Analysis of Adverse Medical Events
Culture, Processes and Tools

Alan Kohrt, MD, FAAP
Jackie Bishop, RN
Paul O'Quinn, MBA CPHQ

HPP Series: UT College of Medicine Chattanooga
Presented January 12, 2021

Presenters

- Dr. Alan Kohrt, MD FAAP
  - Assistant Dean for Faculty Development
- Jackie Bishop, RN
  - Medical Staff QI Director
- Paul O’Quinn, BSISE, MBA, CPHQ
  - Director of Patient Safety & Quality

Disclosure Statement of Financial Interest

- **We, Alan Kohrt, Jackie Bishop, Paul O'Quinn**

DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

Objectives for Learners

1) Create teachable moment for systems thinking

2) Integrate the processes involved in process improvement and patient safety event investigation.

3) Understand action items and the strength of proposed solutions/interventions.

4) Understand the purpose, value and importance of reporting events on eSAFE.

Course Agenda

- Analysis of Adverse Events - Dr. Kohrt
- Causal Analysis/Case Study/Timeline – Jackie Bishop
- Process Map - Paul O’Quinn
- Cause and Effect- Paul O’Quinn
- Strength of Solutions - Dr. Kohrt
- Action Items - All
- Shared Learning - Dr. Kohrt

Feedback

1. Know the Quality Goals for EHS System or for Children's?
2. How many of you have seen or involved in a medical error?
3. Participated in or witnessed a Disclosure to a Patient/Family?
4. Reported an event in eSAFE?
5. Received follow-up information on eSAFE event?
6. Participated in an Event Investigation?
7. Participated in RCA
8. Understand why we do an RCA?

EHS Confidentiality

- The Patient Safety Event System allows us to communicate confidentially about safety and complaint events within this protected reporting system.

- The eSafe report is our protected information, not part of the medical record and is not shared with the patient/family.

Confidential and Privileged Quality Peer Review Protected Material Created Pursuant to the Tennessee Patient Safety and Quality Improvement Act of 2011, the Health Care Quality Improvement Act, the North Carolina Peer Review Statute (at N.C. Gen. Stat. sec. 90-21.22A) and All Other Applicable Law.

Please **do not** document in the medical record ***" an incident report was filled out"*** or write an order stating ***"fill out an incident report"***.

Reporting on eSAFE

- Residents
  - Report sent to Program Director
    - Resident Reported Event
    - Resident part of care team
    - Resident focus of eSAFE
  - Resident/ PD receive status of report, PD can view
  - Receive monthly totals on number of eSafes from and concerning residents
- Faculty reported event
  - Faculty receive status update and call about report when complete
- Faculty and residents can use eSafe's File Submission Tracker to monitor events

File Submission Tracker

Last 3 months

Open (15)

File 267578 (AIRWAY MANAGEMENT) 3
Event date: **01-05-2021**
Submitted date: **01-05-2021**

File 267182 (SURGERY/PROCEDURE)
Event date: **08-10-2020**
Submitted date: **12-23-2020**

File 267027 (SURGERY/PROCEDURE)
Event date: **10-22-2020**
Submitted date: **12-18-2020**

File 267026 (SURGERY/PROCEDURE)
Event date: **12-11-2020**
Submitted date: **12-18-2020**

File 266855 (SURGERY/PROCEDURE) 14
Event date: **12-11-2020**
Submitted date: **12-14-2020**

File 264667 (COORDINATION OF CARE)
Event date: **10-30-2020**
Submitted date: **11-10-2020**

General File Information

File
267578 - AIRWAY MANAGEMENT

State
New | **In Progress** | Closed

Locked File
No

File Confidential
No

Entered By
Jackie Bishop

Site/Campus responsible for failure, defect, nonconformance
BEH

Location within the Department responsible for the failure, defect, nonconformance
Discharge Lounge

Specific Incident Type
obstructed airway

Brief Factual Description
TEST

Closed By

Closed Date

File Updates

Newest to Oldest

01-05-2021	
Jackie Bishop	1 new follow-up(s).
Jackie Bishop	1 file update(s).
Jackie Bishop	File opened 1 time(s).

File submitted on 01-05-2021.

Quality Improvement Priorities for Erlanger

- You as a resident/fellow/faculty are vital to:
  - Patient Outcomes—
    - Quality & Patient Safety Goals
  - Patient Safety Culture
  - Quality Performance and Process Improvement

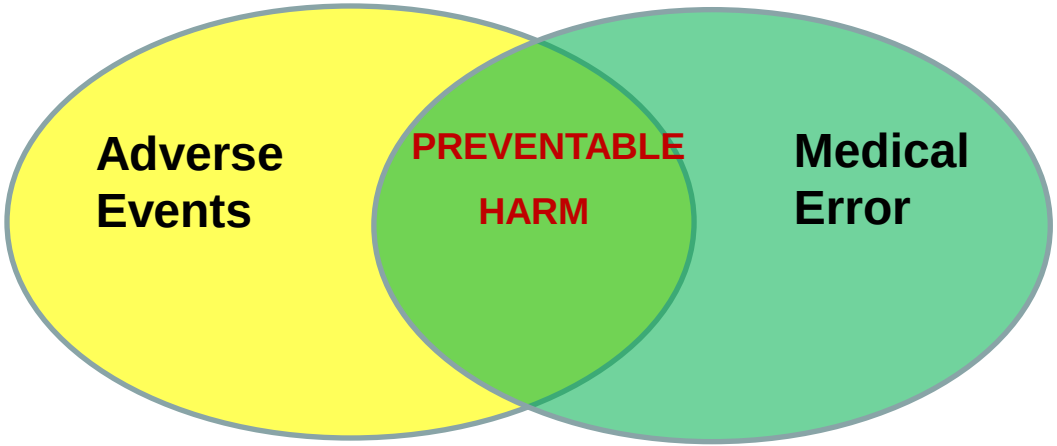
FY21 Erlanger Quality Management Metrics
Corporate Objectives

