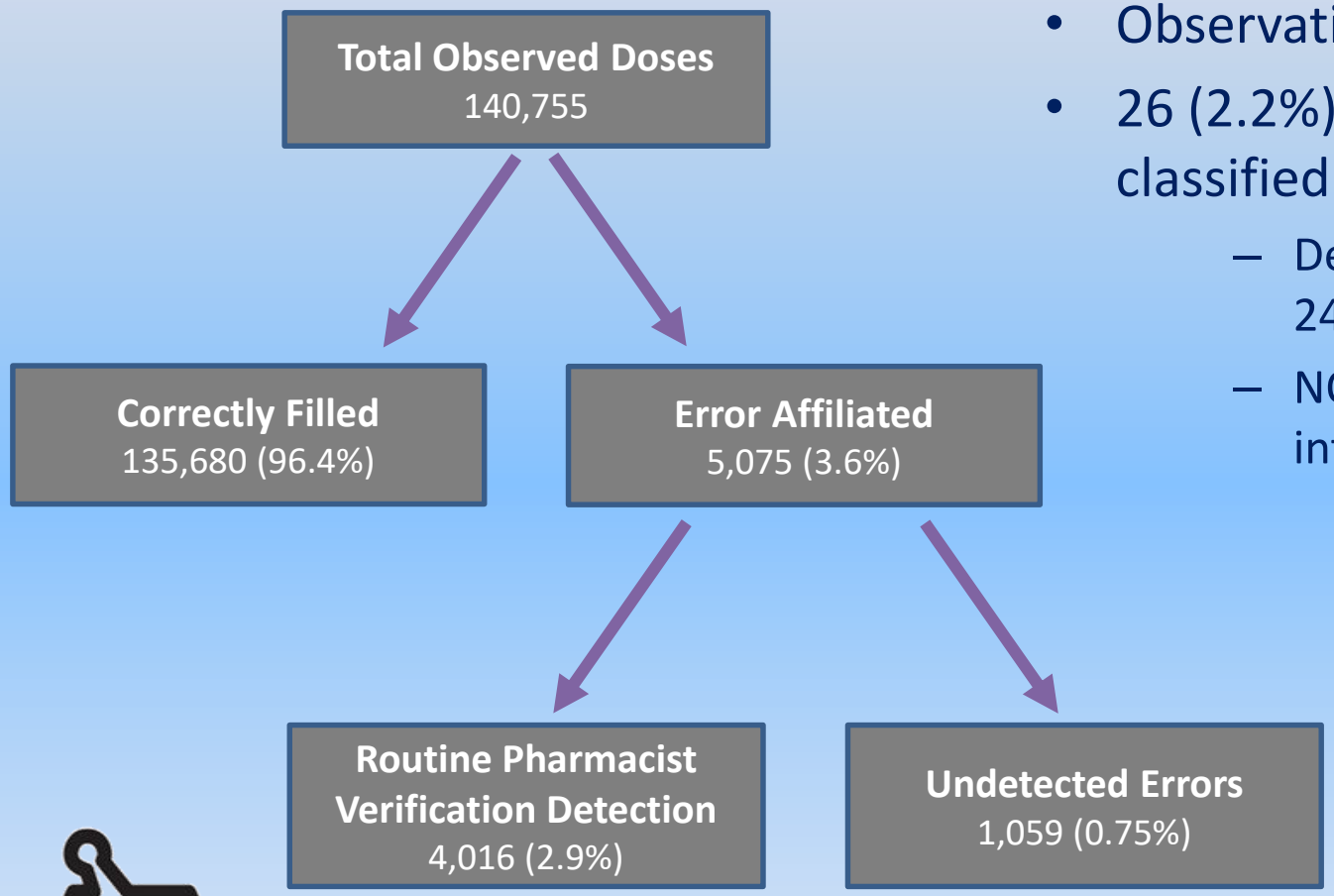
Medication Safety
Acute Care[9]



- Observational study over 7 months revealed
- 26 (2.2%) of all of errors discovered were classified as potentially life-threating
  - Detected by routine pharmacist verification: 24 events
  - NOT detected (i.e., identified through study intervention): 2 events

Distribution Process	Process Error Percentage
Cart Fills	6%
ADCs	4.2%
First Dose Fills	2.9%
Controlled Substances	0.94%

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Medication Safety
Ambulatory Care[10-12]

More than 4.5 million ambulatory care visits occur every year due to ADEs; Patients with these characteristics are more like to experience an ADE

- 65 years or older
- Taking 6 or more medications
- Primary physician practices

Dispensing error rate within community pharmacies has been estimated as 1.5%

ECRI Institute PSO examined more than 4,300 ambulatory care patient safety events from December 2017 to November 2018

- Diagnostic testing errors (47%)
- Medication safety events (27%)
- Patient falls (14%)

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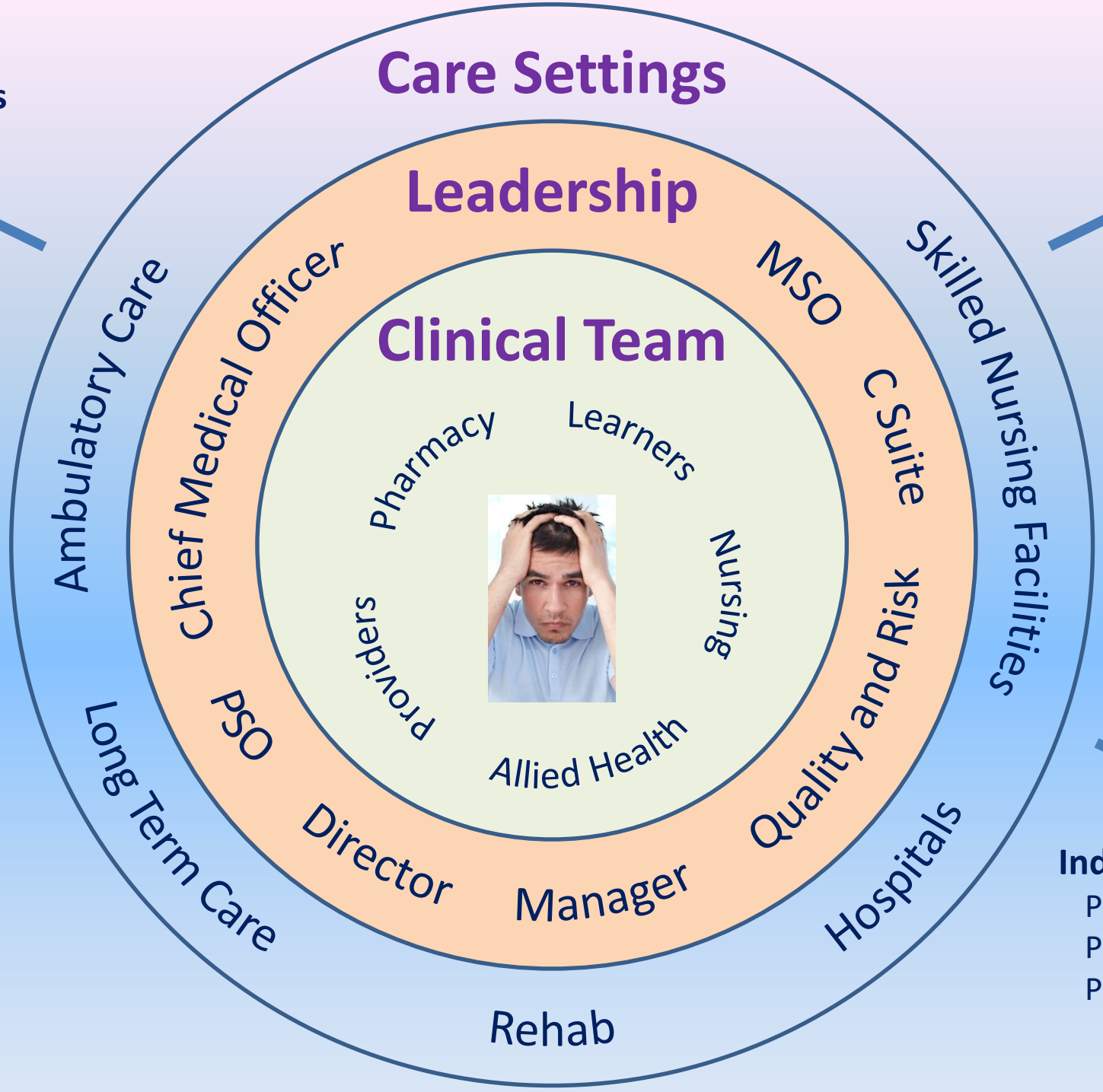
Safety Organizations
- ICPS
- ISMP
- AHRQ

Regulatory
- FDA MedWatch
- Drug Approvals
- Joint Commission



Regardless of where we serve patients…

Center of all decisions
→ **PATIENT**

Included in all roles
→ **SAFETY**

Industry/Drug Companies
- Package inserts
- Post surveillance studies
- Pharmacovigilance

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Incorporating Safety[13]

- While everyone focuses on safety, **HOW** this is incorporated into practice may be accomplished differently
- COS of an organization influences practice
  - Factor needs to be taken into consideration

- Is a subset of the overall organization's culture
- It is a set of shared values, attitudes and behaviors consistently adopted and applied throughout an organization that are designed to prevent harm when caring for patients
- **It's the way we do things around here**


Safe and fair environment where reporting is blame free and without fear of punishment
Acknowledgement of organization's activities are high risk in nature
Safety Culture[14]
Collaboration occurs across ranks and disciplines
Determination to achieve safe operations consistently
Organizational commitment of resources to address safety concerns

Error Management Techniques[13]

Punitive (Blame and Train)	No Accountability (Blame-free Environment)
Believed <u>perfect</u> human performance to be achieved through education	**Believed latent failures will always be present in the system**
• Punitive • Event outcomes focused • Reckless behavior not addressed with no adverse outcomes • "Perfect performance" to avoid errors	• Blame-free; Non-punitive • Human fallibility recognized as a patient safety risk • Focused on the system/processes • Solutions directed to systems' latent failures
Counter productive to reporting, learning, and safety advancement	Confusion with how to manage reckless behavior, disregarding safety procedures, and malicious intent

Error Management Techniques[13,14]

Just Culture

Human behaviors are distinguished and appropriately addressed

- Model asking WHAT, not who, is responsible
- Embraces and supports those who are caught in faulty processes
- Recognizes both latent failures and active failures contribute to errors
- Incorporates accountability

Understands punishment for most active failures (unsafe acts or honest mistakes) is counter-productive to advancement of safety

Recognizes majority of errors are not due to individual failures, but arise as a result of **flawed processes** that create an environment of risk

Maintains individual accountability by establishing zero tolerance for reckless behavior, and focuses on identifying and addressing systems issues that lead people to partake in unsafe behaviors

What will be observed in a “Just Culture” environment?[13]

Staff, patients, and caretakers are treated **fairly**, with empathy and consideration

Questioning attitude is promoted; Resistance to complacency or status quo

Behaviors are **distinguished** and **addressed**, regardless of the event severity

Reported events are blame free and utilized as a learning opportunity

Commitment to **excellence**; Changing processes to prevent unsafe behaviors, while not tolerating reckless behavior

While different actions may result in unsafe acts, not all these warrant disciplinary action

Three categories established to help distinguish and address human behaviors[13,14]

Reckless Behavior

- Choosing an action with knowledge and conscious disregard of the risk of harm
- Person takes a risk (i.e., ignoring required safety step) knowing harm would probably result

