crico | Protecting Providers. Promoting Safety.

Are You Safe?

Patient safety risks for office-based practices

Closing the Loop:
Is my specimen handling process reliable?

Opportunities for Improving Patient Safety

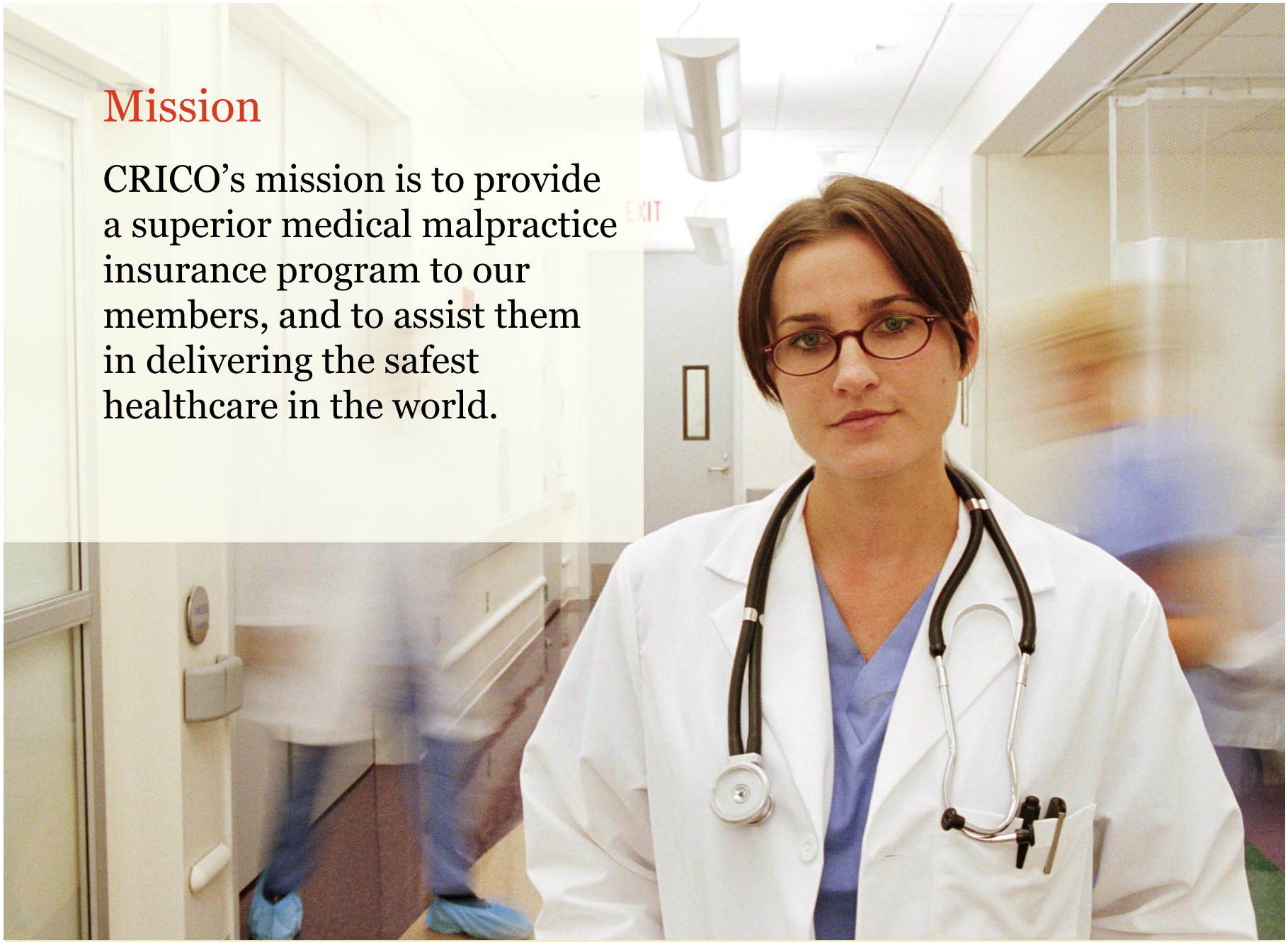
- **Identified through** CRICO's Office Practice Evaluation program and analysis of medical malpractice case data
- **Based on** real events that have triggered malpractice cases
- **Valuable lessons** in communication, clinical judgment, and patient care systems

Purpose

- Help all members of office-based teams reduce the risk of patient harm in the course of diagnosis and treatment.
- Raise awareness and begin discussions about the patient safety issues that most commonly put ambulatory care patients and providers at risk.

