crico | Protecting Providers. Promoting Safety.

Safer Care for Office Practice

Cancer Assessment:
Inadequate Management of a Patient-detected Breast Lump

Opportunities for Improving Patient Safety

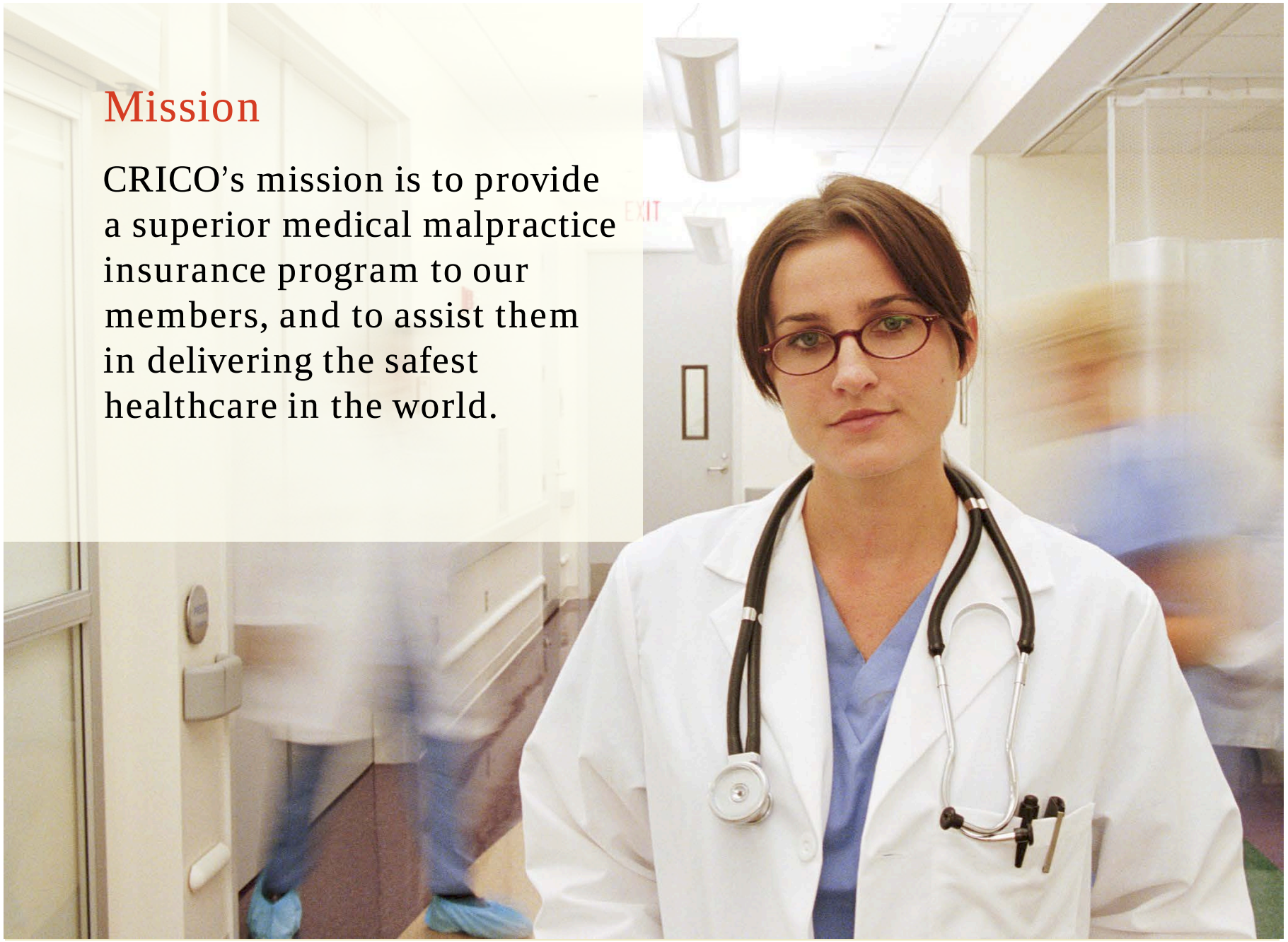
- **Identified through** CRICO's Office Practice Evaluation program and analysis of medical malpractice case data
- **Based on** real events that have triggered malpractice cases
- **Valuable lessons** in communication, clinical judgment, and patient care systems