At-Risk Behavior

- Consciously choosing an action (i.e., shortcut) without realizing the level of risk of an unintended outcome
- Failure to recognize a risk that should have been identified

Human Error

- General agreement that the person should have done other than what they did as an inadvertently outcomes was caused (or could have been caused)
- Inadvertent action: slip, lapse, mistake

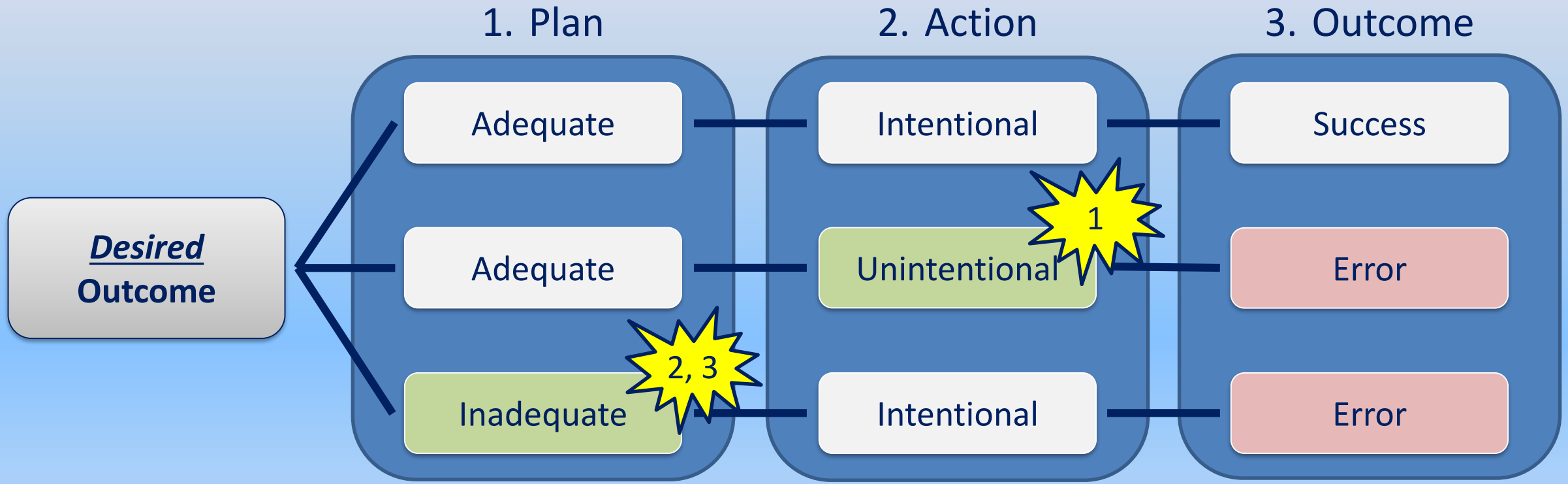
Reckless vs At Risk Behaviors[13]

Key to differentiating between unacceptable and acceptable behaviors

Individual *conscious* disregarded to what they *knew* to be a substantial and unjustifiable risk

	Reckless Behavior	At Risk Behavior
Disregards	• Known risk within a practice	• Policy, procedure, or "safe guard" (Note: Most at-risk behaviors are caused by system failures requiring workarounds)
Perception	• Unsafe action chosen even though risk was recognized AND understood to be substantial and not justified • Knows behavior is not the norm	• Person does not see the risk OR mistakenly believes the risk is insignificant or justified • Behavior is considered norm
Motivation	• Behavioral choice is often self-centered (i.e., puts own needs ahead of others)	• Desire to help others (i.e., patient, team, organization)

Human Error: Failure of a planned action to achieve desired outcome[15]



Errors can occur in both the **planning and action** stages of a task

- Plans can be adequate or inadequate
- Actions can be intentional (i.e., align with developed plan) or unintentional

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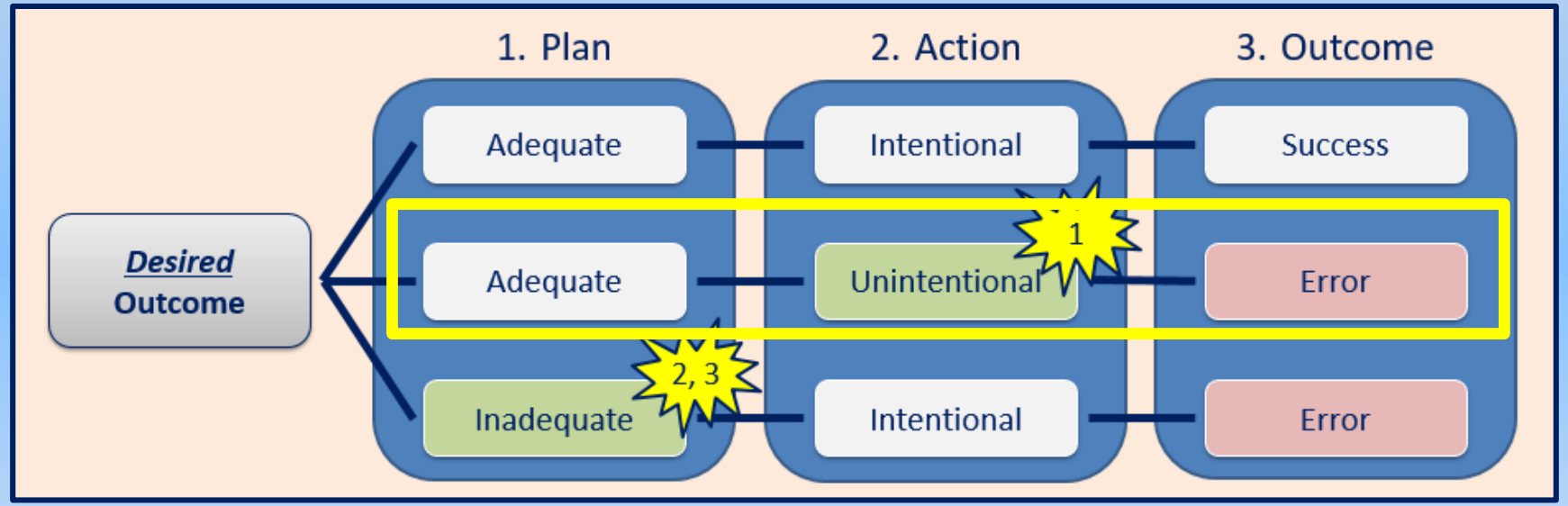
Skill-based

(automatic)[15]



- Generally when these errors occur, the individual has the right knowledge and experience to do the task properly
  - Tend to occur during high routine activities and when attention is diverted (either by thoughts or external factors)
  - Task has probably been performed correctly many times before
- Even the most skilled and experienced people are susceptible to this type of error
  - As tasks become more routine and less novel, they can be performed with less conscious attention (making it easier for the mind to wander)
  - Re-training and disciplinary action are not appropriate responses to this type of error

Activity Type	➢ Performing routine, familiar tasks; No conscious monitoring ➢ Allows for multitasking
Error Type	➢ Slips: Action was not carried out as planned; Attention failures ➢ Lapses: Forgotten action; Memory failures
Error Prevention Theme	➢ Self-checking (stop and think before acting) using STAR
Error Probability	1:1000

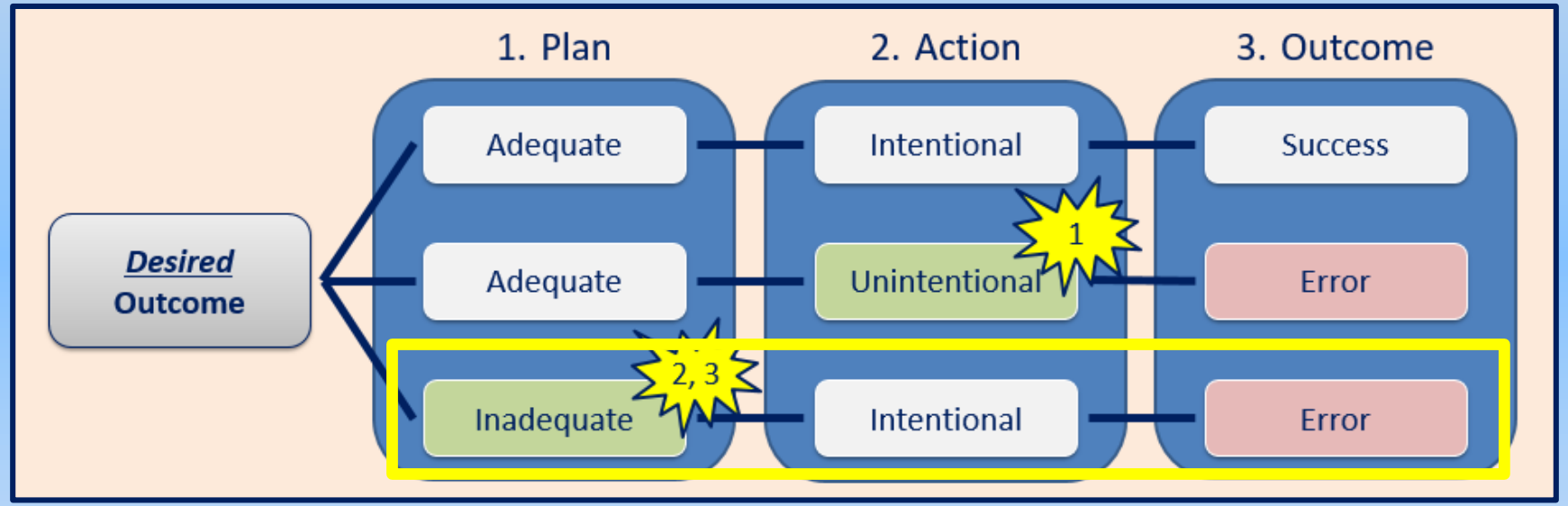
Examples

- Missing a step in an isolation sequence
- Pressing the wrong button or pulling the wrong lever
- Loosening a valve when intending to tighten it
- Transposing digits when copying numbers (e.g. writing 0.31 instead of 0.13)

Reference 15

Rule-based

(intuitive) [15]



- Mistakes are failures of planning, where a plan is expected to achieve the desired outcome, however due to inexperience or poor information the plan is not appropriate
  - People with less knowledge and experience may be more likely to experience
  - Disciplinary action is an inappropriate response as these are not committed “on purpose”
- There are two different types of mistakes
  - **Rule-based errors:** Refer to situations where the use or disregard of a particular rule or set of rules results in an undesired outcome
  - **Knowledge-based errors:** insufficient knowledge about how to perform a task results in the development of a solution that is incorrectly expected to work

Activity Type	➢ Conditions of current problem are matched with past problems ➢ If ____ then do _____
Error Type	➢ Wrong rule ➢ Misapplication of a rule ➢ Non-compliance with rule
Error Prevention Theme	➢ Wrong rule: Educate ➢ Misapplication: Think a second time ➢ Non-compliance: Reduce burden, increase risk awareness, improve coaching culture
Error Probability	1:100

