Safer Care for Office Practice

Internal Office Function:
*Mismanaged Specimen*
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.
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.

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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

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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

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Malpractice Data Overview

Focus: Ambulatory Diagnosis-related Allegations
47% of CRICO malpractice cases occur in the ambulatory setting.

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

<table>
<thead>
<tr>
<th>Cases</th>
<th>Losses*</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,161</td>
<td>$618M</td>
<td>• filed 2009–2013</td>
</tr>
<tr>
<td>544</td>
<td>$237M</td>
<td>• filed 2009–2013, and</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• involving ambulatory care**</td>
</tr>
<tr>
<td>194</td>
<td>$162M</td>
<td>• filed 2009–2013, and</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• involving ambulatory care, ** and alleging a wrong or delayed diagnosis</td>
</tr>
</tbody>
</table>

*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

<table>
<thead>
<tr>
<th>Clinical Service</th>
<th>Percent of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Medicine*</td>
<td>27%</td>
</tr>
<tr>
<td>Radiology</td>
<td>22%</td>
</tr>
<tr>
<td>Gastroenterology</td>
<td>6%</td>
</tr>
<tr>
<td>Neurology</td>
<td>6%</td>
</tr>
<tr>
<td>Pathology</td>
<td>6%</td>
</tr>
<tr>
<td>Gynecology</td>
<td>5%</td>
</tr>
<tr>
<td>Orthopedics</td>
<td>4%</td>
</tr>
</tbody>
</table>

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.
Two-thirds of cases involve permanent injury or death.

Injury Severity in Ambulatory Diagnosis Cases

- 5% low
- 28% medium
- 67% high (including death)

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: Internal Office Function Mismanaged Specimen

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

<table>
<thead>
<tr>
<th>STEP</th>
<th>CRICO % CASES</th>
<th>CBS % CASES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Patient notes problem and seeks care</td>
<td>2%</td>
<td>1%</td>
</tr>
<tr>
<td>2. History/physical</td>
<td>8%</td>
<td>7%</td>
</tr>
<tr>
<td>3. Patient assessment/evaluation of symptoms</td>
<td>39%</td>
<td>26%</td>
</tr>
<tr>
<td>4. Diagnostic processing</td>
<td>45%</td>
<td>34%</td>
</tr>
<tr>
<td>5. Order of diagnostic/lab test</td>
<td>43%</td>
<td>31%</td>
</tr>
<tr>
<td>6. Performance of tests</td>
<td>6%</td>
<td>3%</td>
</tr>
<tr>
<td>7. Interpretation of tests</td>
<td>32%</td>
<td>23%</td>
</tr>
<tr>
<td>8. Receipt/transmittal of test results (to provider)</td>
<td>3%</td>
<td>5%</td>
</tr>
<tr>
<td>9. Physician follow up with patient</td>
<td>26%</td>
<td>18%</td>
</tr>
<tr>
<td>10. Referral management</td>
<td>11%</td>
<td>19%</td>
</tr>
<tr>
<td>11. Provider-to-provider communication</td>
<td>13%</td>
<td>12%</td>
</tr>
<tr>
<td>12. Patient compliance with follow-up plan</td>
<td>8%</td>
<td>15%</td>
</tr>
</tbody>
</table>

*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: Internal Office Function

6% 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.
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.
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

Internal Office Function: *Mismanaged Specimen*

_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

Internal Office Function: Mismanaged Specimen

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

Internal Office Function: Mismanaged Specimen

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

Internal Office Function: *Mismanaged Specimen*

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.
Recommended Practice

Standard protocol and training for disclosure errors to patients/family members.
Practice Assessment
Mismanaged Specimen

What else can we do to avoid a similar event?
Additional Resources

Internal Office Function: *Mismanaged Specimen*

**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.

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.

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.
Facilitator’s Guide: Internal Office Function
Risk: Mismanaged specimen

CASE CHRONOLOGY
27-year-old female, benign health history

Day One
• Presents to PCP with frequency and burning on urination
• Urine culture and sensitivity (C&S) ordered
• Urine specimen obtained in the PCP office
• Preliminary diagnosis: urinary tract infection
• Patient sent home with prescription for Bactrim

Test Result:
• Urine C&S is not sent to lab due to office processing error

Day 14
• Patient calls PCP with increased symptoms including “excruciating” back pain
• PCP refers patient to ED
• In ED, urinalysis (reveals 3+ bacteria) and urine C&S are sent to lab
• Patient discharged home with renewed prescription for Bactrim

Day 16
• Patient returns to ED with fever, nausea, and vomiting; she is admitted
• Results of patient’s urine C&S (from first ED visit) confirm E. coli infection—not sensitive to Bactrim.
• After course of intravenous antibiotics, patient discharged home with peripheral inserted central catheter (PICC) line for home antibiotic treatment
• PCP discloses and apologizes for initial urine C&S never being sent to lab

OUTCOME
• Case Disposition: Settled in the low range (<$100,000)

KEY LESSONS
• A chain of custody helps to track specimens through the process. Specimens logs are recommended as they identify who obtained and sent the specimen should tracking become necessary.
• Office practices must establish a secure process for managing specimens, including reconciliation of specimens obtained and sent. There must also be a process for the receipt of the results by the office to the provider, and finally to the patient.
• Electronic tracking solutions should be used when possible as they may reduce risk of human errors being made when relying on manual handwritten logs.
• A misstep in this process can lead to unnecessary complications—in this case hospitalization, the need for IV antibiotics, insertion of a PICC line, and the need for home nursing care.

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.