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:
  - 12,400+ physicians *(including nearly 4,000 residents and fellows)*
  - 32 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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47% of CRICO malpractice cases occur in the ambulatory setting.

35% of ambulatory cases allege a wrong or delayed diagnosis.

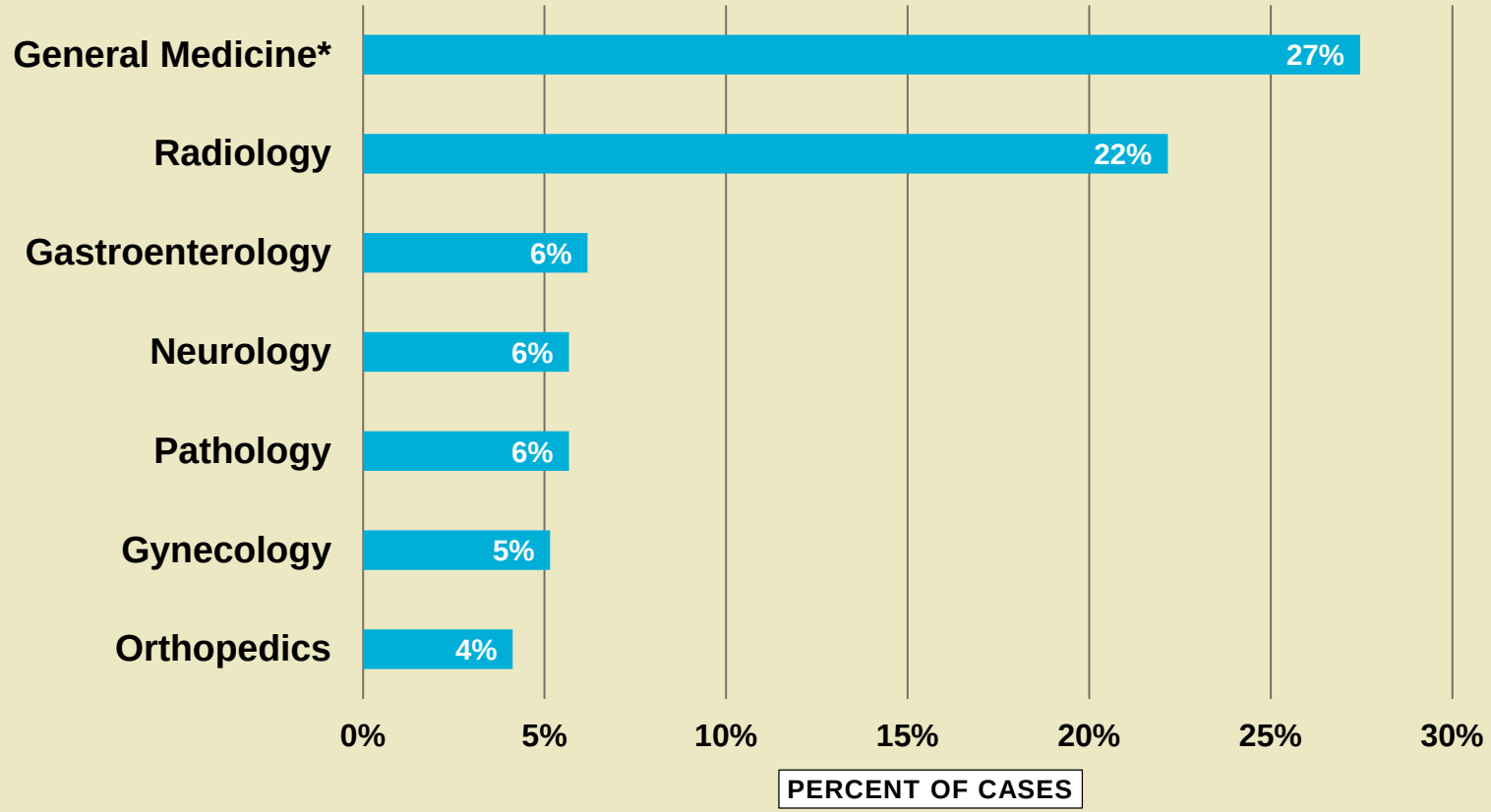
1,161 cases	$618M losses*	• filed 2009–2013
544 cases	$237M losses*	• filed 2009–2013, *and* • involving ambulatory care**
194 cases	$162M losses*	• filed 2009–2013, *and* • involving ambulatory care,** *and* alleging a wrong or delayed diagnosis

