

# Surgery-related Claims and the Systems Involved

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**S**urgery represents an area of high risk and liability. If current trends continue, a surgeon's (annual) probability of being named in a malpractice claim or suit may soon reach one in 20.<sup>1</sup> In conjunction with increased frequency is the rising cost of surgery-related cases.

The average indemnity payment for CRICO cases naming surgeons is 20 percent higher than for other specialties (*Figure 1*). From 1991-2000, 22 surgery-related cases involved a payment exceeding \$1 million (*Figure 2*).

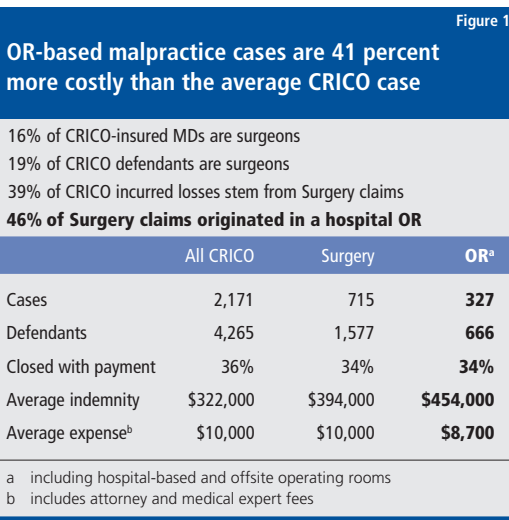
Litigation aside, the costs of surgical adverse events include further operations, extended lengths of stay, additional outpatient visits, and decreased trust in the health care system. Looking beyond the individuals to the systems that may have set clinicians up to fail is vitally important. The accompanying articles in this issue set out a framework in this pursuit.

## National Experience

CRICO's experience is not atypical. The 1990 Medical Practice Study found close to half of iatrogenic injuries were linked to an operation, with technical error in performance causing the majority of surgery-related adverse events.<sup>2</sup>

A 1992 study of 15,000 admissions to 28 hospitals in Utah and Colorado found that three percent of surgery patients encountered an adverse event, accounting for two-thirds of all hospital adverse events. Fifteen percent of surgical events resulted in permanent disability or death.<sup>3</sup> Clinical review indicated that 54 percent of the surgical events were preventable.

In a more recent University of Chicago study, observers following care on three surgical units (one ICU, two floors), determined that avoidable adverse events occurred in 18 percent of the admissions.<sup>4</sup>



## CRICO's Surgery Cases

Each CRICO case<sup>5</sup> was assessed for shortcomings in the process of care. The most common breakdowns were in clinical judgment, technical skill, communication, and documentation (*Figure 3*).

In the majority of the cases, underlying systems failures—small and large—contributed to the cascade of events that led to the claim or suit. Insufficient staffing experience, unreliable handoffs, and collaborative failures were key areas.

## Clinical Judgment and Underlying Systems

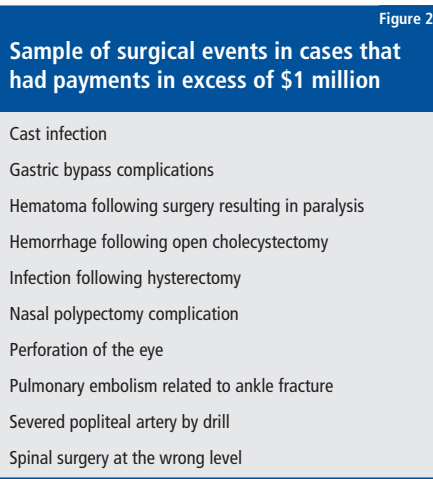
Surgery cases related to clinical judgment arose from many factors that left clinicians lacking the information they needed at key decision points. These included:

- incomplete or inaccurate history-taking,
- overreliance on the referring physician's diagnosis without independent assessment,
- failure to obtain consultation,
- poor office systems for tracking test results,
- misinterpretation of diagnostic studies,
- cognitive biases,
- inadequate supervision, and
- inadequate knowledge.

Particularly worrisome among the clinical judgment cases are those in which postoperative complications are mismanaged. Especially concerning is the failure to recognize signs and symptoms arising from a consequence of injury, with subsequent delays in treatment. Often, the most common complications are overlooked.

## CRICO Case Abstract #1

A 70-year-old woman with a history of abdominal hysterectomy underwent posterior repair, enterocele ligation, and sacrospinous ligament suspension. The surgery was performed, without apparent complication, by the chief Ob/Gyn resident under the attending surgeon's supervision. The procedure was more difficult than usual due to extensive surrounding fat.



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Postoperatively, the patient developed complications both before and after her discharge from the hospital; she called the MDs office several times with worsening symptoms. Ten days after discharge from the hospital, she was diagnosed with a perforated rectum and underwent an exploratory laparotomy, repair of rectal perforation, and transverse colostomy. The operative note for this procedure stated “the obvious rectal tear was closed with four 3-0 silk sutures.”

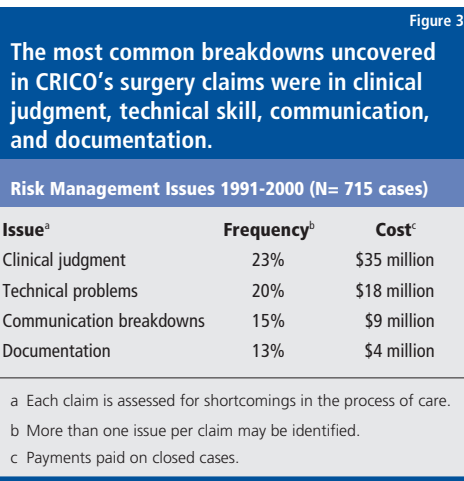
A malpractice suit was filed against the attending surgeon and the senior resident for causing a rectal tear which was not immediately recognized at the time of surgery. The case was settled in the mid-range.<sup>6</sup>

The technical error and the delay in diagnosing the complications were the plaintiff’s key reasons for filing suit. Worth noting, however, is the fact that poor record keeping in this case persuaded the defense team to settle.

The first step to addressing *postoperative* complications with patients takes place during the *preoperative* patient consent process. Actively involving the patient in the medical decision making process is key. Conducting and documenting a discussion about potential complications heightens awareness and may minimize the surprise if something occurs.

If common postoperative complications (e.g., development of infection or pulmonary embolism) are not diagnosed in a timely manner or treated properly when they do occur, the results are often tragic. Such preventable adverse outcomes due to missed or mishandled complications can be avoided by being aware of:

- the scope of potential injuries,
- factors that increase the patient’s risk for post-operative complications,
- techniques for early detection,
- strategies for expert repair, and
- patients with repeated complaints.