As of 1/4/2021

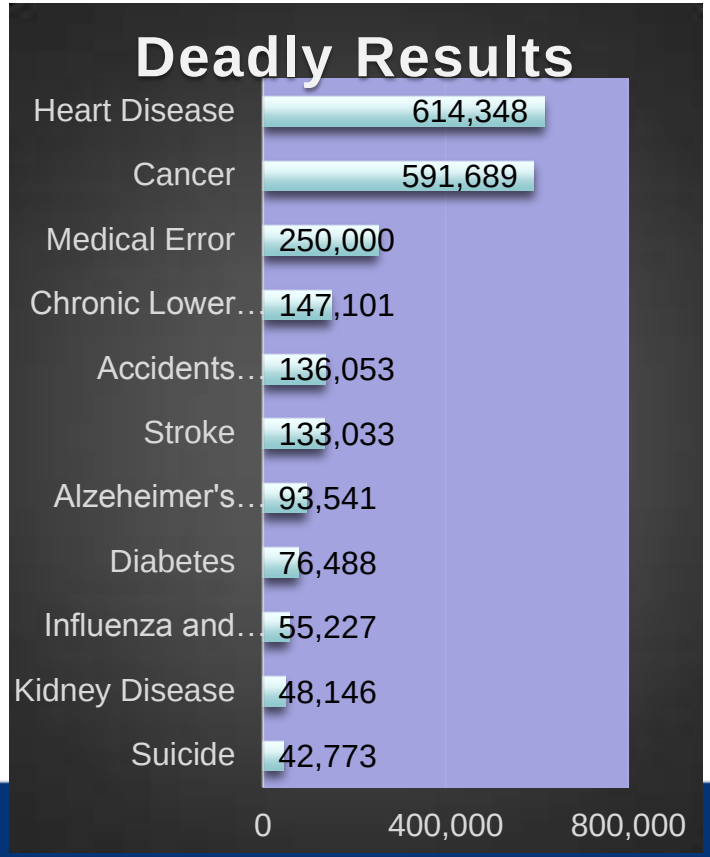
	Desired Direction	Acheivement Levels	
(1) Inpatient Experience - % of Hospitals where our score exceeds other hospitals for Top Box (Rating 9 or 10)	↑	FY21 Fiscal YTD ...Thru	**22%** Early Dec 2020
		FY21 Stretch	38%
		FY21 Target	29%
		FY21 Threshold	22%
(2) Median ED Length of Stay Minutes (Discharged Patients from All ED's)	↓	FY21 Fiscal YTD ...Thru	**163.4** Nov-20
		FY21 Stretch	153
		FY21 Target	158
		FY21 Threshold	163
(3) Median ED Length of Stay Minutes (Admitted Patients from All ED's)	↓	FY21 Fiscal YTD ...Thru	**555** Nov-20
		FY21 Stretch	504
		FY21 Target	514
		FY21 Threshold	524
(4) Mortality Rate (Risk Adjusted, Adult Patients discharged from BEH, East & North)	↓	FY21 Fiscal YTD ...Thru	**1.00** Oct-20
		FY21 Stretch	1.00
		FY21 Target	1.02
		FY21 Threshold	1.04

Harm = Adverse Medical Event (AE)

Adverse Event (AE) - An injury, large or small, caused by the use (including non-use) of a drug, test, or medical treatment. This may be as harmless as a drug rash or as serious as death.*



Medical errors third leading cause of death in 2016*



Deaths per Year by Cause**

- 12,000 - unnecessary surgery
- 7,000 - medication errors in hospitals
- 20,000 - other errors in hospitals
- 80,000 - infections in hospitals
- 106,000 - Non-error, negative effects of drugs

**** Starfield B, *JAMA*, 2000;284(4):483-5**

**** Data Sources: *CDC, 2016;* James, JT. A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care. *J Patient Saf* 2013;9 122-128; Makary M, Daniel M. Medical error—the third leading cause of death in the US, *BMJ* 2016.**

Types of Medical Errors

Diagnostic

- Error or delay in diagnosis
- Failure to employ indicated tests
- Use of outmoded tests or therapy
- Failure to act on results of monitoring or testing

Treatment

- Error in performance of an operation, procedure, or test
- Error in administering treatment
- Error in the dose or method of using a drug
- Avoidable delay in treatment or in responding to an abnormal test
- Inappropriate care

Preventive

- Failure to provide prophylactic treatment
- Inadequate monitoring or follow-up of treatment

Other

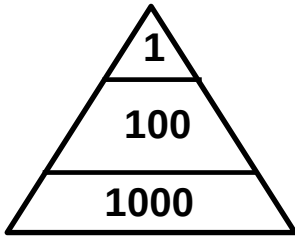
- Failure of communication
- Equipment failure
- Other system failure

Leape L, et al., Qual Rev Bull, 1993 as reported in IOM To Err is Human, 1999

eSafe Outcome Scale: * Based on NCC MERP Category Index

Event Did Not Reach Patient	'Near Miss'	A	Circumstance or event that has the capacity to cause error &/or harm.
		B	An event occurred but did not reach the patient. An 'error of omission' *does reach* the patient
Event Reached Patient	No Harm	C	An event reached the patient but did not cause patient harm.
		D	An event reached the patient that required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm
	Minor Harm	E	Event that may have contributed to or resulted in temporary harm to the patient and required intervention
		F	Event that may have contributed to/resulted in temporary harm to the patient and required initial or prolonged hospitalization.
	Major Harm	G	Event that may have contributed to or resulted in permanent patient harm.
		H	Event that required intervention necessary to sustain life.
	Death	I	Event that may have contributed to or resulted in the patient's death.
	External/ Unavoidable	J	Internal category for patient harm that is deemed to be unavoidable, or happened externally, after investigation.

