Utilizing the FMEA Process: U-500 Pens

To Do or Not to Do

Community Health Network

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Speakers have no actual or potential conflicts of interest to disclose

Objectives

- State the purpose of a FMEA
- Describe the steps included in a FMEA process
- Discuss the importance of a multidisciplinary group when utilizing the FMEA tool

Poll Questions #1

- Have you participated in a FMEA?

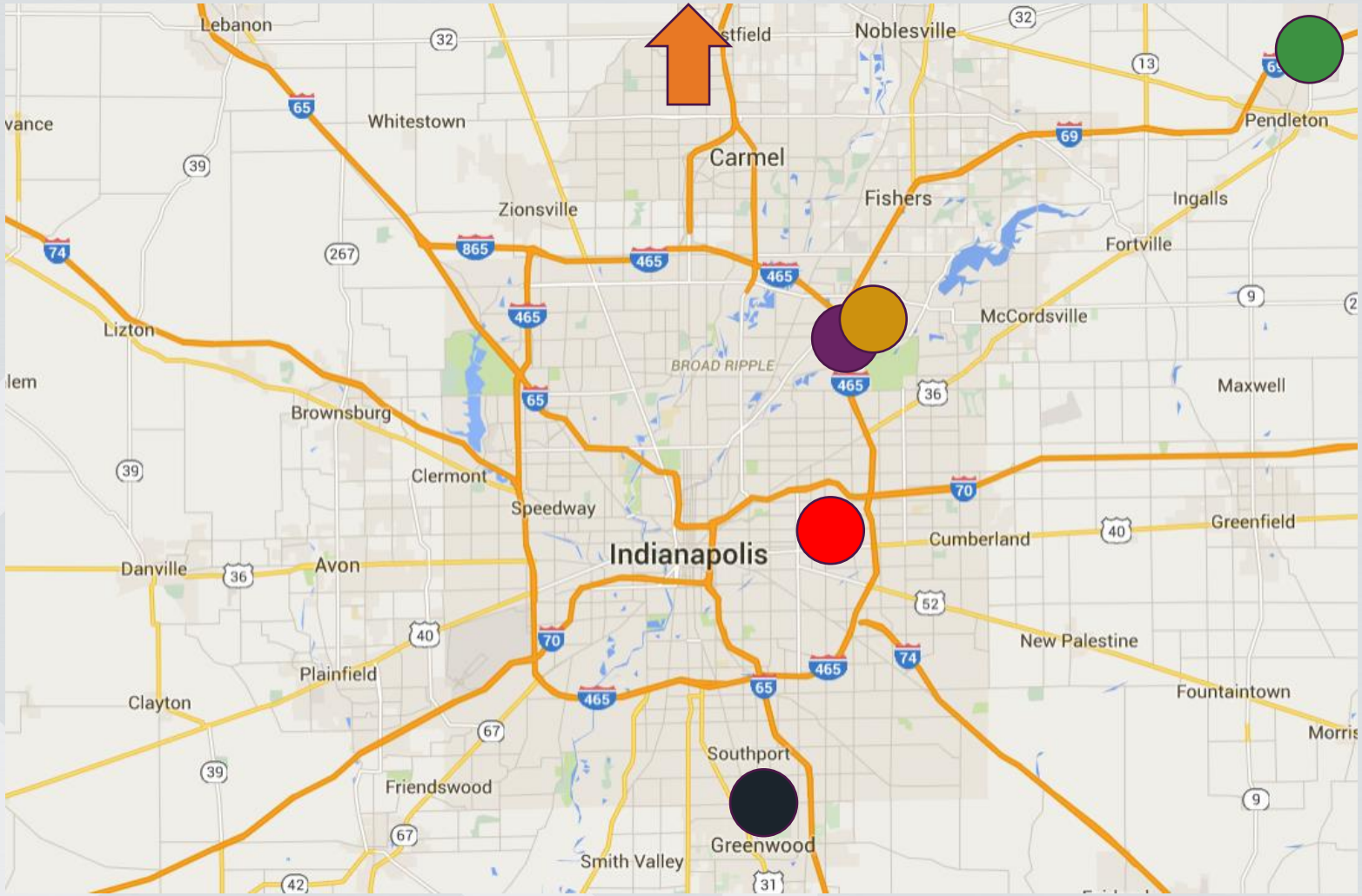
A. Yes
B. No
C. What is a FMEA?

Poll Question #2

- U-500 Insulin is _____ times stronger than U-100 insulin.

A. 3
B. 5
C. 10
D. No clue

Community Health Network: Who Are We?