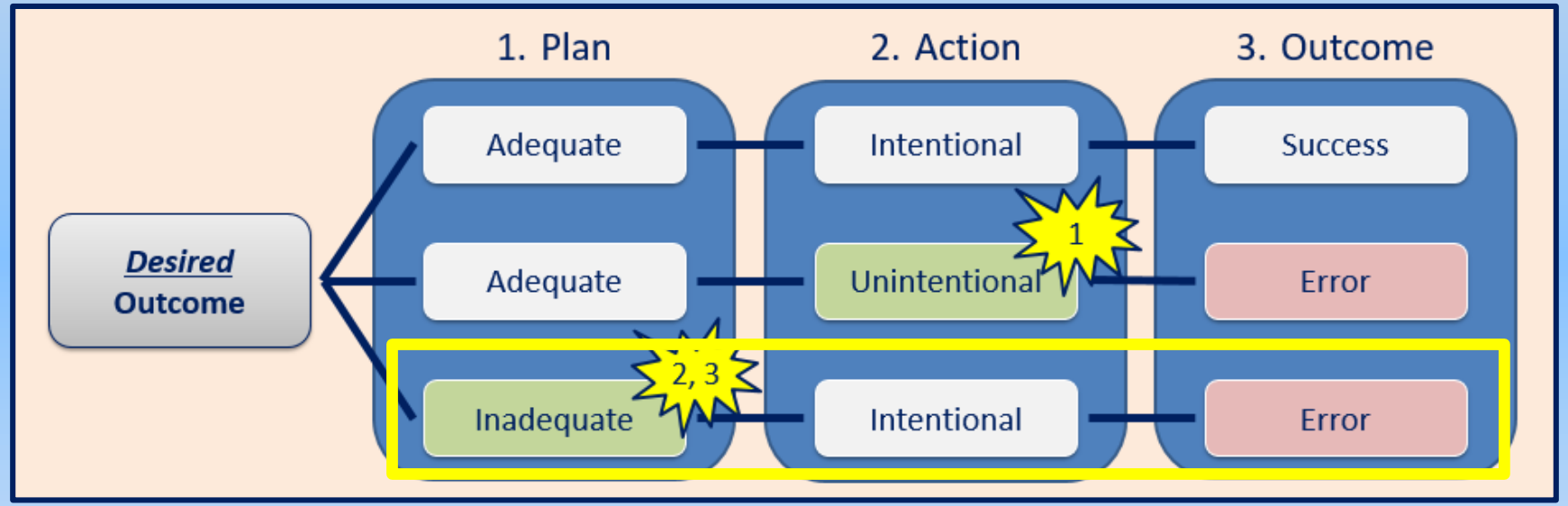
Examples

- Utilizing a vancomycin protocol from a different institution
- Ordering monitoring labs at an incorrect frequency than policy states

Reference 15

Knowledge-based

(analytical) [15]



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Activity Type	➢ Problem solving in new, unfamiliar situation for which the individual knows no rules ➢ Requires action plan to be formulated; Full conscious effort
Error Type	➢ Formulation of incorrect response ➢ “Trial and Error”
Error Prevention Theme	➢ Stop and find an expert ➢ Provide education
Error Probability	3:10 to 6:10

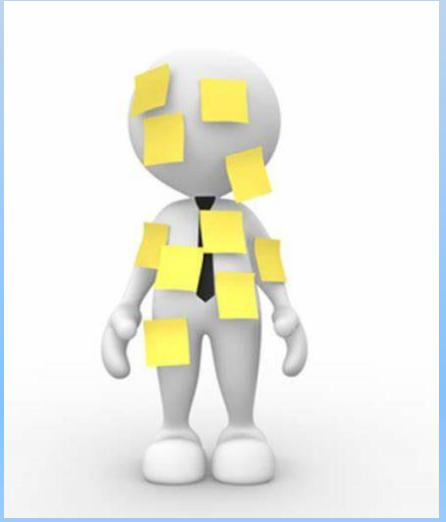
Examples

- Performing tasks in an unfamiliar clinical area that requires special/additional training (i.e., oncology)
- Verifying an unfamiliar medication (i.e., new to formulary, different clinical area, new to market)

Reference 15

Differentiating

- Understanding the different types of human error helps to distinguish HOW humans process information when completing a task
- Remember …
  - Each type will have a different mitigation strategy
    - Education will not be successful in preventing skill based errors



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Addressing Behaviors[13]

Reckless Behavior	At-Risk Behavior	Human Error
Choosing an action with knowledge and conscious disregard of the risk of harm	Consciously choosing an action without realizing the level of risk of an unintended outcome	Inadvertent action: slip, lapse, mistake
PUNISH Disciplinary action	**COACH** Counsel/explain why the behavior is risky; Focus process improvements on preventing people from partaking in this behavior	**CONSOLE** Support person involved with error; Alter system to prevent from occurring again

Hudson – Phases of Safety Culture[13]

It takes time for an organization to incorporate Just Culture allowing them to have a true safety culture. When moving towards a true safety culture, organizations will also see an increase in the following:

- Trust
- Safety
- Accountability
- Efficiency
- Productivity
- Sustainability
- Profitability

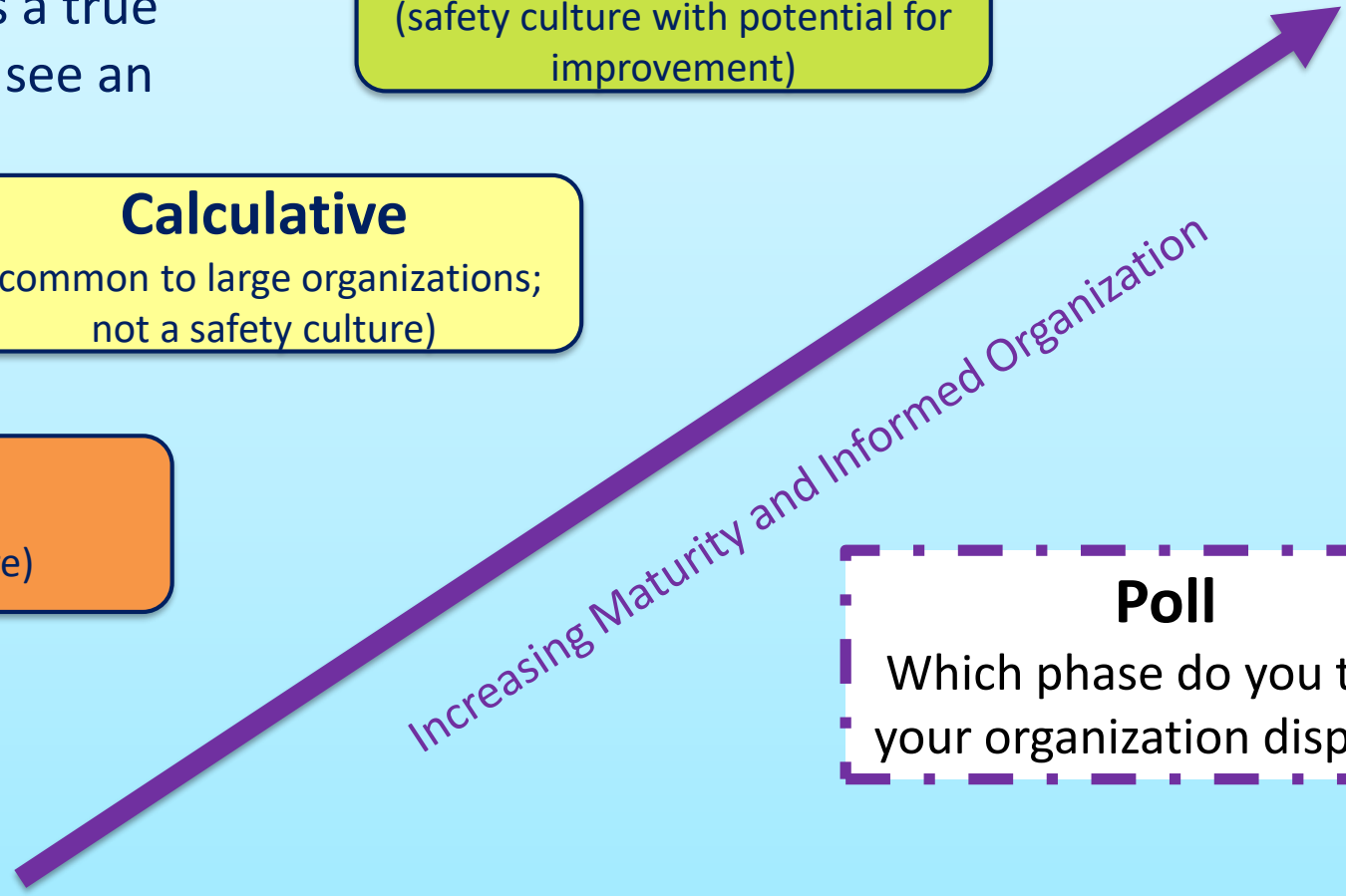
Pathological
(not a safety culture)

Reactive
(not a safety culture)

Calculative
(common to large organizations; not a safety culture)

Proactive
(safety culture with potential for improvement)

Generative
(TRUE safety culture)



Poll
Which phase do you think your organization displays?

How strong is your safety culture?[16]

Moving through each phase…

Focus must shift from PEOPLE to SYSTEMS
Closer to becoming a high reliability organization

- Preoccupation with Failure
- Sensitivity to Operations
- Reluctance to Simplify Explanations
- Deference to Expertise
- Resilience

High Reliability Organization[13]

HRO may be thought of as a very complex organization at high risk for catastrophic accidents, yet has been very successful at maintaining a high level of safety over a long period of time

POLL

What phase do you think your DEPARTMENT displays?

Generative
(TRUE safety culture)

Proactive
(safety culture with potential for improvement)

Calculative
(common to large organizations; not a safety culture)

Reactive
(not a safety culture)

Pathological
(not a safety culture)

POLL

What phase do you think your ORGANIZATION displays?

Generative
(TRUE safety culture)

Proactive
(safety culture with potential for improvement)

Calculative
(common to large organizations; not a safety culture)

Reactive
(not a safety culture)

Pathological
(not a safety culture)

Putting it all together…

In order to have a HRO…

…You must establish a COS

To have a successful COS…

…You must establish a Just Culture

To have a Just Culture…

…People must aligned with safety

Fostering Culture

- Perception can vary between organizations, departments, and roles
- Regardless of where the department or organization is within their journey, **YOUR** actions can influence (positively or negatively)

- What can you do in your everyday practice to enhance COS…
  - Lead by example
  - Ask questions
  - Create a learning environment
  - Stay process focused
  - Do not blame others
  - Support second victims
  - Understand processes from other disciplines
  - Encourage reporting → When in doubt, Fill it out!
  - Don’t turn a blind eye to safety even when you are behind schedule and under pressure
  - Start each meeting/interaction with a safety stories/message
  - Conduct safety rounds

Putting it all together!

Reported Event

Patient experienced Acute Kidney Injury while on vancomycin. First trough level (45 mcg/mL) was not scheduled for appropriate time based on renal function.

When reviewing this event, we must understand WHY the level was not scheduled for the appropriate time.

- ✓ Did the protocol CLEARLY state when to schedule levels?
- ✓ Did the person understand how to execute the protocol?
- ✓ Did the person know how to find all of the information needed in the chart?
- ✓ Did the person know how to enter/schedule the level?
- ✓ Did the environment (i.e., noise, distractions, etc.) contribute to this event?

Putting it all together!

What type of behavior did the resident display?

a) Human Error
b) At Risk
c) Reckless
d) Doesn't matter – Resident will fail

After discussing with the resident that scheduled the vancomycin lab, the following information is discovered:

- ✓ Successfully able to explain how to perform the vancomycin protocol including how to schedule the lab for the correct time
- ✓ When calculating the renal function, the resident used a SCr lab value from 2013
- ✓ This was the first time the resident was involved with an error

Putting it all together!

