




*Champions of  
Quality Improvement Cohort*

*Session 4: Performing FMEA/RCA & Use of Discovery Tool*

*May 1, 2024*

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# Champions for Quality Improvement

**Making the most of today!**

- Engage and participate. We welcome shared experiences, questions and stories
- Please turn cameras on if able.

Chat Box Introductions:

- Name
- Facility
- What is one important skill that you think everyone should have?





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Root Cause Analysis

**RCA<sup>2</sup>**  
Improving Root Cause Analyses and Actions to Prevent Harm

Version 2, January 2016

 **NPSF** National Patient Safety Foundation  
268 Summer Street | Boston, MA 02210 | 617.391.9900 | www.npsf.org

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[Sentinel Event Data CY2023 Annual Summary \(jointcommission.org\)](http://www.jointcommission.org)

**The Joint Commission**

**Sentinel Event Data  
2022 Annual Review**

The Joint Commission Sentinel Event Policy is available online at [http://www.jointcommission.org/Sentinel\\_Event\\_Policy\\_and\\_Procedures/](http://www.jointcommission.org/Sentinel_Event_Policy_and_Procedures/)

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## TJC Definition of a sentinel event

- A sentinel event is a patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in any of the following:
  - Death
  - Permanent harm
  - Severe harm (regardless of duration of harm)

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## Continued

- An event is also considered sentinel if it is one of the following:
  - Suicide of any patient receiving care, treatment, and services in a staffed around-the-clock care setting or within 72 hours of discharge, including from the hospital's emergency department (ED)
  - Unanticipated death of a full-term infant
  - Discharge of an infant to the wrong family
  - Abduction of any patient receiving care, treatment, and services
  - Any elopement (that is, unauthorized departure) of a patient from a staffed around-the-clock care setting (including the ED), leading to death, permanent harm, or severe temporary harm to the patient
  - Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups)
  - Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of any patient receiving care, treatment, and services while on site at the hospital
  - Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site at the hospital
  - Invasive procedure, including surgery, on the wrong patient, at the wrong site, or that is the wrong (unintended) procedure
  - Unintended retention of a foreign object in a patient after an invasive procedure, including surgery
  - Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)
  - Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose

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### Top 10 Leading Reviewed Sentinel Event Types (CY2022)

Event Types	N	% of Total
Fall	611	42%
Delay in treatment	89	6%
Unintended retention of a foreign object	88	6%
Wrong surgery*	85	6%
Suicide	73	5%
Assault/rape/sexual assault/homicide	60	4%
Fire/burns	49	3%
Perinatal event	33	2%
Self-harm	30	2%
Medication management	30	2%

\*Wrong surgery includes wrong site, wrong procedure, wrong patient, and wrong implant.

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## Rules of Causation (1 and 2)

**Rule 1. Clearly show the “cause and effect” relationship.**

**INCORRECT:** A resident was fatigued.

**CORRECT:** Residents are scheduled 80 hours per week, which led to increased levels of fatigue, increasing the likelihood that dosing instructions would be misread.

**Rule 2. Use specific and accurate descriptors for what occurred, rather than negative and vague words.** Avoid negative descriptors such as: Poor; Inadequate; Wrong; Bad; Failed; Careless.

**INCORRECT:** The manual is poorly written.

**CORRECT:** The pumps user manual had 8 point font and no illustrations; as a result nursing staff rarely used it, increasing the likelihood that the pump would be programmed incorrectly.

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## Rules of Causation (3 and 4)

### **Rule 3. Human errors must have a preceding cause.**

**INCORRECT:** The resident selected the wrong dose, which led to the patient being overdosed.

**CORRECT:** Drugs in the Computerized Physician Order Entry (CPOE) system are presented to the user without sufficient space between the different doses on the screen, increasing the likelihood that the wrong dose could be selected, which led to the patient being overdosed.

### **Rule 4. Violations of procedure are not root causes, but must have a preceding cause.**

**INCORRECT:** The techs did not follow the procedure for CT scans, which led to the patient receiving an air bolus from an empty syringe, resulting in a fatal air embolism.

**CORRECT:** Noise and confusion in the prep area, coupled with production pressures, increased the likelihood that steps in the CT scan protocol would be missed, resulting in the injection of an air embolism from using an empty syringe.