Safety Event Classification (MERP)



THREAT OF OR SIGNIFICANT HARM

Order to Discontinue IV missed , patient developed PE and transferred to ICU

TEMPORARY HARM

INCREASED LOS

CAPACITY FOR HARM

Anti-coagulation administration delayed by 12 hours in patient with a PE

NEAR MISS

Pharmacist discovers medication order error and corrects—does not reach the patient—GREAT CATCH

Serious Safety Event

- **Reaches the patient *and***
- **Results in moderate harm to severe harm or death**

F-I

Precursor Safety Event

- **Reaches the patient *and***
- **Results in minimal harm or no detectable harm**

C-E

Near Miss Safety Event

- **Does not reach the patient**
- **Error is caught by a detection barrier or by chance**

A-B

Culture of Safety

- What is a Culture of Safety?
  - Defined by IHI as
    - *"an environment in which providers can discuss errors, near misses, and harm openly, knowing that they won't be unfairly punished and have confidence that reporting safety events will lead to improvement"*
- *What is a "Just Culture?"*

What do we mean by “Just Culture”?

- **Human error** - Humans are not perfect, so any system we create should expect errors to occur and account for them as a normal part of the process. A slip, a lapse, a mistake can happen to the best of us, so human error, rather than being a punishable action, becomes an opportunity to learn and to improve our systems.

- **At-risk behavior** - Sometimes people get complacent and start to drift away from the rules (like driving a few MPH over the speed limit, for example); they begin to engage in at-risk behavior, placing themselves and others at risk. Simply put, they do not perceive the risk, or have temporarily forgotten it. In this case coaching and education are the answer, a reminder of the risks that may have been forgotten or mistakenly justified.

- **Reckless behavior** - In very rare occasions, though, people engage in reckless behavior, choosing knowingly to place themselves or others in harm’s way. The individual(s) responsible for these choices obviously need to be subject to disciplinary action.

Course Agenda

- Analysis of Adverse Events - Dr. Kohrt
- Causal Analysis/Case Study/Timeline – Jackie Bishop
- Process Map - Paul O’Quinn
- Cause and Effect- Paul O’Quinn
- Strength of Solutions - Dr. Kohrt
- Action Items - All
- Shared Learning - Dr. Kohrt

Causal Analysis

- A thorough and credible investigation of a safety event or occurrence
- Identifies the causal and contributory factors
- Development of a corrective action plan
- Goal of reducing the risk of a similar incident
- Will include timeline for implementation and strategy for evaluating the effectiveness of the actions and to sustain the change.
- Apparent Cause Analysis (ACA) and Root Cause Analysis (RCA),are the most common forms of comprehensive systematic analysis (CSA) used for identifying the factors that underlie a safety event or occurrence.

Goals of Apparent Cause Analysis vs. Root Cause Analysis

ACA (2-7 Days)

- Limited investigation
  - Identify action to address the immediate condition
  - Collect information to aid in identification of organization trends
- Typically for events with minimal to no harm and near miss

RCA (48 Business Hours)

- Events with serious harm/death
- Multiple ACAs for same issue
- Review causal/contributory factors
- Develop a corrective action plan, monitoring and sustaining the change

Case Study

Situation:

1953 20 y/o male arrived in the ED for breakthrough seizures. Long history of epilepsy and followed by Neurology. Recently weaned off of valproic acid in November.

2032 Decision to admit

2138 The ED Resident entered an order for valproate (Depacon) 1000 mg IV every 8 hours.

2138 Valproate (Depacon) 1000 mg IV in 100ml 0.9% NS given

2344 Transferred to the ICU

Case Study (continued)

Next Day

0026 Per the H&P by the admitting team Resident (not the ED resident), “While in the ED, patient’s current case was discuss with the Neurologist who recommended starting Valproic acid 1000 mg load which he received.”

> Valproate sodium1000 mg IV every 8 hours was listed in the H&P section as a scheduled medication.

0305 Attestation by the ICU Attending agreed with the Resident’s H&P which designated a 1-time dose.

0532 2nd dose of valproate (Depacon) 1000mg IV in 100ml 0.9% NS given

0832 During the Pharmacy daily fill review, a variation in dosing was noted when compared to H&P stating the intent was 1 time loading dose. The ICU Attending was notified and the medication was discontinued. Monitoring labs ordered – no harm.

Course Agenda

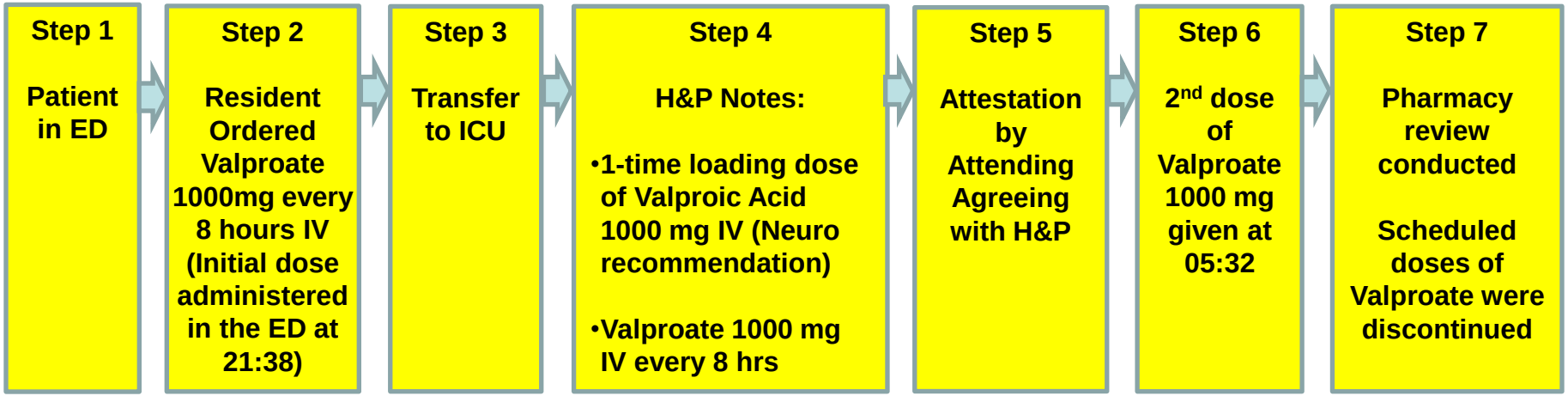
- Analysis of Adverse Events - Dr. Kohrt
- Causal Analysis/Case Study/Timeline – Jackie Bishop
- Process Map - Paul O’Quinn
- Cause and Effect- Paul O’Quinn
- Strength of Solutions - Dr. Kohrt
- Action Items - All
- Shared Learning - Dr. Kohrt

