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FORUM

Patient Safety Target Areas

In this issue: Four Stories

CRICO/RMF analyzed malpractice claims to determine the areas of greatest risk (see "Narrowing the Focus for Patient Safety," next page). These four closed case analyses illustrate the target areas identified.

Case 1: Diagnosis
Four months after giving birth, 28-year-old Jasmina Carabone* presented at her physician's office with complaints of epigastric, upper abdominal, and lower chest pain. Although she told her PCP that her pain "did not feel like heartburn," he diagnosed gastroesophageal reflux disease (GERD) and prescribed ranitidine to reduce acid production in the stomach. Six months later, it was determined that Jasmina was suffering from acute renal failure and had experienced irreversible kidney damage. She eventually underwent a renal transplant that later failed. She is currently on dialysis.

For the complete case analysis, see Page 5.

Case 2: Medication
After surgery to repair a congenital abnormality of his biliary tree, 34-year-old Alex Page suffered from repeated episodes of obstruction and infection. During one of several hospital admissions for infection, he received a small amount of cefotetan and had an anaphylactic reaction. Alex's reaction was noted in his record and added to the list of medications to which he was allergic. On his physician's advice, Alex wore a medic alert bracelet that indicated his drug allergies. Several months later, after a second surgery, Alex was readmitted for a post-op infection, and was accidentally given cefotetan.

For the complete case analysis, see Page 7.

Case 3: Obstetrics
In the 41st week of her first pregnancy, Tina Constanople was induced with misoprostol. Five hours later, Tina's membranes ruptured spontaneously. On several occasions over the next three-and-a half hours, the fetal heart rate strips indicated non-reassuring patterns, but during the last 45 minutes, Tina was not evaluated by a resident nor by an attending physician. After an unsuccessful attempt at forceps delivery, a cesarean delivery followed, and the baby was stillborn. Tina's uterus was discovered to have ruptured.

For the complete case analysis, see Page 8.

Case 4: Surgery
While jumping off a boat dock at a friend's summer cottage, 20-year-old Dan Bockman injured his lower back. Two days later Dan, who is diabetic, underwent surgical repair of a burst lumbar spine fracture. During the 12-hour surgery, Dan lost nearly twice his circulating blood volume. Afterwards he complained of not being able to see, and partial paralysis of both legs. Today he is legally blind and requires braces to walk.

For the complete case analysis, see Page 11.

* Case studies presented in Forum are based on actual clinical events involving health care providers insured through Controlled Risk Insurance Company (CRICO). Names and other identifying facts have been changed.

Narrowing the Focus for Patient Safety

by John L. Mc Carthy

Jack Mc Carthy is President of CRICO/RMF.

Figure 1

CRICO's Top Areas of Patient Safety Risk

N=2,270 cases filed 1995–2005*

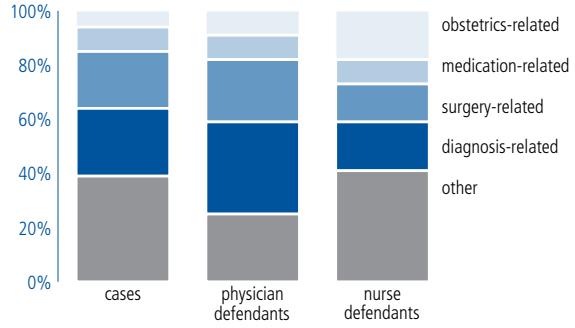

Figure 2

CRICO Cases Asserted 1995–2005*

Cases (claims and suits)	**2,270**	
Open	601	
Closed	1,669	
Physician Defendants	**2,353**	
Staff	1,844	(78%)
Fellows	91	(4%)
Residents	418	(18%)
Top Specialties Named	**2,353**	
Internal Medicine	420	
Obstetrics/Gynecology	374	
General Surgery	248	
Orthopedics	157	
Radiology	145	
Nurse Defendants	**315**	
RNs	263	
NPs	22	
CNMs	27	
Other	3	
Top Injuries	**2,270**	
Death	443	
Emotional trauma	253	
Condition worsened	150	
Adverse reaction	138	
Malignancy	111	
Top Risk Management Issues	**6,683**	
Possible technical problem	271	
Miscommunication among providers	258	
Failure to, or delay in, ordering tests	230	
Selection/management of surgery/invasive therapy	158	
Misinterpretation of diagnostic studies	147	

CRICO Cases Closed 1995–2005*

Cases (claims and suits)	**1,669**	
Closed with payment	715	(32%)
Average payment (of those closed with payment)	$466,000	
Average defense cost (of all closed cases)	$41,000	

*September 1995–August 2005

Medical malpractice cases are often filed after outcomes have not matched what patients expected. While it is true that some of these events have such unusual attributes that it is difficult to find anything "teachable," a much greater number of these cases provide informative snapshots of where processes, systems, and sometimes individual behaviors have truly failed the patient or the patient's family. Conversely, the care may have met professional standards, but an unexpected outcome was exacerbated by poor communication, leading to a decision to sue for malpractice.

Certainly, the four patient stories told elsewhere in this issue are not typical health care experiences. But neither are these four patients' malpractice claims atypical; each year, 200 to 300 patients file malpractice claims and suits against CRICO-insured providers. Across the country the number approaches 90,000 cases annually.[1] While each case has unique attributes, experts are gaining insight by looking at cases as symptoms of a larger problem, not as isolated events. Quite often, the providers named in a claim or suit were just one part of a system that failed to support optimal care or reconcile errors.

The Nagging Questions

The events retold in these examples are, by definition, unexpected. The nagging questions challenging patient safety experts and others seeking to reduce patient injuries are "What *can* we predict, what *can* we prevent, and what systems *can* we build to interrupt and counterbalance those errors we can neither predict nor prevent?" Unfortunately, even the most diligent efforts cannot pinpoint precisely when and to whom an adverse outcome will occur. The wide range of total patient-clinician encounters hinders attempts to detect the (very) few particular events that will lead to unnecessary harm.

Nevertheless, that is the challenge CRICO/RMF has taken on. With nearly 30 years of clinical observation, data collection, and expert analysis, CRICO/RMF has the raw materials for narrowing the focus of patient safety initiatives. The most potentially fruitful source is recently filed malpractice cases associated with severe injuries or death (high-severity cases). Two significant reasons for focusing on this subset of cases are: 1) high-severity cases will likely lead to the most efficient reduction of all types of patient injuries, and 2) plaintiffs' attorneys are more posed to pursue high-severity cases that they perceive as more winnable and profitable.

Finding Commonalities

The first step in CRICO/RMF's effort to narrow the focus for patient safety was to distinguish the broad categories. Four "target" areas *(Figure 1)* constitute two-thirds of the high-risk patient encounters where CRICO/RMF is now focusing programs and initiatives. The cases within these target areas offer solid footing for beginning more detailed analysis. They also reveal patient safety risks common across the full range of case categories *(see sidebar, Page 3)*.

Continued on next page

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The second step involved analyzing the cases within each target area to pinpoint the factors common to a significant percent of cases. What "types" of surgery-related cases (or obstetrics-related, etc.) recur and what makes them similar? Is there a certain type of patient who gets hurt; is there a certain type who files a lawsuit? Do clinicians who get sued demonstrate specific behavioral traits; is there a susceptible bedside manner? Do events that lead to patient harm (that then lead to claims and suits) occur in particular settings; do they *really* occur late at night and on weekends? Do some drugs get misprescribed, or misadministered, more than others? Does a left-handed surgeon encounter risks her right-handed peers don't?

Initial analysis of the high-severity cases led to more precise questions in each category. The third step in narrowing the focus of patient safety efforts and directing resources was to initiate a dialogue with researchers and clinical leaders. The data, studies, analysis, and the claims themselves became the basis for action. For example:

- When an analysis of obstetrics-related cases indicated that many errors could have been prevented by better teamwork, CRICO/RMF put its support behind a project to see how teamwork training in labor and delivery units could reduce such errors.[2]
- The discovery that mismanagement of patients on anticoagulant therapy was a common factor in medication cases drove efforts to develop safer systems for patients on Coumadin therapy.
- A human factors engineering study of operating room behavior sponsored through CRICO/RMF has identified pre-surgery briefings as an improvement opportunity.[3]
- After understanding that malpractice cases alleging a delay in the diagnosis of colorectal cancer often involved missteps in assessing and stratifying the patient's risk, CRICO/RMF coordinated development of an algorithm to help clinicians and patients better understand the risks and to aid the screening decisions.[4]

Keeping Focus on a Changing Picture

The big picture of what patient safety should look like changes along with clinical discoveries and innovations. Maintaining a focus on this moving target requires both vigilance and flexibility. The glint of new risks can distract resources from unfinished business. On the other hand, an effective solution to a significant risk is often an opportunity to free up resources to address other concerns.