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## Rules of Causation (5)

### **Rule 5. Failure to act is only causal when there is a pre-existing duty to act.**

**INCORRECT:** The nurse did not check for STAT orders every half hour, which led to a delay in the start of anticoagulation therapy, increasing the likelihood of a blood clot.

**CORRECT:** The absence of an assignment for designated RNs to check orders at specified times increased the likelihood that STAT orders would be missed or delayed, which led to a delay in therapy.

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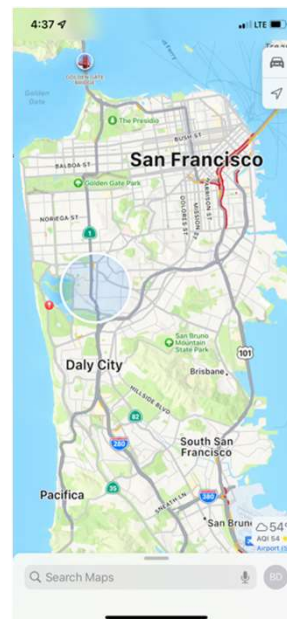
## Failure Mode and Effects Analysis (FMEA)

Identifying and eliminating process failures for the purpose of preventing an undesirable event

Proactively identify and minimize potential failures within an existing or proposed process

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We use  
FMEA  
every day



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## When should we use FMEA in healthcare?

Evaluate new and existing processes and systems

New: identify potential bottlenecks or unintended consequences prior to implementation

Existing: to understand how proposed changes will impact the system

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## Step 1: Select a process to analyze

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Problem-prone or potentially risky process

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Engage front-line by asking their opinions

---

Be certain an identifiable process is chosen

---

Narrow scope to keep variables manageable

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## Step 2: Select people for the team



Designate a facilitator



Assure you have staff who know what 'actually happens', not just 'what is supposed to happen'



Have at least one person from each discipline/shift involved in process



Minimize number of managers/supervisors



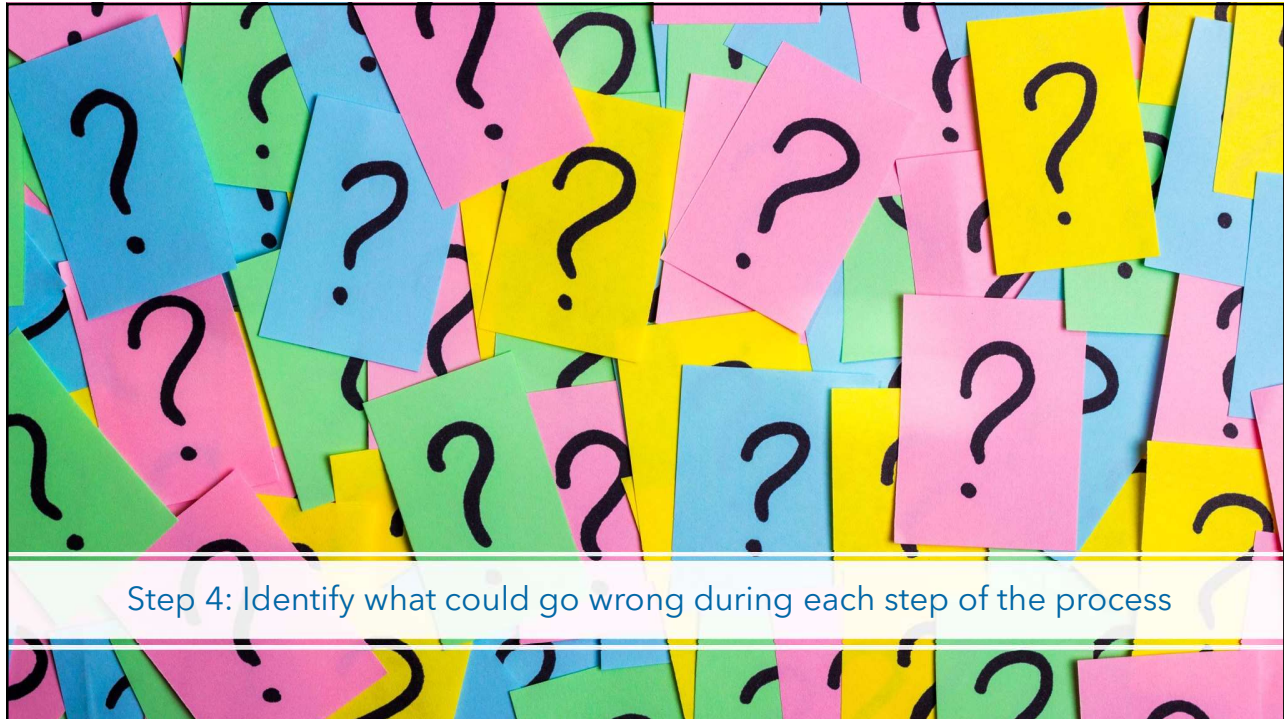
Get the group together to promote quality discussions