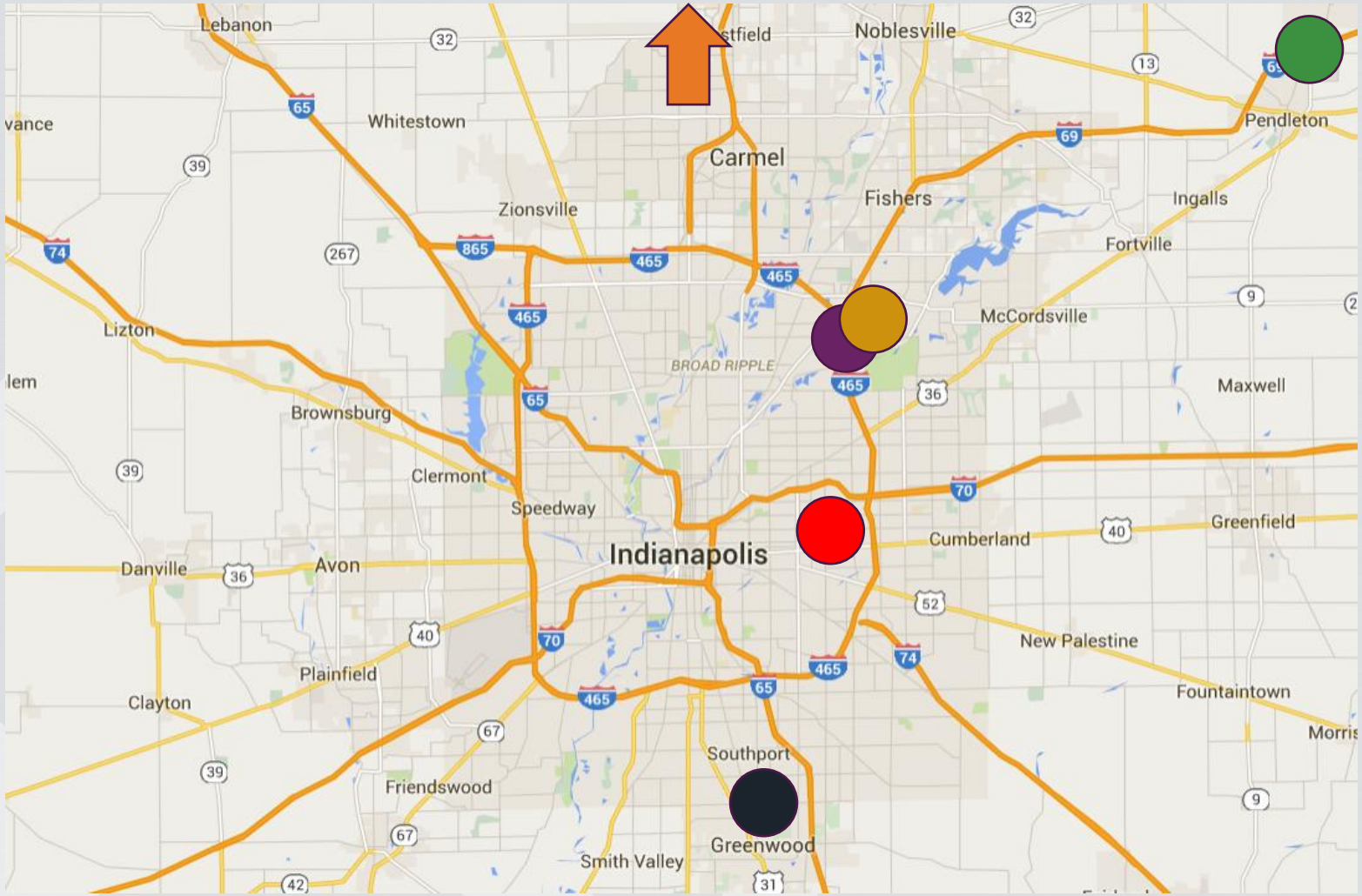
- Not for profit health care system
- 6 hospital system
- Over 1200 inpatient beds
- Over 200 sites of care

U-500 Insulin

- High risk medication
- 5 times stronger than U-100 insulin
- Increased risk of over/underdosing
- Until recently used the same syringe for U-100 and U-500 insulin
- Our policy – must be ordered by endocrinologist/diabetologist