Mission

CRICO's mission is to provide a superior medical malpractice insurance program to our members, and to assist them in delivering the safest healthcare in the world.



Controlled Risk Insurance Company (CRICO)

- Captive insurer of the Harvard medical institutions
- Provides member organizations medical professional liability, general liability and other insurance coverage for:
  - 13,000+ physicians *(including 3,500 residents and fellows)*
  - 25 hospitals
  - 100,000+ employees (nurses, technicians, etc.)
- Services include underwriting, claims management, and patient safety improvement
- CRICO has been analyzing medical malpractice data to drive risk mitigation for more than 30 years

CRICO Member Organizations

- Atrius Health
  - Dedham Medical
  - Granite
  - HVMA
- Boston Children's Hospital
- Cambridge Health Alliance
- CareGroup
  - Beth Israel Deaconess Medical Center
  - Beth Israel Deaconess Needham
  - Beth Israel Deaconess Milton
  - Mount Auburn Hospital
  - New England Baptist Hospital
- Dana-Farber Cancer Institute
- Harvard Pilgrim Health Care
- Presidents and Fellows of Harvard College
  - Harvard Medical School
  - Harvard School of Dental Medicine
  - Harvard T. H. Chan School of Public Health
  - Harvard University Health Services
- Joslin Diabetes Center
- Judge Baker Children's Center
- Massachusetts Eye and Ear Infirmary
- Massachusetts Institute of Technology
- Partners HealthCare System
  - Brigham and Women's Hospital
  - Brigham and Women's Faulkner Hospital
  - Massachusetts General Hospital
  - McLean Hospital
  - North Shore Medical Center
  - Newton-Wellesley Hospital
  - Spaulding Rehabilitation Hospital

Malpractice Data Overview

Focus: Ambulatory Diagnosis-related Allegations

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46% of CRICO malpractice cases occur in the ambulatory setting.