What type of human error did the resident display?

a) Skill Based
b) Rule Based
c) Knowledge Based

Skill-based (automatic)

- Slips: Action was not carried out as planned; Attention failures
- Lapses: Forgotten action

Rule-based (intuitive)

- Wrong rule
- Misapplication of a rule
- Non-compliance with rule

Knowledge-based (analytical)

- Formulation of incorrect response
- “Trial and Error”

Putting it all together!

How would we appropriately address the resident regarding this situation?

a) Console
b) Coach
c) Punish

After investigating, it is recognized the default setting in the system includes ALL lab values regardless of encounter or time frame

Telling the resident “you should have looked better” puts blame onto them, but with this system design it could have happened to anyone

- Providing knowledge can still occur when consoling, but blame should not be placed on the resident

- Appropriate follow up includes:
  - Consoling resident
  - Submitting an event into your risk system (remember: Risk systems are NOT punitive)
  - Sharing event with team to increase risk awareness
  - Having key stakeholders (i.e., those completing the work on a daily basis) partake in system/process redesign

Detecting
(Section 1)

- What information can we utilize to recognize process opportunities?
- Where can we retrieve data to identify potential system concerns?

Reviewing
(Section 2)

- What do you do after collecting this information?
- What tools can we utilize to organize and review the information collected?
- How do we strategize our efforts?

Improving
(Section 3)

- How can we make sustainable solutions within each step of the medication use process?

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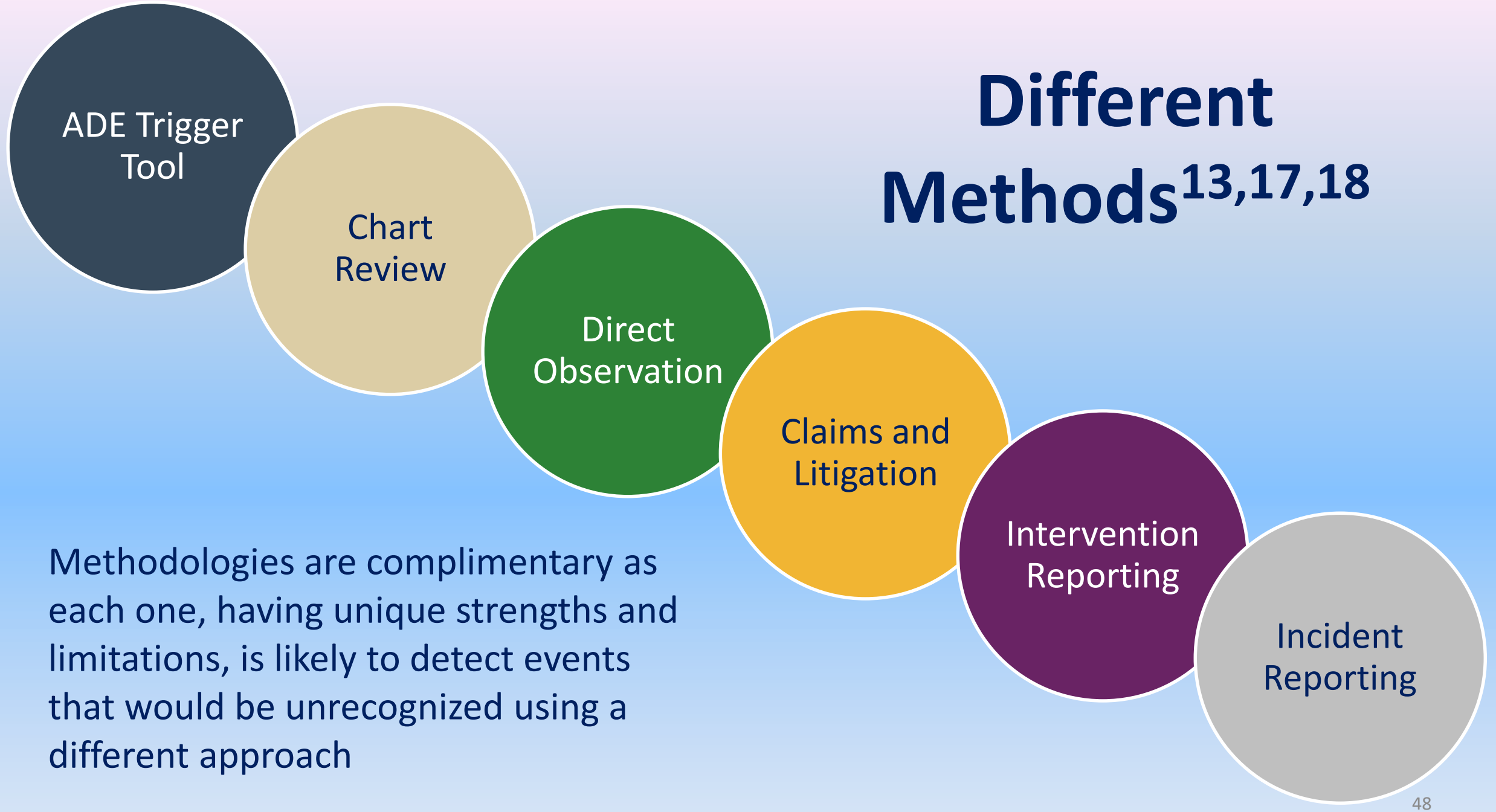
Detecting Medication Incidents

Section 1

Different Methods[13,17,18]



Methodologies are complimentary as each one, having unique strengths and limitations, is likely to detect events that would be unrecognized using a different approach

Detecting Medication Incidents[13,17,18]

ADE Trigger Tool	Chart Review	Direct Observation
Use of "triggers", or clues, to identify possible adverse events in the medical record	Collect information through various patient cases to retrieve particular data for discovery	Any intervention that a caregiver has initiated with a patient that has improved the quality of treatment/ patient care

Claims and Litigation	Intervention Reporting	Incident Reporting
Disputes that arise between the organization and third parities (e.g., patients, insurance companies, family, other facilities)	Any intervention that a caregiver has initiated with a patient that has improved the quality of treatment/ patient care	Any intervention that a caregiver has initiated with a patient that has improved the quality of treatment/ patient care

ADE Trigger Tool

- To use successfully within practice
  - Complete understanding of report build
  - Reviewer to ensure false negatives are removed
  - Standardize patient review/deep dive form
  - Information shared with key stakeholders to ensure process improvements occur
- IHI provides many different examples[19]

International Normalized Ratio (INR) Greater than 6	Glucose Less than 50 mg/dL	Naloxone (Narcan®) Administration
Look for evidence of bleeding to determine if an adverse event has occurred. An elevated INR in itself is not an ADE.	Review for symptoms such as lethargy and shakiness documented in nursing notes, and the administration of glucose, orange juice, or other intervention. If symptoms are present, look for associated use of insulin or oral hypoglycemics.	Naloxone is a powerful narcotic antagonist. Usage likely represents an AE except in cases of drug abuse or self-inflicted overdose.

ADE Trigger Tool

Example: Hypoglycemia[20]

Sep 2016
- Reports reviewed to align with definitions, criteria, and scope
- Past data changed to align with changes
- Patient specific data shared with key stakeholders

Dec 2016
- Documentation of root causes start
- Increase data transparency with one centralized location

Jan 2017
- ADE committees established

Jun 2017
- Standardized patient review occurs utilizing HEAT tool

Jan 2018
- Root causes modified from original HEAT tool

Jan 2019
- Root causes reviewed; Additional responses included
- Standardized documentation of root causes

Jan 2020
- Root causes reviewed/updated
- Additional information documented
- Data display enhancement

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ADE Trigger Tool

Example: Hypoglycemia

MSO

Generates report;
Filters appropriate locations;
Places data on G drive

Site Designee

Reviews patients to ensure criteria met;
Completes deep dive (HEAT tool);
Documents on G drive

MSO

Reviews G drive documentation from site designees; Ensures network excel sheet set up correctly

Site Specific Activities

Outcome data provided to Network;
Data reviewed/ Information distributed;
Processes improved

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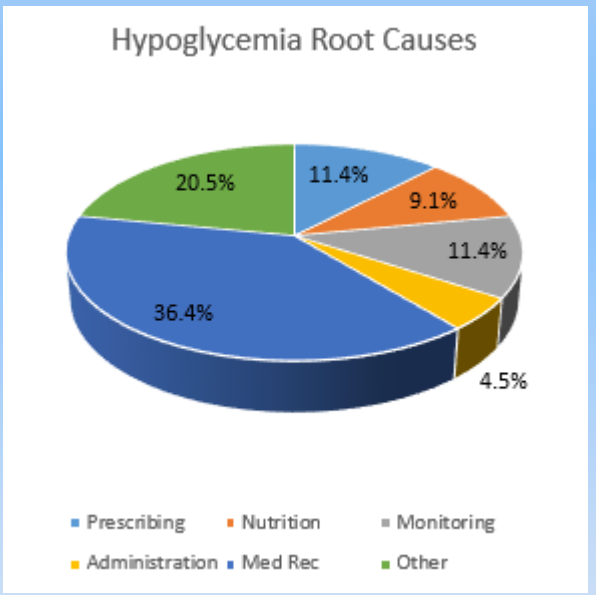
YTD Data	Results (# of hypoglycemic events)	Percentage (# of hypoglycemic events/# of inpatients receiving a hypoglycemic agent)
2017	562	3.43%
2018	416	2.43%
2019	378	1.89%
2020*	189	1.63%

*Through September 2020



Root Causes	Jan 2020	Feb 2020	Mar 2020	Apr 2020	May 2020	Jun 2020	Jul 2020	Aug 2020	Sep 2020	Oct 2020	Nov 2020	Dec 2020	Total	Percentage
Prescribing	2	0	1	0	2	0	0	0	0	0	0	0	5	11.4%
PRESCRIBING: Glucose < 100 without regimen modification													0	0.0%
PRESCRIBING: Glucose < 70 without regimen modification	1		1										2	4.5%
PRESCRIBING: Patient not receiving basal insulin													0	0.0%
PRESCRIBING: Patient on Sliding Scale Insulin alone													0	0.0%
PRESCRIBING: Incorrect dose prescribed	1				2								3	6.8%
Nutrition	0	2	2	0	0	0	0	0	0	0	0	0	4	9.1%
NUTRITION: No regimen modiciation after diet change **ordered** (i.e. sudden NPO, loss of parenteral glucose, clear liquid diet)													0	0.0%
NUTRITION: No snack given		1											1	2.3%
NUTRITION: Sudden patient loss of appetite (includes nausea, vomiting, etc)		1	1										2	4.5%
NUTRITION: Tube feed held/wrong tube feed			1										1	2.3%
Monitoring	0	2	3	0	0	0	0	0	0	0	0	0	5	11.4%
MONITORING: BG obtained > 30 minutes from treatment			3										3	6.8%
MONITORING: Monitoring protocol not completed correctly		2											2	4.5%
Administration	0	1	3	0	1	0	0	0	0	0	0	0	5	11.4%
ADMINISTRATION: Gave sliding scale without eating													0	0.0%
ADMINISTRATION: Orderset not followed			2										2	4.5%
ADMINISTRATION: Stacking (bolus or basal)			1		1								2	4.5%
ADMINISTRATION: Intentional patient behavior													0	0.0%
ADMINISTRATION: Lack of meal-insulin coordination		1											1	2.3%
Med Rec/Transitions of Care (TOC)	2	1	6	1	6	0	0	0	0	0	0	0	16	36.4%
TOC: Patient stated taking differently than indicated in med history													0	0.0%
TOC: Increase in home insulin (NOT basal)					1								1	2.3%
TOC: Increase in BASAL home dose	1	1	1		1								4	9.1%
TOC: Decrease in BASAL home dose													0	0.0%
TOC: Outpatient to Inpatient Treatment changed (ex: utilizes pump at home but not inpatient; Inpatient treatment different than home)	1		2	1	3								7	15.9%
TOC: Home insulin regimen continued on admission without appppropriate modification/reduction			3		1								4	9.1%
Other	2	2	2	0	3	0	0	0	0	0	0	0	9	20.5%
OTHER: Unknown		2	1		1								4	9.1%
OTHER: Unknown - Documentation Not Available													0	0.0%
OTHER: Lack of documentation (see comments: hypoglycemia treatment, snacks, meals)	1												1	2.3%
OTHER: Cause Not Listed (see comments)	1		1		2								4	9.1%
Total Number of Root Causes for Month	6	8	17	1	12	0	0	0	0	0	0	0	44	
Total patients for month	3	4	11	1	7	2	1	0	0	0	0	0	29	
Average Number of Root Causes Identified per Patient	2.0	2.0	1.5	1.0	1.7	0.0	0.0	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	1.5	