U500 Insulin: Low Use

Data from August 2020 – August 2022

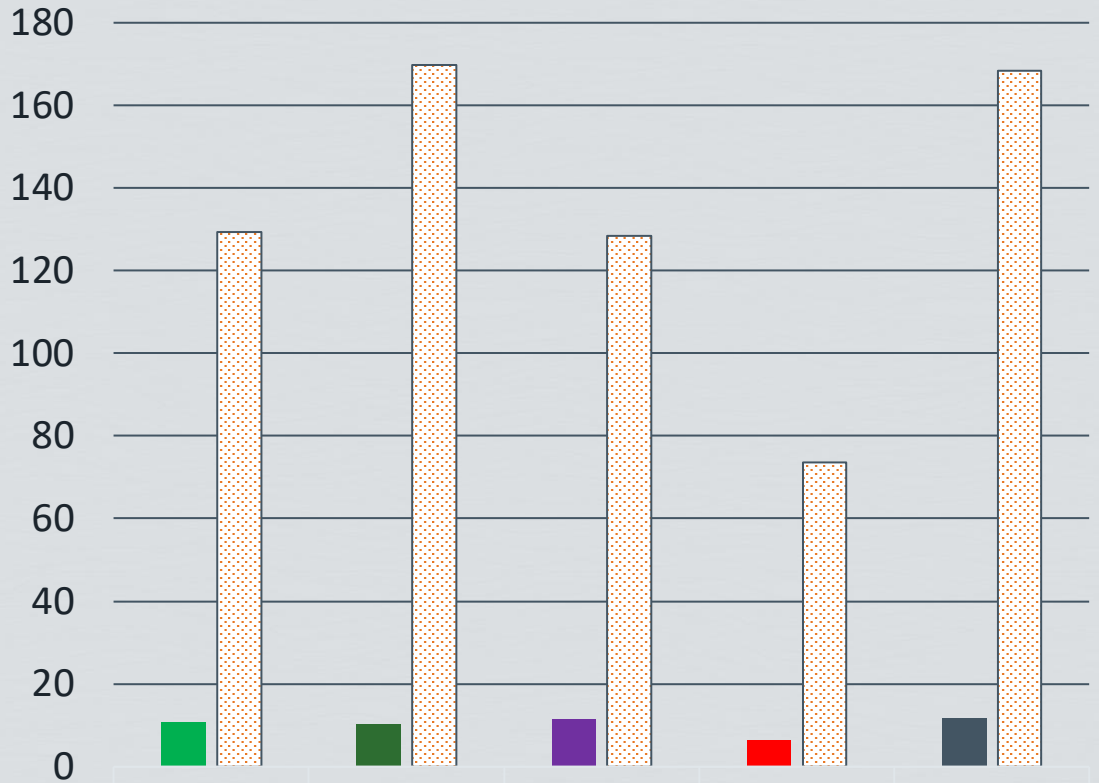


41 patients in 2 years at CHNw

High Waste of Vials

1.45 mL used

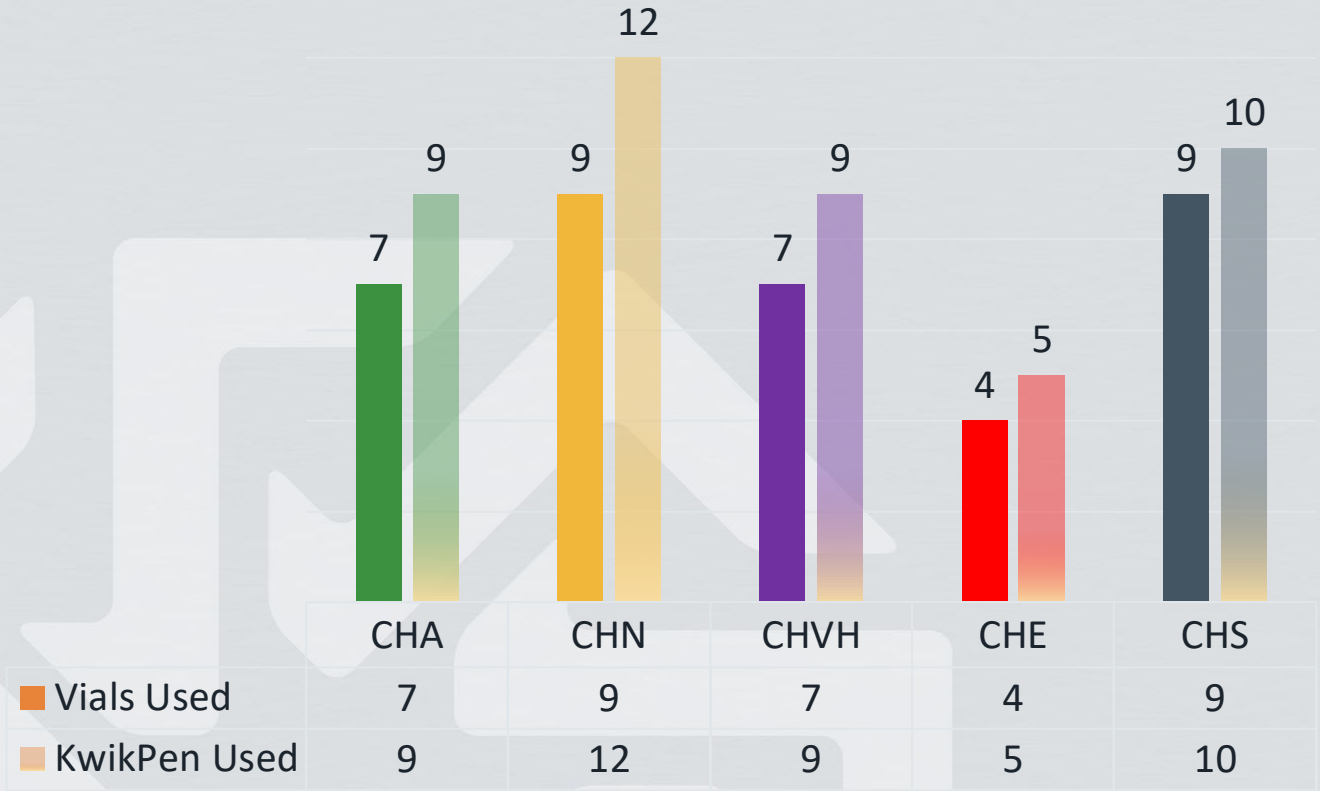
Average 18.55 mL wasted