To keep pace, CRICO/RMF continues to work with health care entities to collect and analyze error-related information, while digging deeper within the malpractice claims files to code the data based on systems issues. At the same time, CRICO/RMF looks to patient safety directors and researchers to direct the study of error-related information from near-miss events, which are more frequent and more current than malpractice claims and suits.[5]

Putting Our Money Where Our Mouth Is

CRICO premiums have continued to be stable in the New England area. Financial resources derived from savings on claims costs are being re-directed into patient safety and research. For each of the past three years, the CRICO Board has allocated $500,000 for patient safety research, resulting in an impressive array of high-impact safety studies *(see Page 15)*. Premium incentives have been established for anesthesiologists and for obstetricians who participate in simulation and team training. These efforts and many others cost 5–10 percent of total premium, but everyone involved, from insured physicians to board members, has expressed a willingness to make the necessary investments in patient safety. The results of these efforts are beginning to speak for themselves. ■

Notes and References

1 National Association of Insurance Commissioners

2 Evaluation of the MedTeams Intervention in Labor and Delivery Care, coordinated by Benjamin Sachs, MD, Obstetrician-Gynecologist in Chief, Beth Israel Deaconess Medical Center, Boston, Massachusetts.

3 Roth EM, et al. Using field observations as a tool for discovery: analysing cognitive and collaborative demands in the operating room. *Cognition, Technology & Work* 2004;6(3):148-57.

4 RMF Colorectal Cancer Screening Algorithm: a decision support tool for primary care providers. www.rmf.harvard.edu/reference/guidelines/colorectal/RMFCRC.pdf

5 A malpractice claim or suit need not be filed for up to three years from the date of loss—or discovery of loss—and up to seven years for minors. In some instances, by the time the case details can be captured, coded, and analyzed, more than 10 years has passed since the precipitating event occurred. Potential sources for more timely error information are: incident/near miss reports, online reporting data, root cause analyses, and patient complaints that are already compiled by individual institutions.

Common Factors in CRICO Cases

CRICO/RMF analyzed the factors that contributed to patient injuries and adverse outcomes cited in the most severe cases filed against CRICO-insured health care providers from 1995–2005. Across all types of patient encounters, the following factors occur frequently enough to merit increased attention.

- A clinician fails to share critical patient information with another member of the care team (especially during handoffs).
- A physician does not fully communicate to a patient the risks associated with a procedure.
- The treatment rationale, or a finding from a physical exam, is not fully documented.
- A patient seeing multiple providers for episodic visits goes years without a physical exam or cancer screenings.
- A clinician weighs (and acts upon) diagnostic information differently than another member of the care team.
- Multiple providers fixate on an erroneous assumption or dated information (about symptoms, diagnosis, medications, family history, appointment/testing compliance, etc.).
- A patient exhibiting stress behaviors is not adequately monitored.
- A cesarean-section is delayed.
- A treatment decision triggers a relatively rare adverse drug event.
- A patient's post-operative management is mishandled.
- A clinician lacks the necessary technical skills.
- A patient receives an incorrect and inappropriate drug.
- A foreign object is unintentionally left in the patient following surgery.
- A surgeon's misidentification of an anatomical structure during surgery leads to patient harm.
- Poor systems prevent clinical decision-makers from receiving test results in a timely manner.
- Poor systems impede follow-up of patient care.
- Patients taking high-risk medications, such as anticoagulants, are inadequately managed.
- Care is provided by inadequately trained or supervised residents working in an environment that does not compensate for their inexperience, lack of assertiveness, or workload.

ABOUT FORUM

FORUM provides in-depth analyses of specific medical malpractice cases and issues along with practical loss prevention advice and case abstracts.

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STAFF

Diagnosis-related Risks

by Ann Louise Puopolo, BSN, RN

Ann Louise Puopolo is Program Director, Loss Prevention/Patient Safety for CRICO/RMF.

Approximately one-quarter of all malpractice cases naming CRICO-insured providers involve missed, delayed, or incorrect diagnoses. The vast majority (82 percent) stem from ambulatory care. Almost one-third of the physician defendants in all cases opened from 1995–2005 were named in diagnosis-related cases.

Missed or delayed diagnosis of cancer—especially colorectal, lung, and breast cancer—is the top case type. Other common scenarios include missed myocardial infarctions, pulmonary emboli, meningitis, and aneurysms. At the root of most diagnosis-related cases are the following themes:

- absence of a proper medical history and physical examination;
- narrow diagnostic focus;
- diagnostic tests not ordered;
- critical results of ordered tests not received or not reviewed by the ordering provider;
- inadequate communication of abnormal test results among clinical colleagues and with the patient; and
- incorrect interpretation of test results (by pathologists, radiologists, etc).

Colorectal Cancer

Colorectal cancer cases recently surpassed those involving breast cancer as the most common type filed against CRICO physicians. General medicine physicians are named in these cases three times more than other physician specialty groups. Analysis of colorectal cases identified failure to order diagnostic tests and missed opportunities for assessing the patient's potential risk as the key missteps in patients' care. To address the problem, a committee comprising Harvard general practice gastroenterologists, high-risk gastroenterologists, and primary care physicians (PCPs) developed CRICO/RMF's *Colorectal Cancer Screening Algorithm.* This decision support tool assists PCPs in screening:

- average-risk patients who are asymptomatic, and age 50 or over;
- moderate-risk patients who have a family or personal history of colon cancer and adenomas; and
- high-risk patients who have a genetic syndrome or inflammatory bowel disease.

This tool includes a risk management component to address such diagnostic gaps as assessment of patient risk factors; documentation of patient discussion regarding screening modalities; follow-up of the patient; and coordination of care between gastroenterology and PCPs. The algorithm has been distributed throughout the Harvard medical system, and several institutions are working to embed it (along with the Breast Care Management Algorithm) into their electronic medical record systems. Upon request, educational presentations are made to groups of internists and gastroenterologists.

In addition, an on-line continuing medical education course developed by Harvard physicians in collaboration with CRICO/RMF is available to educate providers with the most recent evidence-based information for assessment of familial and genetic risks for developing colorectal cancer.[1]

An updated edition of the *CRICO/RMF Colorectal Cancer Screening Algorithm* will be published in March 2006. The changes include recommendations for screening that have recently surfaced within the gastroenterology literature, as well as the addition of guidance in the work-up and management of various colorectal complaints including rectal bleeding and anemia.

Breast Cancer

From 1990–1999, CRICO malpractice claims involving breast cancer were nearly double the number from the prior decade. Nearly all alleged a failure in timely diagnosis. The assertion of breast cancer cases has stabilized since 1999, partly due to the development of CRICO/RMF's *Breast Care Management Algorithm.* That tool was initially disseminated in 1995 (updated in 2000) with a goal to systematically guide physicians through diagnostic steps that have proved particularly problematic. It was updated again in 2003 with a new section addressing personal, family, and genetic risks and has been distributed with its companion continuing medical education course[2] throughout the Harvard system. Upon request, educational presentations are made to groups of internists, gynecologists, radiologists, and breast surgeons.

Additional Diagnostic Concerns

CRICO/RMF is striving to identify or develop best practices in several other high-risk areas including missed MIs, diagnosis-related problems in the ED, and gaps in office practice systems (e.g., test result reconciliation, referral management, and patient compliance with follow-up processes). While algorithms and guidelines have proved beneficial in supporting safer care, other diagnostic pitfalls may require different solutions. For example:

- What training tools might help physicians avoid a narrow diagnostic focus?