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## Step 3: Describe the process

- High-level flowchart of the steps
- Sticky notes with major steps
- If team members can't agree on how the process currently works and process scope cannot be narrowed to obtain agreement, you have a very unreliable process
- If process is complex with lots of steps, do several FMEA's

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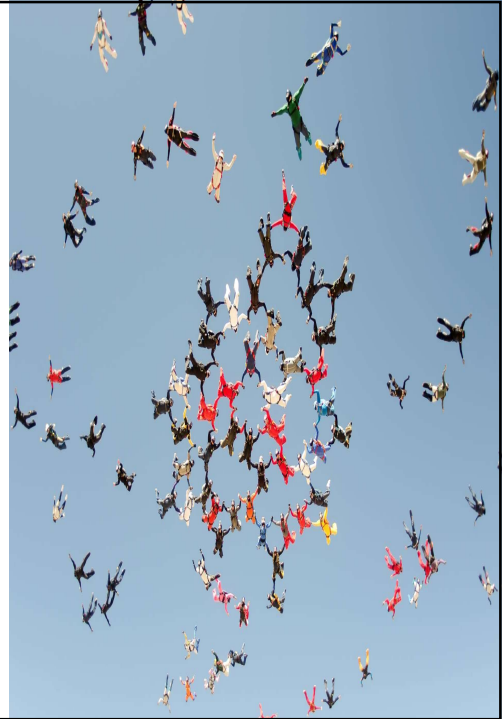
Step 4: Identify what could go wrong during each step of the process

- What can go wrong or what can fail (these are the 'failure modes')
- Need the people who do this work every day
- Create safe atmosphere to decrease 'protectionism'
- Not a 'name, blame, shame' game
- Brainstorm: write failures on sticky-notes and line them up beneath the sticky notes that list the process steps
- Might need to gather additional input from staff not officially on the FMEA team

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## Step 5: Pick which problem(s) to work on eliminating

- Should be based on two factors:
  - How likely the failure will occur
  - How the failure will affect the patient if it does occur
- For each failure, the team decides:
  - What could happen should this failure occur? (outcome)
  - How serious would the outcome be? (severity)
  - How often is this failure likely to occur? (probability)



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## What would happen if this failure occurs?



ADVERSE OUTCOME



DELAYED TREATMENT

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## Outcome severity rating scale

Rating	Outcome Category	Description
5	Catastrophic	Resident experiences death or major permanent loss of function (sensory, motor, physiologic, or intellectual),
4	Major	Resident experiences permanent lessening of bodily function (sensory, motor, physiologic, or intellectual), disfigurement, surgical intervention required, or increased level of care for 3 or more days.
3	Moderate	Resident experiences an event, occurrence, or situation which could harm the resident but will not cause permanent injury or lessening of bodily function or require the delivery of additional healthcare services
2	Minor	Resident may experience a minor injury, but most likely would not be affected by the failure and it would not cause any changes in the delivery of care.
1	Near miss	Resident would not experience any injury, changes in delivery of care, or an increased level of care.

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## VA National Center for Patient Safety

Figure 5. Hazard Scoring Matrix

	Severity of Effect			
	Catastrophic	Major	Moderate	Minor
Probability				
Frequent	16	12	8	4
Occasional	12	9	6	3
Uncommon	8	6	4	2
Remote	4	3	2	1

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## Options for rating scale

Numeric severity ratings are not required

Team can rate outcomes

- Low (minimal patient harm)
- Moderate (short-term patient harm)
- Severe (permanent or long-term harm)
- Fatal (death)