Process Map
(flow diagram)

- A high-level graphic representation of the event
- Process maps can be created quickly by placing ‘stickies’ on the wall, labeling each with the relevant process step

Create Process Map
(flow diagram)

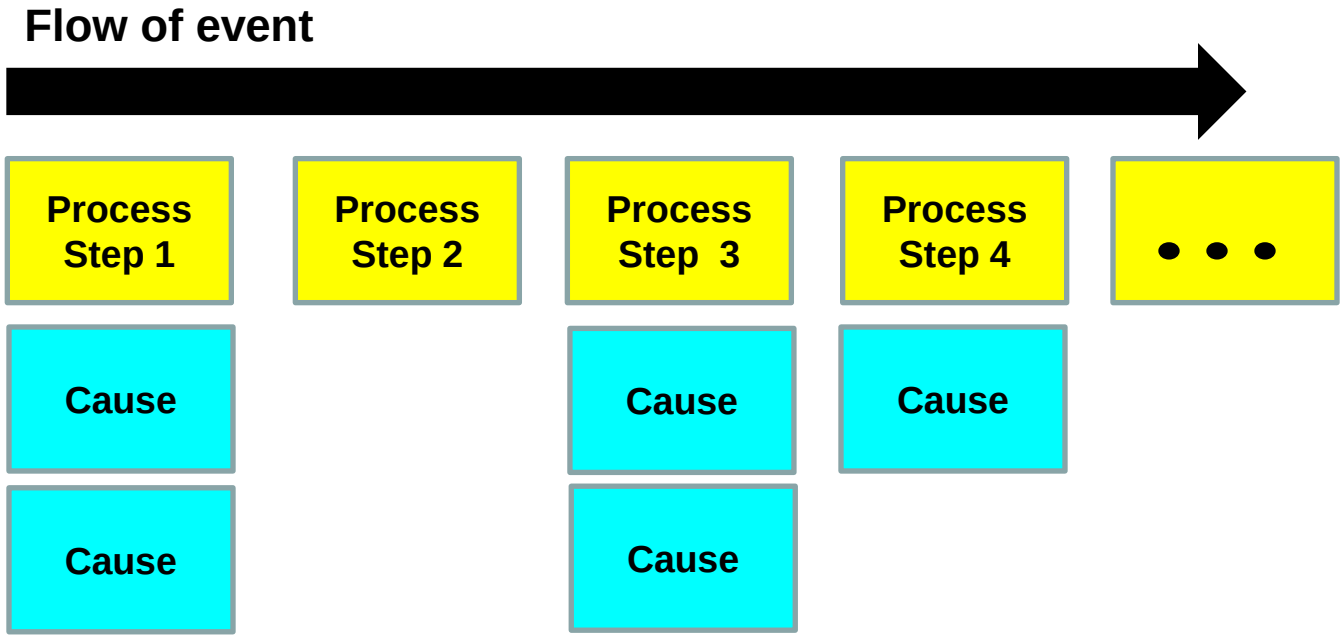
The Case Study



Process Map
(flow diagram)

- Once the process map is completed, the team should identify potential causes perceived to contribute to the event outcome.
- Each potential cause should be written on a sticky and placed under the corresponding process step (some process steps may not have a cause).

Create Process Map
(flow diagram)



Exercise 1:

- Brainstorm for potential causes that contributed to the event outcome, “Excess medication administered”.
- You may pull up the reference material posted to the chat at the beginning of the class if helpful.

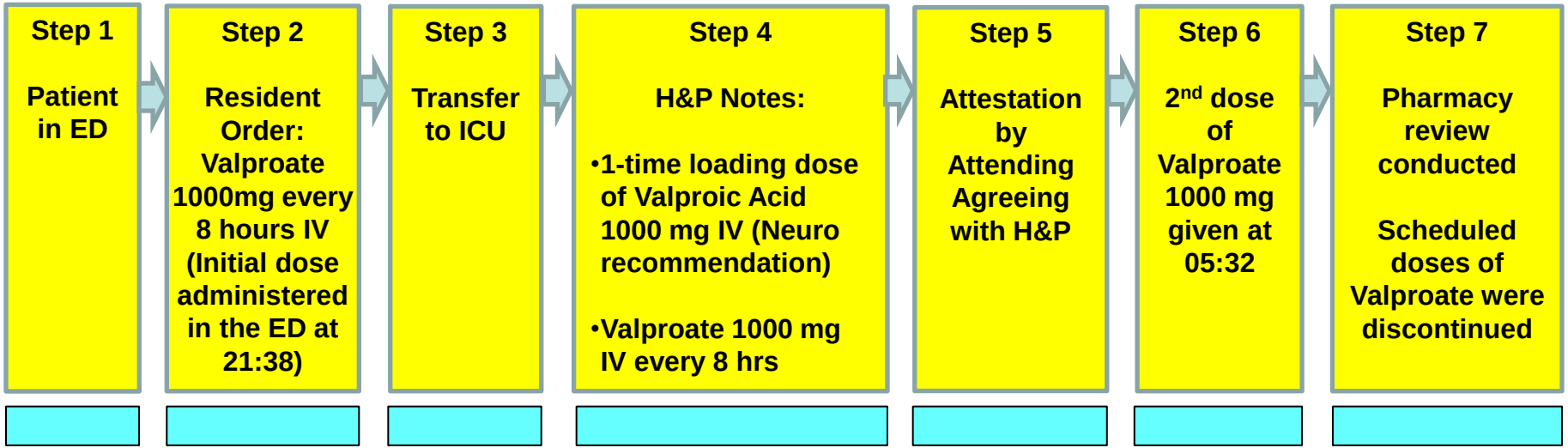
Exercise 1 (continued):