Continued on page 6

Diagnosis-related Cases Asserted 1995–2005*		
Cases (claims and suits)	**557**	
Open	182	
Closed	375	
Physician Defendants	**798**	
Staff	645	(81%)
Fellows	30	(4%)
Residents	123	(15%)
Top Specialties Named	**798**	
Internal Medicine	268	
Radiology	90	
General Surgery	54	
Obstetrics/Gynecology	49	
Pediatrics	44	
Nurse Defendants	**56**	
RNs	41	
NPs	13	
CNMs	1	
Other	1	
Top Injuries	**557**	
Death	187	
Malignancy	109	
Condition worsened	32	
Emotional trauma	28	
Infarction	27	
Top Risk Management Issues	**1,917**	
Failure to order test *e.g., a patient being seen for multiple episodic visits by multiple providers goes years without a physical exam or cancer screenings*	156	
Misinterpretation of diagnostic studies *e.g., a clinician weighs (and acts upon) diagnostic information differently than another member of the care team*	102	
Miscommunication among providers *e.g., a clinician fails to share critical patient information with another member of the care team*	94	
Failure to establish a differential diagnosis *e.g., a physician fails to recognize a post-operative pattern that indicates an aberrant physiologic process*	85	
Failure to rule out abnormal finding *e.g., multiple providers fixate on an erroneous assumption and underestimate the need to order diagnostic tests*	80	
Setting	**557**	
Outpatient	82%	
Inpatient	18%	

CRICO Cases Closed 1995–2005*		
Cases (claims and suits)	**375**	
Closed with payment	167	(34%)
Average payment (of those closed with payment)	$685,000	
Average defense cost (of all closed cases)	$56,000	

*September 1995–August 2005

Case Example: Missed Opportunities

A 28-year-old patient was diagnosed with acute pancreatitis and irreversible kidney damage six months after she first complained of epigastric, upper abdominal, and lower chest pain.

Clinical Sequence

Four months after giving birth, 28-year-old Jasmina Carabone† presented at her physician's office with complaints of epigastric, upper abdominal, and lower chest pain. She was seen by one of her physician's associates, who confirmed epigastric tenderness and diagnosed gastroesophageal reflux disease, or GERD. Jasmina openly disagreed, saying it did not "feel like heartburn." Nonetheless, the physician prescribed ranitidine to reduce acid production. He also told Jasmina to make a follow-up appointment within four weeks if the pain did not subside, and that further diagnostic testing would be considered at that point.

Jasmina continued to experience pain, but did not make a second appointment. Two months later, when she brought her son in for his six month visit, she sought out her primary care physician—even though she did not have an appointment. She conveyed what his colleague had diagnosed two months earlier and what medication she had been prescribed. Jasmina also informed him that the pain had not decreased. Her PCP wrote a prescription for another medication. He did not order any diagnostic testing.

Three months after that—five months after her initial complaints of discomfort—Jasmina returned to her PCP complaining of (over the previous 24 hours) severe vomiting, diarrhea, reduced urination, and upper abdominal pain so severe that it made her cry. He found epigastric tenderness and administered a "GI cocktail" of Xylocaine, a local anesthetic, and Maalox. He performed no laboratory tests or radiological studies. Jasmina was discharged to home.

Later that day, Jasmina became so ill that she presented at a local emergency department where she was diagnosed with acute pancreatitis. She was found to have acute renal failure/anuria and irreversible kidney damage. After several months of dialysis treatments, Jasmina underwent a renal transplant that later failed. She is currently on dialysis.

Claim Sequence

Jasmina sued her PCP and his colleague for failure to recognize her renal complications.

Disposition

After a lengthy trial, the jury deliberated for several days before reaching a verdict in favor of the physicians. Although no indemnity was paid, the defense costs were nearly $300,000.

Discussion Points

One: Missed opportunities are often crystal clear—in hindsight. In this case, the office practice did not track Jasmina's compliance re: the recommended follow-up appointment. The physician (who may not have known Jasmina as well as her PCP) assumed she would follow through if the pain persisted. Her failure to make that appointment impacted the jury's decision, and quite possibly Jasmina's health.

Because the diagnosis ("probable GERD") was tentative, the physician's duty to encourage a more definitive process (i.e., testing)—and then track Jasmina's compliance—was elevated. Uncertainty is part of the process, but it can leave a patient unclear on next steps. Jasmina would have had a good context for deciding whether to actually make, and keep, the appointment if her physician had said: "I think this is reflux, but I'm not entirely certain. Let's try some medicine, but let's also have a follow-up appointment already scheduled. If the symptoms disappear, you can cancel; if not, please keep the appointment." An office system that helps patients make the follow-up appointment before they end the current visit also aids compliance.

Two: A second missed opportunity was Jasmina's "drop-in" appointment with her PCP (in conjunction with her infant's appointment). When he suggested a change in her medication, Jasmina may have assumed that his decision was based on more information than he had at hand. In fact, he was not prepared to see her; he did not have her record in front of him, and was unfamiliar with the

†Not her real name

Continued on next page

Diagnosis-related Risks (continued)

Continued from previous page

details of her most recent visit with his associate, until Jasmina mentioned it during that informal encounter.

Informal interactions with patients are rife with risk. A physician without the documented context from prior visits cannot do much for the patient except—as in this case—prescribe a different medication. When unscheduled contact is initiated by the patient, physicians should defer to a time (e.g., a schedule appointment) when they can devote adequate attention to the patient's concerns. A comment such as "I would feel more confident speaking to you when I have your record in front of me and the time to focus on your questions. Let's see when we can arrange an appointment or schedule a phone call and do this right." lets the patient know he or she will get your full attention.

Three: Early on in this case, Jasmina openly disagreed with the physician's diagnosis that her pain was caused by "heartburn." The ultimate diagnosis proved her right, and her decision to file a lawsuit was based, in part, on a sense that the first physician did not listen to her.

The combination of an inconclusive diagnosis and the patient's disagreement with that assessment is a red flag for formal follow-up. Patients who experience a bad outcome may be motivated to file a law suit because—in retrospect—they feel as though nobody was listening to them. Even when the evidence cannot link their outcome to a clinician's breach of duty, the patient is determined to be heard, and sometimes they win in court despite the medicine. When the sequence of events does demonstrate a connection between the patient's concerns being ignored and the bad clinical outcome, the plaintiff is, indeed, likely to win and the jury is award may well reflect that personal slight. ■

Continued from page 4

- What safe-practice models could ensure that physicians receive critical test results?
- What decision-support systems should be promulgated to prompt clinicians to order screening tests and necessary diagnostic tests?

While efforts to tackle those problems are unfolding, CRICO/RMF is also supporting these diagnosis-related initiatives through its research grant program *(see Page 15)*:

- Designing a computerized system for follow-up of abnormal cancer screening tests
- Outpatient acute myocardial infarction: identifying patient and system risk factors
- The effect of a results management system on physician awareness of post-discharge laboratory and radiology results. ■

Notes

1 *Liability in Colorectal Cancer* at www.rmfcme.com

2 *Breast Care Algorithm: A Clinical Guide* at www.rmfcme.com

Medication-related Risks

by Robert Hanscom, JD

Robert Hanscom is the Director of Loss Prevention/Patient Safety for CRICO/RMF.

The complex process of selecting, ordering, preparing, administering, and monitoring medications is repeated so often that the temptation for assumption, inattention, or workarounds is significant. The most common types of errors are:

- mismanagement of high-risk medications;
- failure to see the "whole picture" (drug interactions, side effects, etc.); and
- lack of safety nets to catch errors.

To counter those potential risks, a system of checks and double checks is needed to ensure safety through each step in the medication process for both inpatients and outpatients so that:

- the drug and dose ordered is appropriate and safe for the particular patient at that particular time;
- the drug and dose prepared is what was ordered;
- the administering clinician receives the drug and dose that was ordered;
- any changes ordered by the originating physician are made prior to administration;
- the patient receives the drug and dose ordered; and
- the patient is monitored for adverse drug reactions.

CRICO/RMF has joined in several regional and national efforts to improve patient safety in regards to medication therapy. As part of the Massachusetts Coalition for Patient Safety, CRICO/RMF has participated in an initiative on safe practices for reconciling medications and reducing ambulatory medication errors. At the local level, CRICO/RMF has co-sponsored projects designed to reduce risks related to:

- medication errors in pediatric settings,
- medication errors in outpatient settings,
- anticoagulation management, and
- administration of outpatient chemotherapy.

