Introduction

Recognizing the importance of identifying errors and learning from them is paramount. WE ALL MAKE MISTAKES.

Failure Mode and Effects Analysis (FMEA) is a proactive risk assessment used to evaluate areas of vulnerability. FMEA creates processes to prevent and reduce errors. FMEA is a *proactive/prospective* process.

Root Cause Analysis (RCA) is a process used to analyze adverse events when they have already occurred. The Joint Commission now requires an RCA to be performed within 45 days for all sentinel events that occur in a clinical department. RCA is a *reactive/retrospective* process.

An unexpected death, loss of function, or wrong-site, wrong-procedure, wrong-patient procedure are sentinel events. Sentinel events require urgent inquiry and response. An adverse event is an unanticipated, unwanted, or potentially harmful occurrence. A near miss is any process variation that did not alter the result but for which the recurrence carries a considerable possibility of a major adverse outcome.

Healthcare organizations should learn both techniques to reduce or prevent the likelihood of adverse events.

FMEA and RCA
Similarities & Differences

	FMEA	RCA
Timeframe	Prospective (What if analysis)	Retrospective (What happened analysis)
Focus	Choose topic (item) for evaluation Process and Design	Individual adverse event System Issues
Goal	Works to prevent adverse events from occurring	Works to prevent adverse events from recurring
Advantage	Asks what could go wrong?	Asks what happened and why?
Method	Process & Chronological Flow Diagram	Interdisciplinary team; Cause & Effect Diagram (Fishbone diagram) ; and Brainstorming (Triage/Triggering Questions)
Measure	Detectability & Criticality Testing Intervention	Corrective Actions and Outcomes

Breast Imaging Clinic Case:

A 55-year-old woman had a screening mammogram. The screening mammogram revealed new architectural distortion in the right breast. An add-on afternoon diagnostic mammography confirmed the new finding as suspicious and recommended an ultrasound with ultrasound-guided biopsy.

The referring clinician returned later in the afternoon to request an ultrasound and biopsy. Very busy clinic, but the patient was added to the schedule. Ultrasound verified the mammogram findings, and the architectural distortion was biopsied.

On Monday, neither the procedure technologist nor the pathology lab could find entries regarding the biopsy specimen. The specimen was not found in the breast imaging department or the pathology department. No one knew where the specimen went.

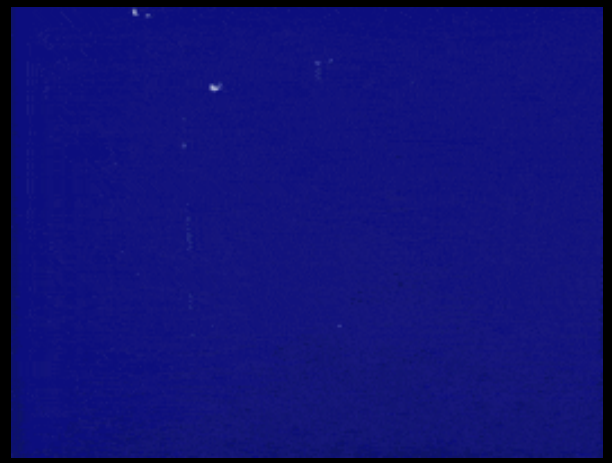
An RCA was started after an institutional safety event was filed. The patient was contacted and told a rebiopsy was needed.

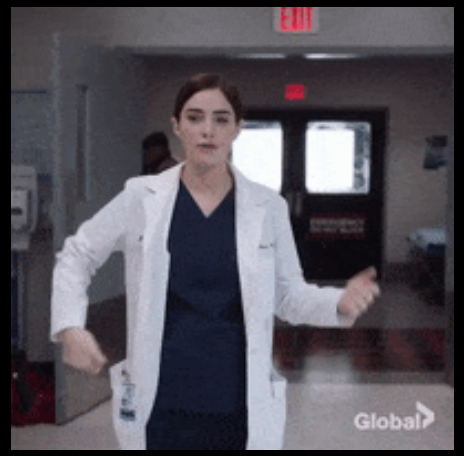
Ultrasound-guided rebiopsy was performed. Pathology confirmed cancer.