- For each potential cause, enter the process step followed by your identified cause in the Zoom chat. For example:

  Step 5 – Failure to…

- Examples of causes will be copied from the chat to the process map

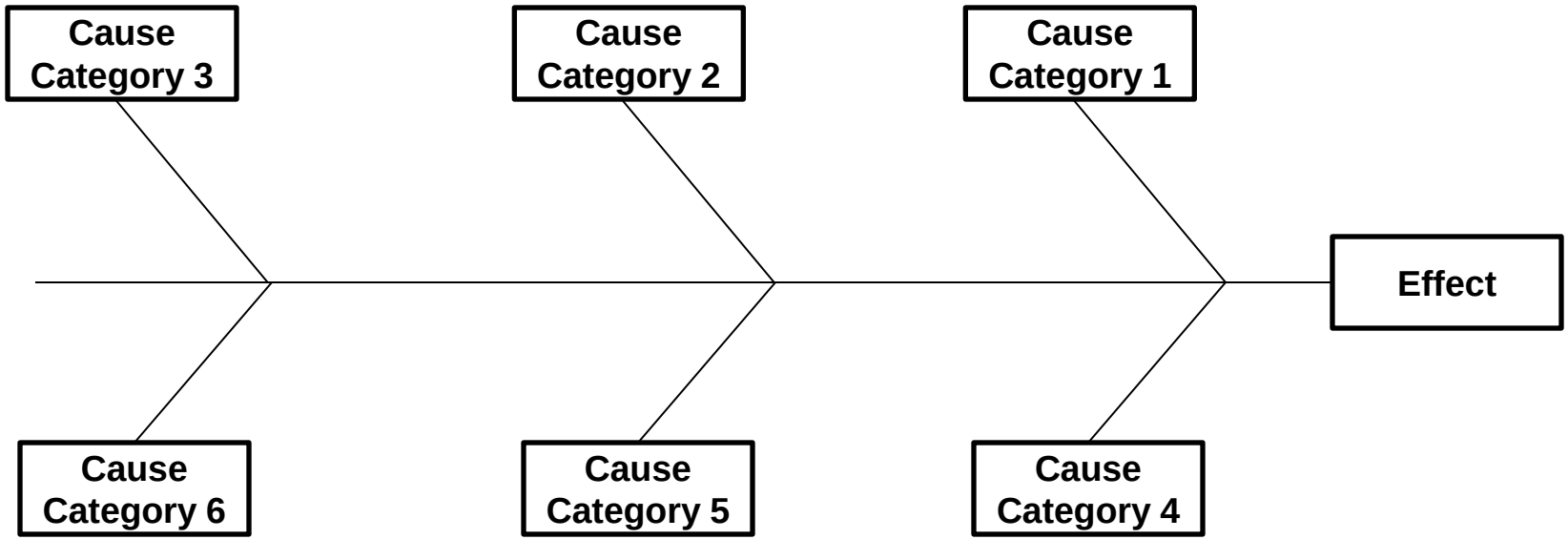
The Case Study



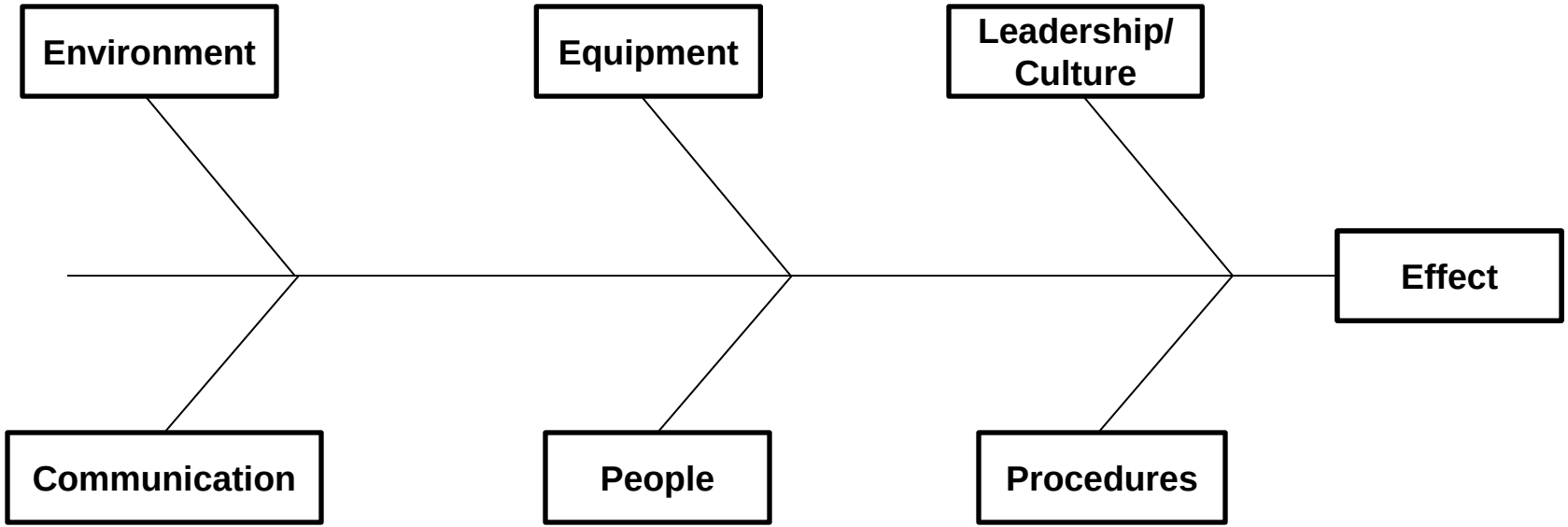
Course Agenda

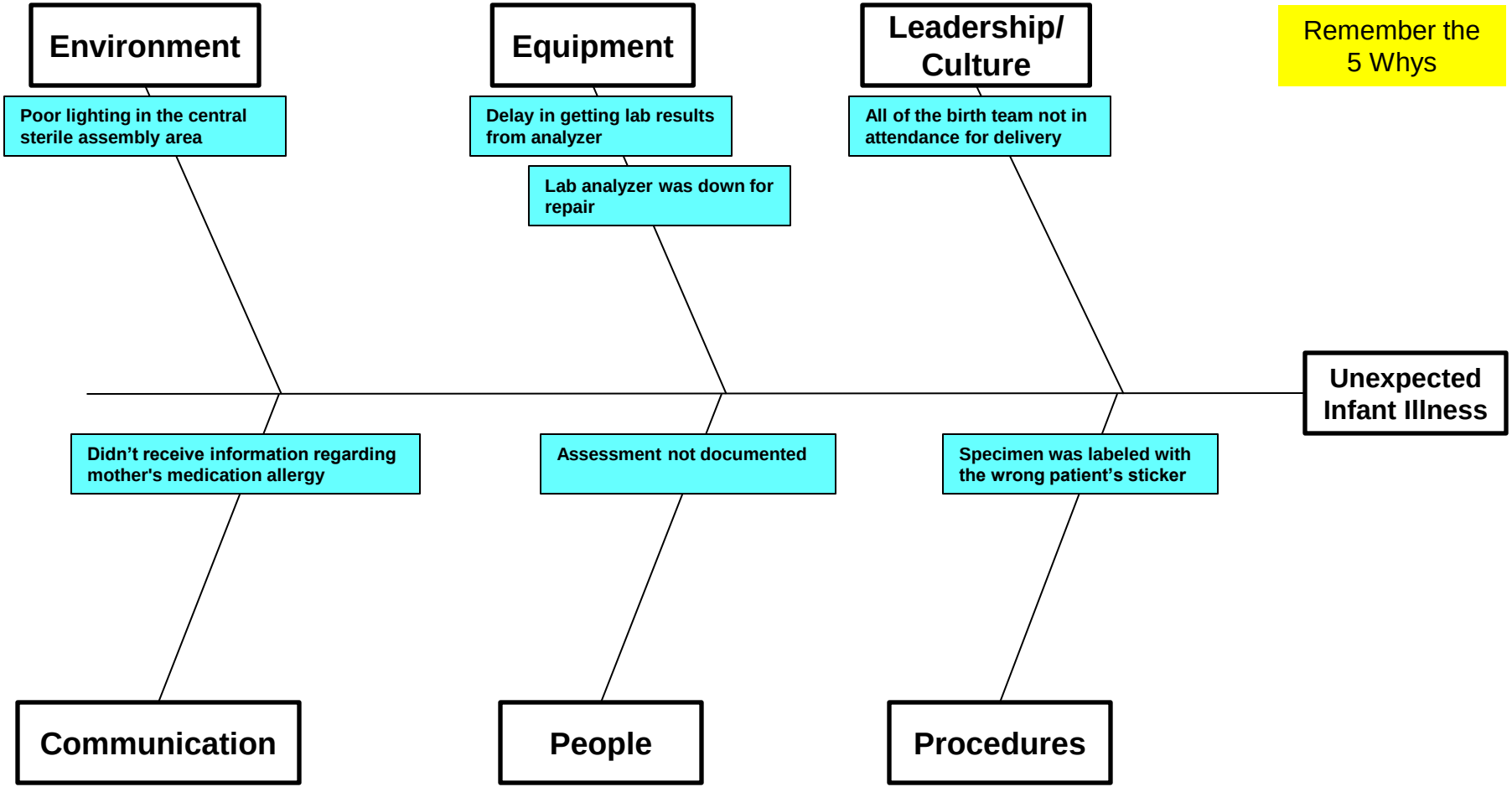