*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.

General Medicine and Radiology are most frequently involved.

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



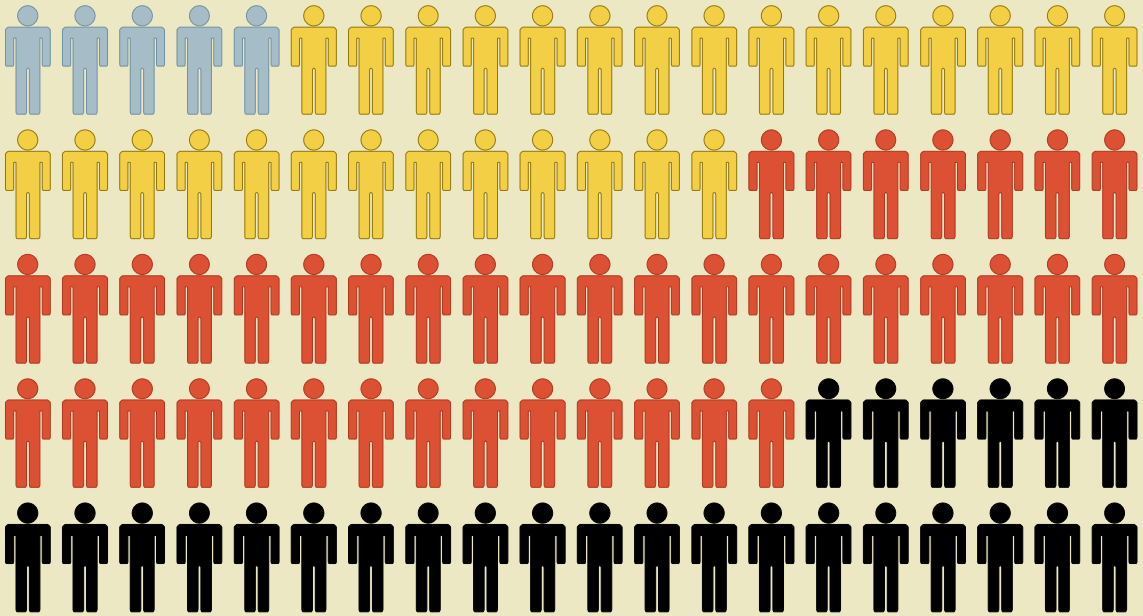
CRICO N=194 MPL cases asserted 1/1/09–12/31/13 involving ambulatory care and alleging diagnostic failure.

*General Medicine includes Internal Medicine and Family Practice.

194 cases

Two-thirds of cases involve permanent injury or death.

Injury Severity in Ambulatory Diagnosis Cases



CRICO N=194 MPL cases asserted 1/1/09–12/31/13 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 194 ambulatory diagnosis-related cases involve a cancer related allegation.

- 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: Cancer Assessment

Patient-detected Breast Lump

The following example is from a closed malpractice case.