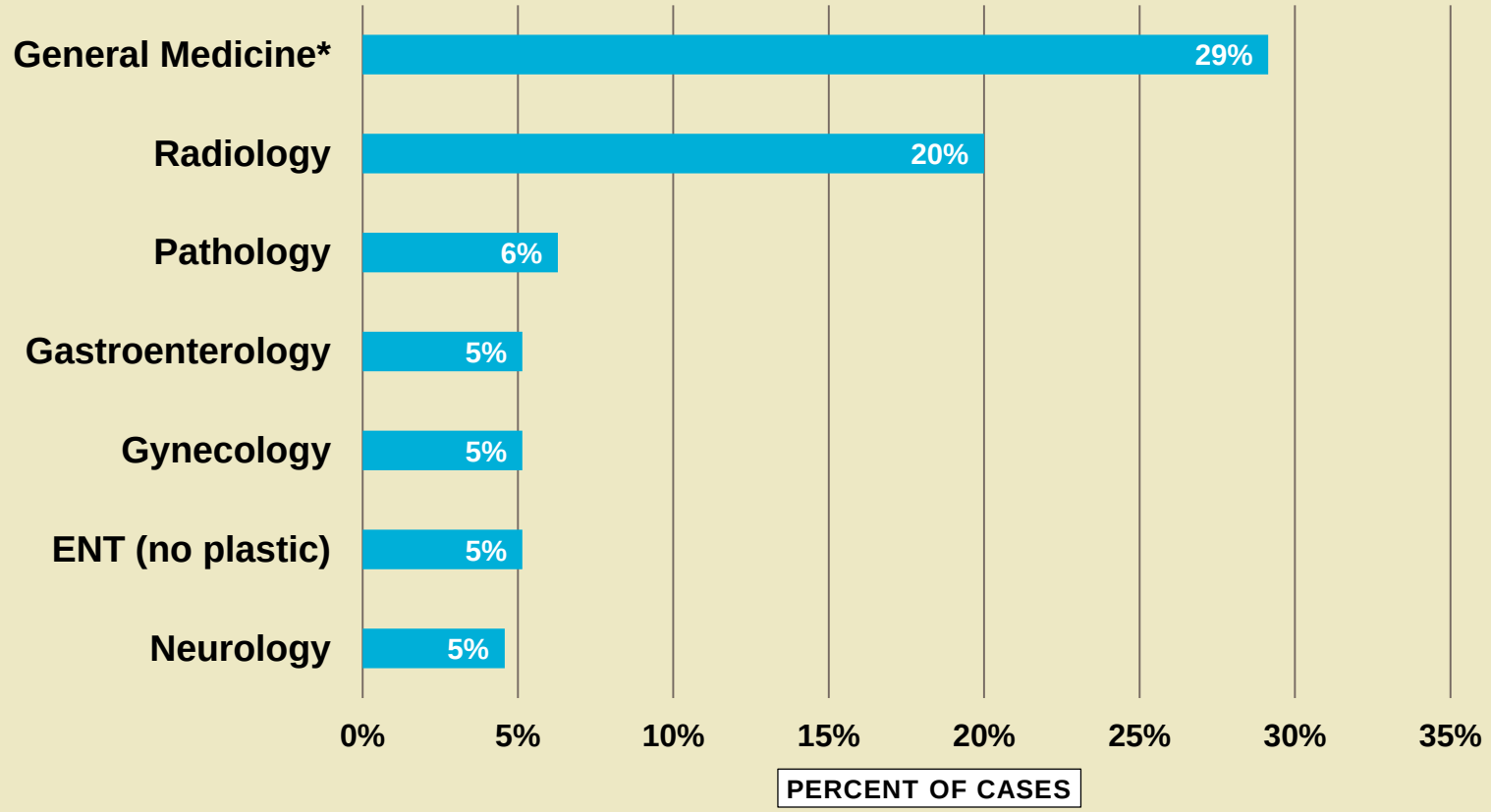
38% of ambulatory cases allege a wrong or delayed diagnosis.

*Losses are “total incurred losses,” which includes reserves on open and payments on closed cases.

**Ambulatory care cases involve an outpatient but exclude cases occurring in Emergency departments. CRICO N=175 MPL cases with claims made date1/1/11 – 8/31/16.

General Medicine and Radiology are most frequently involved.