Treatment Utilized/Type	Jan 2020	Feb 2020	Mar 2020	Apr 2020	May 2020	Jun 2020	Jul 2020	Aug 2020	Sep 2020	Oct 2020	Nov 2020	Dec 2020	Total	Pt Percentage
N/A													0	0%
Hyperkalemia treatment			1		2								3	10%
Insulin pump utilized					1								1	3%
Insulin drip prescribed			1										1	3%
U500 insulin prescriibed													0	0%
Additional insulin type ordered (see comments)													0	0%
Total	0	0	2	0	3	0	0	0	0	0	0	0	5	17.2%
Patient Percentage	0%	0%	18.2%	0%	43%	0%	0%	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	17.2%	

Direct Observation

Interviewing Questions[21]

- **Focus:** Look at the event from the perspective of those involved to understand WHY they behaved the way they did at that moment
- **Goal:** Gain a better idea of "why things made sense" at the time to those involved in the event
  - **Example:** All information appears to have been available during the event, but after discussions it is recognized:
    - Information is displayed only one piece at a time
    - Screen does not have information prominently viewed
    - Presented information was not viewed as significant to those involved

Direct Observation

Interviewing Questions

Starting conversation

- Include discussion purpose (i.e., event involvement)
- Share OBJECTIVE, high level overview to help those involved remember event

Open ended questions

- “In your words, could you please share what occurred? What do you remember was going on at this time?”
- Suggested questions (next slide) do not need to be asked specifically, but try to listen for this information

Ending discussion

- “What recommendations or process changes do you think we could implement to prevent from occurring again?”
- Thank them for the information
- Any next steps required or will occur

Direct Observation

Interviewing Questions[21]

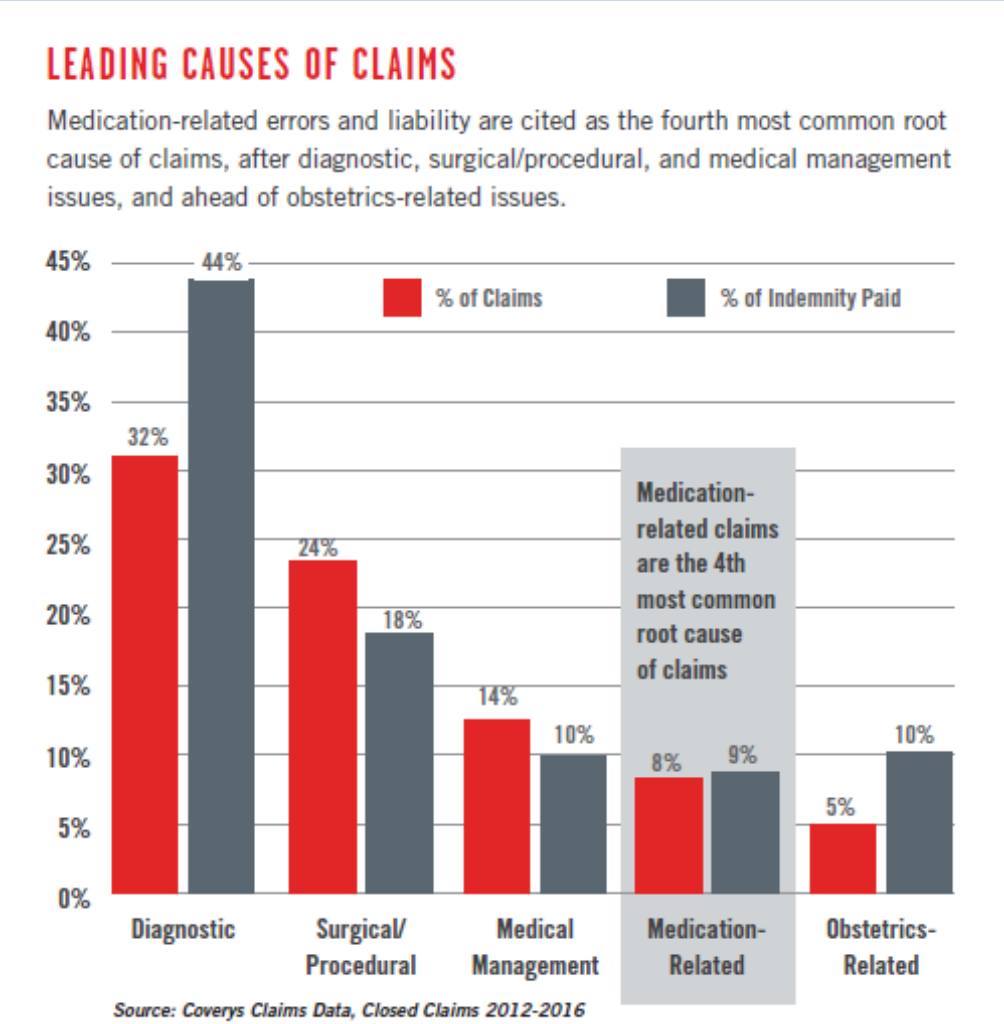
1) What was your understanding of the process/situation at this time?
2) What information or data was available to you at this point?
3) What did that information mean to you at this time?
4) What was the process/system doing at this time?
5) What changes in the process/situation required you to change your behavior?
6) What were other people doing at that moment?
7) What were you trying to achieve or accomplish at that point?
8) What assumptions were you making?
9) What options or alternatives did you have?
10) What were you focusing on?
11) What did you expect to happen?
12) At what point did you realize that the situation was different from what you believed it to be previously?

Claims and Litigation

- Often an unmined source of rich information
- Fully investigated liability claim will include the following:
  - Allegations of primary and secondary causes of the claim
    - e.g., medication-related, diagnostic, surgical/procedural
  - Patient health and demographic information
  - Injury severity
  - Physician specialty
  - Risk management issues
    - e.g., clinical systems, clinical judgment, documentation
  - Location of the alleged error
    - e.g., office/clinic, room/bed, surgery, ED/urgent care
  - Human and financial costs
- Trends can be utilized to identify signals and opportunity to help providers avoid potential lawsuits

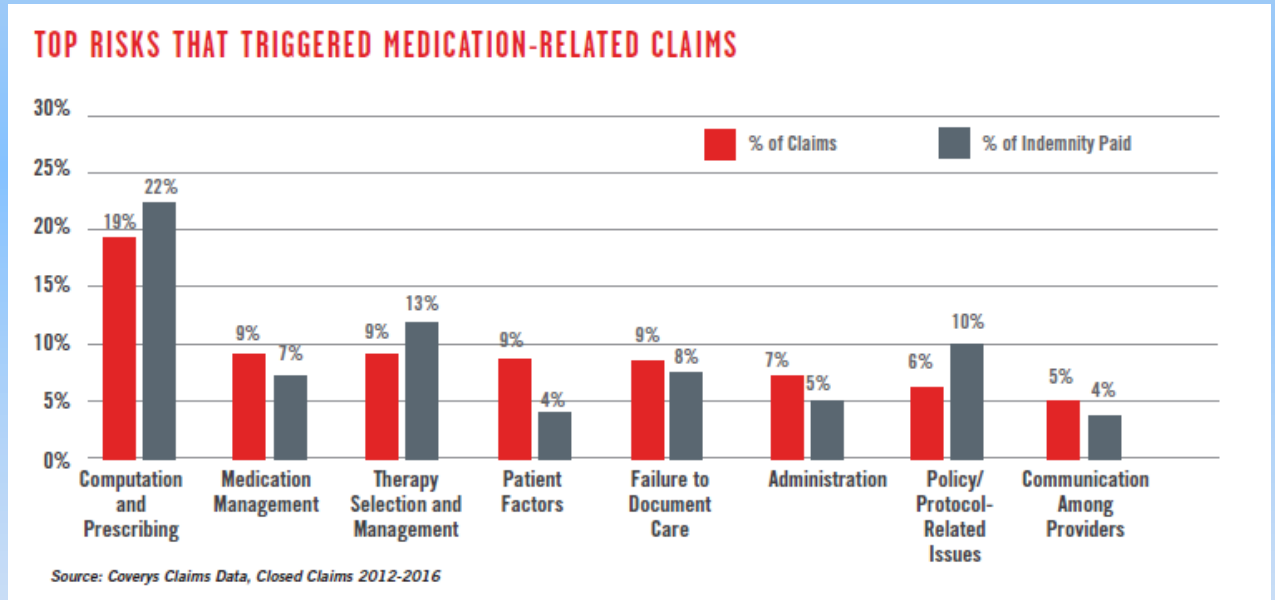
Claims and Litigation

Study Data[22]



Percentage of medication errors …

- Occurring in an office or clinic setting: 42%
- Related to inadequate monitoring: 31%
- Cases ultimately involving a patient death: 38%



Incident Reporting

Reporting System: Design and Features[23]

To have a successful reporting system:

- Supportive environment protecting staff privacy
- Structure mechanism for reviewing reports and developing action plans
- Timely dissemination of reported event summaries
- Barriers must be identified and addressed

Perception

- Events are too trivial”
- Information not used to improve process
- Fear of blame/managerial scrutiny/legal penalties

Process

- Lack of knowledge
- Forgot to report
- Form confusing or time consuming
- Unsure who should report
- Inadequate feedback

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Incident Reporting

Reporting System: Design and Features[13,24]

Controversy Features

Anonymous vs Reporter Name	Voluntary vs Mandatory
• Reduces the real or perceived risk to the reporter • Potential to increase reporting	• Main purpose is to hold hospitals accountable for taking actions to improve safety • Policies and procedures usually state that all errors "will" be reported, but in reality, they are not
• No mechanism to follow-up with those most closely involved with the event	• Subject to bias due to voluntary nature • Only capture a fraction of events and may not reliably identify serious events • Spectrum of reported events is limited due to types of caregivers (i.e. pharmacists, nursing, etc.) more likely to utilize the system to report versus those who do not

Collecting Data Tips

Ensure you know HOW the report was built

Create a standardized form to collect data

- Reduces bias between reviewers

Utilize a variety of data sources

Involve key stakeholder to determine

- Scope
- Important points of interest
- Expected results

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POLL

Which of these data sources will you start incorporating into your practice?

Detecting
(Section 1)

- What information can we utilize to recognize process opportunities?
- Where can we retrieve data to identify potential system concerns?

Reviewing
(Section 2)

- What do you do after collecting this information?
- What tools can we utilize to organize and review the information collected?
- How do we strategize our efforts?

Improving
(Section 3)

- How can we make sustainable solutions within each step of the medication use process?