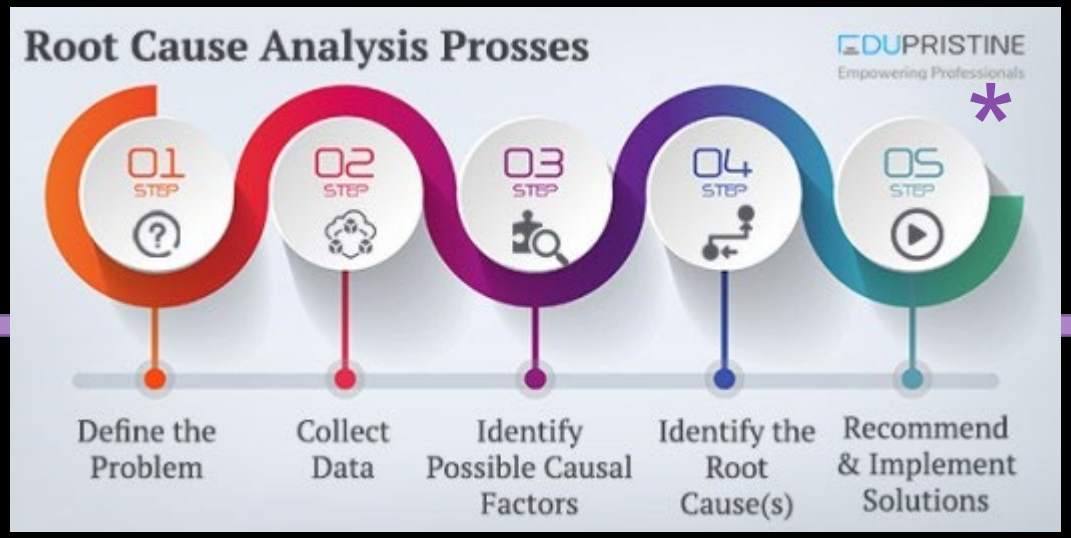
Please click on the images to the left play the tomosynthesis

There is architectural distortion at the 10 o'clock position of the right breast 6cm from the nipple.

Pathology – invasive ductal carcinoma







Defining the problem and Collecting data

The patient presented for screening mammography → A new suspicious finding was seen → A diagnostic mammogram was added to the already busy afternoon schedule → The diagnostic mammogram confirmed the findings → Ultrasound with biopsy was recommended → Ultrasound and biopsy were added on to a busy schedule → Another radiologist offered to do the procedure, but the initial radiologist declined the help → Ultrasound-guided biopsy was done → The following Monday, the specimen was not found → Rebiopsy was necessary

We had an open and honest conversation with the patient and with our team.

*https://www.edupristine.com/blog/root-cause-analysis

Identify possible causal factors

Question: What do you see as possible causal factors that resulted in the lost breast specimen?

External causal factors	*Internal causal factors*
Low wages	Lack of skill
Time and trouble saving	Professional pride
Work overload	Attentional lapse
Defective equipment	Misperception
Inadequate training	Misconduct
Pressure from management	Lack of adequate comprehension
Coworker's fault	Risky work behavior
Loss of concentration	Inexperience
Operational procedures	Carelessness
Misassignment	Urge to show off
Curse, spell, or witchcraft	Ignorance
Religious faith	Sense of job security
Poor housekeeping	Mood, had a bad day
Lack of appropriate gear	Tiredness and exhaustion
Ambiguity and task difficulty	Deliberate, wilful violation

Source: Gyekye (2001, 2003).