- Analysis of Adverse Events - Dr. Kohrt
- Causal Analysis/Case Study/Timeline – Jackie Bishop
- Process Map - Paul O’Quinn
- Cause and Effect- Paul O’Quinn
- Strength of Solutions - Dr. Kohrt
- Action Items - All
- Shared Learning - Dr. Kohrt

Cause and Effect (fishbone)



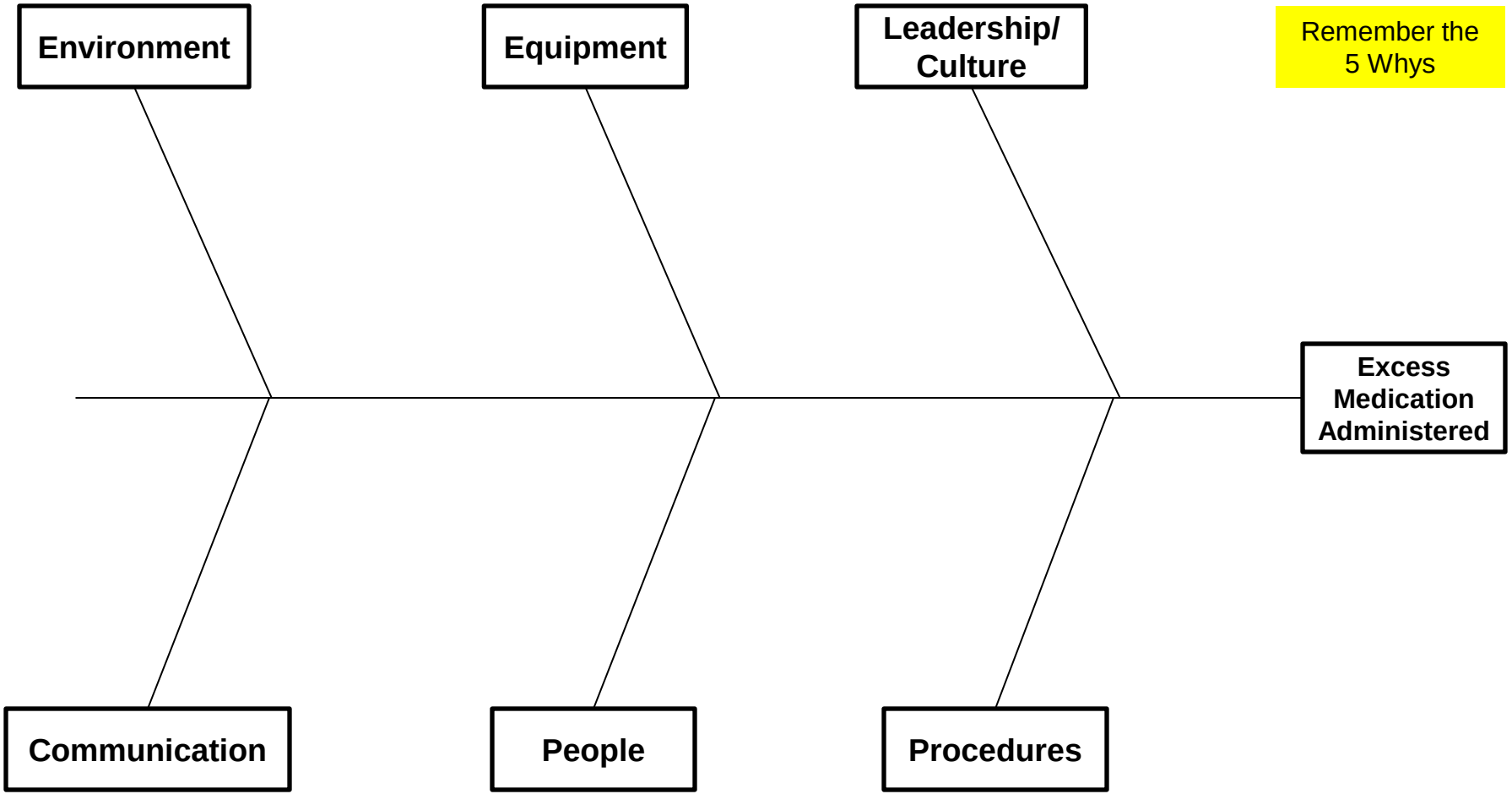
Cause and Effect (fishbone)