Nominal group technique or multi-voting

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## Determine Probability

Failure probability rating scale

Rating	Description	Definition
5	Very high probability: failure is most inevitable	1 failure in 5 attempts
4	High: repeated failures	1 failure in 50 attempts
3	Moderate: occasional failures	1 failure in 500 attempts
2	Low: relatively few failures	1 failure in 5000 attempts
1	Remote: failure is unlikely	<1 failures in 500,000 attempts

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## VA National Center for Patient Safety

### Figure 4. Probability Rating

**Frequent** - Likely to occur immediately or within a short period (may happen several times in one year)

**Occasional** - Probably will occur (may happen several times in 1 to 2 years)

**Uncommon** - Possible to occur (may happen sometime in 2 to 5 years)

**Remote** - Unlikely to occur (may happen sometime in 5 to 30 years)

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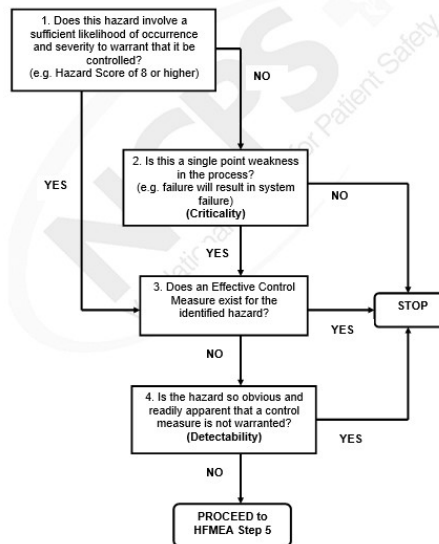
Prioritize  
failures for  
improvement  
action

- Choose the most likely outcome, not the worst-case scenario
- In absence of data, ask team members to estimate, based on experience and a sense of what happens in the facility
- Might be best if management level personnel are not in the room
- Be aware of 'turf protection' and steer clear of 'winners and losers'
- Acknowledge we can't do it all today

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## HFMEA streamlines the hazard analysis

Figure 6. Decision Tree



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## Step 6: Design and implement changes to reduce or prevent problems

- Identify the root cause of each failure
- The Five Whys
- Develop actions to reduce or prevent the failure:
  - What safeguards are needed to prevent this failure from happening?
  - What would have to go wrong to have a failure like this happen? How can we prevent this from going wrong?
  - How could we change the way we do things to make sure this failure never happens?
  - If a failure like this happened, how quickly can we catch and correct the problem?
  - If the patient is harmed by this failure, how could we minimize the effect of the failure on the patient's condition?

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# Corrective actions

Stronger

- Change physical surroundings
- Engineering controls into system (forcing function)

Intermediate

- Checklists/cognitive aids
- Reduce distractions

Weaker

- Warnings/labels
- Inservice/training
- Warnings/labels

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## TOOLS & RESOURCES – Convergence Health Consulting

**Discovery Tools**

Discovery Tools are a quick, efficient method for identifying process gaps so organizations can start taking health care quality improvement measures in their own hands. To complete a Discovery Tool, download the topic tool you are interested in using, and use it to review 5–10 medical records. In 20–30 minutes, you will be able to see which processes to focus on with your team.

Read Stewardship ~ Readmissions Discovery ~ Sepsis ~ Sepsis Transfer ~ Post-Op Sepsis

**DOWNLOAD THE DISCOVERY TOOLS**

Enter your email to receive a link to all Convergence Discovery Tools.

Email Address  **DOWNLOAD**

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CAUTI Process Improvement Discovery Tool

Review a minimum of **5** and a maximum of **10** medical records.

**Focus:**  
For this review, review randomly selected charts of inpatients (e.g. the last 5) who had a diagnosis of a CAUTI made while an inpatient. Do not include patients who were admitted with a diagnosis of a CAUTI.

**Instructions:**  
When reviewing the medical record, if documentation is found for the process, mark **"Yes"** in the box. If documentation is not found for the process, mark **"No"**. If the process being reviewed is not applicable to the medical record, mark **"N/A"**. After completing the review of all records, note the rows with the highest number of "No" responses. This will identify priority focus areas for improvement.