The Clinical Service Responsible for the Patient's Care at the Time of the Event

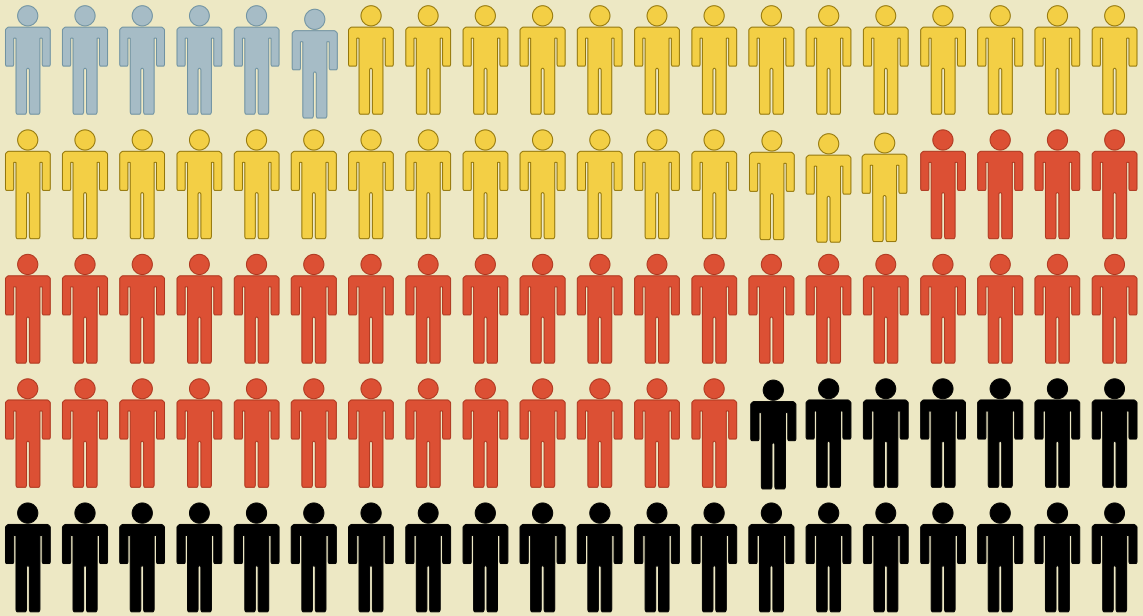


CRICO N=175 MPL cases with claim made date 1/1/11–8/31/16 involving ambulatory care and alleging diagnostic failure.

*General Medicine includes Internal Medicine and Family Practice.

Two-thirds of cases involve permanent injury or death.

Injury Severity in Ambulatory Diagnosis Cases



6% low

30% medium

64% high

including death

CRICO N=175 MPL cases with claim made date 1/1/11–8/31/16 involving ambulatory care and alleging diagnostic failure.

Severity Scale: High=Death, Permanent Grave, Permanent Major, or Permanent Significant
Medium=Permanent Minor, Temporary Major, or Temporary Minor
Low= Temporary Insignificant, Emotional Only, or Legal Issue Only

60% of 175 ambulatory diagnosis-related cases involve a missed/delayed cancer diagnosis

- The top ambulatory diagnosis-related allegations in CRICO ambulatory malpractice cases are:
  - Cancers (top three: breast, lung, colorectal)
  - Diseases of the heart
  - Fractures

Case Study: Closing the Loop

Is my specimen handling process reliable?

The following example is from a closed malpractice case.

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CRICO maps contributing factors to the way care is experienced by the patient.

CRICO Diagnostic Process of Care

STEP	CRICO % CASES	CBS % CASES
1. Patient notes problem and seeks care	1%	1%
2. History/physical	10%	8%
3. Patient assessment/evaluation of symptoms	35%	31%
4. Diagnostic processing	43%	35%
5. Order of diagnostic/lab test	40%	31%
6. Performance of tests	5%	3%
7. Interpretation of tests	37%	23%
8. Receipt/transmittal of test results (to provider)	4%	5%
9. Physician follow up with patient	21%	18%
10. Referral management	13%	21%
11. Provider-to-provider communication	12%	12%
12. Patient compliance with follow-up plan	14%	17%

*A case will often have multiple factors identified.

CRICO N=175 MPL cases with claim made date 1/1/11–8/31/16 involving ambulatory care and alleging diagnostic failure.

CBS (Comparative Benchmarking System) includes >300,000 medical malpractice cases across the nation

CBS N=2,919 MPL cases with claim made date 1/1/11–8/31/16 involving ambulatory care and alleging diagnostic failure.

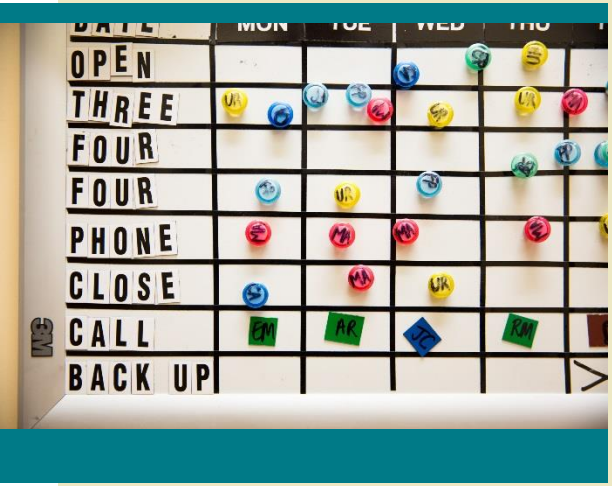
Malpractice case study focus: Internal Office Function

5%
of cases

had an error in the management of an ordered test identified as a contributing factor, i.e., ordered test/imaging is not performed, performed incorrectly, or specimen is mislabeled or mishandled

CRICO N=194 MPL cases asserted 1/1/09–12/31/13 involving ambulatory care and alleging diagnostic failure.