Although communicating unexpected outcomes can be difficult to discuss, such communication is an essential aspect of surgical patient safety. Learning and practicing effective techniques for giving bad news can help to maintain a trusting relationship with your patients and greatly reduce your risk exposure.

### Technical Skill and Underlying Systems

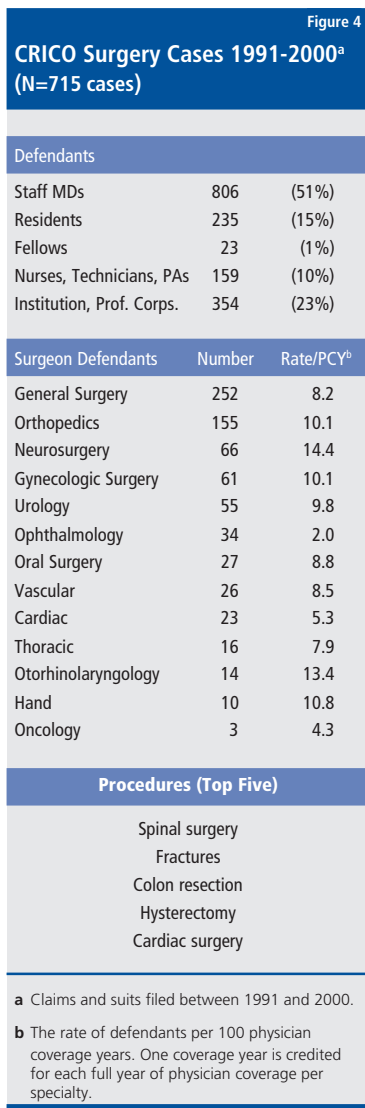
In the CRICO cases examined, experienced and inexperienced surgeons alike encountered technical operative complications. These were due to a multitude of causes including inadequate surgical technique, the learning curve for new procedures, communication breakdowns, and inadequate supervision. Common factors included:

- collateral injury to organs,
- misuse of equipment,
- inappropriate delegation of procedures to a less-experienced resident,
- lack of “alert hovering” by attending surgeons leading to delayed diagnosis of intraoperative complications,
- lack of information sharing among team members, and
- inexperience with the particular surgical procedure.

### CRICO Case Abstract #2

After undergoing the resection of an arterial venous malformation, a 56-year-old male suffered a stroke resulting in left side paralysis. The patient filed a malpractice suit, alleging that the stroke was caused by damage to an artery during the surgery, which was performed by the chief resident after she consulted with the attending surgeon. The case was settled in excess of \$1 million.

The assumption that the resident was inexperienced was a key factor in the filing of this malpractice suit. Worth noting, the supervising attending altered the operative report in an effort to distance himself from the event.



Technical errors are rarely straightforward problems of human error; organizational issues are often implicated. Many of the events that led to claims against CRICO surgeons could have been prevented if a coordinated team approach to care and communication had been in place. Complex and incomplete dialogue, production pressures, and multiple teams working under pressure can foster misunderstanding and a lack of coordination that lead to the operative injury and litigation. Most errors, were matters of confusion or distraction.

### CRICO Case Abstract #3

A 50-year-old male underwent bilateral osteotomy and left tendon lengthening. Surgery started on the left leg, then proceeded to the right leg. After completion of the right leg procedure, it was noted that the tourniquet had remained on the left leg for an extended period of time. As a result, the patient developed a peroneal nerve palsy. The case was settled in the mid-range.<sup>6</sup>

### Communication and Underlying Systems

Although a breakdown in communication is rarely the stated cause of a surgical injury, it is often a significant contributing factor. A patient's or family's reaction to an unexpected clinical outcome is often directed by their relationship with the primary caregivers involved. Poor communication among clinicians can lead to diagnostic and technical errors. Inadequate physician-patient communication can trigger malpractice claims—even when the surgical treatment meets the standard of care. Communication trouble spots include:

- not listening or not paying attention to the patient's preferences;
- not evaluating patients promptly;
- not returning phone calls;
- inadequate discussion of alternatives to surgery and risks of complications;
- a failure to prepare patients for the realities of surgery, i.e., closing the "expectation gap."

As research shows, the perception held by the patient and family regarding the quality and tone of medical care has real impact on their course of action following an adverse outcome.<sup>7</sup> Patients who misunderstood the risks of surgery, who are confronted with a defensive attitude when they seek an explanation of what happened, or who witness the physician shift from healer to adversary, are prime candidates to file a malpractice claim.

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Figure 5

### Trigger Points Identified in Surgery Claims

Many different systems breakdowns lead to the events that risk patients' safety and trigger malpractice claims. Here are some of the trigger points identified in CRICO's surgery-related claims:

- ◆ Failure to meet patient expectations
- ◆ Failure to seek appropriate data
- ◆ Incomplete information sharing among surgical team members
- ◆ Insufficient training
- ◆ Lack of checklists, standardization
- ◆ Lack of critical information when making decisions
- ◆ Lines of authority not clear, including the role of consultants
- ◆ "One size fits all" credentialing shortcomings
- ◆ Overconfidence in abilities
- ◆ Overlooking diagnostic studies
- ◆ Patient's emotional distress not fully addressed
- ◆ Poor equipment maintenance
- ◆ Poor office systems for tracking tests
- ◆ Rush to "clear" patient for surgery
- ◆ Scheduling/workload pressures
- ◆ Surgeons not answering pages, phone calls
- ◆ Weekend coverage
- ◆ X-rays, medical records not available in the OR

The goal of systems analysis is to focus on redesigning systems in order to prevent individual mistakes from recurring, and from triggering collateral mishaps. For example, researchers using the systems analysis approach have studied communication and teamwork errors in the operating room where rigid, hierarchical lines of communication prevent critical information getting to the right people. Unfortunately under such circumstances, several relatively small errors can cascade into a much bigger problem. Fortunately, the genesis of such errors can be determined and methods for reducing them developed.<sup>8</sup>

Improving the patient's decision making process is paramount. Several of CRICO's surgery cases stemmed from inadequate explanations of risks and repeated failures to communicate with the patient and family.

### CRICO Case Abstract #4

A 32-year-old woman, seven months pregnant, was referred to a surgeon for treatment of "bilateral inguinal hernias." The surgeon noted, in a single line in the record, "*bilateral inguinal hernias*," and suggested hernia repair one month after the patient's planned cesarean section.