**Note:** Do not spend more than 20-30 minutes per medical record.

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CLABSI Process Improvement Discovery Tool

Chart Identifier #																				
<b>(INSERTION) The patient had:</b>																				
An order to insert a central line																				
A hospital-defined evidence-based clinical indication for a central line																				
Documentation that the central line was inserted using maximum sterile technique <small>(i.e., mask, cap, sterile gown by all involved in procedure; full-body sterile drape during insertion)</small>																				
Catheter placed in site other than the femoral vein																				
A non-sutured securement device utilized																				
<b>(MAINTENANCE) The patient had documentation of:</b>																				
Assessment and documentation for the clinical necessity for continued use of central line per hospital policy <small>(e.g., daily or every shift)</small>																				
Assessment of insertion site is assessed <small>(e.g., dressing intact, no signs of inflammation) per hospital policy (e.g., daily or every shift)</small>																				
Patency of all central line lumens																				
If daily chlorhexidine gluconate (CHG) bathing is an established practice in the unit where patient was housed <small>(note N/A if not an established practice in your hospital)</small>																				
There is evidence that patient and/or family was educated about risks associated with a central line that is no longer clinically indicated																				
<b>(BLOOD CULTURE COLLECTION) The patient had:</b>																				
Blood drawn from two different peripheral sites, not the central line <small>(lab result should indicate the source of the blood sample)</small>																				
Other (specify):																				

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**(MAINTENANCE)** The patient had documentation of:

- Assessment and documentation for the clinical necessity for continued use of central line per hospital policy (e.g., daily or every shift)
- Assessment of insertion site is assessed (e.g., dressing intact, no signs of inflammation) per hospital policy (e.g., daily or every shift)

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**CAUTI Process Improvement Discovery Tool** 

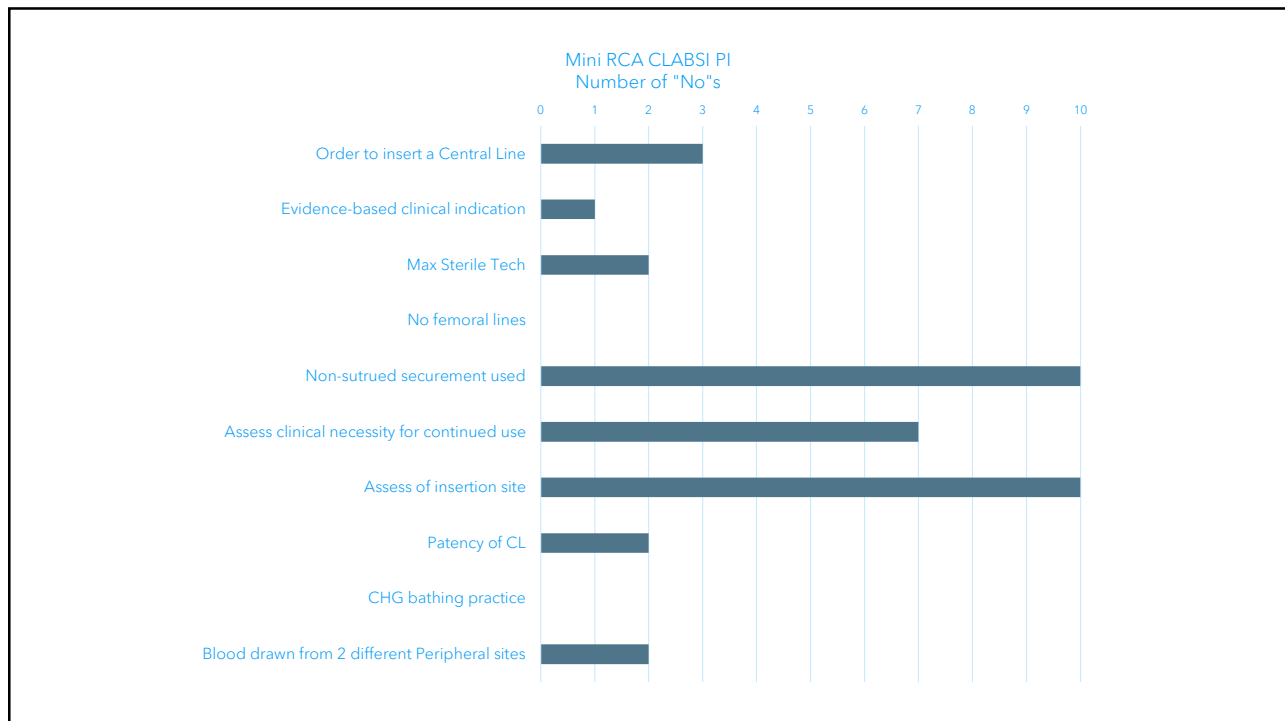
Chart Identifier	Pt A	Pt B	Pt C	Pt D	Pt E	Pt F	Pt G	Pt H	Pt I	Pt J
<b>(INSERTION)</b> The patient had:										
An order to insert a urinary catheter										
A hospital-defined clinical indication for a urinary catheter										
Urinary catheter inserted using sterile technique. Perineal wash and meatal cleansing performed prior to insertion										
A two-person insertion (e.g., two nurses)										
Alternatives to urinary catheter (e.g., external catheter) considered and documented										
<b>(SIGNS/SYMPTOMS)</b> The patient had:										
At least one of the following: new onset or worsening of fever, rigors, altered mental status, malaise or lethargy with no other identified cause; flank pain, costovertebral angle tenderness; acute hematuria; pelvic discomfort										
A urinalysis that demonstrated at least one abnormality (e.g., + Nitrite, + Leukocyte esterase (LE), ≥ 5 WBC/hpf)										
<b>(DOCUMENTATION)</b> The patient had:										
Assessment and documentation for the clinical necessity for continued use of urinary catheter per hospital policy										
Documentation of catheter care (e.g., closed system maintenance with seal intact, bag and tubing off the floor, no dependent loops, drainage bag secured) per hospital policy										