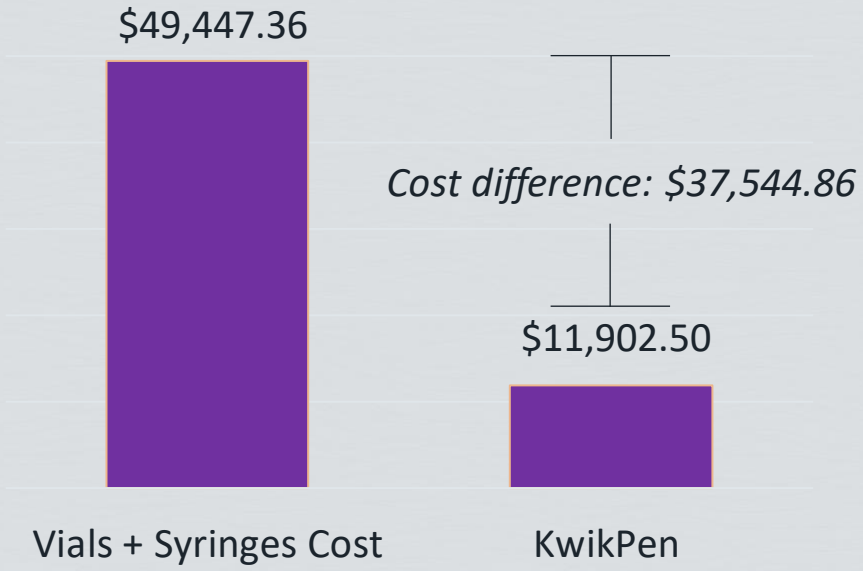
	CHA	CHN	CHVH	CHE	CHS
Insulin Used (in mL)	10.72	10.16	11.62	6.43	11.7
Vial Wasted (in mL)	129.28	169.84	128.38	73.57	168.3
Number of vials	7	9	7	4	9

1

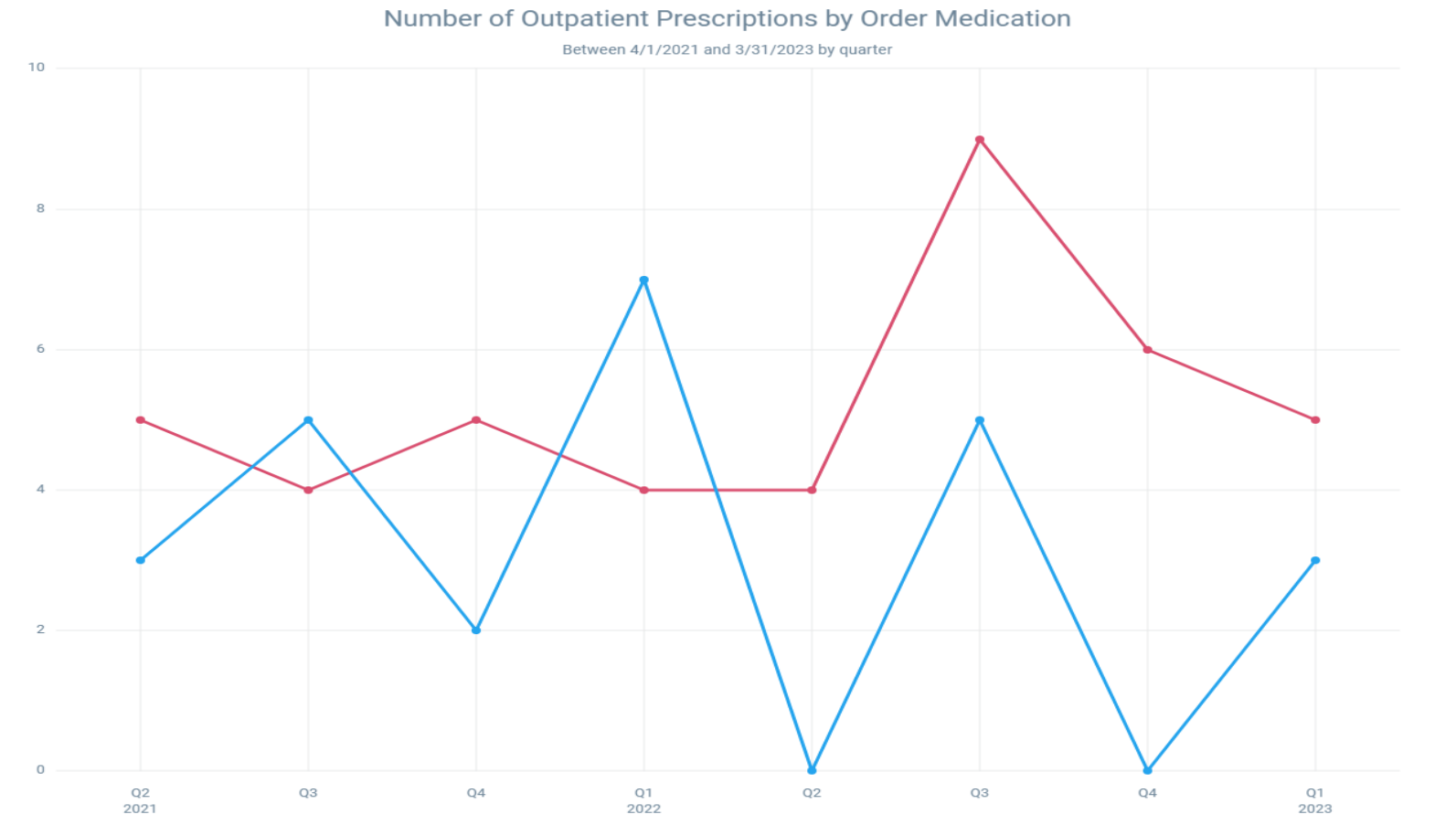
What if we switched to KwikPens?