At the appointed time, the patient, who was then asymptomatic, presented to the surgeon for a pre-operative exam. The brief exam did not include her groin area. Relying upon the pre-existing diagnosis, the surgeon performed a herniorrhaphy, which revealed no evidence of a hernia. The postoperative course was complicated by infection and an additional procedure to remove

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retained suture material. The patient brought suit against the surgeon for unnecessary surgery. Her medical record was devoid of documentation of her symptoms, physical exam, or the clinical rationale for doing the surgery. The case was settled in the low range.<sup>6</sup>

Cases stemming from inadequate preoperative assessment are difficult to defend. Overreliance on the opinion of the referring physician, and haste, can be contributing factors. As Case 4 illustrates, going forward without one's own assessment of the patient's complaint can lead to significant trouble. The record must contain the clinical conditions that justify the surgical intervention and a thorough informed consent.

## Documentation

Every physician—regardless of specialty—is simultaneously hounded by paperwork and reminded about the importance of good documentation. Nevertheless, each of the CRICO cases detailed above involved inappropriate or inadequate documentation. And in each case—as is true with the majority of malpractice cases—documentation issues impacted the defensibility of the care provided. For the most part, jurors tend to see inadequate, missing, or altered documentation as a reflection of the provider's overall competence.

## Summary

Patients—and, increasingly, plaintiffs' attorneys—seem to demand perfection from physicians, especially surgeons. But, the inevitability of human error demands that health care providers learn from mistakes and strive to reduce their recurrence. The recommendations provided within this article and those that follow can help surgical teams position themselves to address the individual and systems issues that are key to identifying harm and reducing adverse events. ■

### Notes & References

- 1 Based on six CRICO-hospitals where surgery is performed, the likelihood of a surgeon being named in a malpractice claim or law suit in a given year was 1 in 30 from 1994-96 and 1 in 24 from 1997-99. The projected rate for 2000-2002 is 1 in 19.
- 2 Brennan TA, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *New England Journal of Medicine*. 1991;324:370-76.
- 3 Gawande AA, et al. The incidence and nature of surgical adverse events in Colorado and Utah 1992. *Surgery*. 1999;126:66-75.
- 4 Andrews LB, et al. An alternative strategy for studying adverse events in medical care. *The Lancet*. 1997;349:309-13.
- 5 Based on claims in which a surgeon was named as a defendant or co-defendant, or in which there was a surgery-related allegation or diagnosis-related allegation involving a surgeon, or an injury alleged to result from an operation, or from care related to an operation.
- 6 Low range: < \$99,999; Mid range: \$100,000 - \$499,000; High range: >\$499,999.
- 7 Beckman H, et al. The doctor-patient relationship and malpractice. *Archives of Internal Medicine*. 1994;154:1365-70.
- 8 Helmreich RL and Schaefer HG. Team performance in the operating room. In: M.S. Bogner (Editor), *Human Error in Medicine*. Hillsdale, NJ: Lawrence Erlbaum and Associates. 1991:225-53.

"Patients who misunderstand the risks of surgery, who are confronted with a defensive attitude when they seek an explanation, or who witness the physician shift from healer to adversary, are prime candidates to file a malpractice claim."

Figure 6

## Recommendations for Reducing Surgery-related Claims

Given the increased complexity of treatment options and shortening inpatient stays, the potential for iatrogenic injury to surgery patients is expanding. Looking at solutions from multiple vantage points including the provider, the system in which the event occurred, and the organizational context requires a truly multidisciplinary effort. The following recommendations run the gamut from easy fixes to system overhauls.\*

- Aim for high quality training (e.g., simulation) and supervision.
- Build trust; act as advocates for your patients.
- Communicate honestly with the patient and the patient's family no matter what the outcome.
- Consider procedural standardization and checklists.
- Document the thought process that resulted in your actions.
- Encourage second opinions, as necessary. Respond to requests without defensiveness.
- Gain communication expertise, particularly when informing the patient about a poor surgical outcome or mistake. Avoid moving from the role of a healer to adversary.
- Identify (and document) specific risk factors that place surgery patients at high risk of poor outcome and engage patients in deciding whether or not the potential benefits of surgical repair offset those risks.
- Improve your patients' decision-making process through informed consent:
  - ◆ more education about the diagnosis and treatment,
  - ◆ realities of surgery,
  - ◆ more attention to patient's wishes and preferences, and
  - ◆ ask confirmatory questions to gauge patient understanding (and document).
- Increase awareness of practice patterns:
  - ◆ failure to see and evaluate patients promptly,
  - ◆ lack of returning patient/family's telephone calls,
  - ◆ cross-coverage not airtight,
  - ◆ unreliable check and balance system for reviewing diagnostic studies, and
  - ◆ lack of vigilance in the post-operative period in the high-risk patient.
- Look for common system factors that cause the most injuries and target improvement efforts there (e.g., learn from near-miss events).
- Value all communication regardless of position and rank.

\* For assistance implementing these recommendations (within the CRICO-insured community), contact RMF's Loss Prevention Department at 617-495-5100, x519

**F**orum recently sat down with Dr. Lucian Leape, Adjunct Professor of Health Policy at the Harvard School of Public Health and member of the Institute of Medicine Quality of Care in America Committee. Formerly a pediatric surgeon, Dr. Leape has pioneered the patient safety movement through his research into medical errors.

*As we enter the new millennium, what is the essential ingredient for making health care safer?*

**Leape:** Leadership. If the CEO says “this is important and we’re going to do it,” then it will happen. It’s really a matter of identifying the things that you’re most interested in working on and freeing people up to do it.

Setting the priorities is the first order of business. The second is creating a non-punitive environment, and then giving people responsibility and support. Several hospitals that I know don’t seem to be held back by anything that others are talking about—not having the time or resources. The problem is a matter of lack of will, but it doesn’t have to be.

*Setting priorities can be daunting. Where do you start?*

**Leape:** Change works best when people are working on the things they are interested in. So, if they’re really concerned about their medication system then they should work on their medication system. If they’re really concerned about the operating room, then they should do that. But the key ingredient is leadership and support at the top, because the people on the front lines cannot, by themselves, change the systems. They have to have support. There has to be an edict that says, “We do not punish people for making or reporting errors. Period. We only punish people for misconduct.”

*What’s the difference?*

**Leape:** Very few errors are due to misconduct. Most errors are caused by systems failures, not people failures. It’s what I call the transforming concept that the Institute of Medicine reiterated, but really originated with James Reason about 10 years ago.<sup>1</sup> We’re all taught just exactly the opposite of that. Probably the single biggest barrier is getting over that conceptual hurdle. Once you do, the world opens up because you begin to see *how* systems fail. Once you take a systems view, then a whole lot of things become pretty obvious to you.

Patients don’t go in the hospital without somebody to watch over them any more. What kind of indictment is that? You don’t trust the hospital enough that you have to have somebody there watching you? We have to do something about that.

*What else is crucial to getting this going?*

**Leape:** We have to go to work on interpersonal relations. This has to do with teamwork and the way in which health professionals relate to one another, physicians and nurses alike. It is something we really haven’t addressed yet.