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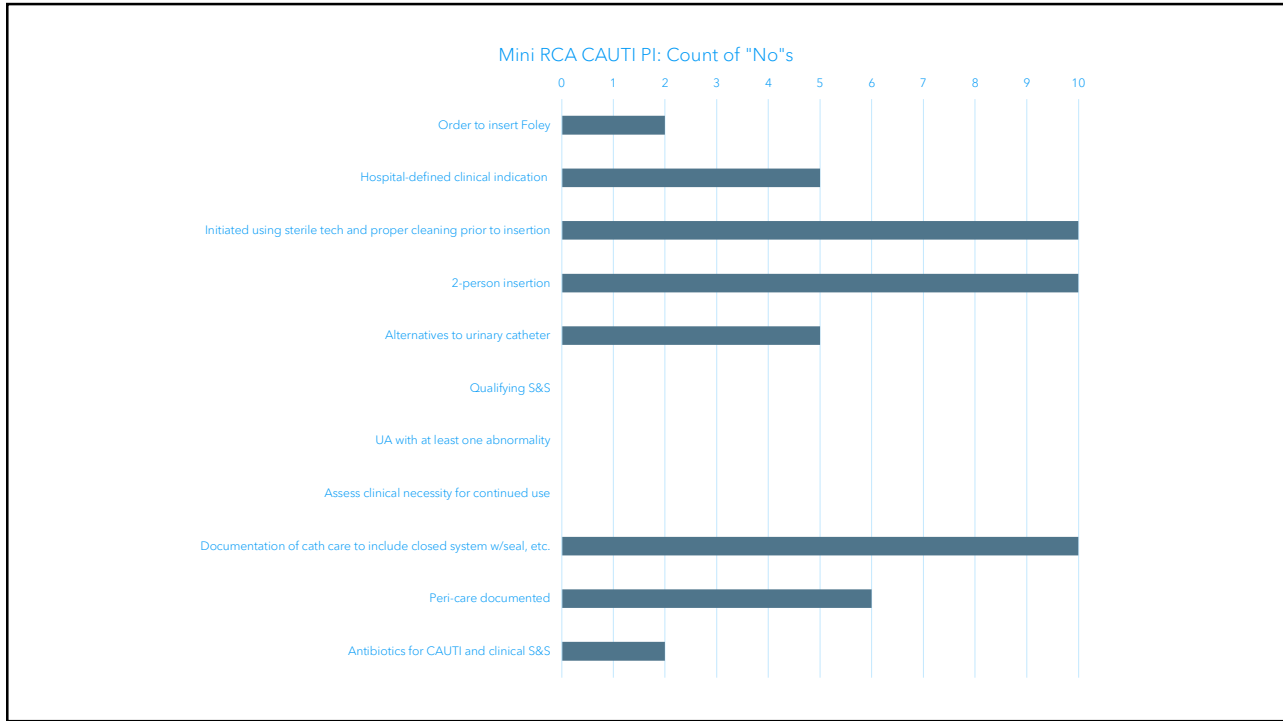
**(INSERTION) The patient had:**