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	2%	1%
2. History/physical	8%	7%
3. Patient assessment/evaluation of symptoms	39%	26%
4. Diagnostic processing	45%	34%
5. Order of diagnostic/lab test	43%	31%
6. Performance of tests	6%	3%
7. Interpretation of tests	32%	23%
8. Receipt/transmittal of test results (to provider)	3%	5%
9. Physician follow up with patient	26%	18%
10. Referral management	11%	19%
11. Provider-to-provider communication	13%	12%
12. Patient compliance with follow-up plan	8%	15%

*A case will often have multiple factors identified.

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

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

CBS N=2,685 MPL cases asserted 1/1/09–12/31/13 involving ambulatory care and alleging diagnostic failure.

Malpractice case study focus: Patient Assessment

39%

of cases

had an error in patient assessment identified as a contributing factor, i.e., the patient's complaints or symptoms were not thoroughly addressed

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

Case Study

Patient

Gina, 34-year-old female

Day 1

Gina is seen in her gynecologist's office for a self-detected breast lump. Her physical exam is noted as normal. The gynecologist orders a mammogram, but does not indicate Gina's complaint (lump) on the order.

Case Study

Gina, 34-year-old female

Four months later

- Gina undergoes a screening mammogram, which is reported as “normal” with a “very dense stromal pattern” noted.
- The gynecologist receives the Radiology report, which does not recommend an ultrasound.

Case Study

Gina, 34-year-old female

Nine months later

Gina returns to her gynecologist, complaining of the same breast lump. The gynecologist palpates the lump and orders a diagnostic mammogram and surgical consult. The workup reveals breast cancer.

Case Study

Gina, 34-year-old female

Outcome

- Gina undergoes a radical mastectomy and axillary node dissection; she has metastases to her spine.
- *After* her diagnosis, Gina's medical record was updated to reflect that her family history included a relative with breast cancer.

Case Study

Gina, 34-year-old female w/fh of Breast Cancer

Vulnerability

Failure to order the appropriate test and consult led to a delayed diagnosis.

Safer Care Recommendation

Prioritize efforts to decrease diagnosis-related harm through use of decision support tools such as the *CRICO Breast Care Management Algorithm*.

Case Study

Gina, 34-year-old female w/fh of breast cancer

Vulnerability

Failure to update Gina's family history led to a missed opportunity to identify her as at increased risk for breast cancer.

Safer Care Recommendation

Consider using a checklist or template for details that are often overlooked (e.g., family history) but can be relevant for improving diagnostic reasoning.

Practice Assessment

Has this type of event ever happened here?

Practice Assessment

Cancer Assessment

Does our clinical team use disease-specific recommended guidelines?

Recommended Practice

Identify relevant clinical guidelines (e.g., *CRICO Breast Care Management Algorithm*) for all practice providers.

Practice Assessment

Cancer Assessment

How do we incorporate recommended guidelines into our provider education and practice?

Recommended Practices

- Educate staff regarding implementation of practice guidelines and periodically audit compliance.
- Establish a systems-based process to identify that patients undergo recommended tests per guidelines.

Practice Assessment

Cancer Assessment

What else can we do to avoid a similar event?