Certainly, nurses need to be paid more and we have to figure out a way to get them better hours. But it’s a much bigger issue than that, it’s the way nurses are treated and their role in the health care system.

Doctors don’t provide care, they prescribe care. Nurses actually provide it. It’s time for physicians to treat them as partners instead of servants. If nurses aren’t given the appropriate responsibility and authority, and if they aren’t given the time to do it, then it won’t be surprising when they quit. If we don’t address that, we [physicians] are going to be taking care of the patients by ourselves.

*What is the most important new area in patient safety?*

**Leape:** Problem doctors. It is time to address this issue. The public identifies “bad-apples” as the major cause of the health care safety problem, one that it believes the medical establishment is not controlling.

While the first perception is incorrect, the latter is on the mark. The vast majority of errors are made by competent and careful practitioners, so safety will not be measurably improved by going after the two to five percent of doctors who are the “bad apples.” But few hospitals have effective mechanisms for identifying and dealing with unsafe doctors. Hospital boards have preferred to delegate this responsibility to the administration, which in turn refers it to the medical staff. But the medical staff in most hospitals has been reluctant to judge professional competence except in the presence of overpowering evidence of deficiency.

*What do you suggest?*

**Leape:** We need to develop a professional standards system. It should include at least the following essential elements: 1) it should be proactive, identifying problem people *before* they hurt someone; 2) it should be objective, not subjective, which means it sets standards of perfor-

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mance (which is not easy) and measures compliance; and 3) it should be fair: everyone gets monitored. If this approach is promising, then the challenges are to develop performance criteria, to develop unobtrusive and workable monitoring systems, and to establish and implement a broad repertoire of responses to the failings that are identified.

Crucial to success is a sincere and, if necessary, extensive effort to enable the individual to continue to practice medicine. Referral to the Board of Registration in Medicine for disciplinary action would be reserved for failures of the system to remediate the individual. Implementation of such a system may require some re-thinking of the respective roles of the hospitals and the Board, with a fair amount of two-way trust as it was worked out.

### *Are we moving closer to addressing fatigue as a safety issue?*

**Leape:** I hope it's sooner rather than later, but I have no doubt that 10 or 20 years from now we will look back and ask, "Did doctors and nurses really work more than 12 hours at a time?" Just like we now can't imagine people driving without seat belts. It's the same sort of thing.

It's clearly in the cards. Most of us don't function very well after 8-10 hours of work, and we certainly don't function well after 12 hours. So it's really just a matter of time before it'll be against regulations for any physician to work more than 12 hours. It's the just thing to do.

### *How?*

**Leape:** Well, we need some rules. For example, if you're up all night taking care of a trauma patient, you don't operate the next day. We have to accept the fact that we run a 24-hour, seven day a week service and we need to design a system to provide that. We need a lot of help from operations research people who can chart the flows of our demand and see what the patterns are, and adjust our staffing to those patterns, and work it out. When people do that, they find they give better care and they're happier. Figuring how the load ebbs and flows, as it always does, and arranging staffing to fit that can be done, but it starts with deciding that it's something you want to do.

### *Are you advocating overhauling health care?*

**Leape:** This is the main thrust of the second IOM report<sup>2</sup> which has received much less publicity, unfortunately, than the first, which is too bad, because it's much more profound. We really need to reorganize our health care system

The vast majority of errors are made by competent and careful practitioners, so safety will not be measurably improved by going after the two to five percent of doctors who are the "bad apples."

around a few basic principles, including patient-centeredness, i.e., rethinking what we do in terms of meeting the patient's needs instead of organizing our care in terms of meeting our needs.

Currently, the patient has to fit into the hospital's system for getting a lab test, or getting an X-ray, or seeing a doctor. You, the patient, adjust to their system, rather than the system adjusting to your needs. Obviously it would be better to have a system where people wouldn't have to miss work in order to get a blood test done, or an X-ray done, or see a physician.

Well, we can do that, if we decide that's what we want to do. What the IOM said was, it's time to rethink how we do everything. We should quit doing things we know don't work, we should make arrangements to make sure that people get what they do need, and we should reorient toward meeting the patient's needs. If you have a two-year-old child, who's screaming with an ear infection, you ought to be able to get the same quality of care at 2 a.m. as you get at 2 p.m., and we can do that. We're really talking about safety as part of a much bigger problem, which is the way we approach the organization of health care.

### *Is there support for such dramatic change?*

**Leape:** The pressure is building for some fairly major changes. Fortunately we're seeing some interesting models develop that we can replicate. I'm optimistic that we're going to see important and worthwhile changes in the next few years. For example, it is time to make a priority of moving ahead on the electronic medical record, and computerized order entry. We've got to get out of the paper-based system, it is such a barrier to moving ahead in terms of efficient utilization of information, as well as learning.

For example, new medications are now tested on about 5,000 people, and that shows 90 percent of the problems. If we had computerized patient records, you could know *all* of the problems from a new medication in two to three months because you'd have data from 100,000 people. That's just a simple example, but the potential for improving quality is terrific.

*Have you always been optimistic or is something different today?*

**Leape:** I'm optimistic because I've seen too much. In the early days of pediatric cardiac surgery, we were losing 25 percent of our babies. But we don't anymore. We solved those problems which were as big as these problems. How did it happen? A lot of smart people went to work on it.

That's what's happening today in safety. A lot of smart people are going to work on it, people who really care and who understand it. We are beginning to get some doctors in the hospitals focusing their intellect on it. We solved tougher problems than this, so of course we can solve this. We finally have safety on the agenda. That is why I am optimistic.

*Is supervision a significant patient safety problem?*

**Leape:** I think so. In the Libby Zion case<sup>3</sup>, the big point wasn't fatigue, it was lack of supervision. The least experienced person on the team is taking care of the sickest people. Again, it is a leadership issue: these things occur because they are permitted to occur. I leave it at the doorstep of the deans, the CEOs, and the department chairmen. If and when they want to change this, it will change for the better.

*Why do we see a transition in thinking from "errors" to "harm"?*

**Leape:** In the Medical Practice Study<sup>4</sup>, we started out asking how many people are getting hurt and what are the costs and consequences of that? We discovered that a lot of those harms were caused by errors and, therefore, were at least potentially preventable.

Now when you say "error," one of the problems is that people link that word with finger pointing and blame. We are trying to overcome that by reframing the question in terms of process defects that cause "harm" and getting rid of the word "error." We want to get to the point where we can say "error" and people don't take it personally. That's what we are talking about.