Environment
Poor lighting in the central sterile assembly area
Equipment
Delay in getting lab results from analyzer
Lab analyzer was down for repair
Leadership/ Culture
All of the birth team not in attendance for delivery
Remember the 5 Whys
Unexpected Infant Illness
Didn't receive information regarding mother's medication allergy
Assessment not documented
Specimen was labeled with the wrong patient's sticker
Communication
People
Procedures

Exercise 2:

- Move causes from the process map to the relevant category on the Cause and Effect diagram


Environment
Equipment
Leadership/ Culture
Remember the 5 Whys
Excess Medication Administered
Communication
People
Procedures

Exercise 2 (continued):

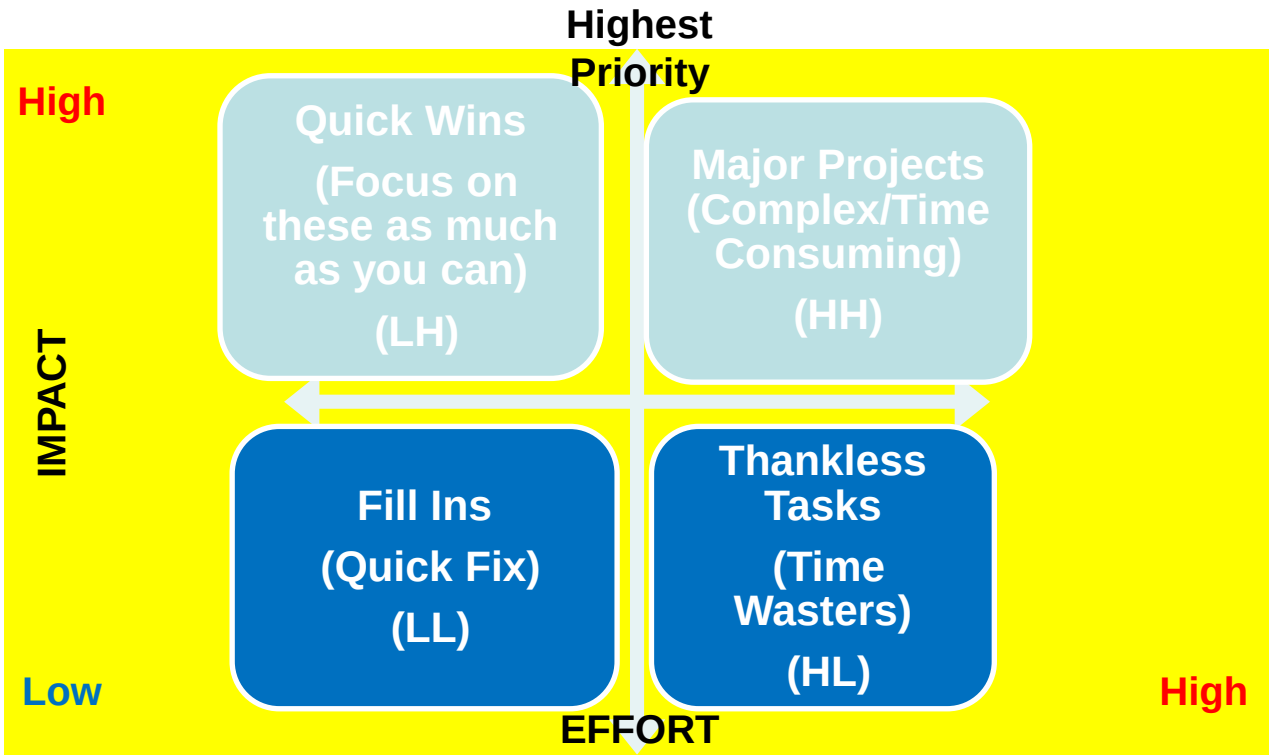
- Thinking about the categories, brainstorm for any additional causes you think may have contributed to the effect
- For each new potential cause, enter the category name followed by your identified cause in the Zoom chat. For example:

Procedures – Failure to…

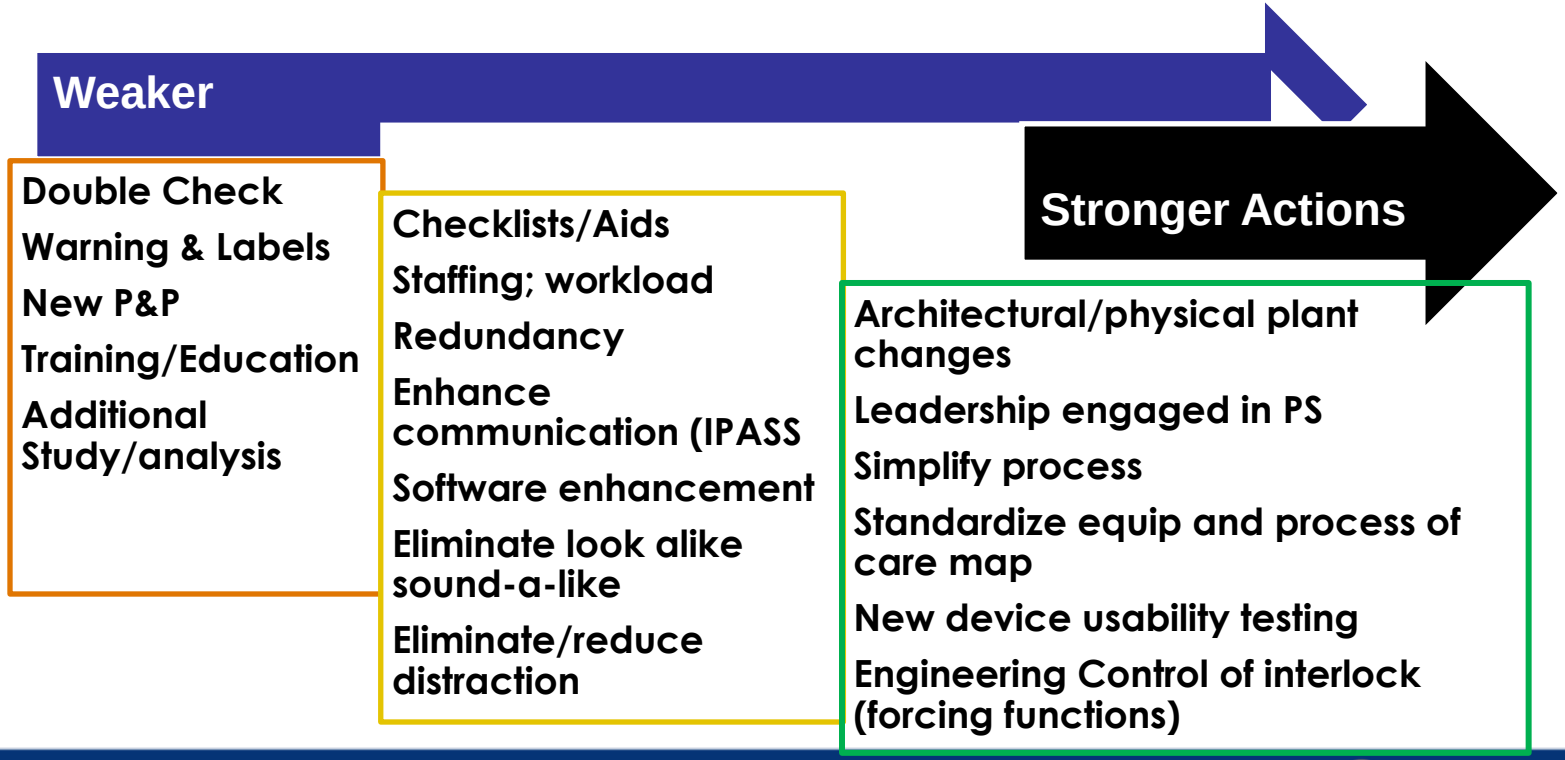
Course Agenda

- Analysis of Adverse Events - Dr. Kohrt
- Causal Analysis/Case Study/Timeline – Jackie Bishop
- Process Map - Paul O’Quinn
- Cause and Effect- Paul O’Quinn
- Strength of Solutions - Dr. Kohrt
- Action Items - All
- Shared Learning - Dr. Kohrt

Solution Impact/Effort Grid



Strength of Interventions



Course Agenda

- Analysis of Adverse Events - Dr. Kohrt
- Causal Analysis/Case Study/Timeline – Jackie Bishop
- Process Map - Paul O’Quinn
- Cause and Effect- Paul O’Quinn
- Strength of Solutions - Dr. Kohrt
- Action Items - All
- Shared Learning - Dr. Kohrt

Action Items

Task ID	Date Identified	Root Cause/Concern	Action Item	Responsible Person	Status	Due Date	Date Completed
1	1/12/21	[Example] Lab analyzer down for repaired	Increase frequency of preventative maintenance service for the analyzer	Johnny Smith	In progress	2/1/21	

Shared Learning

What are the critical lessons from today?

- Health Care is delivered in a complex environment/system
- Errors will occur—System/Humans/and interactions of Systems/Humans
- We are striving for zero harm to the patient
- Residents, faculty, nurses, all staff need to report any event that has the potential to or did harm a patient
- Errors need to be investigated in a systematic process – a diagnostic process using timelines, process evaluation, causal assessment and action items

Second Victim Support

Residents, Fellows, and Students: If a Resident, Fellow, or Medical Student is feeling overwhelmed, they should call and talk with their Program Director; they may also contact the ENI NexGen Total Well-Being Program for second victim support. More Information on our website at: **https://www.uthsc.edu/comc/well-being/nexgen-eap.php**

ENI NexGen Total Well-Being Program
for UT Residents and Medical Students
Phone: (800) 327-2255.
Identify yourself as a UT Resident, Fellow, or Student.
NexGen Website: www.nexgeneap.com.
Enter the company ID as 8665 if asked.
Support is available through both 24 hours a day, 365 days a year.

Erlanger Employee: If you are an Erlanger Employee, 2nd Victim Support is available through:

Erlanger Pastoral Care: 423-778-7177
Employee Assistance Program (EAP): 800-854-1446
http://ehsintranet/Campuses/Baroness/HR/benefits/EAPResources%20for%20Living/Aetna%20-Life%20Brochure.pdf