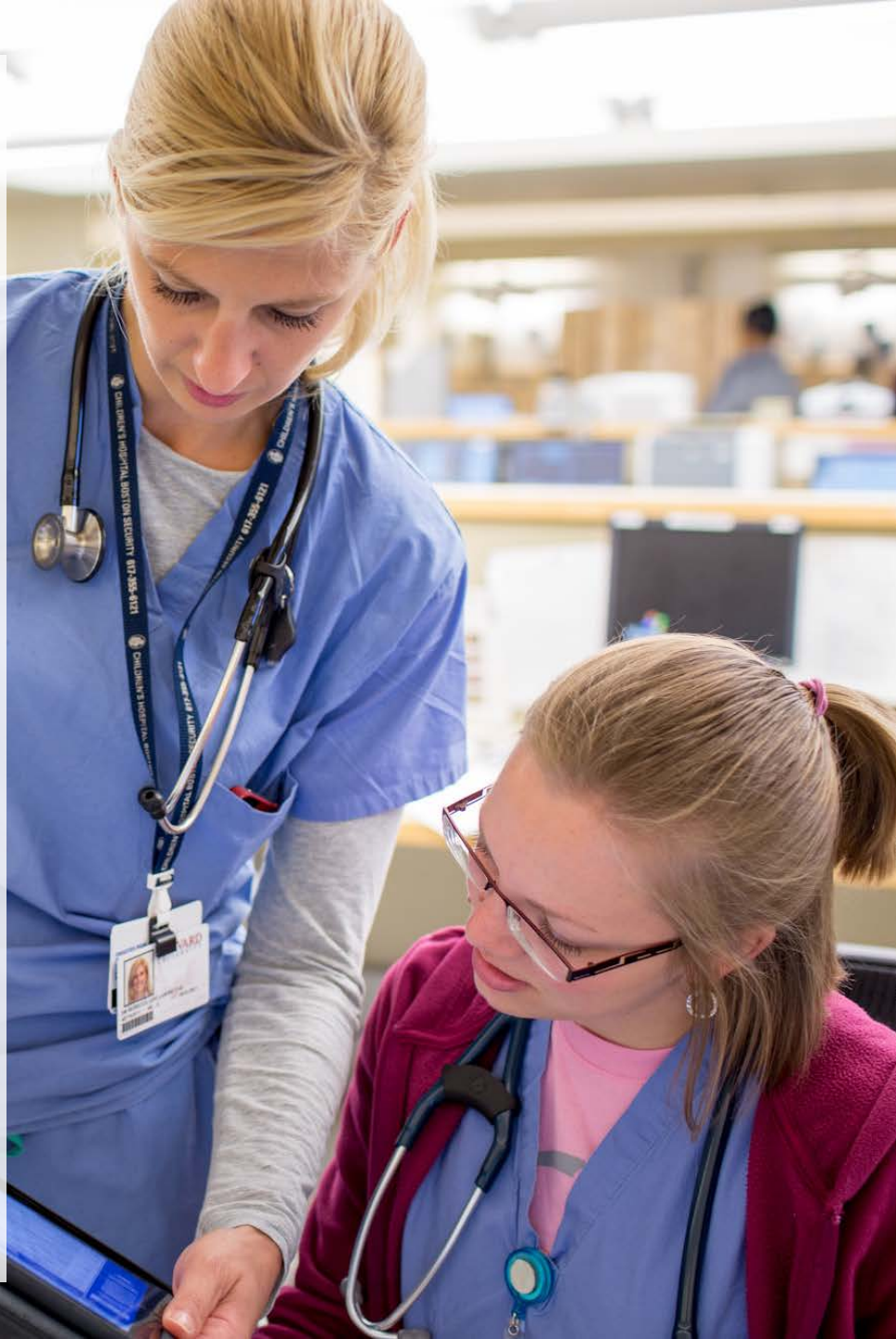
Additional Resources

Cancer Assessment:
Inadequate Management of a Patient-detected Breast Lump

Safer Care extras

For more information

Email
safercare@rmf.harvard.edu



Facilitator's Guide

This Guide supports presentation of a CRICO *Safer Care* module via the print, online, and presentation format.

Purpose

CRICO's *Safer Care* modules provide a brief overview illustrating how a systems-based problem in an office practice led to an actual malpractice case. For each module, the vulnerabilities that most likely triggered the malpractice allegation are highlighted, along with recommended best practices, discussion questions, and prompts to assess your practice's processes related to the risks identified in the case. Together, the components of each module can help you identify opportunities to improve your practice.

Audience

The *Safer Care* modules draw on experiences from primary care providers in Internal or Family Medicine practices. However, many of the inherent lessons are applicable to outpatient specialty care practices. The modules are intended for all members of your team (physicians, advanced care providers, nurses, medical assistants, allied health professionals, administrative staff). Each module highlights ambulatory patient safety risks/vulnerabilities to stimulate discussion and help your practice identify opportunities to assess and (if necessary) improve systems.