*How can systems thinking be applied to surgery?*

**Leape:** Watching a good surgeon can be a real delight. There is a minimum of unnecessary motion, things go smoothly, and everyone knows what to do. They have an efficient team. They have standardized the process and simplified it, and they have made it elegant. When we talk about systems thinking, we are talking about extending that kind of thinking to everything we do: preparation, standardization, teamwork, definition of what you are doing, being clear about what your objectives are, and how you are going to carry out the plan.

Watching a good surgeon can be a real delight. There is a minimum of unnecessary motion, things go smoothly, and everyone knows what to do.

After a transplant operation, for example, postoperative orders are fairly complex, but also fairly standardized. Good surgeons make sure that all these things happen. All we are saying is, let's do more of that and then also pay much more attention to the interpersonal teamwork aspects. A good operation needs a good team, but we need it outside the operating room as well as inside. So I think surgeons, in a sense, may have more experience in some of this than some other parts of medicine.

However, most surgeons don't look at their complications that way, and that has to change. Everything that goes wrong is a systems/operation/process problem. Train your mind on it and see if you can figure it out. Once surgeons get engaged, they're going to take off. For example, orthopedic surgeons years ago realized that their hip patients had a high risk of thromboembolic phenomena so they put their patients on anticoagulants and did studies that showed a decreased incidence. It has now become standard procedure. Surgery is an area where progress might be more rapid than other areas because we tend to think in those kinds of terms.

*What role do you see for human factors engineering in patient safety?*

**Leape:** There is tremendous potential in getting human factors engineers to look at what we do. We get very used to our ways and it is very hard when you're in the middle of something to see what's not right or how it can be done better. A person who comes with a different set of glasses sees very different things.

But, we have a big secret weapon, and that is that doctors, and nurses, and everybody really want to do the right thing. They want to give high quality care and not make mistakes, so the burden is on us to show them how to do that. Not to motivate them to do it, but to show them how to do it, and most of all, get rid of the barriers. ■

Notes & References

1. Reason J. *Human Error*. Cambridge, England. Cambridge University Press, 1990.
2. Kohn LT, Corrigan JM, and Donaldson MS, Editors. *To Err Is Human: Building a Safer Health System*. Washington, D.C.: Committee on Quality of Health Care in America, Institute of Medicine.
3. Zion v. New York Hosp., 183 A.D.2d 386, 389 (1992).
4. Leape LL, et al. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. *New England Journal of Medicine*. 1991;324:377-84.

# Effective Leadership for Patient Safety: Creating and Leading Significant Change

## James B. Conway

Jim Conway is the chief operations officer of the Dana-Farber Cancer Institute, Boston, board member of the National Patient Safety Foundation, and steering committee member of the Massachusetts Coalition for the Prevention of Medical Error.

In 1995, two tragic and heavily publicized medication errors had a dramatic impact on the leadership at Dana-Farber Cancer Institute (DFCI). As clear evidence that much of learning is based on examining errors, representatives of DFCI continue to receive many invitations to teach what they learned from this experience. In conjunction with the American Hospital Association, and with input from organizations and colleagues from across the country, we put together an informal checklist by which health care leaders can measure their commitment to improving patient safety.

This tool, *Hospital Executives and Their Role in Patient Safety*, is an effort to give leaders a range of choices to consider, periodically revisit, and use to trigger action. Completing the self-assessment with others is an opportunity not only for setting priorities, but also for reinforcing the rewards of honest appraisal. Having a number of checks in the “yes” column of self-assessment is far more significant than having none, but identifying a plan to move some checks from “no” to “yes” could be equally significant.

While I wish this tool could be extensively annotated, externally validated, and backed by a 100 percent guarantee that it will drive massive improvement, that is not the case. However, the tool does reflect much of the best learning to date.

## Hospital Executives and Their Role in Patient Safety

### Personal Education

#### Y N

- Read *To Err Is Human: Building a Safer Health System*. Kohn LT, Corrigan JM, and Donaldson MS, editors. Washington, DC: National Academy Press; 1999.
- Read other primers on patient safety:
  - ◆ *Human Error*, Reason JT. Cambridge University Press, 1990.
  - ◆ *The Psychology of Everyday Things*, Norman D. Basic Books, 1988.
  - ◆ *Managing the Risks of Organizational Accidents*, Reason JT. Ashgate Pub. Co., 1997.
  - ◆ *Normal Accidents: Living with High Risk Technology*, Perrow C. Basic Books, 1984.
  - ◆ Lucian Leape’s seminal articles.
  - ◆ *Human Factors in Aviation*, Wiener EL and Nagel DC (eds). Academic Press, 1989.
- Participate in external safety education programs, CME, conferences, etc.
- Hold detailed conversations with in-house experts on our realities of practice.
- Walk my hospital with a human factors expert.
- Walk my hospital as a patient.
- Familiarize myself with enhanced JCAHO Patient Safety Standards.
- View Bridge Medical video “*Beyond Blame*” and Partnership for Patient Safety video “*First Do No Harm*”

### Call to Action

#### Y N

- Speak publicly to various audiences on the unacceptability of the current state of and my commitment to patient safety as a personal and corporate priority. Include safety focus in hospital publications, strategic plans, etc.
  - ◆ Board and hospital leaders
  - ◆ Medical and hospital staff
  - ◆ Patients/consumers
  - ◆ Media
- Implement a proactive effort on patient safety design, measurement, assessment, and improvement. Include direct care, administrative and clerical staff, and patients and family members in all aspects.
- Set the goal of establishing an environment of trust with a non-blaming, responsibility-based approach to the causation of incidents and errors; establish policy in this area.
- Set the expectation for timely and interdisciplinary error and near-miss investigations with an emphasis on: patient/family impacted by the error; the broader institutional implications of and learning from the error; and the support of staff at the sharp end [closest to care].
- Build quality improvement and patient safety policies into staff orientation and continuing education offerings.
- Set the expectation for executive involvement in significant incident investigations.
- Establish a policy to ensure patients/families are notified ASAP when an error reaches a patient.
- Establish effective grievance systems for patients/families who see themselves as “victims of error.”

- Establish mechanisms to train leadership and other experts in patient safety.

## **Hospital Executives and Their Role in Patient Safety** *continued*

### **Practicing a Culture of Safety**

**Y N**

- Openly engage with medical staff, nursing, and other leaders in patient safety planning.
- Continuously articulate the business case for safety improvement.
- Personally participate in a significant incident investigation/root cause analysis.
- Tell “my story” around incidents/errors that I have been involved with and the systems improvements that could have prevented them.
- Routinely involve myself, all levels of our staff, and our patients and family members in direct and ongoing communications around the patient safety work of our institution and areas for improvement.
- Routinely bring patient safety matters, trending data, and specific cases to the board and other hospital leadership committees.
- Routinely probe staff perceptions of risk areas from existing or proposed systems and take immediate actions wherever possible.
- Openly support staff involved in incidents and their root-cause analysis.
- Ensure that there is ongoing prioritization and achievement of safety improvement objectives.
- Ensure that articles on patient safety matters regularly appear in my organization’s communications vehicles.
- As part of annual budget preparation, ensure resources are funded for priority safety areas.
- Request and routinely receive reports on facility utilization of and comparison with best-practice information from the AHA, NPSF and ISMP.
- Ensure self-assessments from the AHA and others are completed and used internally for quality improvement activities.
- Cultivate media understanding of patient safety and my organization’s efforts to improve safety.
- Ensure effective systems are in place to assess individual accountability and competence.