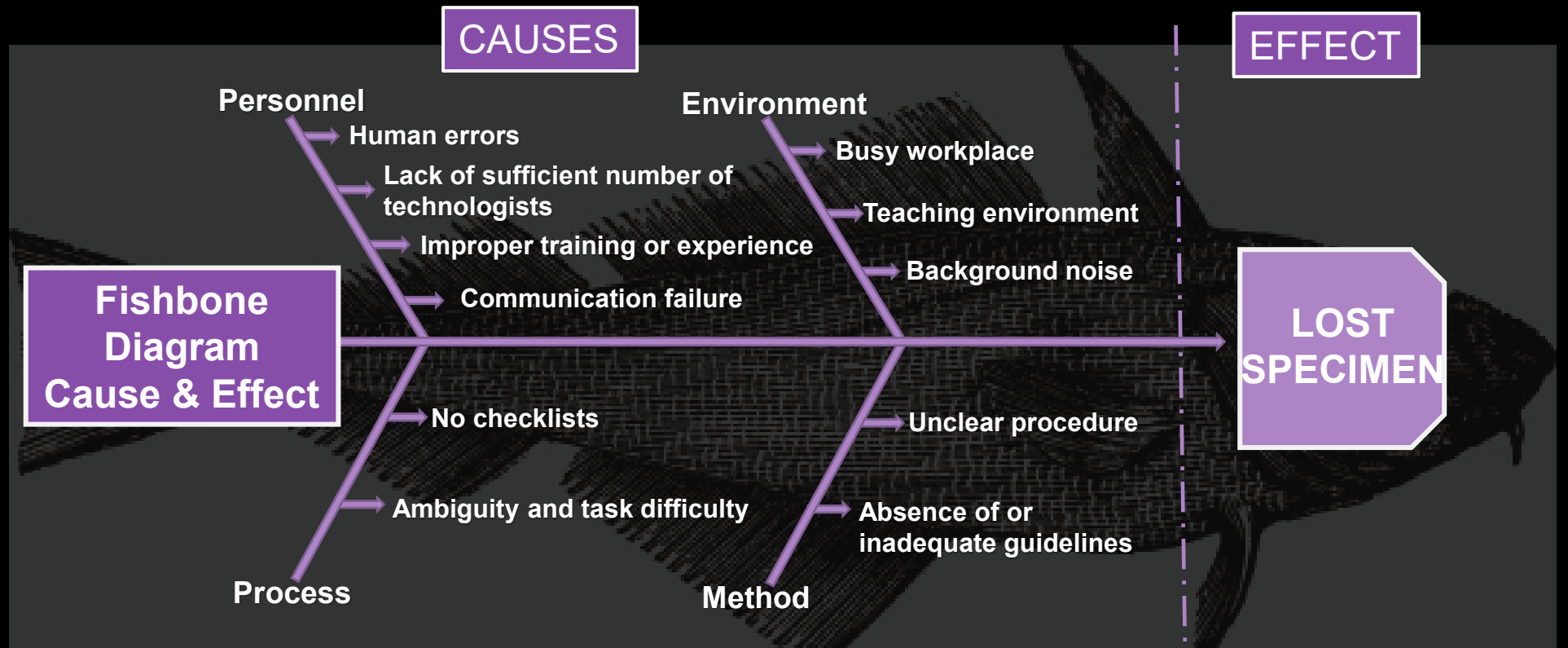
The Joint Commission lists communication errors among the most common attributable causes of sentinel events.

The risk management literature further supports this finding, ascribing communication error as a major factor (70%) in adverse events.

Despite numerous strategies to improve patient safety, which are rooted in other high-reliability industries (e.g., commercial aviation and naval aviation), communication remains an adaptive challenge that has proven difficult to overcome in the sociotechnical landscape that defines healthcare.

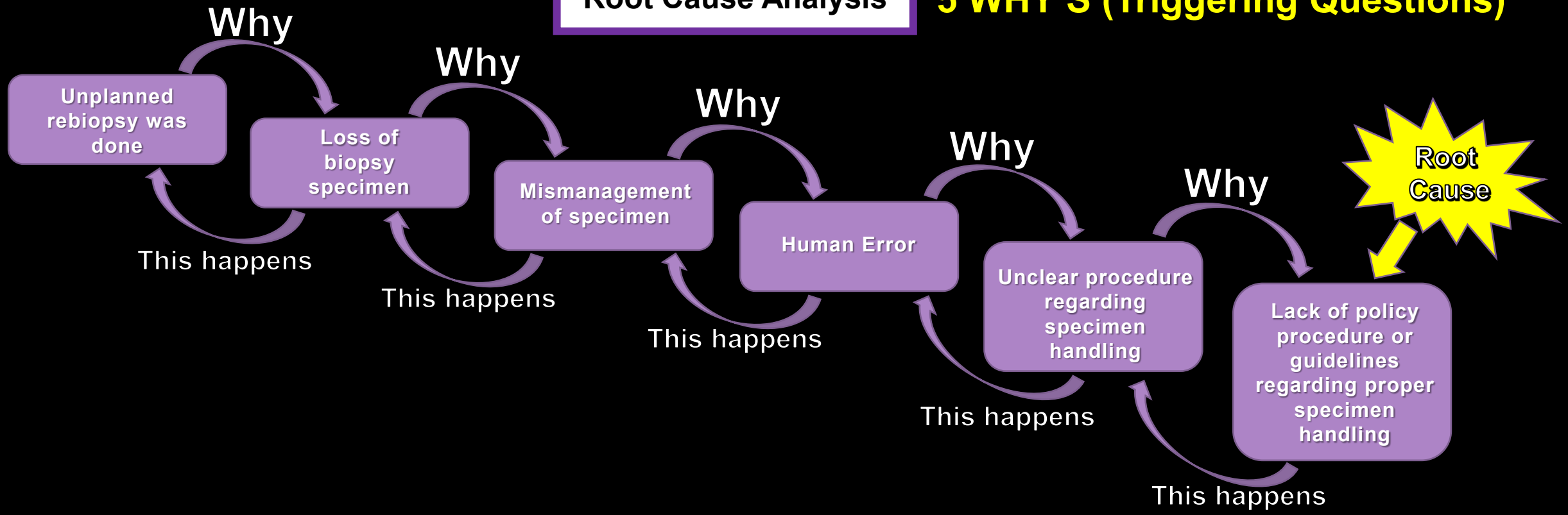
Webster, KL, Gisick, LM, & Baker, AL (2018)