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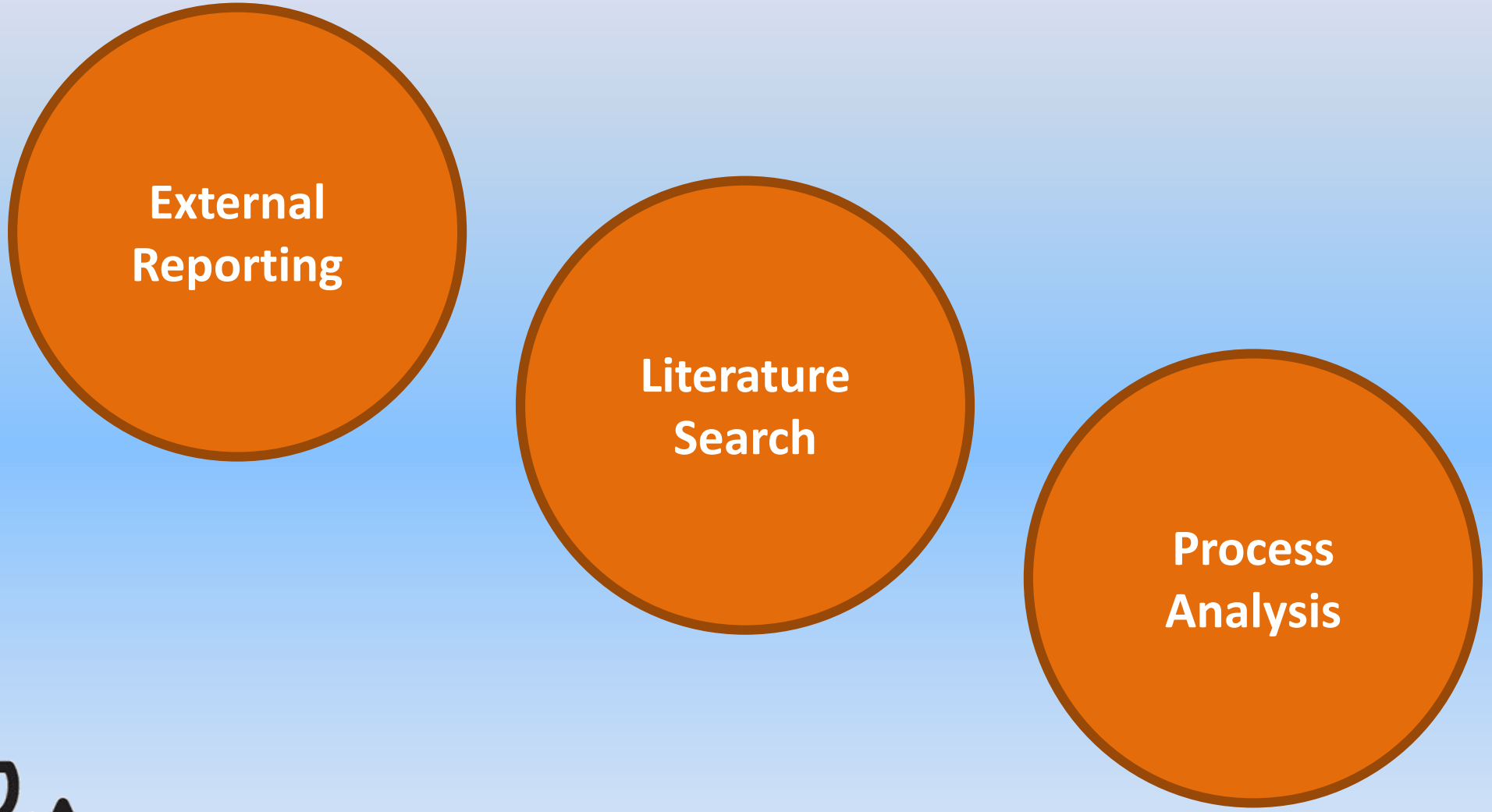
Overall Process



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External Reporting[13,25]

Each event report can be communicated through established and informal systems existing

- Within an organization (i.e. internal reporting)
- Outside the organizations (i.e. external reporting)

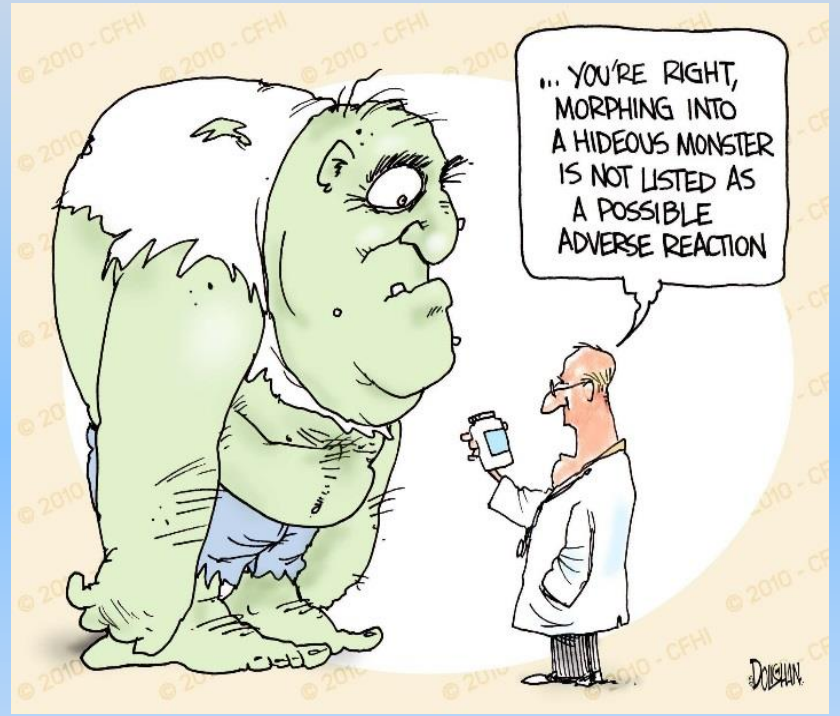
External Reporting Programs	

	• USP-ISMP Medication Error Reporting Program
	• MedMARx
	• FDA
	  – Sentinel Event Reporting
	  – MedWatch Database
	• State mandatory reporting
	• Patient safety organizations (example: ICPS site sharing)

- Allows health professionals to serve the public health beyond their organization by alerting other health professionals of problems
  - Others can learn from these experiences (aligns with ISMP Best Practice #14)
  - Can help to prevent future injury to other patients
  - Serves an early warning detection for potential hazards

Literature Search[13,25,26]

- FDA MedWatch FAERS Database
- ISMP Newsletters
- Guidelines: ISMP, AHRQ
- ISMP Best Practices/Gap Assessments
- Other discipline resources
- Utilize different keywords
  - ADR, ADE, Medication Error, Error
- Compare against outside organizations



Process Analyses

Root Cause Analysis

Barrier Analysis

Apparent Cause Analysis

Failure Modes and Effect Analysis

Root Cause Analysis[13]

- Systematic process for identifying WHY an event occurred
  - Prevents “band-aid” placing and treating symptoms seen on the surface of the problem
  - Identifies true, underlying system problems to ensure mitigation strategies (i.e. fixes or process improvements) are appropriately placed

BA and ACA[27,28]

Barrier Analysis

- Definition: Barrier analysis defines the hazards, targets, and the pathways through which hazards affect targets, and identifies barriers and controls that would block the pathway, and maintain the target within the specified range or set of conditions.
  - Target: person, equipment, set of data
  - Hazard: any adverse event, anything that moves target outside of range conditions
  - Barrier: passive construct between a hazard and a target

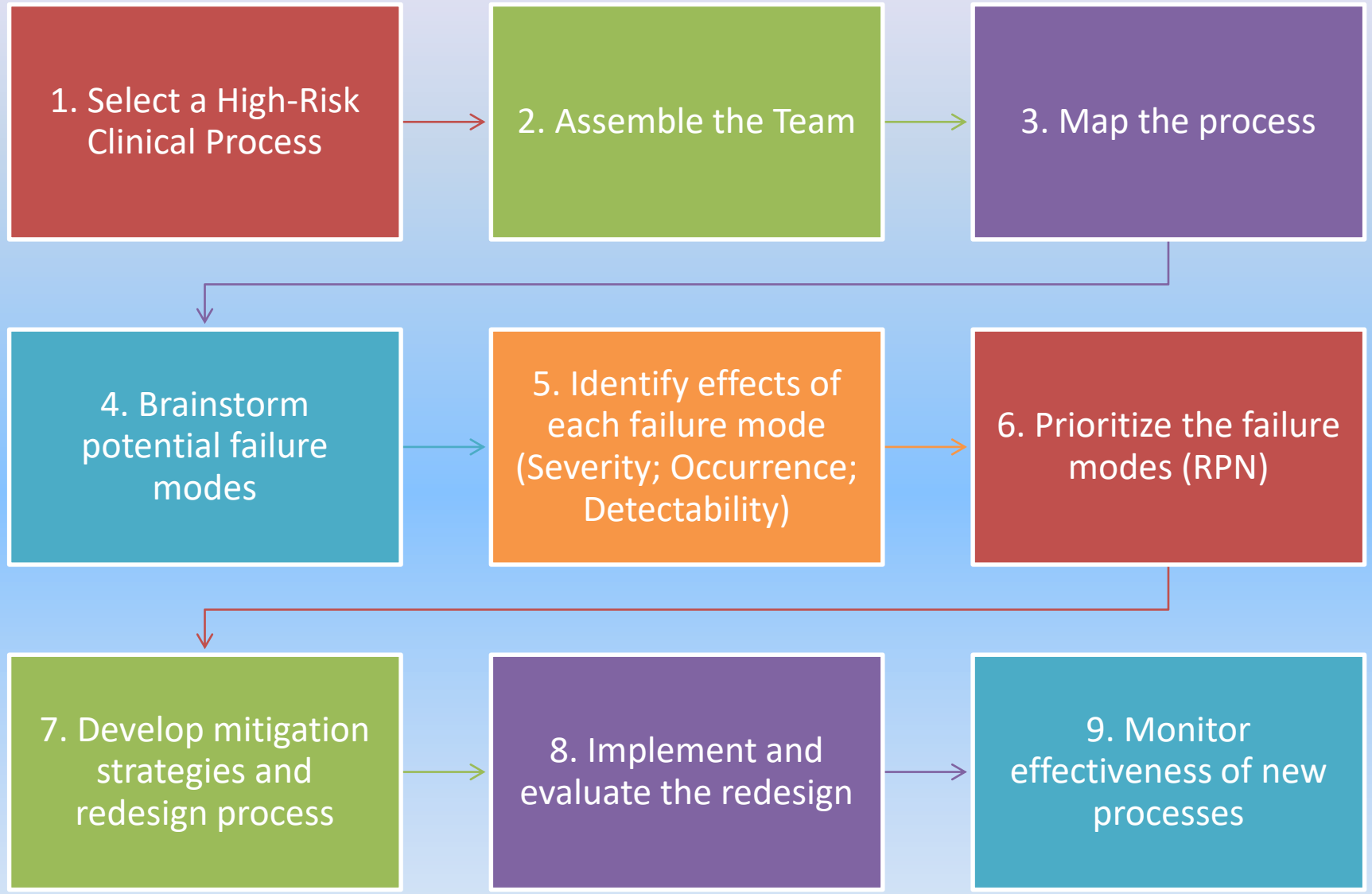
Apparent Cause Analysis

- Definition: straightforward analytical approach used to identify obvious causes based on the facts pertaining to the incident / finding.
- Not in-depth as RCA
- Addresses circumstance not causes

Failure Mode and Effects Analysis (FMEA)[13]

- FMEA is a structured approach to:
  - Identify the ways in which a product or process can fail
  - Estimating risk associated with specific causes
  - Prioritizing the actions that should be taken to reduce risk
- When to conduct an FMEA:
  - PROACTIVE approach
  - Early in the process improvement investigation
  - When new systems, products, and processes are being designed
  - When existing designs or processes are being changes
  - When carry-over designs are used in new applications
  - After system, product, or process functions are defined, but before specific hardware is selected or released to implement

Failure Mode and Effects Analysis (FMEA)[13]



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Failure Mode and Effects Analysis (FMEA)[13]

Step in Process	Failure Mode	Causes	Effects	Occurrence	Detection	Severity	Risk Profile Number (RPN)	Actions to Reduce Failure Mode
State step	State all manners processes and systems may fail	State all reasons each failure mode could occur	State effects that would occur if failure mode was to occur	State how likely this is to occur (Scale 1-10)	State how likely this failure will be detected (Scale 1-10)	State severity of patient consequence if failure mode was to occur (Scale 1-10)	Multiply the score from likelihood, severity, and probability	Develop action plan to prevent failure more from occurring

Quality improvement tool to **PROACTIVELY** determine points of potential failure and predict their effects

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Failure Mode and Effects Analysis (FMEA)[13]

Likelihood of occurrence

- Frequency with which a given cause occurs and creates failure modes (obtain from past data if possible)
- How likely is it that this failure mode will occur?