20 mL Vial Cost (WAC)	**$1369.96**
3 mL KwikPen (WAC)	**$264.50**



Outpatient Prescription Data



- *Red:* Insulin KwikPen U-500, *Blue:* Insulin Vial U-500

Insulin Pen Safety

Joint Commission

- Requirements specific to management of patients with diabetes in the inpatient setting:
  - Patient identifiers required for labeling of an insulin pen
  - Process for storing insulin pens
  - Education of staff on safe and appropriate use of an insulin pen, including infection control
  - Information on maintaining the integrity of an insulin pen, which can only be used for a single patient

Institute for Safe Medication Practices (ISMP)

- *Statement from October 2013:*
  - Despite the consideration to move *away* from insulin pen use in the hospital, U-500 KwikPen is the best option to prevent dosing errors
- U-500 insulin is 5x more concentrated than U-100 insulin
- Patients may be more familiar with U-500 insulin pen than the U-500 insulin syringe

Risks to Mitigate

High alert medication

New formulation

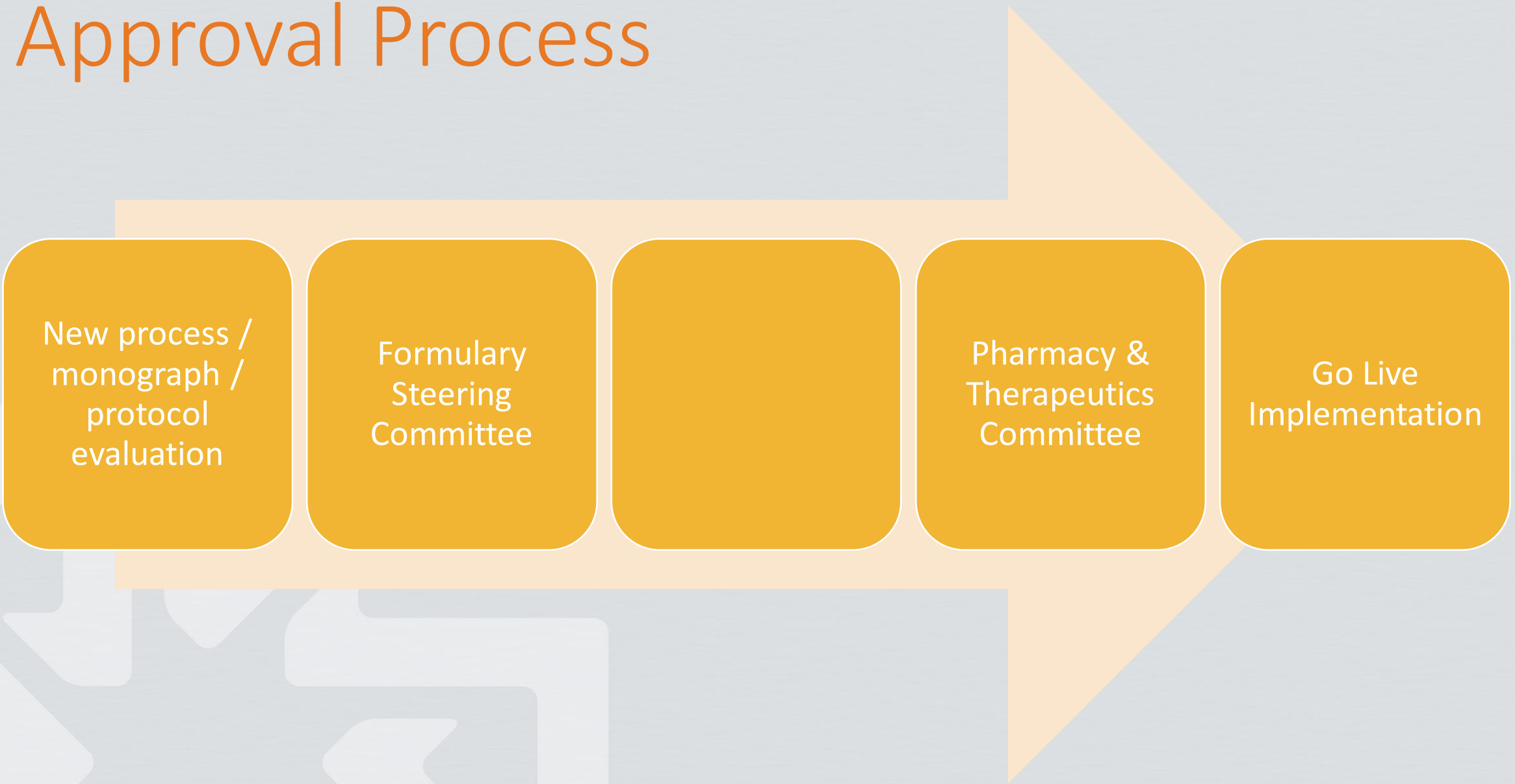
Stakeholders

Process changes

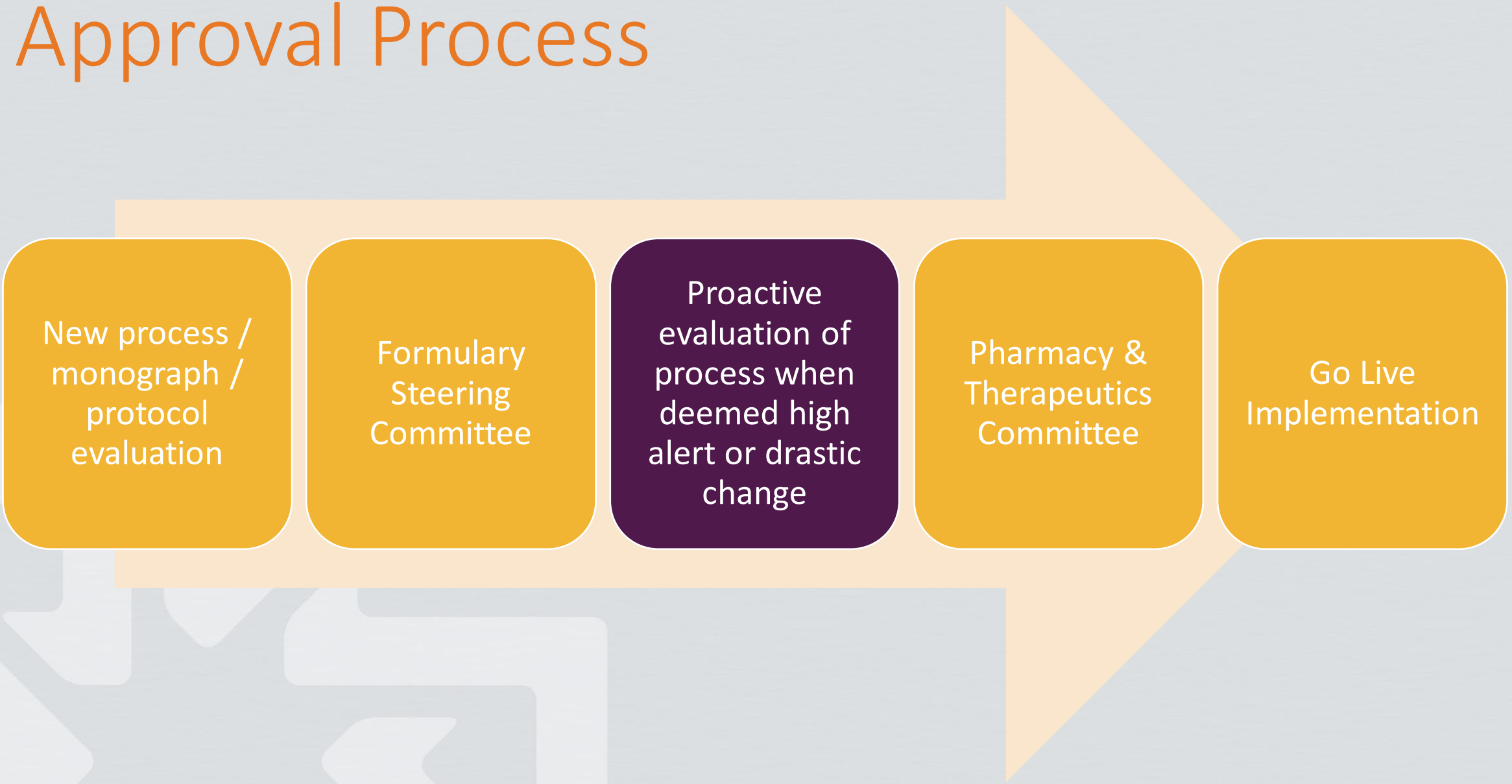
Policy changes

Education

Approval Process



Approval Process



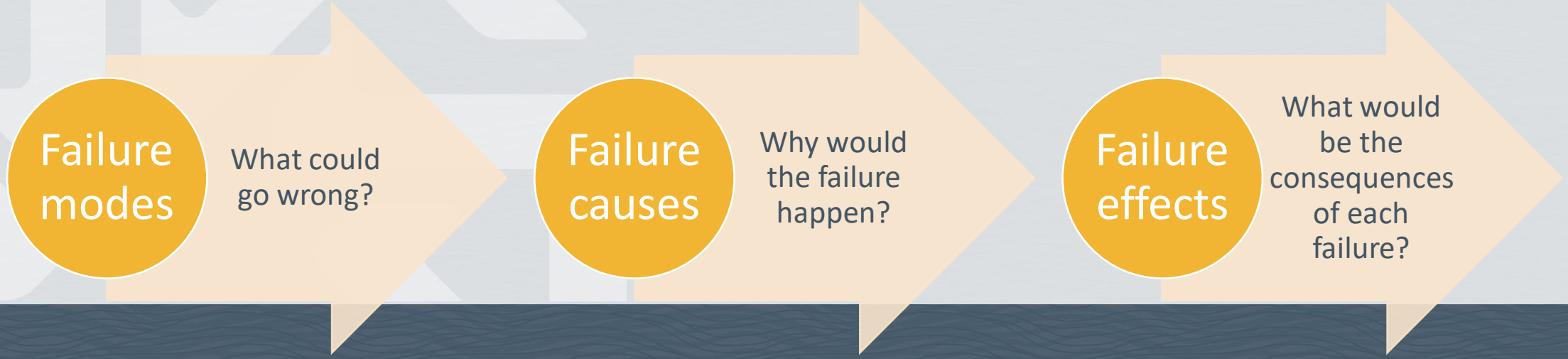
How did we get here?