CRICO/RMF is also funding these initiatives *(see Page 15)*:

- Prevent harm/promote efficacy: nurses' critical thinking during process medication
- Chemotherapy error reduction in the pediatric ambulatory setting following computerized order entry implementation
- Assessing the frequency of failure to adhere to black-box warnings in outpatients
- Implementation and evaluation of a medication reconciliation protocol at a large teaching hospital ■

Medication-related Cases Asserted 1995–2005*		
Cases (claims and suits)	**193**	
Open	51	
Closed	142	
Physician Defendants	**208**	
Staff	159	(76%)
Fellows	11	(5%)
Residents	38	(18%)
Top Specialties Named	**208**	
Internal Medicine	60	
Psychiatry	20	
Anesthesiology	13	
Cardiology	12	
Pediatrics	12	
Nurse Defendants	**27**	
RNs	24	
NPs	2	
Other	1	
Top Injuries	**193**	
Adverse reaction	101	
Death	44	
Condition worsened	8	
Infection	5	
Anaphylaxis	4	
Top Risk Management Issues	**659**	
Incomplete patient/family education *e.g., the care team is unable to fully convey to a patient (and family members) the information needed to safely take prescribed medications*	62	
Selection of medication *e.g., a physician is unaware of a patient's complete list of medications*	55	
Inadequate patient monitoring *e.g., an adverse drug reaction is not promptly recognized*	53	
Wrong drug/dose *e.g., a nurse administers a medication to the wrong patient*	41	
Miscommunication among providers *e.g., a clinician fails to share critical patient information with another member of the care team*	30	
Setting	**193**	
Outpatient	65%	
Inpatient	35%	

CRICO Cases Closed 1995–2005*		
Cases (claims and suits)	**177**	
Closed with payment	82	(46%)
Average payment (of those closed with payment)	$305,000	
Average defense cost (of all closed cases)	$42,000	

*September 1995–August 2005

Case Example: Inattention to Allergy

On two separate occasions, a patient required emergency medical treatment after being given medications to which he had known allergies.

Clinical Sequence

After surgery to repair a congenital abnormality of his biliary tree, 34-year-old Alex Page† suffered from repeated episodes of obstruction and infection. During one of several post-operative hospital admissions for infection, he received a small dose of cefotetan. Alex had an anaphylactic reaction that was treated quickly with good results. Cefotetan was added to the list of medications to which Alex was allergic, which also included Compazine. On his physician's advice, Alex began wearing a medical alert bracelet indicating his drug allergies.

Two months later, during another admission, Alex was given Compazine for nausea. When Alex questioned the nurse after the injection, he received Benadryl in time to mitigate his allergic reaction.

Four months later, after a second surgery, Alex was readmitted for a post-op infection, and ofloxacin was ordered. When asked to consult on Alex's post-op care, an Infectious Disease specialist—apparently unaware of Alex's allergy—changed the order to cefotetan, which Alex received and reacted to adversely. He was stabilized and admitted to the ICU for overnight observation. The next day, Alex refused to be admitted to the floor where the drug error occurred.

Claim Sequence

Alex filed a claim against the institution alleging multiple incidents of negligence regarding the ordering and administration of medication.

Disposition

This claim was settled in the low range (<$99,999).

Discussion Points

One: This case involved multiple errors involving common factors (i.e., same patient, same drugs) but different providers. When different people repeat the same mistake, the blame should fall on the systems they are relying on to prevent such errors from occurring (even once).

Everyone along the medication path needs a system of checks and double checks to ensure that the patient receives the right amount of the right drug in the right manner at the right time(s).

Two: Alex had chronic health problems, and multiple hospital admissions. Without his own intervention and watchfulness, more errors—and more serious consequences may have resulted.

Patients who know a lot about their health care are key members of the health care team. Physicians and nurses who engage such patients in all aspects of chronic care reduce the likelihood of error. If and when errors, or potential errors do occur, the patient who is comfortable communicating with caregivers is more likely to be an ally than an adversary.

Three: After experiencing multiple errors, or near errors, the patient in this case refused to be admitted into what he perceived to be a risky setting, perhaps avoiding one risk, but potentially creating another risk by being placed in a less suitable unit.

A patient who expresses distrust—or, worse, fear—of a particular procedure, clinician, or setting may raise the stakes for a potential complaint, malpractice claim, or lawsuit. Anything short of taking such concerns seriously and addressing them appropriately invites the perception that the patient is being mistreated. Any problems that ensue after a patient has expressed such concerns or fears, can easily be perceived as verification of his or her trepidation. ■

†Not his real name

Obstetrics-related Risk

by Roxane Gardner, MD, MPH

Roxane Gardner is a faculty member of Boston's Brigham and Women's Hospital's Department of Obstetrics and Gynecology, and a consultant to CRICO/RMF.

While malpractice insurance premiums—especially for obstetricians—have skyrocketed nationwide[1], CRICO's rates have risen relatively slower. But at the same time that the frequency of CRICO obstetrical malpractice claims has remained relatively stable, case acuity and subsequent payouts have risen dramatically. Among the more problematic missteps that have led to adverse obstetrical events are delays in diagnosis and therapeutic intervention, knowledge deficits, miscommunication, and poor teamwork. To address those opportunities for improvement, CRICO/RMF has been working with the CRICO-insured obstetrical services to improve risk management and patient safety education and to help them develop the skills and tools necessary to better manage crisis situations.[2,3]

CRICO/RMF's approach to reducing obstetrics-related risks have been multi-dimensional. The analysis process centered around a 2001 review of CRICO obstetrics-related cases showing that 43 percent of adverse events could have been prevented or mitigated had better teamwork been in place.[4] The nature of the clinical missteps identified in that study underscored the need for formal training in teamwork and communication skills for labor and delivery staff. To that end, CRICO/RMF co-sponsored the labor and delivery staff of Beth Israel Deaconess Medical Center's participation in a two-year, nationwide teamwork training study.[5,6]

Simultaneously, CRICO/RMF supported the development of a simulation-based team training course for Labor and Delivery physicians and nurses at the Center for Medical Simulation in Cambridge, Massachusetts.[7] This course brings together a multidisciplinary team of obstetrical providers, obstetrical anesthesiologists, and labor and delivery nurses to learn and practice principles of crisis resource management. Using simulated scenarios based on actual obstetrical experiences of Harvard's affiliated perinatal units, the training emphasizes the non-technical skills of teamwork and communication.

As the teamwork training programs matured, CRICO/RMF launched an incentive program whereby obstetricians who completed a series of perinatal risk reduction activities (including one of the teamwork training programs) could receive a malpractice insurance premium.[8] In 2004, about 75 percent of eligible obstetrical attendings and fellows completed the program; 96 percent reported they were satisfied (or very satisfied) with the program.[9]

Continued on page 17

Case Example: Dysfunctional Teamwork

A 38-year-old woman, induced with misoprostol, delivered a stillborn baby via cesarean-section.

Clinical Sequence

In the 41st week of her first pregnancy, Tina Constanople† arrived at labor and delivery for a planned induction of labor. Her pregnancy had progressed normally until the last month of her third trimester, when her blood pressure began to increase. She was diagnosed as having mild pregnancy-induced hypertension that responded to reduced activity and bed rest. At her 40-week visit, her cervix was found to be long and closed, her blood pressure was slightly elevated but stable, and she had +1 proteinuria. Plans were made for inducing her labor and delivering her baby.

6:45 a.m.	In Labor and Delivery, Tina had intra-vaginal placement of misoprostol. The nurse observed her briefly and then, at 11:00 a.m., Tina was discharged from the unit. She went for a walk.
12:00 noon	Tina's membranes spontaneously ruptured and she returned to the Labor and Delivery unit. The nurse, a recently hired new graduate, admitted Tina to a labor room and took her vital signs and checked the fetal heart rate. Tina's blood pressure was 176/95; the nurse thought this was related to Tina's nausea, vomiting, and the discomfort of contractions.
12:10 p.m.	The resident on duty examined Tina, and determined her cervix was 5–6 cm, 90 percent effaced, and the vertex was at 0 station. An internal fetal heart monitor was placed to more accurately record the fetal heart rate. The fetal heart rate was 120 with no decelerations.
2:05 p.m.	Following painful contractions, Tina requested an epidural. After placement of the epidural, the monitor indicated a prolonged fetal heart rate deceleration. The heart rate returned slowly to the baseline rate of 120 as the nurse repositioned Tina, increased her intravenous fluids, and administered oxygen by mask.
2:15 p.m.	An epidural analgesia infusion pump was started. The fetal heart rate strip indicated another deceleration that recovered to baseline. The nurse informed the resident who checked the strip and told her to "keep an eye on things."
2:45 p.m.	The primary nurse noted in the labor record that the baseline fetal heart rate was "unstable, between 100–120;" she did not report this to the resident.
3:05 p.m.	As the nurse recorded that the fetal heart rate was "non-reassuring: flat, no variability," the patient expressed a strong urge to push. The nurse called for an exam.
3:20 p.m.	A second resident came to the bedside, examined Tina, and noted that she was fully dilated with the caput at +1. A brief update was written in the chart, but not initialed.
3:30 p.m.	Tina was repositioned and began pushing.
4:05 p.m.	The fetal heart rate suddenly dropped and remained profoundly