Likelihood of detection

- The ability of the current control scheme to detect (then prevent) a given cause (may be difficult to estimate early in the process operations)
- If this failure mode occurs, how likely is it that the failure will be detected?

Severity

- Impact on patient care or importance of the effect on customer requirements
- If this failure mode occurs, how likely is it that harm will occur?

Failure Mode and Effects Analysis (FMEA)[13]

Rating Scales

Occurrence
Assign a score between 1 and 10, with 1 meaning “Not Likely” and 10 meaning “Very Likely”

Detection
Assign a score between 1 and 10, with 1 meaning “Easy to Detect” and 10 meaning “Not Easy to Detect”

Severity
Assign a score between 1 and 10, with 1 meaning “Not Severe” and 10 meaning “Very Severe”

Risk Priority Number (RPN)

RPN is the product of the severity, occurrence, and detection scores

Implement actions to reduce failure first that are affected by highest RPN score

Detecting
(Section 1)

- What information can we utilize to recognize process opportunities?
- Where can we retrieve data to identify potential system concerns?

Reviewing
(Section 2)

- What do you do after collecting this information?
- What tools can we utilize to organize and review the information collected?
- How do we strategize our efforts?

Improving
(Section 3)

- How can we make sustainable solutions within each step of the medication use process?

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Process Improvements

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Change Management[29]

- Discipline that guides how we prepare, equip and support individuals to successfully adopt change in order to drive organizational success and outcomes

- Change initiatives will fail ~75% of the time!
- Failure reasons
  - Unskilled leaders
  - No clear vision
  - Inadequate communication
  - Lack of alignment
  - Low engagement

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Zone of Status Quo

- Occurs before change is introduced

Zone of Disruption

- All change will create disruption (i.e., lost time, extra cost, etc.)
- Occurs when results begin to suffer from new realities of the change
- Zone continues until all team members move past the Point of Decision

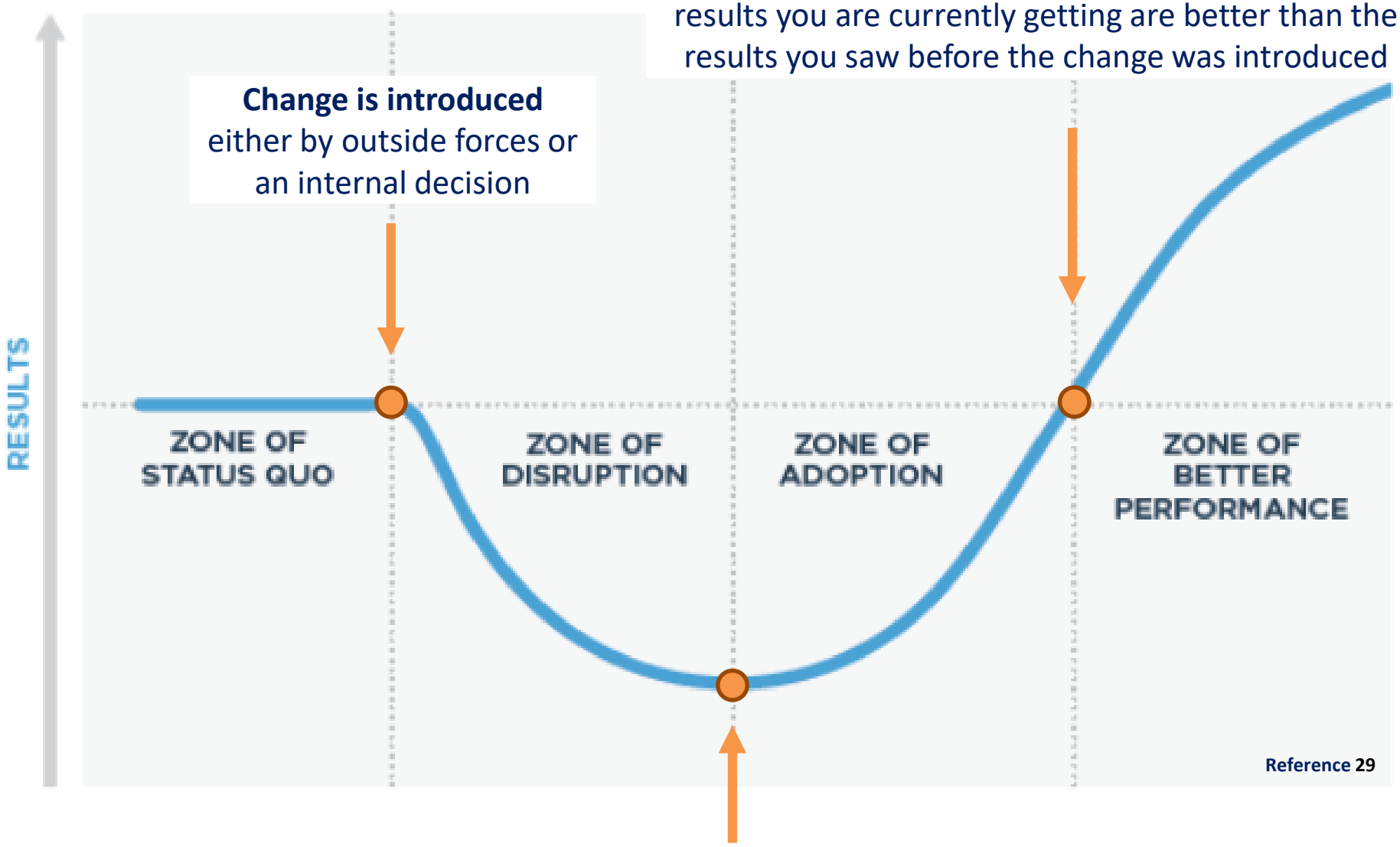
Zone of Adoption

- Adaption to the new rules affiliated with the change
- The change is driving what occurs within the process

Zone of Better Performance

- Begins when the results are better than what was experienced before the change was introduced
- Benefits of the change will occur

The Zone of Better Performance begins wen the results you are currently getting are better than the results you saw before the change was introduced



The Point of Decision (POD) is crossed when the team and you:

- Are aware of what is changing and why
- Know what it means for you personally
- Have decided what will do about it (as opposed to doing nothing)

Influencing Change[30]

1) **Awareness** for the need for change
   - Share patient stories
   - Provide data
   - Compare to best practices (externally and internally) from other facilities/organizations
2) **Desire** to support the change
   - Tie back to goals/values/vision of department or organization
     - Connect the dots for others… How does this change align? Why does the current process not align?
   - Understand process by asking those partaking in the process
     - What they FEEL are issues/pain points
     - Wanted outcomes
     - Motivational factors

Influencing Change[30]

3) Ability to demonstrate skills and behaviors

- *Ability* is turning knowledge into action; Tangibly applying and demonstration intellectual understanding in the real-world environment
- Feedback is essential

4) Knowledge of how to change

- Hands on training is best
- Information to include

Purpose for change **Previous and new state gaps** **Discrete action items**

5) Reinforcement to ensure sustainable change

- Recognize absence of negative outcomes
- Provide data
- Develop accountability plan

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Benefits of Applying Human Factors

- Improve the safety culture of teams and organizations
- Enhance teamwork and improve communication between healthcare staff
- Improve the design of healthcare systems and equipment
- Identify what went wrong and predict what could go wrong

https://www.youtube.com/watch?v=8Jnf1kwaDoc&feature=youtu.be

Human Factors[13,31]

- Examines the relationship/interaction between people and systems
  - Brings an understanding of WHY people make errors
- Goal: accommodate the system for all users
  - Meaning the same task can be accomplished by both

calm, rested, experienced

stressed, fatigued, rushing, inexperienced

- Make it easier to complete the task the correct way
- Design the system to fit people instead of having the person fit the system

Various Reasons Errors Occur[32]

Root Cause Types	Causal Factors/Root Cause Details
Communication Factors	• Communication breakdown between and among teams, staff, and providers • Communication during handoff/transitions of care • Language or literacy • Information availability • Misinterpretation of information • Presentation of information
Environmental Factors	• Noise, lighting, flooring conditions, etc. • Space availability, design locations, storage • Maintenance, housekeeping
Equipment/Device/Supply/ Health IT Factors	• Equipment, device, or product supplies problems or availability • Health information technology issues such as display/interface issues (including display of information), system interoperability • Information availability • Malfunction, incorrect selection, misconnection • Labeling instructions missing • Alarms silenced, disabled, overridden

Various Reasons Errors Occur[32]

Root Cause Types	Causal Factors/Root Cause Details
Task/Process Factors	• Lack of process redundancies, interruptions, or lack of decision support • Lack of error recovery • Workflow inefficient or complex
Staff Performance Factors	• Fatigue, inattention, distraction or workload • Staff knowledge deficit or competency • Criminal or intentionally unsafe act
Team Factors	• Lack of speaking up, disruptive behaviors, lack of shared mental model • Lack of empowerment • Failure to engage patient
Management/Supervisory/ Workforce Factors	• Disruptive or intimidating behaviors • Staff training • Appropriate rules/policies/procedure or lack thereof • Failure to provide appropriate staff or correct a known problem • Failure to provide necessary information
Organizational Culture/ Leadership	• Organizational-level failure to correct a known problem and/or provide resource support including staffing • Workplace climate/institutional culture • Leadership commitment to patient safety

Process Design[31]

