**Overview**

More and more, health care is delivered at an office-based setting. For patients, clinicians, and non-clinical staff, the safety culture and systems underlying office-based care varies significantly from inpatient care—and from one practice to another. Through its Office Practice Evaluation (OPE) program and analysis of medical malpractice case data, CRICO and its primary care community identified six key safety principles in primary care. In concert with clinical experts and experienced office-based providers, CRICO produces *Are You Safe?* to help practices understand and address potential risks to patient safety via malpractice data and case examples.

The *Are You Safe?* case studies are designed to help all members of the team reduce the risk of patient harm in the course of diagnosis and treatment. Office-based events that trigger malpractice cases present valuable opportunities to identify vulnerabilities in communication, clinical judgment, and patient care systems. *Are You Safe?* is designed to meet the following objectives:

- Highlight common office-based malpractice risks
- Explore areas of improvement in your practice

**FOCUS**

*Are You Safe?* case studies are being developed for specific risks organized under a broader outline of six key safety principles in primary care:

- Establish and sustain a culture of safety
- Build and support effective teams
- Partner with patients and families in their care
- Ensure closed-loop processes for referrals and tests
- Develop systems for reliable diagnosis and delivery of evidence-based care
- Standardize communication among all care providers

Each *Are You Safe?* case study focuses on a single area of risk, but addresses issues that arise across a range of patient presentations, diagnoses, and clinical scenarios.

**USING THE ARE YOU SAFE? CASE STUDIES**

**Download a PowerPoint**

In addition to the two-page worksheet, CRICO has produced PowerPoint presentations for use by providers and practice staff interested in sharing one (or more) of the *Are You Safe?* case studies with colleagues. The PowerPoint presentations include additional data and complementary information. *Are You Safe?* presentations can be downloaded from the CRICO website.

**Additional Resources**

For each *Are You Safe?* case study, additional related materials developed by CRICO and other leaders in patient safety are made available on our website: www.rmf.harvard.edu/areyousafe. These include:

- CME bundles
- Podcasts
- Clinical decision support tools
- Patient safety alerts
- Additional case studies

**Earn Category 2 Risk Management Credits**

Each *Are You Safe?* case study is suitable for 0.25 Category 2 risk management credit for MA physicians. Practices may be able to earn additional CME credits by developing education sessions that employ multiple cases along with pre- and post-course testing.

**Participation and Feedback**

CRICO hopes the *Are You Safe?* case studies will help raise awareness about the patient safety issues that most commonly put patients and providers at risk. We know that you are our best source for what does and does not work in everyday practice, and we encourage you to share your ideas, concerns, and innovations with us and your peers across the CRICO-insured community.

Email comments, resources, or questions to areyousafe@rmf.harvard.edu.
Overview, continued

CASE STUDY COMPONENTS

Closed Malpractice Cases

The Are You Safe? case examples are drawn from actual events. Every case in the CRICO database is coded to catalogue what happened, and why. The provider-based and systems-based factors that led to the allegation of malpractice are the underpinning of CRICO’s patient safety initiatives, and drive the case selection process.

Patient Safety Vulnerabilities

For each malpractice case presented, the Are You Safe? case studies identifies two or three key vulnerabilities exposed by the event. For each, Safer Care recommendations are included. These vulnerabilities and recommendations are designed to guide the risk assessment process for individuals or teams reviewing each module.

Data

Our goal is to present data and case examples that help caregivers anchor the underlying issues that pose risk to patients and providers. The data are drawn from malpractice cases filed against CRICO-insured providers as well as from our national comparative benchmarking system (CBS) repository of more than 350,000 claims and suits.

Improvement Opportunities Matrix

Each Are You Safe? case study includes a list of recommended practices related to the patient safety vulnerabilities identified in malpractice data and case examples. Practices are encouraged to compare their current practice to the recommended practice and, if necessary, explore possible improvements.