### **Advancing the Field**

**Y N**

- Share my personal and the institution’s patient safety learning outside of the organization.
- Participate in local, regional, and national conferences, coalitions and other efforts to improve patient safety.
- Engage in initiatives to drive enhancements in regulatory, facility/professional licensing, and accreditation agencies that support safety improvement and cultural change in consort with the specific goals of the agency.
- Advocate for my professional association to make/keep patient safety a high priority. ■

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### **Acknowledgment**

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**RISK MANAGEMENT FOUNDATION** HARVARD MEDICAL INSTITUTIONS

# Principles for Developing Education and Training to Improve Patient Safety

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Patient safety has become a touchstone for much of what ails health care systems of industrialized nations. What a community of researchers and experienced providers have known for decades has suddenly become a public discussion forum—the economic and ethical burden of preventable injury due to medical management failures is large and unacceptable.

Harmful variation in processes, needless complexity, barriers to flow of critical information, and perverse incentives for individual and organizational performance have emerged as key themes in the broader analysis. Given this emphasis on systems and structures, what is the role of medical education and training in improving patient safety?

Some cast preventable health care failures largely as medical errors made by providers, and call for tighter accountability and improved clinical training. The caution is offered that an overemphasis on systems can undermine professionalism and personal responsibility—amounting to passing the buck.<sup>1-3</sup> Another view points out that exhortation to do better coupled with blame—explicit or implicit—is ineffective given already strong motivation to succeed, and, the inescapable fact that humans are imperfect.<sup>4</sup> Error-retraining cycles will not have a broad impact, will not win the hearts and minds of employees and providers, and will probably waste scarce resources.

Others have called for human factors training, widespread rehearsal using simulators, and courses in patient safety.

Given the foundation that medical education provides for practice, a compelling case can be made to develop and test safety-related training, and attempt to evaluate its impact. Additionally, thought leaders in the patient safety movement have suggested models from other complex, risky but reliable industries that highly value work force development, continuous training, teamwork and safety culture.<sup>5</sup>

## Process

Before considering a list of principles that can serve as a framework to guide development of safety-related training, it is useful to briefly discuss several general concepts. Safety means freedom from harms, but is also a code word for several important related notions including process control and respect for individuals. Unpacking these ideas has implications for idealized medical education. Systems such as health care are characterized by task variety, surprises (contingencies), resource constraints, forced decisions under ambiguity, and key social inputs—team dynamics and culture, or “how the work gets done around here.” These elements combine with clinical actions and factors to create complex processes.

Given the foundation that medical education provides for practice, a compelling case can be made to develop and test safety-related training, and attempt to evaluate its impact.

The real connection here is that providers no longer function as 1:1 deliverers of expertise to patients. As managers of populations, information, teams, and participants in distributed systems, providers have seen their work evolve as it has in other industries over the past several decades.<sup>6</sup> Health care has never been simple, but recently the complexity of health care has logarithmically increased at the same time that demands for greater value and expectations for predictable safety have increased as well.

These trends place a burden on educators and decision makers who deliver resources for training. Providers must become aware of their role as actors in the system, learn to manipulate resources for patients’ benefit, and develop metacognitive skills—or “thinking about thinking”—to keep the care path safely on track.

Having an accurate four-dimensional representation of the patient, providers, tasks, tools, and goals in time requires practice. The role models who do this well did not achieve their status as a result of an explicit, systematic protocol. A major challenge to medical pedagogy will be to demystify this process, assess complex process management behaviors more effectively, and reduce variation in providers’ acquisition of these skills, and attitudes.

## Complexity

Ecological metaphors have long been a part of conversations about complex systems dynamics but only recently have made their way into the health care improvement dialogue. Ecological metaphors are useful because most people now understand and accept non-intuitive complex systems concepts in terms of their concrete effects in biospheres, e.g., outcomes associated with straightening streams, using pesticides, and erasing wetlands to get rid of mosquitoes. Other related concepts are just as important but may not have the same primacy, currency, or direct relation to core education about process control, e.g., the generation of great variety does not require combinations of complex rules, a few simple rules will do.

- Small things can have a large impact.
- Large things can have little or no impact.
- Beware of the “law of unintended consequences:” a well-intended plan can have the opposite effect.
- Starting conditions are important.

People do not inherently understand or manage complex processes well. They tend to underestimate the rate of change, have a constricted view of their own sphere, and oversimplify interactions and interpretations.<sup>7</sup> An additional problem is not having a full mental model of the system at hand. Performance can be improved by increasing awareness of these issues, training in complexity management, providing a richer model that maps to the system more fully and insuring/seeking frequent feedback during trials.<sup>7,8</sup> The current health care apprenticeship system does not deal with these issues effectively.

### Relationship to Safety Culture

Behavior change among adults—including physicians—derives from a complex combination of goal setting, deliberate practice, feedback, and reinforcement.<sup>9</sup> Behavior change, especially in complex and important domains like medical clinical competence, is effortful and time-consuming. It also has affective consequences as one’s sense of self-efficacy and motivation to perform are shaped and strengthened by successive mastery experiences.<sup>10</sup>

Given the complexity of the balance of incentives and constraints, combinations of methods to shape physician behavior are more likely to succeed than one intervention alone.<sup>11</sup> And, given that safety in complex work is a systems level characteristic, it is critical to frame advanced safety training as a component of a systems-level intervention and not simply a provider deficiency.

A classic model of safety culture describes the elements or subcultures as reporting, learning, flexibility, and justice.<sup>12</sup> Providers must know what to report, how, and why, and they need to do so safely with rapid cycle feedback to keep the reporting coming—with incentives and lack of fear of retribution. The organization must honor learning above blame, improvement over the status quo, and use all available means to learn, including “safety imagination” about what could happen given known risks and near misses data.

“Flexibility” refers to role-sharing, and shifting of decision making in the moment when authority gradients become less important than using all available resources most intelligently. The “just” aspect of a strong safety culture

Given that safety in complex work is a system level characteristic, it is critical to frame advanced safety training as a component of a systems-level intervention and not simply a provider deficiency.

signals that only egregious, negligent, reckless acts obvious by broad consensus are punished. Errors, mistakes, and actions in retrospect which were part of a causal failure chain, but could have been made by any competent practitioner, are seen as learning opportunities—not occasions for negative reinforcement.