Factors leading to non compliance

People

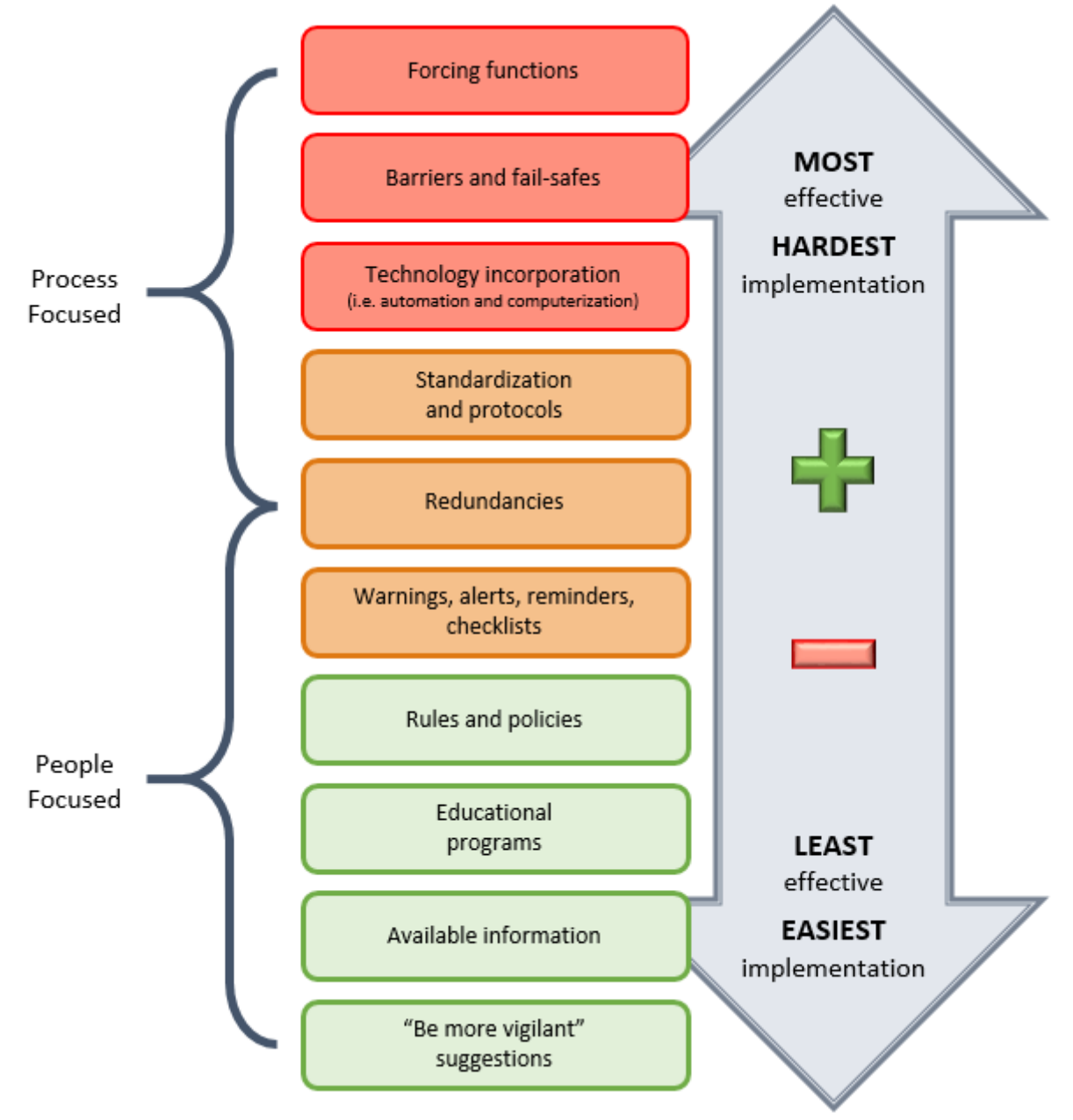
- Perceived low likelihood of detection
- Lack of awareness/understanding of policies and procedures
- Misperception or lack of recognition of risk
- Self-perceived authority to violate (ignore the rules)

Workflow

- Time pressure/pressure to get the job done
- Policy/procedure overload (for example, confusion over which procedure applies when)
- Mismatch between the policy/procedure and how the job is actually done

Leadership

- Lack of leadership
- Lack of end-user engagement when policies and procedure are written
- Copying behavior (i.e., learn to do the procedure from a colleague who is non-compliant)
- Ambiguous or conflicting messages in the policy/procedure
- Lack of training/reinforcement of key policy messages over time
- No sanctions imposed for non-compliance
- Lack of monitoring systems to check procedural compliance
- Policies and procedures are inaccessible
- Out of date procedures/policies



High-leverage Strategies

- Most effective as they focus on the system and 'design out' hazards
  - Can eliminate the risk of errors and associated harm
  - They do not rely heavily on individual human attention and vigilance
- May involve complex implementation plans because they often require system redesign

Medium-leverage Strategies

- Do not eliminate hazards, but reduce the likelihood of errors or minimize harm
  - Highly dependent on the behavior of people using the system
- Relatively easy to implement but may need periodic updating and reinforcement to maintain knowledge and the currency of the process or product

Low-leverage Strategies

- Often easy and quick to implement but need constant updating and reinforcement to maintain knowledge and currency
- They aim to improve human performance and are more effective when combined with other medium- or high leverage strategies

Reference 33, 34

Project Management[35]

- Leadership buy-in
- Keep track of meeting follow ups/action items
  - WHO does WHAT by WHEN?
- Downstream effects
- Create implementation checklist
  - New formulary products
- RACI

R Responsible	Who is/will be doing this task? Who is assigned to work on this task?
A Accountable	Who's head will roll if this goes wrong? Who has the authority to take decision?
C Consulted	Anyone who can tell more about this task? Any stakeholders already identified?
I Informed	Anyone whose work depends on this task? Who has to the kept updated about the progress?

RACI matrix.

R	Responsible
A	Accountable
C	Consulted
I	Informed

Project tasks	Product Owner	Business Analyst	Financial Lead	Design Director	Design Lead	CRM Lead	Head of CRM	Senior Stakeholders*	Senior Stakeholders**	AGENCY
1. Research										
Econometric model	C	C	A	I	I	C	I	C	I	R
Strategic framework	A	C	C	I	I	C	I	C	I	R
2. Define										
Product concept	A	C	I	C	I	C	C	C	I	R
User testing	A	C	I	I	I	C	I	I	I	R
User journey	A	C	I	I	I	C	I	C	I	R
Design framework	C	C	I	R	A	I	I	C	I	R
Technology recommendations	C	A	I	I	I	I	I	C	I	R
Measurement framework	R	C	A	I	I	C	I	C	I	R
Product backlog	A	R	I	C	I	C	I	C	I	C
Delivery roadmap	A	R	I	R	C	C	I	C	C	R

*Senior Stakeholder 1, Senior Stakeholder 2, Senior Stakeholder 3, Senior Stakeholder 4
** Senior Stakeholder 5, Senior Stakeholder 6, Senior Stakeholder 7, Senior Stakeholder 8

Stepwise Project Planning

Steps in project planning

Step 0: Select project

Step 1: Identify project scope and objectives

Step 2: Identify project infrastructure

Step 3: Analyze project characteristics

Step 4: Identify project products and activities

Step 5: Estimate effort for each activity

Step 6: Identify activity risks

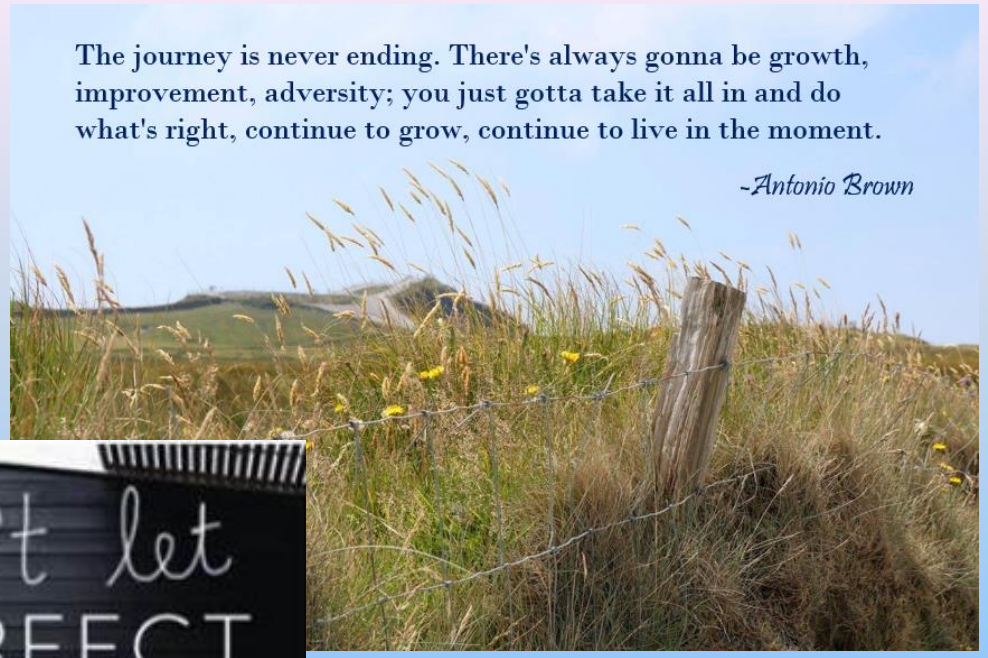
Step 7: Allocate resources

Step 8: Review/Publicize plan

Step 9 & 10: Execute plan/Lower level of planning

Organizational Factors

- Navigating politics
- Communication/Transparency is KEY
- Utilize other existing committees (product lines, operational, clinical)
- Timing of other initiatives
  - People can only handle a maximum amount of change
  - Resource allocation (IT build support, financial, meeting time, etc.)



Group Therapy

Poll everywhere

Kick off Group Therapy …

- It may be difficult to balance/prioritize the many responsibilities that fall within this role…
- Here are some suggestions from ICPS and SLAMS
  - Focus on potential level of harm
  - Remember prioritizing can be difficult because everyone sees/values things differently
    - Importance of having leadership buy-in
  - Items discovered through incident reporting
    - Reporter dedicated time to report, which means it was perceived as a concern
    - Events are directly affiliated with patient care processes
  - Do not forget about politics
    - Items may be deprioritized from others in the organization
  - Ensure you have a platform to drive transparency

Group Discussion

- What other tips/tricks do you have to help balance/prioritize?
- What platforms do you utilize to help drive transparency?

What questions do you have for the group?

(What keeps you up at night?)

CME Learner Information

Accreditation Statement

In support of improving patient care, this activity has been planned and implemented by Indiana University School of Medicine and Indianapolis Coalition for Patient Safety, Inc. Indiana University School of Medicine is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

Nurses

Indiana University School of Medicine designates this activity for a maximum of 6.0 *ANCC contact hours*. Nurses should claim only the credit commensurate with the extent of their participation in the activity.

Physicians

Indiana University School of Medicine designates this live activity for a maximum of 6.0 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Pharmacists and Pharmacy Technicians

Indiana University School of Medicine designates this activity (ACPE UAN JA4008178-9999-21-007-L04-P and JA4008178-9999-21-007-L04-T) for 6.0 ACPE contact hours. Pharmacists and Pharmacy Technicians should only claim credit commensurate with the extent of their participation in the activity. Credit will be provided to NABP CPE Monitor within 60 days after the activity completion.

Text Attendance Set-Up Information

1. Pair your CME profile and cell phone by texting your email address to **317-671-8998**. **Be sure to use the same email address you used to register for this activity.**

2. After receiving a confirmation text, send the activity code **59849** to **317-671-8998.**

3. You will receive a confirmation response text and your attendance will be immediately documented on your CME transcript.

4. You have until **11 p.m**. to text your attendance.

Learners will receive a separate email with instructions on how to download your CME transcript. For questions and concerns, please contact IU School of Medicine, Division of Continuing Medical Education, 317-274-0104, or cme@iu.edu.

MEDICATION SAFETY BOOTCAMP

102: Application of Medication Safety Basics

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Thursday, November 5th, 2020

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Midwest Medication Safety Symposium

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