- Why did we think we needed to use the FMEA for U-500 insulin
- Overall benefit of FMEA – improving quality, reliability, and safety of a process
  - We looked and saw potential errors
- Reasons for FMEA
  - Errors with current process
  - Nursing change in their practice
  - Cost savings
- These reasons led us to utilizing the FMEA to ensure our new process included quality, reliability, and safety

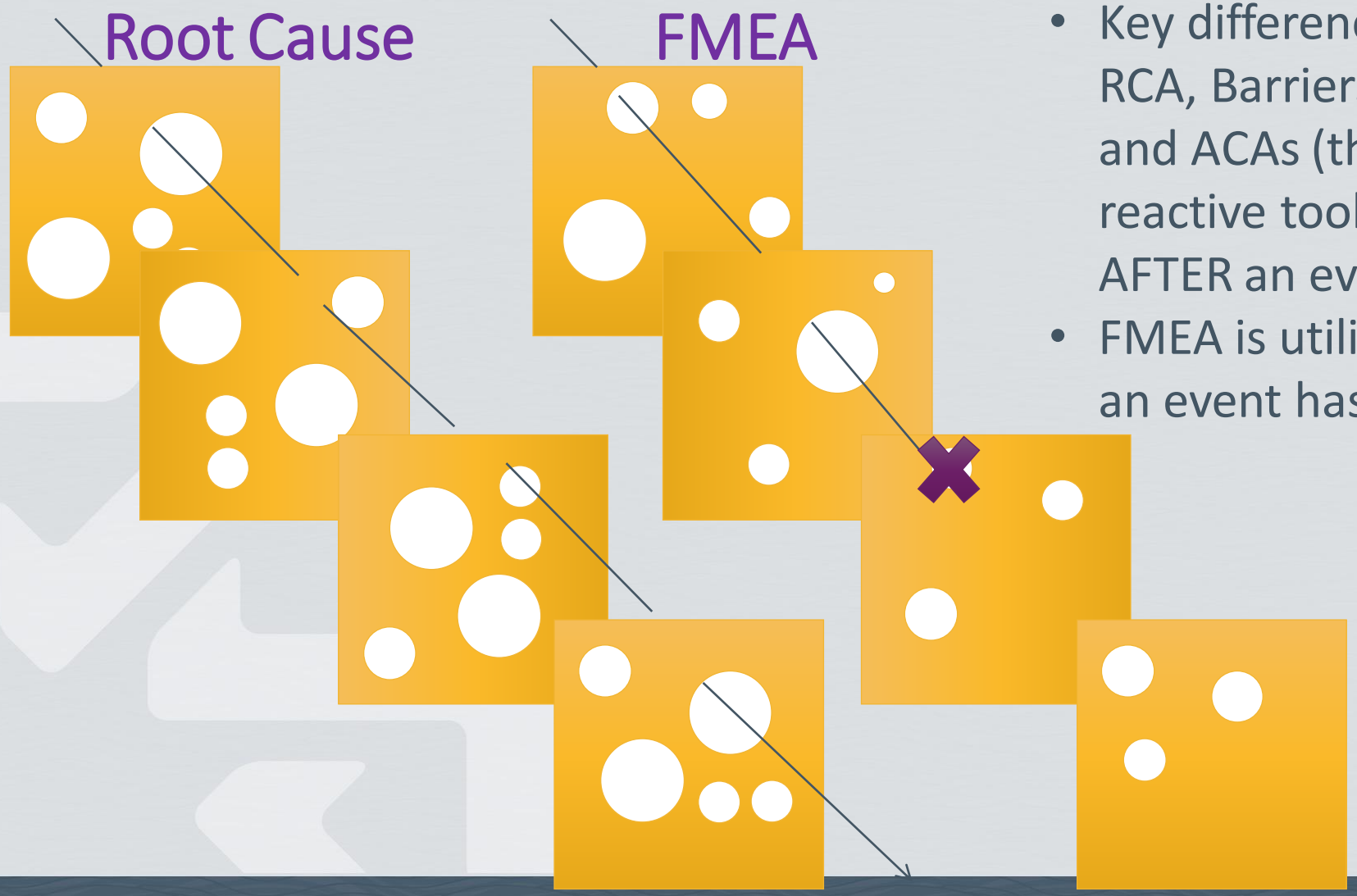
Proactive Process Evaluation

- FMEA = Failure Modes and Effects Analysis
  - Failure mode refers to how a process might fail
  - Effects refers to the consequences of a failure

- FMEA is a step by step tool for identifying and measuring the possible failures in a process or service
  - Prevent harm by correcting the processes **proactively** rather than reacting to adverse events after failures have occurred



Safety Investigation Tools



- Key difference between RCA, Barriers Analysis, and ACAs (these are all reactive tools to utilize AFTER an event)
- FMEA is utilized BEFORE an event has occurred

Why FMEA?

Can be applied / utilized at any time

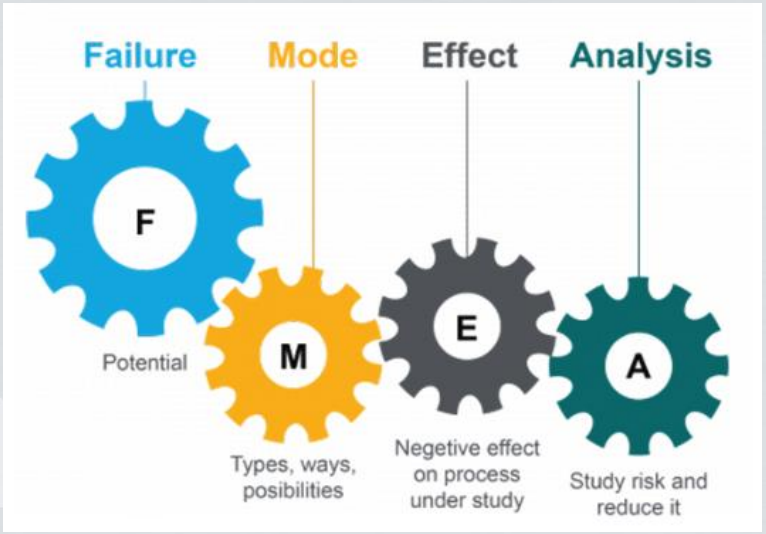
Proactive

Preventative

Semi-quantitative

Structured methodology

Scalable



FMEA Steps

- **Step 1:** Identify scope
- **Step 2:** List all steps of the process
- **Step 3:** Identify all failures that can occur within each steps
- **Step 4:** List all of the causes and effects of each failure
- **Step 5:** Score each failure utilizing three factors/questions
  - Question 1: Severity
  - Question 2: Occurrence (Frequency)
  - Question 3: Detection
- **Step 6:** Establish overall score (Risk Priority Number or RPN) is created by multiplying the factors
- **Step 7:** Prioritize failures team wants to address
- **Step 8:** Action plan/Solution/Implementation
- **Step 9:** Rescore failures with action plans to determine new RPN

FMEA: The Terms & Tool

- Failure Mode: Manner in which the failure could occur
- For each failure mode we will determine the following:

Severity	The amount of harm or damage the failure mode may cause to a person of equipment	What harm would be seen? How severe is the harm?
Occurrence	Likelihood that the failure will occur	How often does this occur?
Detection	Likelihood that the failure will NOT be detected	If the problem occurred, how easily can someone recognize the occurrence?