In the absence of a just culture and an effective, non-punitive system to learn from near misses and adverse events, a safety curriculum is not likely to have a positive impact and could be viewed as lip service.

### Convergent Developments in Medical Education

Recent changes in medical education emphasize:

- ◆ small, facilitated team learning;
- ◆ case-based teaching;
- ◆ earlier introduction to direct contact with patients;
- ◆ courses using information technology; and
- ◆ deliberate practice for eventual simulation-based licensure tests using objective, structured clinical exam skill stations.

These developments converge with the trend to provide advanced safety-related or process management training.

Debates about whether safety is a characteristic of the system or individual actors in the system are circular. Safety is all of the above. Arguments that providers are heroes struggling with a dysfunctional system are true but unrelated, and suggest specious corollaries that additional training is unlikely to have much benefit. The principles suggested below reflect the philosophy that the level of safety is a dimension of health care delivery that is critical for nurturing systemic trust, management of process and continuous improvement, and ultimately solvency in today’s climate. As such, safety training itself is a systems-level intervention that if wisely applied would be designed and implemented with an ecological mindset.

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## Suggested Principles for Developing Education and Training to Improve Patient Safety

- 1) Knowledge is power:** Small things do make a difference in complex systems, and this includes provider perceptions, decisions, and actions. Arming health care providers with the kinds of awareness and skills that other high performance professionals acquire as a result of systematic training will help level the playing field vs. complex process. Providers can generalize the ability to maintain situation awareness and distrust simple interpretations, and replace "error-free" with failure detection and correction. Safety training need not be prescriptive, but creative. As an emergent property of the system, safety must be fostered by leadership and design but also manifest as a bottom-up provider-take-action phenomenon.
- 2) Design systematic safety education and training:** Both are necessary, and not interchangeable. Some core didactic knowledge is likely to be useful, such as limitations and strengths of human performance, basic complexity concepts with concrete examples, explicit characterization of teamwork, aspects of safety culture, etc. Safety training must use experiential learning techniques and deliberate practice with feedback, including a variety of simulations and on-the-job reinforcements.
- 3) Build on cutting edge quality improvement and change management knowhow:** As with complexity management above and teamwork (below) the assumption cannot be made that individuals arrive ready made with these skills or can acquire proficiency rapidly. Improving safety in health care represents a major change in the status quo. Many barriers exist, including persistent lack of ability to see the safety problem, lack of systemic perspective, and pathological or bureaucratic organizational traditions which limit learning, growth and change.<sup>15</sup>
- 4) Small wins approach:** Look for opportunities to begin small, effective projects with a high chance of measurable success and future leverage in the organization.
- 5) Emphasize teamwork:** The team is a key unit of analysis for thinking about point of care mid-course corrections in complex organizations. Even highly trained experts can benefit from team training if their work is a team task.<sup>16</sup> Teams represent on-the-spot, flexible redundancy and have been repeatedly shown to outperform individuals. Inexpensive, low fidelity simulations may turn out to be rather effective for some aspects of training. The safety movement represents a major opportunity to explicitly address this long-standing deficiency in medical education and training.
- 6) Simulate well and often:** The most powerful attributes of simulation programs may lie in the quality and depth of their objectives and delivery. While these technologies and approaches are still limited in their scope and application in health care, they hold significant promise as powerful means to deliver both understanding of complexity and metacognitive skills to cope with it. Behavior change sustained with rapid cycle video feedback and inculcation of safety culture are potential benefits in addition to training for routine algorithm competency, rare interventions, teamwork, and critical incident management. Simulation also sends a strong ethical message to all stakeholders that patients are not commodities of training.
- 7) Horizontal and vertical integration across the organization:** Small interdisciplinary groups (horizontal) and top to bottom learning (across the authority gradient) will help break down barriers to understanding microprocesses, build common decision premises, trust, flexibility, and a strong safety culture. This will be understandably more difficult for some organizations to achieve than others.
- 8) Integrate into ongoing efforts:** As opposed to designing and trying to insert a block of safety practice into an already full schedule, imagine ways to knit advanced safety conversations into the fabric of the organization using ongoing morbidity and mortality conferences, ethics curricula, rounds, electives, continuing medical education, routine administrative functions and retreats, and other venues. This does not, however, obviate the need for a centralized, responsible safety function with direct reporting requirements to leadership.

Safety should ultimately be interesting and exciting to practitioners if framed as a component of expert practice, something to which all aspire. Experts rapidly understand nuance, gracefully juggle whatever situations arise, resolve conflicts, push and pull information when needed, and steer the right course without causing harm. The mark of a true expert is not error-free performance, but coping with complexity and contingency, recognizing failure early, and correcting course.

Advancing effective safety education and training in health care organizations will require strong leadership from respected clinicians and administrators, who can act as role models and provide sustained resources. Champions must also insure that safety education and training is integrated with and supports other key initiatives such as introduction of new informatics tools and reporting systems that together create robust safety culture. ■

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# Models of Error and Adverse Events

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Errors and the adverse events that sometimes arise from them can be viewed in relation to either the person or the system.<sup>1</sup> The actions to be taken to prevent or mitigate errors differ dramatically depending on the perspective used. Although the person model is more intuitive, and sometimes more emotionally satisfying, the systems model offers a more effective means of managing errors.

## The Person Model of Error Reduction

The person model is dominant in health care. It assumes that adverse events arise from unsafe acts or omissions committed by providers, and that those acts or omissions are the result of inattention, carelessness, laziness, lack of knowledge, or lack of motivation. These failures are seen resulting from choices made by providers to act safely or unsafely, and are viewed as the direct causes of adverse events.

Solutions under the person model are directed at individuals, in the form of exhortation, discipline, blame, punishment, and retraining. Any examination of contributing causes is screened by the underlying assumption that providers should be able to compensate for problematic working conditions, if they would only try hard enough.

Several difficulties limit the effectiveness of the person model.