†Not her real name

Obstetrics-related Cases Asserted 1995–2005*		
Cases (claims and suits)	**128**	
Open	49	
Closed	79	
Physician Defendants	**207**	
Staff	161	(78%)
Fellows	3	(1%)
Residents	43	(21%)
Top Specialties Named	**207**	
Obstetrics/Gynecology	199	
Neonatology	3	
Gynecology	2	
Nurse Defendants	**58**	
RNs	31	
NPs	1	
CNMs	26	
Top Injuries	**128**	
Death	32	
Organ loss/damage	31	
Birth injury	25	
Emotional trauma	8	
Nerve damage	7	
Top Risk Management Issues	**466**	
Selection/management of labor & delivery *e.g., a cesarean section is delayed*	92	
Miscommunication among providers *e.g., a clinician fails to share critical patient information with another member of the care team*	25	
Misinterpretation of diagnostic studies *e.g., a clinician weighs (and acts upon) diagnostic information differently than another member of the care team*	25	
Inadequate patient monitoring *e.g., a woman with a high-risk pregnancy is not closely monitored*	20	
Selection/management of pregnancy *e.g., the treatment rationale or finding from a physical exam is not fully documented*	19	
Setting	**128**	
Inpatient	94%	
Outpatient	6%	

CRICO Cases Closed 1995–2005*		
Cases (claims and suits)	**108**	
Closed with payment	35	(44%)
Average payment (of those closed with payment)	$1.1M	
Average defense cost (of all closed cases)	$70,000	

*September 1995–August 2005

bradycardic for 11 minutes. The resident was called and, since the fetal head was at +2 station, attempted a vacuum delivery. The attending then entered and attempted forceps delivery.

4:35 p.m. An emergency cesarean delivery was performed; the baby was stillborn. The physician identified a uterine rupture that required significant blood replacement.

Defense Sequence

In a medical malpractice claim filed against two attendings, two obstetrics residents, and the primary nurse, the plaintiffs alleged that a serious fetal heart rate pattern was either unrecognized or misinterpreted. They further alleged that the fetal heart rate changes should have prompted a more aggressive delivery strategy.

Disposition

This claim was settled in excess of $1 million.

Discussion Points

One: At least six individuals were involved in Tina's care over the nine hours following her induction. Gaps in communication about Tina's blood pressure and her baby's heart rate impacted the care team's mutual understanding of both situations—and contributed to their decisions and their timing regarding those issues.

Having the right information shared with the right individuals at the right time is essential to good and safe care. The culture in a given health care setting often influences how gaps in the flow of information are identified and resolved. When everyone involved—even the newest nurse on a work shift—shares a common set of behaviors and routinely briefs, shares, and reviews clinical information in a timely fashion, the ability to ensure safe care is greatly enhanced.

Two: After responding appropriately to the first bradycardia, no other efforts to address subsequent decelerations and bradycardias were documented—e.g., changing Tina's position, giving her oxygen, increasing her fluids, or calling the obstetrical provider to come re-evaluate the situation. When the situation became critical, the obstetrical care team was insufficiently prepared. The impact that more timely attention might have had on the baby's chance for survival is inconclusive, but the opportunity to re-evaluate and adjust the management of Tina's labor was lost.

Cross-monitoring of clinical events by professional colleagues helps to assure sure that A) signs of clinical deterioration in health status are recognized and addressed in a timely fashion by even the most inexperienced members of a care team; B) members of the care team are sharing their concerns with each other about their patient so that problems can be addressed before they become critical; and C) any fear, embarrassment, or reluctance in asking for help is diminished.

Three: Although the care team—nurse, resident, and attending—responded promptly to the profound fetal bradycardia, it is unlikely that other members of the care team: resource nurse, anesthesiologist, pediatrician, were alerted to the evolving crisis until the last minute.

Certain clinical events often extend beyond the obvious problem. The need for intense maternal and fetal monitoring may adversely impact staffing, thus the resource nurse should be alerted promptly when clinical circumstances deviate from normal. The potential for emergency surgery, anesthesia, and neonatal care should be conveyed before the situation is in crisis mode. Experienced clinicians can decide what to do with the patient information they receive; but, decision-making is optimal when critical information is provided in a timely fashion.

Four: Junior members of Tina's care team, in this case a nurse and one of the residents, shied away from voicing their concerns or challenging decisions made by more senior clinicians. Quite possibly, the delays in performing a cesarean section were related to their inability to convey their concerns.

All members of the care team should be encouraged to speak up if they disagree with a management plan or have serious concerns about a patient's care. Every institution should have a conflict resolution policy or guideline to help all providers feel comfortable escalating their concerns to the next level. A system that promotes an atmosphere of safety can facilitate open discussion and cross-monitoring, allowing providers to speak up and learn from each other without the fear of reprisal or of being rejected or alienated for expressing their concerns. Such a system embodies a learning organization and a culture of safety. ■

Surgery-related Risks

by Kathleen Dwyer

Kathy Dwyer is a Senior Loss Prevention Specialist for CRICO/RMF.

The top areas of concern identified in analysis of CRICO malpractice cases involving surgical patients are:

- clinical judgment issues;
- technique-related complications;
- postoperative monitoring gaps; and
- communication breakdowns (failure to report deterioration in a patient's condition).

Surgery-related claims are the second highest category of cases asserted against CRICO-insured providers over the past 10 years. General Surgery, Neurosurgery, and Orthopedic Surgery are the most commonly named specialties. Overall, increasingly complex procedures are being performed on sicker patients against greater production pressures. That combination expands the potential for error and challenges methods of rescue.

Surgery Initiatives

As is evident elsewhere in health care, poor teamwork in the operating room is a significant factor in surgical adverse outcomes. With this understanding comes the impetus to change the longstanding culture of the operating room environment. In recent years, CRICO/RMF has supported a number of efforts aimed at keeping patients safer during surgery and improving the work environment for surgeons.

1) Surgery Team Training

Does team training improve surgical team performance? CRICO/RMF has supported several projects aimed at answering that question. Both simulator-based team training programs and didactic sessions have been created, tailored specifically to the needs of teams that work in the operating room. To date, multiple teams have been trained and the effects of their training have been assessed (participants' responses to post-training follow-up indicate that simulation training was useful). The results of these initial interventions will guide subsequent team training programs (e.g., interpersonal communication and team response).

2) Impact of 80-hour Resident Work Week

This study explored the impact of the 80-hour resident work week on quality, safety, and the training of surgery residents. While several positive factors emerged, some areas of concern were also identified, most notably, a loss of critical patient information with each "hand-off." Attention needs to be paid to identifying and teaching the critical elements of information sharing among providers as they transfer responsibility for a patient.

Continued on page 12

Surgery-related Cases Asserted 1995–2005*

Cases (claims and suits)	**471**	
Open	136	
Closed	335	
Physician Defendants	**545**	
Staff	429	(79%)
Fellows	17	(3%)
Residents	99	(18%)
Top Specialties Named	**545**	
General Surgery	128	
Orthopedics	92	
Gynecology Surgery	67	
Neurosurgery	46	
Plastic Surgery	40	
Nurse Defendants	**44**	
RNs	42	
NPs	2	
Top Injuries	**471**	
Foreign body	75	
Death	52	
Condition worsened	47	
Nerve damage	37	
Puncture/perforation	31	
Infection	31	
Top Risk Management Issues	**1,352**	
Technical problem *e.g., damage to the collateral organs, lack of knowledge*	135	
Selection/management of surgery/ invasive procedure *e.g., failure to consider a non-operative approach before a planned procedure*	111	
Retained foreign body *e.g., the surgical team fails to account for and remove all materials introduced into the surgical site*	69	
Misidentified anatomical structure *e.g., a physician unintentionally injures anatomy adjacent to the intended structure*	60	
Inadequate consent *e.g., a physician does not fully disclose the risks associated with a procedure, alternate procedures, or option of doing nothing*	53	
Setting	**471**	
Inpatient	69%	
Outpatient	31%	

CRICO Cases Closed 1995–2005*

Cases (claims and suits)	**441**	
Closed with payment	141	(32%)
Average payment (of those closed with payment)	$543,000	
Average defense cost (of all closed cases)	$35,000	

*September 1995–August 2005

Case Example: Blindness Following Spine Surgery

A 20-year-old diabetic suffered from ocular nerve damage following prolonged back surgery.

Clinical Sequence

Dan Bockman†, a 20-year-old with insulin dependent diabetes, injured his back on a submerged rock while jumping off a boat dock at a friend's home. He was taken by ambulance to a local hospital, then transported to a Boston Emergency Department. He arrived at 8:30 p.m., Saturday, June 28th.

In the ED, Dan was seen by a neurosurgeon and an orthopedic resident. The initial neurological exam showed upper leg weakness and no reflexes in his lower extremities; X-rays revealed a burst fracture of his lumbar spine at L-4. The resident placed Dan on steroids and had him admitted. Over the next 40 hours, Dan's neurological condition improved, although he had decreased sensation below both knees, and no reflexes in either leg.