Case Study



Patient

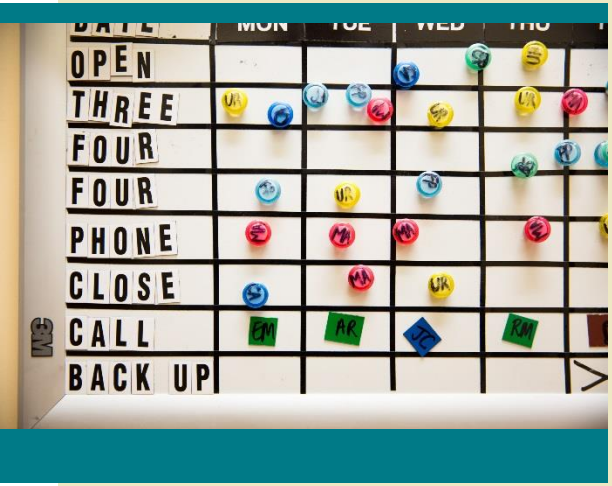
Lorraine, 27-year-old female

Day 1

- Lorraine visits her PCP with c/o frequent and burning urination. Her PCP orders a urine culture and sensitivity (C&S), and prescribes Bactrim.
- Inadvertently, the urine specimen is not sent to the lab.

Case Study

Lorraine, 27-year-old female

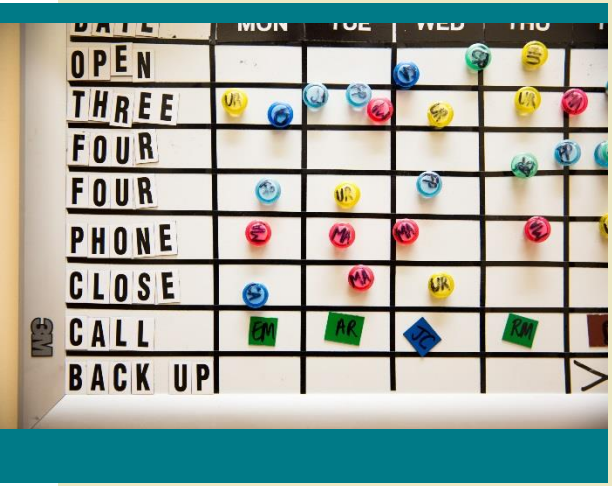


Day 14

- Lorraine calls her PCP with c/o excruciating back pain. She is referred to an ED.
- In the ED, urinalysis confirms 3+ bacteria and a urine C&S is sent to the lab.
- Lorraine is discharged with a renewed Bactrim prescription.

Case Study

Lorraine, 27-year-old female

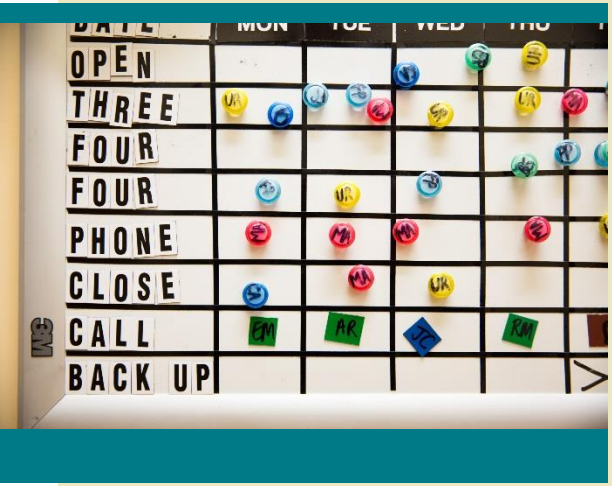


Day 16

- Lorraine returns to the ED with fever, nausea, and vomiting, and is admitted to the hospital.
- The urine C&S ordered during her previous ED visit confirms E. coli, which is not sensitive to Bactrim.
- A new antibiotic is ordered.