<table>
<thead>
<tr>
<th>RECOMMENDED PRACTICE</th>
<th>CURRENT STATE</th>
<th>HOW TO IMPROVE (IF NECESSARY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most often, the “recommended practice” is a general concept rather than a specific tool or methodology. This enables providers and practices to focus on the intended result rather than the approach. While the CRICO Are You Safe? modules offer suggestions for assessing and addressing patient safety, they should not be construed as a standard of care.</td>
<td>For the gap analysis to be productive, the current state (&quot;how we do things now&quot;) should be compared to the identified recommended practices. To be most dynamic, this should be explored from a variety of perspectives—either by soliciting input from a cross-section of clinical and non-clinical staff, or via group discussion.</td>
<td>While some improvements may lend themselves to a quick fix, practices are likely to identify issues that require more time and thought. Addressing one issue at a time might be more productive than taking on too many improvements at once.</td>
</tr>
</tbody>
</table>

CRICO’s mission is to provide a superior medical malpractice insurance program to our members, and to assist them in delivering the safest health care in the world. CRICO, a recognized leader in evidence-based risk management, is a group of companies owned by and serving the Harvard medical community.
Is my specimen handling process reliable?

**RISK: MISMANAGED SPECIMEN**
Patient suffers unnecessarily due to improper management of lab specimen obtained during a physician office visit

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**Closed Malpractice Case**

A 27-year-old female was seen in the office for complaints of frequency and burning on urination. A urine culture and sensitivity (C&S) was ordered. The patient was prescribed Bactrim and instructed to follow up with any ongoing issues. The urine specimen was never sent to the lab. Two weeks later, the patient called the office with complaints of excruciating back pain, and was referred to the emergency department. In the ED, urinalysis confirmed 3+ bacteria. Urine C&S was sent, the patient’s Bactrim prescription was renewed, and she was discharged.

Two days later, the patient was admitted to the hospital through the ED with fever, nausea, and vomiting. The urine C&S obtained in the ED confirmed E-coli (not sensitive to Bactrim), and a new antibiotic was ordered. After a four-day inpatient admission, the patient was discharged home with a peripherally inserted central catheter line for prolonged antibiotic treatment. A disclosure and apology to the patient revealed that her urine C&S had never been sent from the initial office visit.

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**Diagnostic Process of Care in Ambulatory Diagnosis Cases**

Test performance is a contributing factor in 5% of CRICO (3% of CBS) ambulatory cases alleging a missed or delayed diagnosis.

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

* Cases with claim made date 1/1/11–8/31/16
** A case will often have multiple factors identified
† CBS is CRICO’s Comparative Benchmarking System

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**Patient Safety Vulnerabilities**

1. A lack of reliable systems for specimen handling can lead to missed opportunities for earlier treatment.

**SAFER CARE:** 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.

2. Imaging, diagnostic, or lab results that fail to reach you or your patients—or if the information is not integrated into the care plan—exposes patients to unnecessary risk.

**SAFER CARE:** Implement systems that assist in reconciliation of all results, including confirmation of provider receipt, review, and transmission of results and recommendations to the patient. When possible use electronic health record (EHR) reminders in this effort.
Quick Assessment

1. Has this type of event happened at our practice?
2. How does our practice reconcile that requested labs are completed and reviewed by a clinician?
3. Does our practice have a process to track that collected specimens are sent to the lab?
4. Do we have a standardized process for specimen handling that all team members follow? How do we ensure the process is being followed?
5. What other processes, similar to specimen handling, pose major risks to our patients?

Improvement Opportunities

<table>
<thead>
<tr>
<th>RECOMMENDED PRACTICE</th>
<th>CURRENT STATE</th>
<th>HOW TO IMPROVE (IF NECESSARY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. A standard process for appropriate specimen collection and management</td>
<td></td>
<td></td>
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<tr>
<td>2. A responsible person is identified as accountable for specimen processing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Specimen handling is included during staff orientation and annual competencies review</td>
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</tr>
</tbody>
</table>

CRICO Are You Safe? materials are designed to help all members of a multidisciplinary team reduce the risk of patient harm in the course of diagnosis and treatment. Office-based events that trigger malpractice cases present valuable opportunities to identify vulnerabilities in communication, clinical judgment, and patient care systems. Successful practices shared by local and national peers inform the Are You Safe? recommendations. CRICO works closely with your organization’s Patient Safety and Risk Management staff to build expert resources for individual and team-based education and training.

Email comments, resources, or questions to areyousafe@rmf.harvard.edu.

Additional Resources

www.rmf.harvard.edu/safercare

Please visit the CRICO website for related:

- CME Bundles
- Podcasts
- Clinical Decision Support
- PowerPoint presentations to share with your team
- Patient Safety Alerts
- Additional topics in the Are You Safe? series

How to Earn Category 2 Risk Management Credits

This Are You Safe? case study is suitable for 0.25 Category 2 risk management credit for Massachusetts physicians. Risk Management Study is self-claimed; complete, date, and retain this page for your record keeping.

About CRICO

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