Root Causes



Root Cause Analysis

5 WHY'S (Triggering Questions)



1 Root Cause Statement

No policies/procedures/guidelines regarding the proper handling of breast biopsy specimens increased the likelihood of specimen mismanagement and loss that led to an unplanned rebiopsy.

2 Corrective Action Plan

-The institution will create applicable policies/procedures/guidelines that clearly define the person(s) responsible for and the proper steps required to manage the handling of each breast biopsy specimen.

-All staff from this institution involved in the handling of a breast biopsy specimen will be educated about the new policies/procedures/guidelines.

3 Measure of Effectiveness

-The institution will ensure that each staff member is educated about the new policy/procedure/guidelines.

-A random sample of ultrasound-guided breast biopsies will be monitored for 3 months to ensure that the handling of the breast biopsy specimens follows the new policies/procedures/guidelines. A compliance rate of 100% is expected.

Failure Mode and Effects Analysis

Aim: Using FMEA to reduce the likelihood of error in the Breast Imaging Clinic.

Process Data

Step 1

Description

55-year-old woman had a screening mammogram. The screening mammogram revealed new architectural distortion in the right breast. An add-on afternoon diagnostic mammogram confirmed the new finding suspicious and recommended an ultrasound with ultrasound-guided biopsy.

Failure Mode	Causes	Effects	Occ	Det	Sev	RPN	Actions
Ultrasound and biopsy were added to a busy schedule.	There is a need to confirm the new suspicious finding promptly even though the schedule was already busy.	That need increased the likelihood of medical error.	8	8	10	640	Develop a new process to properly manage add-ons to the schedule.
The initial radiologist declined help from another radiologist.			5	10	10	500	Develop a new process to manage contingency during busy schedules.
The specimen from the biopsy was lost.			6	10	10	600	Create a policy or procedure or guidelines to properly handle specimens.

Calculated Total

1740

Occ: Likelihood of Occurrence (1-10)
Det: Likelihood of Detection (1-10)
Sev: Severity (1-10)
NOTE: 1 = Not Very likely & 10 = Very likely
RPN: Risk Priority Number (Occ x Det x Sev)

An FMEA would have reduced the chance of losing/mishandling the sample.

Implementing Our New Process

- Daily huddle briefings to reinforce adherence to the new protocol for invasive biopsy procedures and the handling of breast biopsy specimens.
- Daily independent review of the biopsy specimen verification forms.

- **What began as an error with an invasive procedure in Breast Imaging has now led to standard protocol improvements.**
- **We provide continuing education for technologists using errors as educational tools to remind them (and the radiologists) that the potential for errors always exists.**
- **We encourage staff to help and observe other staff members and give feedback whenever necessary.**
- **We promote awareness that errors will be seen as an opportunity to enhance our safety culture.**

References

1. Senders JW. FMEA and RCA: the mantras; of modern risk management. BMJ Quality & Safety 2004 Aug 1;13(4):249-50.
2. Latino RJ, Flood A. Optimizing FMEA and RCA efforts in health care. Journal of Healthcare Risk Management 2004 Jun;24(3):21-8.
3. Battles JB, Dixon NM, Borotkanics RJ, Rabin-Fastmen B, Kaplan HS. Sensemaking of patient safety risks and hazards. Health Services Research 2006 Aug;41(4p2):1555-75.

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