Case Study

Lorraine, 27-year-old female

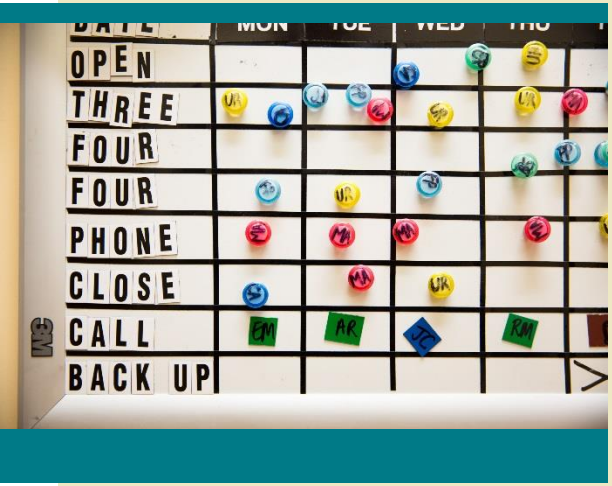


Outcome

- Four days later, Lorraine is discharged home with a peripherally inserted catheter line for prolonged antibiotic treatment.
- Lorraine's PCP discloses and apologizes for the fact that her initial urine C&S was never sent to the lab.

Case Study

Lorraine, 27-year-old female



Vulnerability

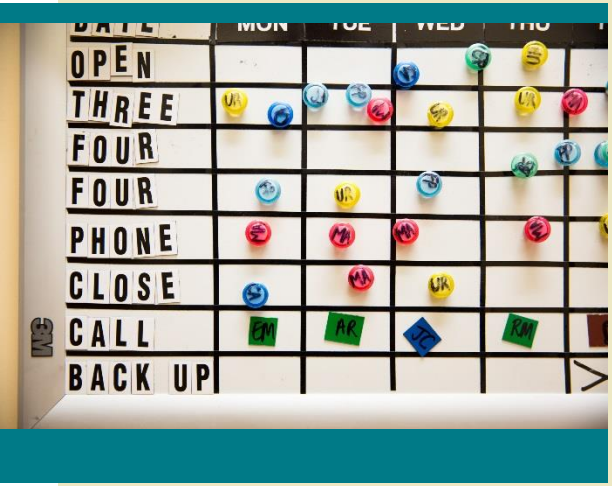
An unreliable system for specimen handling led to a delayed diagnosis and treatment.

Safer Care Recommendation

Maintain a chain of custody to track specimens from collection to final disposition. Implement a quality monitoring system, e.g., specimen log. Investigate discrepancies to close potential gaps in test result processing and communication. Incorporate patient huddles and include specimens in a patient care checklist.

Case Study

Lorraine, 27-year-old female



Vulnerability

A lab result that failed to reach the PCP (or Lorraine) also failed to raise an alarm—and exposed her to unnecessary risk.

Safer Care Recommendation

Implement systems that assist in results reconciliation, including confirmation of provider receipt, review, and transmission of results and recommendations to the patient. When possible, use electronic health record reminders in this effort.

Practice Assessment

Has this type of event ever happened here?

Practice Assessment

Closing the Loop

Do we have a process to track that collected specimens are sent to the lab?

Recommended Practice

A standard process for appropriate specimen collection and management.

Practice Assessment

Closing the Loop

Do we have a standard process for specimen handling that all team members follow? How do we ensure the process is being followed?

Recommended Practice

A redundant system to identify that patient had recommended test.

Practice Assessment

Closing the Loop

How is the ordering provider's review/ acknowledgement of outstanding imaging studies and other tests reconciled?

Recommended Practices

- A responsible person(s) is identified as accountable for specimen processing.
- Specimen handling is included during staff orientation and annual competencies review.

Practice Assessment

Closing the Loop

What other processes, similar to specimen handling, pose major risks to our patients?

Recommended Practice

Analyze similar events (including near misses) for patient safety improvement opportunities.

Practice Assessment

Closing the Loop

What policy or training do we have for conducting a disclosure and apology?

Recommended Practice

Standard protocol and training for disclosure errors to patients/family members.