- An order to insert a urinary catheter
- A hospital-defined clinical indication for a urinary catheter

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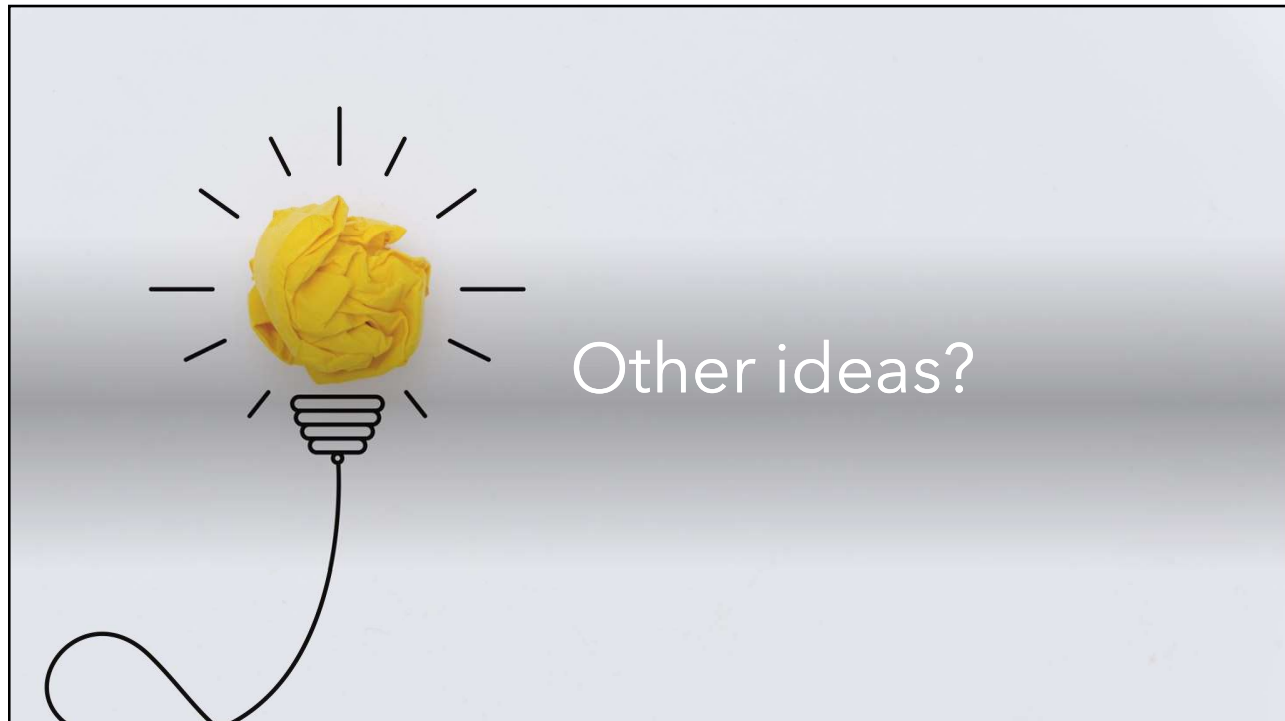
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Readmissions Discovery Tool										
Medical Record Review										
Medical Record #										
Is the Index Admission Diagnosis a chronic condition?										
Discharge disposition from index admission. (WRITE: home, home health, SNF, other)										
# Days between discharge date and readmission date. (WRITE: 1-7, 8-14, 15-21, 22-30)										
Have there been 4 or more hospitalizations at this organization in last 12 months for this patient?										
Documentation that a medication list was provided to patient or caregiver at discharge.										
Information about the patient's condition was documented and provided to the next level of care receiver.										
For patients with a comorbid behavioral health condition, a follow up appointment with a behavioral health provider is documented.										
For patients that require assistance from social services, a direct linkage documented instead of asking patient to self-navigate.										
The primary learner/caregiver is identified and documented in the medical record.										

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## Schedule

March 6:	Session 1: Get to Know You
March 20:	Session 2: Facilitation & Project Management Skills
April 24:	Session 3: Engaging others in QI
May 1:	Session 4: Performing FMEA/RCA/etc. & Use of Discovery Tool
May 22:	Session 5: Data Collection, Analysis & Display
June 12:	Session 6: Just Culture & Communication

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# Contact

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