Feedback to CRICO

Please help improve and expand the value of the *Safer Care* modules by sharing feedback about the content and the learning process with CRICO via safercare@rmf.harvard.edu.

WHAT YOU WILL NEED

- Computer and projector, or handouts
- Enough time (e.g., 30 minutes) to discuss the patient safety concerns that relate to your practice

PREPARATION TIPS

- Do a test run (preferably in the actual venue) to ensure that all equipment is working correctly

PRESENTATION COMPONENTS

(applies to all *Safer Care* module slide presentations)

1. Background (slides 1–6): CRICO's role in patient safety
2. Malpractice data (slides 7–11): focus on ambulatory diagnosis related allegations
3. Diagnostic process of care vulnerabilities (slides 13–14): vulnerabilities identified in the diagnostic process of care via malpractice cases. CRICO's coding taxonomy enables data analyses from patient access to the health care system to diagnosis to follow-up plan, and helps identify common breakdowns throughout the process.
4. Closed malpractice case chronology: follows the case from initial presentation to outcome
5. Vulnerabilities from case: one or two aspects of the case that most likely triggered the allegation of malpractice, with recommendations for avoiding similar missteps
6. Practice assessment and improvement opportunities: each module features a quick assessment, with questions related to the case example and the underlying patient safety issues. While each module features topic-specific questions, all begin with "Has this type of event happened at our practice?"
7. *Safer Care* extras: Links to additional topic-related content on the CRICO website, including case studies, decision support tools, and evidence-based articles.

Facilitator's Guide: Cancer Assessment

Risk: Inadequate management of a patient-detected breast lump

Discussion Tips

Each Safer Care module includes prompts for discussing the vulnerabilities exposed by the case example, and for assessment of your practice/systems. Focus on the broader patient safety issues that may impact future care. Limit narrow analyses of the facts, this case is an illustrative example to initiate discussion.

- Acknowledge that discussions about medical errors, delays in care, or patient grievances are difficult for the individuals involved and impacts the entire care team/ practice.
- Frame the conversation, for example: the purpose of this discussion is to learn from what occurred, identify opportunities to improve the system, and prevent recurrence of a similar event
- Recognize that everyone comes to work to help others but, at times, systems do not support the individual.
- Engage multiple perspectives in discussions related to patient safety vulnerabilities by soliciting input from all disciplines.

Practice Assessment & Improvement Tips

This is a team-wide opportunity to review whether this could happen at your practice and identify improvement opportunities.

CASE CHRONOLOGY

34-year-old female, benign health history

First MD Appointment

- Patient presented to her gynecologist with a self-detected breast lump
- The gynecologist exam is documented as "normal"
- An order was placed for a screening (not diagnostic) mammogram. The order did not note the patient's self-detected lump

Four Months Later

- Patient underwent screening mammogram
- Mammogram noted as "normal" with "very dense stromal pattern" (reduces sensitivity for cancer detection)
- Ultrasound not recommended
- Report reviewed by gynecologist; no further evaluation initiated

Nine Months Later

- Patient returns to gynecologist expressing concern re: same breast lump
- Gynecologist palpates lump and orders diagnostic mammogram and surgical consult

OUTCOME

- Patient evaluated by surgeon; ultrasound, MRI, and biopsy completed.
- Patient diagnosed with ductal carcinoma with lymph extension into 6 of 18 nodes
- ***Case Disposition: Settled in the high range ($500,000-$999,999)***

KEY LESSONS

- Following established decision support tools, e.g., *CRICO Breast Care Management Algorithm* can help reduce diagnosis-related harm. In this example, screening mammogram was ordered when diagnostic mammogram appropriate (even without knowledge of family history).
- Updating personal/ family history at time of initial complaint can help clinical decision making.