Practice Assessment

Closing the Loop

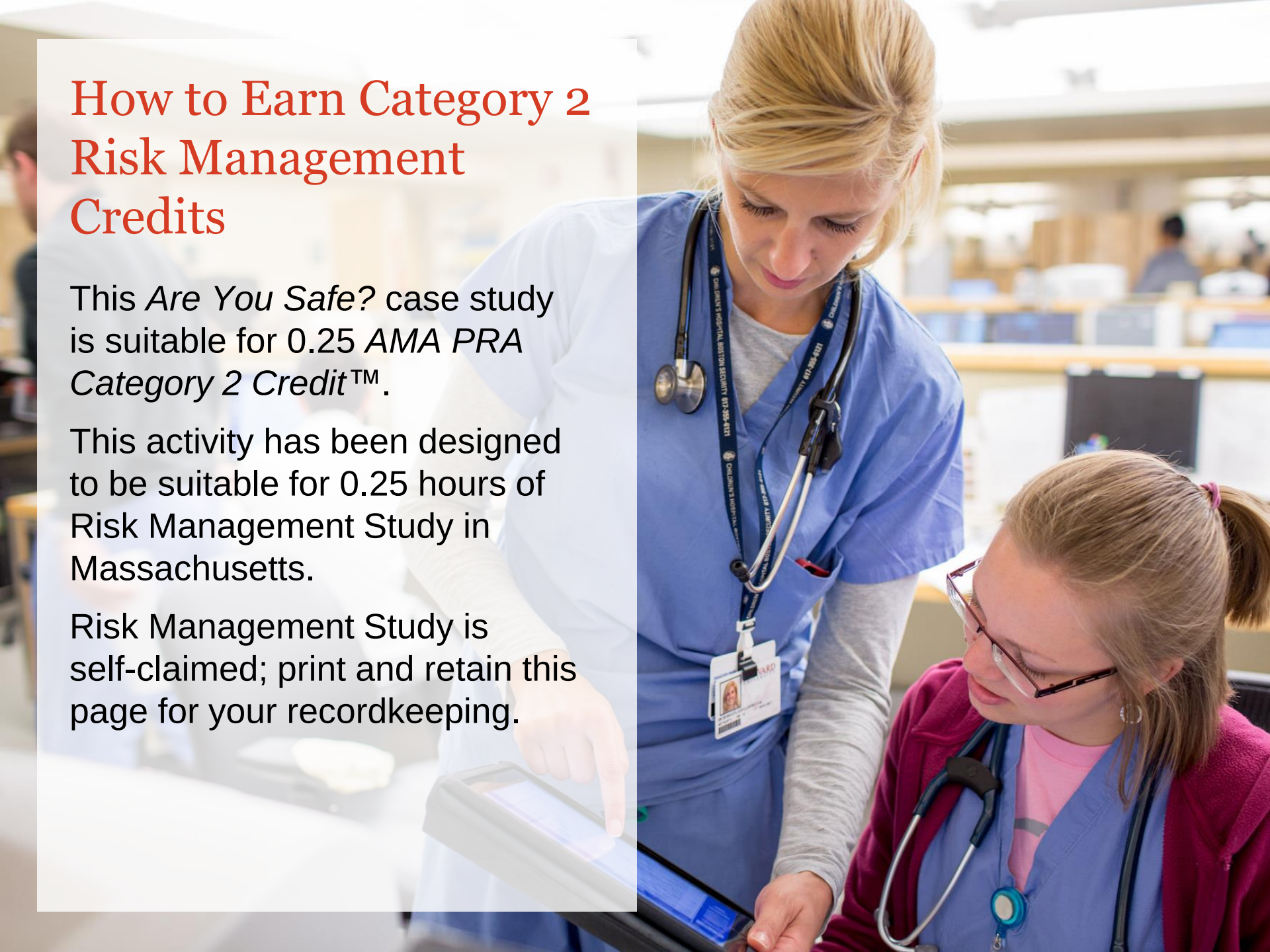
What else can we do to avoid a similar event?

How to Earn Category 2 Risk Management Credits

This *Are You Safe?* case study is suitable for 0.25 *AMA PRA Category 2 Credit*™.

This activity has been designed to be suitable for 0.25 hours of Risk Management Study in Massachusetts.

Risk Management Study is self-claimed; print and retain this page for your recordkeeping.



Additional Resources

Closing the Loop:
Is my specimen handling process reliable?

Are You Safe? extras

For more information

Email

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