Monday afternoon, a staff orthopedic surgeon reviewed Dan's X-rays and advised the orthopedic resident that surgery was necessary. Tuesday morning, the staff surgeon discussed with Dan (and Dan's mother) the risks of the surgery, including nerve and vessel damage, bleeding, infection, and non-union. Neither the surgeon, the patient, nor the record recall a discussion regarding the risk of vision loss.

The surgery started at 1:30 p.m. Wednesday with the patient on his back. The attending orthopedic surgeon (assisted by a general surgery resident) removed part of the vertebra and bone fragments at L-4. He then placed a cage in the area of the partially removed vertebra. Six hours after the procedure began, after verification from the anesthesia resident that the patient was stable enough for the second stage of the procedure, Dan was turned face down. The surgeon then mechanically secured the spine. He elected not to extend the surgery further to remove one bone fragment in the spinal cord that he determined was not pressing on any nerve roots. The posterior surgery ended at 1:45 a.m., Thursday, July 3rd. During the 12 hours of surgery, Dan lost nine liters of blood, which required administration of 23,000 cc of fluid.

Post-op, the attending surgeon left for a camping trip in Maine. Dan was taken to the ICU and remained intubated. His face was swollen from the fluid replacement and he did not open his eyes for most of the day, Thursday. Around 7:00 p.m., Dan complained he couldn't see. When the ICU staff was unable to reach the attending surgeon, they consulted with Ophthalmology and Neurology. Hyperbaric oxygen treatments were discussed. At midnight, another surgeon examined Dan, who was now blind. Testing revealed that damage to the posterior optic nerve —likely caused by the heavy blood loss during the spine surgery—had caused the vision loss.

In addition to the permanent vision loss, Dan also suffered permanent paralysis of the front muscles of his right lower leg, causing foot drop.

Claim Sequence

Dan sued the attending and resident surgeons, alleging that their decision to complete both stages of the procedure during one operating session was directly responsible for his blindness.

Disposition

All parties agreed to take this case to mediation, which led to a payment in excess of $1 million. ■

Discussion Points — Prior to recommending this case for mediation, the defense team evaluated the care from both the plaintiff's and the defendants' perspectives.

Care Issue	Defendants' Perspective	Plaintiff's Perspective	Risk Management Advice
Indication for Surgery	The surgery was indicated due to the patient's neurological status and the angle of his spine resulting from his diving accident.	The surgeon was negligent in recommending surgery for the repair of the burst fracture at L4, rather than a trial of nonoperative treatment.	Treatment decisions for trauma patients are particularly susceptible to hindsight when the outcome is less than what the patient expected. Patients and/or their families should be confident that the decision is based on what's best for the patient's long-term quality of life, and is not influenced by staffing, financial, or scheduling factors.
Informed Consent	The surgeon is not obligated to advise patients of every possible, rare risk of surgery (e.g., vision loss). Even if Dan had been advised of the risk, he (and any reasonable person) still would have proceeded with the surgery.	The patient could not fully exercise his informed consent to the surgery because he was not advised of the risk of vision loss.	Advising a patient about the risks of treatment is a balancing act in which the likelihood of any risk is weighed against what's important to the patient. A slight risk of hearing loss may impact the decision of a musician, but not a lawyer. In this case, the patient's diabetes might have justified a discussion of the risk of vision impairment.
One vs. Two Procedures	If possible, one long operation is preferable to two shorter ones. The blood loss did not require stopping the surgery after the first stage. The anesthesiologist felt it was appropriate to complete the surgery at this time.	The surgeon was negligent in choosing to go forward with the second stage of the surgery at that time in light of the extensive blood loss, rather than waiting several days before proceeding with the second stage.	A team preparing for a long and complex procedure can reduce the risk of compromising the patient's health by having a clear plan with checkpoints that provide an opportunity for adjustments. If possible, having a disinterested third party facilitating those discussions helps keep them focused on the patient's best interest.
Surgical Skill	Exact etiology of this phenomenon remains unclear.	The surgeon was negligent during the surgery in his technique, causing trauma to the nerve roots affecting Dan's right leg.	Spinal surgery, with its inherent risk of nerve damage and paralysis, requires special attention to the patient's expectations and fears, and clear documentation. It may be prudent to include the possibility of post-operative vision loss in the operative consent, since the damages can be severe.

†Not his real name

Surgery-related Risks (continued)

Continued from page 10

3) Surgery /Human Factors: Phase II

The second phase of a landmark study[1] sought to design new interventions to improve surgical safety. The areas of focus in this phase were:

- exploration of a technological solution (a bar-coded sponge system) to prevent retained sponges,
- development of an operative safety score using a mix of easily observed indices, and
- creation of a strategy for peer-consultation to combat errors of inexperience.

4) Human Factors/Systems Study and Pediatric Surgery

A research study has been recently initiated to identify those human factors that most influence a clinical outcome after complex pediatric surgery. Determination of those factors will help in the design of policies, procedures, education, and process changes that will prevent or reduce adverse outcomes.

In addition to these, CRICO/RMF is also providing funding for the following surgery-related patient safety projects *(see Page 15):*

- A proposed double-blind randomized controlled trial of capnography for increasing the safety of children undergoing procedures with conscious sedation
- Communication during post-operative patient hand-off in the pediatric intensive care unit
- Development of a simulator-based orientation program for rotating surgical residents
- Assessment of impact of team training in perioperative care ■

Reference

1 Christian C, et al. A prospective study of patient safety in the operating room. (manuscript accepted)

Patient-centered Risk Management Analysis

by Luke Sato, MD

Luke Sato is Vice President of Loss Prevention/Patient Safety for CRICO/RMF.

Prior to 2003, analyses conducted by CRICO/RMF of high-severity malpractice cases rarely included the patient's perspective, at least in any systematic fashion. The documented chronology of events, the experts' opinions, and the defendant's formal recollections (depositions) were studied and translated into a narrative that tried to pinpoint what individuals or systems (if any) faltered during the course of the patient's care.

But what about the patients? What did they expect to be the outcomes of their care episodes. What did they feel, see, hear, (or not hear)? Did the standard of care meet *their* standards, and if not, why not?

In recent years, CRICO/RMF has been exploring those questions on a regular basis. Although the new analysis model is often referred to as "patient-centered," it does not replace nor ignore the clinical dynamics of a case. Rather, it provides a broader perspective about communications and systems factors that influence clinical judgments, actions, and outcomes. The overarching questions posed in these expanded high-severity case analyses are:

- What specific patient expectations were not met?
- What dimensions of care (e.g., delays, barriers, hazards) were unsatisfactory to the patient?
- What systems issues led to an adverse outcome?
- What factors motivated the patient to bring suit?

By systematically exploring an adverse event from the patient's point of view, analysts gain a better understanding of where interventions and systems improvements can be most effective. *Overlooking* the patient's perspective jeopardizes solutions based solely on the providers account of what went wrong.

Getting the Patient's Perspective

In conducting a patient-centered analysis, take care to avoid inferences or conclusions about a participant's perception or state of mind made without supportive evidence from the case materials. The CRICO/RMF process involves these four steps:

1. List and briefly describe the individuals who view the case from the patient's perspective: patient; family members; friends; advocacy group members, and clinicians ancillary to the malpractice claim, but not to the patient (e.g., a PCP in a case naming a specialist).
2. From the patient's point of view, summarize the case chronology:

- clinical encounter,
- diagnosis/assessment of the problem,
- development and execution of a treatment plan, and
- outcome/follow-up/reassessment of the plan.

3. Examine any available depositions (from all parties involved in the case) to hear the patient's voice regarding the chronology of the events and the outcome *(see Guiding Questions below).*
4. Write a narrative summary of the case that captures the patient's story. This may eventually be blended together with the accounts from the providers, experts, and legal team. ■

Guiding Questions

The following questions are a guide for capturing the patient's perspective of an adverse event (Step 3). If you can actually ask the patient some or all of these questions, you have the optimal opportunity. More likely, these questions can serve as a guide as you read through the case documents.

Clinical encounter

1. Was the patient seen promptly?
2. Was the patient asked to relate (or update) a full history periodically?
3. Did the patient (or any family member) feel ignored?
4. What information (if any) did the patient think was not solicited or received?
5. Did the patient understand what symptoms or concerns he/she should report to the physician (or nurse) subsequent to each visit?