- Risk Priority Number (RPN): Combined score of a mode

Severity X Occurrence X Detection = RPN

FMEA: Scoring Systems

- For each question, score utilizing a scale of 1 to 10

0 = Never/No
1 = Very Low
3 = Low
5 = Somewhat/Sometimes
7 = Likely
9 = Very Likely/High

Severity	1 = Least Harm; 10 = Most Harm
Occurrence	1 = Least Likely to Occur; 10 = Most Likely to Occur
Detection	1 = VERY Detectable; 10 = Not Easily Detectable

FMEA: Scoring Systems Key Elements

Establish clear definitions for each score

Rationalize each score for each failure mode with the other scores and modes

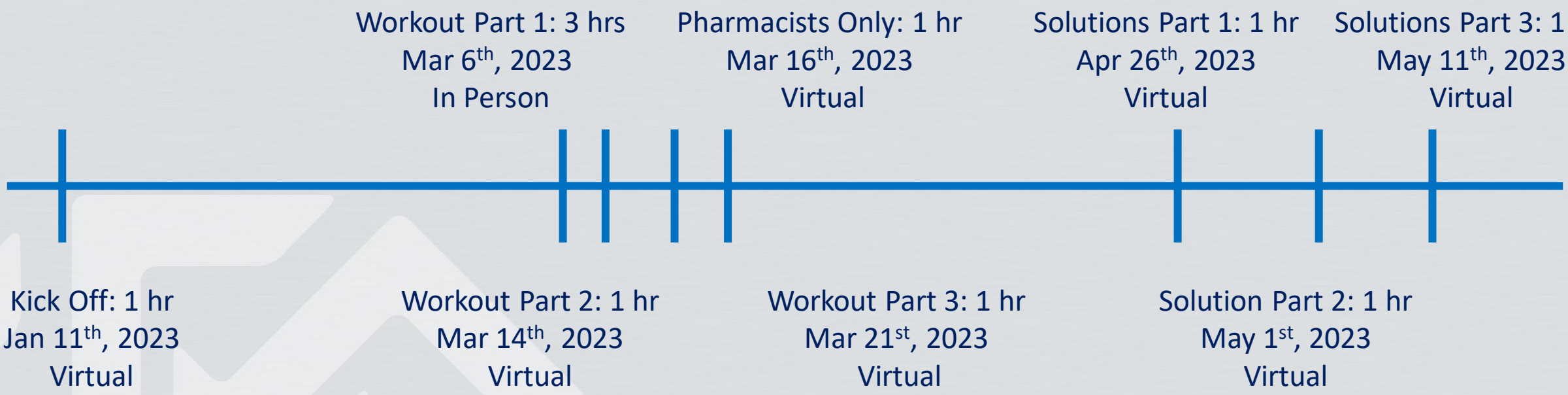
- Accomplished by comparing scores and modes to each other to ensure they make sense

Analyze and update the process, failure modes, and scores on a regular basis and whenever the process or its systems and structures change

FMEA Decision

- Team decided to complete FMEA to ensure IF we switched then all barriers would be addressed
- Team Members:
  - Starr Bacon – Clinical Nurse Specialist
  - Carolyn Fiutem – Executive Director, Network Infection Prevention & Blood Management
  - Jill Gagne – Director of Pharmacy (Community South)
  - David Miller – Certified Diabetes Educator
  - Jaclyn Myers – Informatics Pharmacist
  - Norma Walden – Director of Procurement
  - Jessa White – Network Medication Safety Director/FMEA Facilitator
  - Lisa Kingdon – Pharmacy & Therapeutics Coordinator

Meetings



Total Meeting Time: 10 hours
Occurring over 5 months

FMEA Documentation Example

Step Description	Failure Mode Name (What Could Go Wrong?)	Causes (Why Would This Failure Occur?)	Effects (What Would Be The Consquences Of This Failure?)	Likelihood of Occurrence (1 - 10)	Likelihood of NOT Detection (1 - 10)	Severity (1 - 10)	RPN	Actions
Medication order for U500 (continues to align with current policy "The Use of U500 Insulin" where Endocrinologist or Diabetologist required to order)							2128	
Clinical Assessment	U500 insulin not recognized is needed	Lack of up to date past medical history; patient does not disclose; blood glucose controlled during clinical assessment	High blood glucose	3	3	5	45	
Medication history completed	Incorrect dose	Patient disclosed incorrect information; SureScripts not up to date; Order entry error; U500 vs U100 syringe confusion	Hypo/Hyperglycemia	7	7	9	441	Pharmacist must review medication history to ensure dose and syringe type are accurate prior to verifying order
	Medication missed	Patient did not disclose; not in surescripts due to being a sample; cash patient; incorrect insulin type entry	Hyperglycemia; Delay of therapy	5	7	5	175	
	Delay in assessment (completed > 24 hrs or not completed at all)	Completing priorities	Inaccurate information for clinical assessment (old information); hypo/hyperglycemia	5	5	9	225	
Provider contact Endo/Diabetologist	Provider not contact	Lack of knowledge; Competing priorities; Lack of access to specialist	No orders; incorrect dose; delay in therapy	9	5	9	405	Including language in order for pharmacist to review pharmacy OLH document, which contains list of approved prescribers
Endo/Diabetologist places 1-3 orders	Not all orders placed	Competing priorities; Incorrect ordering process (ex: utilizing comments)	hypo/Hyperglycemia	3	7	9	189	
	Incorrect dose	Incorrect information; Incorrect ordering process	hypo/Hyperglycemia	3	9	9	243	
	Orders placed by non-specialty provider	Lack of knowledge; Lack of access	hypo/Hyperglycemia	9	5	9	405	Requesting BPA for providers to address when ordering