Diagnosis/assessment of the problem

6. Did the patient feel that everything reasonable was done to diagnose his/her medical problem?
7. Did the patient receive accurate explanation of why a test was recommended/ordered?
8. Did the patient learn the results of his/her tests in a timely manner?
9. Did the patient understand the seriousness of his/her condition?
10. Did the patient request a specialty consult that went unheeded?

Development and execution of a treatment plan

11. Did the patient feel fully informed about his/her treatment options?
12. Did the patient understand the potential risks and benefits of the treatment enough to make an informed decision?
13. Did the patient feel that everything reasonable was done to treat his/her medical problem?
14. Did the patient understand who would be performing his/her surgery (e.g., a resident)?
15. Did the patient understand the purpose of each medication?

Outcome/follow-up/reassessment of the plan

16. Was the patient's medication monitored and documented?
17. Did the patient understand the results of his/her treatment/surgery?
18. Did the patient receive appropriate discharge or follow-up instruction?
19. Was the patient informed that an error had occurred?
20. Did the patient understand who among multiple providers was the ultimately responsible caregiver?

Other issues

21. Was the patient ever misidentified or given the wrong medication?
22. Did the patient believe any of his/her clinicians lacked knowledge, skill, or tact?
23. Did the patient feel disrespected, belittled, or marginalized by any clinician or employee?
24. What errors did the patient believe were made in the course of his/her diagnosis and treatment?
25. Did the patient feel he/she deserved an explanation or apology regarding the errors made in his/her care?

Effective Practices for Office-based Care

by Jennie Wright, RN

Jennie Wright is Office Practice Evaluation Manager for CRICO/RMF.

When office-based care and, as a result, office-based malpractice claims, began increasing in the late 1990s, CRICO/RMF began conducting Office Practice Evaluations to give physicians and office managers a tool for identifying potential risks and developing mitigating strategies.

In the course of that work, CRICO/RMF noted those systems that reliably support clinicians in their day-to-day work and provide safe patient care in a lower risk environment. CRICO/RMF's goal is to help providers in office-based care settings learn about, duplicate, and enhance the most effective models. As a part of that effort, CRICO/RMF maintains a comprehensive database of effective and exemplary practices, called *What Works*.

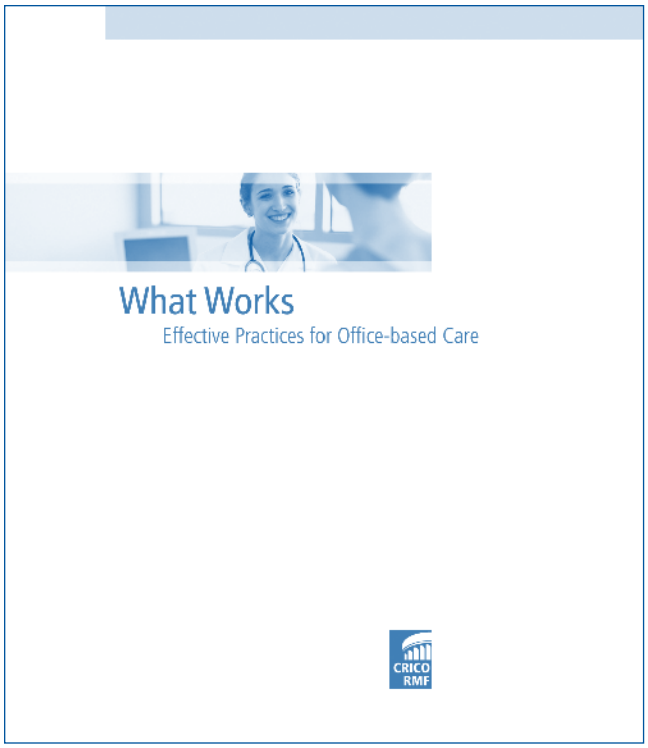
Effective and Exemplary Practices

What Works: Effective Practices for Office-based Care currently covers more than 120 areas of concern within one of the following categories:

- appointments and telephone calls
- components of the medical record
- confidentiality
- documentation of patient assessment
- documentation of patient outcomes
- health screening guidelines
- interpreters
- management of anticoagulation patients
- management of asthmatic patients
- management of cholesterol patients
- management of diabetic patients
- management of drug seeking patients
- management of HIV patients
- medication management
- provider access
- provider access after hours
- quality improvement
- referrals
- staff development
- telephone triage
- tracking of abnormal screening tests
- tracking of test results

Each topic includes one or more exemplary or effective practice example.

An **Effective Practice** is a system or process that efficiently closes a potential gap in the delivery of patient care. Such gaps may involve patient access or communication of information.



An **Exemplary Practice** is a solution to a potential care issue that suggests a proactive approach to problem solving. The development of one system may enhance delivery of care in more than one focus area.

The criteria for both effective and exemplary practices are efficiency, cost effectiveness, and easy duplication. Effective and exemplary systems need not be electronic; paper-based solutions are frequently easier to initiate and within the reach of many providers. In 2004, CRICO/RMF began conducting risk assessments at hospital entry points (e.g., Emergency Department, Labor and Delivery). As those evaluations are completed, exemplary and effective practices identified in those settings will be added to the *What Works* database (www.rmf.harvard.edu/whatworks).

To find out more about more about *What Works,* visit the web site or contact CRICO/RMF at 617.679-1525. ■

CRICO Patient Safety Research Grants

by Jessica Bradley, MPH

Jessica Bradley is a Loss Prevention Specialist for CRICO/RMF.

Over the past three years, CRICO/RMF has awarded funding to 29 patient safety projects at several Harvard-affiliated medical institutions. The grants are made possible by the board of directors of Controlled Risk Insurance Company[1], which has set aside $500,000 each year to advance improvements in patient safety since 2003. Grantees from 2003, 2004, and 2005 are listed below.

Michael Agus MD, Children's Hospital:
Implementation of a Pediatric Care Unit: Effects on Patient Safety

Richard Balaban, MD, Cambridge Health Alliance:
Redefining and Redesigning Hospital Discharge to Enhance Patient Safety

Barbara Bierer MD, Dana-Farber Cancer Institute:
Chemotherapy Error Reduction in the Pediatric Ambulatory Setting Following Computerized Order Entry Implementation

Joan Fitzmaurice RN, Massachusetts General Hospital:
Transitions in Care: Technical and Relational Communication During Handoffs

Allan Frankel MD, Partners HealthCare Systems:
Towards a High Reliability Perinatal Unit: Demonstration Program to Embed Principles of Simulation-based Event Management and Teamwork

Ruth Fretts MD, Harvard Vanguard Medical Associates:
Reduction of Adverse Perinatal Outcomes in Pregnancies with Decreased Fetal Movement

Tejal Gandhi MD, Brigham and Women's Hospital:
The Effect of a Results Management System on Physician Awareness of Post-Discharge Laboratory and Radiology Results

Lisa Horowitz, PhD, MPH, Children's Hospital:
Capturing and Utilizing Patient Safety Observations from Parents/Families of Pediatric Patients

Ann Hurley RN, DNSc, Brigham and Women's Hospital:
Prevent Harm/Promote Efficacy: Nurses' Critical Thinking During Process Medication

Allen Kachalia MD, Brigham and Women's Hospital:
Where Do Teamwork and Communication Breakdowns Need Intervention? An Analysis of Sentinel Events and Events Reported to Risk Management

Gila Kriegel MD, Beth Israel Deaconess Medical Center:
Designing a Computerized System for Follow-up of Abnormal Cancer Screening Tests

Karen Lasser MD, Cambridge Hospital/Brigham and Women's Hospital:
Assessing the Frequency of Failure to Adhere to Black-Box Warnings in Outpatients

Deborah Levine, MD, Beth Israel Deaconess Medical Center:
Gynecologic Ultrasound Reporting System: A QA Project to Standardize Reporting of Pelvic Sonograms

Jenifer Lightdale MD, Children's Hospital:
A Proposed Double-Blind Randomized Controlled Trial of Capnography for Increasing the Safety of Children Undergoing Procedures with Conscious Sedation

Shan Liu, MD, Massachusetts General Hospital:
Frequency of Adverse Events and Errors Among Chest Pain, Pneumonia and Cellulitis Patients Boarding in the Emergency Department

Kshitiji Mistry MD, Children's Hospital:
Communication During Post-operative Patient Handoff in the Pediatric Intensive Care Unit

Donald Moorman MD, Beth Israel Deaconess Medical Center:
Assessment of Impact of Team Training in Perioperative Care

Zeev Neuwirth, MD, Harvard Vanguard Medical Associates:
The Impact of Communication Skills Training and Team Building Initiative on Patient's Perception of Physician Communication and Relationship Building in a Multi-site Primary Care Practice

Lynn Nuti, BSN, JD, Newton Wellesley Hospital:
What You Don't Know Can Hurt You: Demonstration Project on the Implementation of a Full Disclosure of Unanticipated Outcomes and Medical Errors Program

Mitchell Rein, MD, North Shore Medical Center:
Rapid Response Team Pilot

David Roberson MD, Children's Hospital:
Development of a Simulator Based Orientation Program for Surgical Residents Rotating at Children's Hospital

Daniel Rosenthal MD, Massachusetts General Hospital:
Important Findings Alert

Jeffrey Rothschild, MD, Brigham and Women's Hospital:
Implementation and Evaluation of a Rapid Response System

Jeffrey Rothschild MD, Brigham and Women's Hospital:
Intercepting Near Miss Adverse Events: The Critical Care Nursing Safety Net

Jeffrey Schnipper, MD, MPH, Brigham and Women's Hospital:
Implementation and Evaluation of a Medication Reconciliation Protocol at a Large Teaching Hospital

Thomas Sequist MD, Brigham and Women's Hospital:
Outpatient Acute Myocardial Infarction: Identifying Patient and System Risk Factors

Charles Chris Smith MD, Beth Israel Deaconess Medical Center:
Preventing Procedural Errors: Creation and Evaluation of an Inpatient Procedure Service

Henry Tom Stelfox, MD, PhD, Massachusetts General Hospital:
Content Analysis of Patient Complaints

Robert Ursprung MD, Children's Hospital:
Random Safety Audits to Reduce Errors in Neonatal Intensive Care

This spring, CRICO/RMF will be reporting the results of the 2004 awarded projects and research, and passing those findings and lessons on to everyone involved in improving patient safety. For more information, visit the CRICO/RMF web site (www.rmf. harvard.edu) or contact CRICO/RMF at 617.679.1248. ■

Note

1 Harvard-affiliated physicians, hospitals, and their employees are insured for professional liability by the Controlled Risk Insurance Company (CRICO).

Finding Answers to Patient Safety Questions

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CRICO/RMF has developed an information resource for sharing answers to the most frequently asked risk management and patient safety questions. The more than 100 FAQs cover a wide range of concerns about risk, liability, and legal issues. Here are a few FAQs from the "target" high-risk areas analyzed elsewhere in this issue of *Forum*.

What should be done if an obstetrical patient refuses to sign a consent form during delivery?

If concerns about potential medical interventions are leading to the refusal to sign the form, more dialogue about the patient's preferences vis-a-vis medical judgment during labor and delivery is indicated. This discussion should be documented.

If the patient has issues of trust which cannot be resolved—and is in the early stages of pregnancy—referral to another practitioner may be indicated. Referral to another practitioner during the third trimester is not advised. This could give rise to allegations of abandonment. The obstetrical practitioner, labor and delivery nurses, administration, and the risk manager should develop a coordinated plan to manage the delivery of a patient with unresolved issues of trust.

In the latter situation, the absence of an institutionally required signed consent form still needs to be addressed. Document in office and hospital medical records the dialogue about the pregnancy and plans for labor and delivery that have occurred during the prenatal period. Note the proposed obstetrical procedures and activities, risks and benefits, including unexpected risks and complications. The patient's verbal consent for continuing obstetrical care and refusal to sign a consent form should also be documented. The institution's printed obstetrical consent form provides an excellent outline for the detailed note. The situation should be discussed with the institutional risk manager who may have additional advice to offer.

What documentation practices can help reduce allegations of a failure to diagnose breast cancer?

- Document a thorough breast examination in the history and physical examination; enter, in quotes, the patient's breast complaints and what she says.
- Use a diagram (or descriptive notes) to record the exact location of all lesions.
- In the event that a patient's breast care is being managed by another clinician, document the date of the patient's last exam to ensure that subsequent exams are performed when appropriate.
- During each visit, update the patient's risk factor assessment and your recommendations for screening based on their current risk for developing breast cancer.
- Consider using a problem list to highlight patients with a positive family history of breast cancer.

What are the patient safety issues surrounding prescribing over the phone?

The decision about whether to prescribe over the phone depends upon the physician's relationship with the patient, the type of medication, and the circumstances of the call.

Prescribing new medications to known patients over the phone without a recent clinical evaluation is not recommended, especially when a drug's appropriateness cannot be readily assessed. If such prescriptions are made by phone, the physician should document that the patient's clinical status and other medications have been assessed, that possible side effects were discussed, and that the patient was told under what circumstances to call again.

For prescription renewals by phone, an assessment of clinical status to check for side effects and the appropriateness of continuing the medication is important and should be documented in the patient's record. When prescribing controlled substances over a long period of time to a patient whose disease process is stable, the Massachusetts Board of Registration in Medicine (BRM) recommends that the physician see the patient at least once every six months. For patients who are using Schedule II substances, the BRM recommends that the physician see these patients as often as possible and clinically re-evaluate the patient at least every four months.

Access FAQs Online

You can view the entire collection of FAQs on the CRICO/RMF web site at www.rmf.harvard.edu. To ask your own questions related to patient safety and risk management, select "submit a question" on the FAQ home page.

CRICO-insured providers with urgent or confidential questions may contact their institution's risk management representative or telephone the CRICO/RMF Loss Prevention/Patient Safety Department at 617.495.5100.

While the FAQ information provided is not intended to substitute for advice given by your own attorney, risk manager, or claims representative, the questions serve as a starting point for exploring some of the issues. ■

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In addition to teamwork training, the ongoing incentive program requires participants to, each year, review Harvard's obstetrical care guidelines[10] (and pass a test on them), and to complete two online continuing medical education courses.[11] The program initially targeted obstetrical attendings and fellows but, now, obstetrical residents and family practice attendings and residents are actively being encouraged to participate. Harvard-affiliated midwives are also encouraged to participate in these risk reduction activities.

In addition to didactic and simulation-based team training, the use of clinical guidelines to standardize obstetrical care across Harvard-affiliated labor and delivery units strengthens CRICO/RMF's system-wide efforts to reduce obstetrical errors and adverse events. The *Clinical Guidelines for the Obstetrical Services of the CRICO-insured Institutions* were originally disseminated in 1988 and undergo frequent review and revision by a multi-disciplinary team of Harvard's Obstetrics chiefs, Labor and Delivery nursing leaders, and Certified Nurse Midwives. The current edition of the clinical obstetrics guidelines addresses 26 specific issues and provides samples of informed consent for several obstetrical procedures. The next revision will be issued in early 2006.

Complimenting these initiatives, CRICO/RMF has provided funding for the following obstetrics-based patient safety projects:

- Towards a high reliability perinatal unit: demonstration program to embed principles of simulation-based event management and teamwork
- Reduction of adverse perinatal outcomes in pregnancies with decreased fetal movement

Notes

1 American College of Obstetricians and Gynecologists. Preserving patient access to women's health care: the facts and figures behind the liability crisis. 2004. www.acog.org/from_home/departments/dept_notice.cfm?recno=11&bulletin=2688

2 ACOG: Red Alert Women's Health Care at Risk: The Professional Liability Crisis. American College of Obstetrics and Gynecology (Washington, DC), 2002.

3 Preventing infant death and injury during delivery. Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Sentinel Event Alert, Issue 30, July 21, 2004. JCAHO Sentinel Event Newsletter, 2004

4 Groff H, Martin PB (eds): Perinatal risks. Risk Management Foundation of the Harvard Medical Institutions, Forum, 2001; 21(1):1-14.

5 Effects of a team intervention in labor and delivery. LD Study Summary 24 Nov 2004 – FINAL(3page).doc. Department of Defense, Patient Safety Library. Accessible at: patientsafety.satx.disa.mil/Library

6 Clinical Crossroads, Conferences with Patients and Doctors: A 38-year-old woman with fetal loss and hysterectomy. Discussant: Sachs, BP. JAMA, 2005; 294(7):833-840.

7 Raemer DB, et al. Development of a simulation-based labor and delivery team course. Anesth Analg, 2003;97(2S):S17.

8 CRICO Obstetrics Risk Reduction Rewards Program. Risk Management Foundation of the Harvard Medical Institutions. Accessible at: www.rmf.harvard.edu

9 CRICO/RMF internal document: CRICO Obstetrics Risk Reduction Rewards Program, Final Report, 2004-2005 Program Participation.

10 CRICO/RMF references: Obstetrical Guidelines for CRICO Insured Institutions, available at: www.rmf.harvard.edu

11 www.RMFCME.com

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