FMEA Overview

Step #	Step Description	RPN	Highest Ranked
1	Procurement of U500 pens and pen needles by cardinal buyer at all sites	404	9
2	Storage of U500 pens and pen needles in main pharmacy (fridge)	853	6
3	Medication order for U500 (continues to align with current policy "The Use of U500 Insulin" where Endocrinologist or Diabetologist required to order)	2128	1
4	Pharmacist verifies medication order	1576	4
5	Pharmacy dispenses / verifies physical U500 pen + pen needles (quantity to dispense?)	509	8
6	Pharmacy technician delivers patient specific U500 pen to patient bin in medication room	1206	5
7	Obtains U500 pen + pen needles	671	7
8	Nurse administers dose as ordered using the pen needles provided, Used needle is disposed of in sharps container	2125	2
9	Returns pen to patient medication bin for future doses	1800	3
10	Nursing recieves order for patient transfer	356	10
11	When patient discharges, U500 pen is disposed in Compatible Hazardous black waste	315	11
		11943	

FMEA Overview

Step	Step Description	Number of Substeps	Failure Modes (FM)	FMEA Total Score	FMEA Score/FM
1	Procurement of U500 pens and pen needles by cardinal buyer at all sites	6	12	404	34
2	Storage of U500 pens and pen needles in main pharmacy (fridge)	7	12	853	71
3	Medication order for U500 (continues to align with current policy "The Use of U500 Insulin" where Endocrinologist or Diabetologist required to order)	4	8	2128	266
4	Pharmacist verifies medication order	4	8	1576	197
5	Pharmacy dispenses / verifies physical U500 pen + pen needles (quantity to dispense?)	8	11	509	46
6	Pharmacy technician delivers patient specific U500 pen to patient bin in medication room	3	6	1206	201
7	Obtains U500 pen + pen needles	4	7	671	96
8	Nurse administers dose as ordered using the pen needles provided, Used needle is disposed of in sharps container	10	13	2125	163
9	Returns pen to patient medication bin for future doses	4	8	1800	225
10	Nursing recieves order for patient transfer	3	6	356	60
11	When patient discharges, U500 pen is disposed in Compatible Hazardous black waste	1	3	315	105

FMEA Overview

Total Failure Modes Identified	94	Note: Only 93 scored
Total Substeps Identified	54	Note: Only 52 scored
Total RPN Score	11943	
Average RPN Score	128	
Total RPN Score >400	12	13%
Total RPN Score 300 - 399	2	2%
Total RPN Score 200 - 299	11	12%
Total RPN Score 100 - 199	14	15%
Total RPN Score < 100	54	57%
Unscored	1	1%
Score of 9 - Occurance	6	6%
Score of 9 - Detection	18	19%
Score of 9 - Severity	35	37%

U500 Process Solutions

- Requires ordering by Endocrinologist/Diabetologist
  - BPA to reinforce
- Pharmacist double checks with home med history to ensure and dose and syringe type are accurate
- Alert in Central Pharmacy Manager for dispensing short dating
- Information for pharmacist in order referencing policy and OLH document
- Add information in nursing EPIC administration screen about priming (pop up that occurs during administration)
- Required nursing education
- Double check with IT build will occur

U500 Process Solutions

- Education Highlights
  - Priming
  - Wiping off pen, place on paper towel, and hand washing BEFORE placing back into patient bin

What is the value to doing a FMEA?

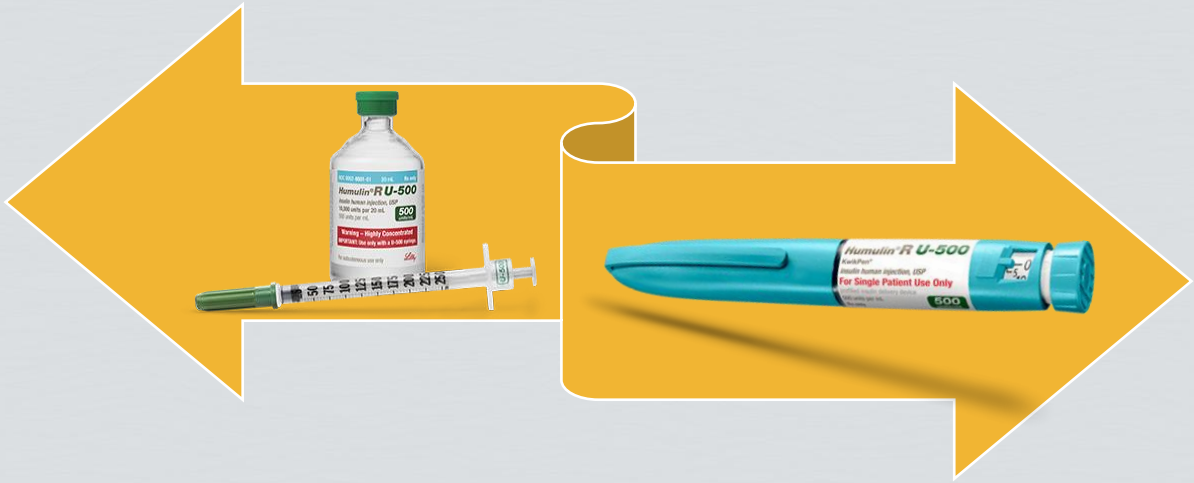
- Key stakeholders
- Multidisciplinary input on their "reality" – how it is in their world
- Professional growth/learning
  - See one, do one, teach one
- Collegiality
  - Companionship and cooperation between colleagues who share responsibility

What is the value to doing a FMEA?

- Ability to use objective ratings
  - 1, 3, 5, 7, 9 – rating similar activities comparatively
- Extremely thorough process evaluation
  - This lead to the next value
- Mitigating organizational risk
  - Potentially identified and/or solved existing risk points in current state

Lessons Learned

- Identified missing stakeholders
  - Willow/EPIC build – need identified after 1st meeting
- Are we evaluating current state or the potential new state?
  - Some risk points/high scores were not different than current state with U500 vials
- Reference previous scores to align with similarly identified risks at different steps in the process
- KISS principle – 1-10 vs 1-3-5-7-9
  - No need for debate between a 4 & 5



Lessons Learned

- Organizational operations
  - What is vs what we think
- Listening Skills
  - Listening and hearing each others' concerns
- Team value and effectiveness
  - *"one of the most thorough evaluations of a process that I have ever been a witness to /part of the discussion"*

FMEA Category	*Sum*
Starting steps	*11*
Total steps (including sub-steps)	*94*
Total scores assigned	*93*
Average Risk Priority Number (RPN)	*128*
RPN >400 – discussed and planned mitigation strategies	*12*

Lessons Learned

- It takes everyone's eyes to look at the situation
- Education is KEY to success
- It takes WORK to get everyone together but it pays off in the end

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