- It is subject to hindsight bias, in that it fails to note that the course of action that seems so obvious after an adverse event has occurred may not have been so apparent before the fact.<sup>2</sup>
- Errors tend to occur in characteristic patterns, but by dealing with each event as if it resulted from an aberrant individual, the contextual information about the conditions of work that contributed to the error is lost. Not coincidentally focusing on the individual provider tends to remove questions about management and institutional accountability, raising further questions of the justness of this approach.
- It does not lead to improvement within an already highly-trained and strongly-motivated work force. Don Berwick has pointed out that, if we suspend every doctor who makes an error today, tomorrow's error rates will be exactly the same as today's.<sup>3</sup>

## The Systems Model of Error Reduction

The systems model, in contrast, assumes that providers, no matter how conscientious, well-motivated, and well-trained, will sometimes make errors in spite of themselves. For health care systems to be safe, they must account for these

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occasional errors. Thus, errors leading to adverse events are seen as the consequences of poor design or bad systems, not as causes in themselves.<sup>4</sup> In addition, the systems model rarely finds a single cause for an adverse event, or even a primary cause. Instead it uncovers a set of causal factors that are individually insufficient but whose conjunction leads to an accident or adverse event. These factors can be divided into two broad classes: "active" and "latent" failures.

**Active failures** are the unsafe acts or omissions committed by those in direct contact with the patient, at the so-called sharp end of the system.<sup>5</sup> Active failures can take three forms:

- 1 action failures, or slips: e.g., picking up the wrong drug vial;
- 2 cognitive failures: memory lapses or misperceptions of a situation; and
- 3 violations: deviations from safe operating practices, procedures, or rules.

Violations are a distinctly different kind of active failure, since they are often (but not always) intentional. While at first glance it might seem that violations are a problem best suited to the person model, in fact many violations are 1) routine, 2) generally accepted in the workplace, 3) viewed as either necessary or at least convenient ways to get the work done, and 4) only come to attention after an adverse event.<sup>6</sup>

A classic example of necessary violations comes from air traffic control: when controllers participating in job actions have "worked to rule," the normal flow of traffic has been seriously disrupted. Presumably, the desired and routinely accepted effectiveness of the controllers' work process involved working outside the rules.

**Latent failures** are faults created by decisions remote from immediate patient care, at the blunt end of the system. Latent failures typically occur at higher levels in the organization. The consequences of active failures are immediately apparent. Latent failures may lie dormant in a system for quite a long time, only becoming evident when the combined presence of latent failures and local triggering

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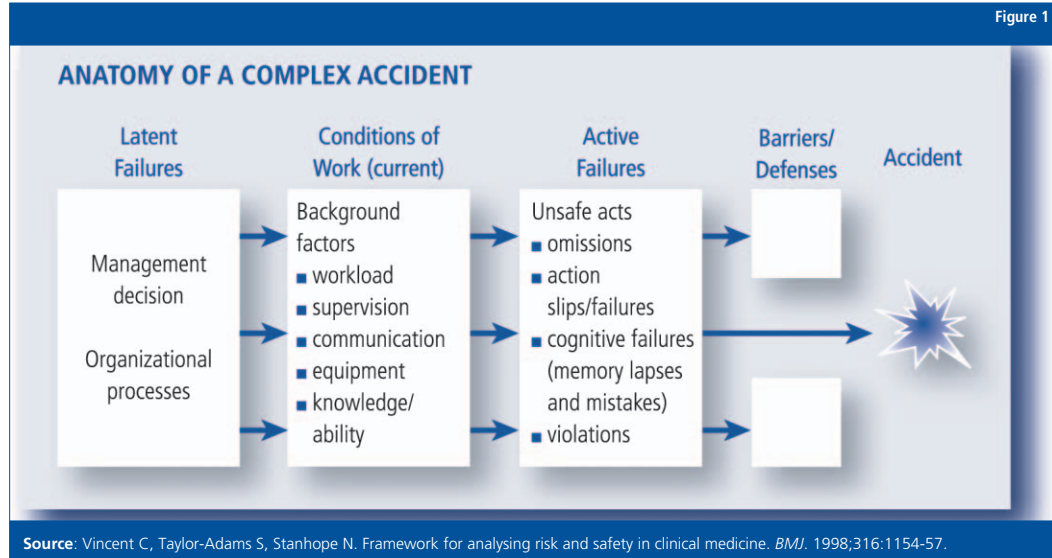
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factors (that may include active failures) leads to a system breakdown. The latency of these failures provides a greater opportunity for detection and control than with active failures.

Latent failures basically provide the context in which unsafe acts are elicited from providers. In Neville Moray's words, "The systems of which humans are a part call forth errors from humans, not the other way around."<sup>7</sup> Examples of latent failures include:

- heavy workloads,
- inadequate experience or supervision,
- a stressful environment (noise, frequent interruptions, production pressures),
- rapid organizational change,
- incompatible goals (cost reduction and clinical need), and
- poorly designed or maintained equipment.

Human factors and safety experts have identified a number of distinct levels at which both active and latent faults can occur, and any investigation of a critical incident should specifically examine all of them, rather than prematurely stop at the first reasonable fault.<sup>8,9</sup>



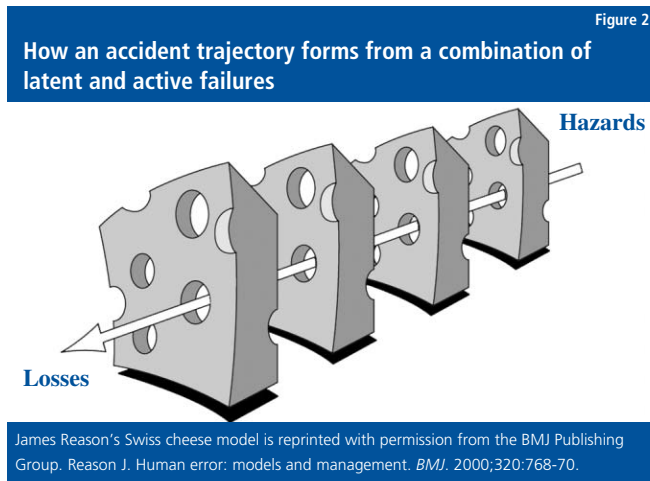
Moving from the lowest to the highest, we should examine

- 1 patient factors (complexity of case, communication barriers),
- 2 task factor (availability and clarity of protocols or procedures),
- 3 provider factors (fatigue, knowledge, motivation),
- 4 team factors (team structure and communications),
- 5 work environment (workload, noise, interface design),
- 6 organizational factors (financial constraints, safety culture), and
- 7 the institutional context (economic and regulatory world of health care organizations).<sup>4,10</sup>

The active and latent failures associated with a critical incident can be arranged in a hierarchy that can represent even complex 'organizational' accidents (*Figure 1*).<sup>4,10,11</sup> At the highest level, organizational influences and decisions create latent faults in the activities of planning, communication, maintenance, etc. These faults are realized in departmental and workgroup conditions that favor the commission of errors and violations.

### Systems Defenses

Although many active faults arise in the course of clinical work, most of them are caught by systems defenses. The providers themselves are a major systems defense, in that they frequently catch their own or their co-workers' errors before harm occurs. However, systems defenses are not perfect and occasionally (in fact, rarely) an active fault will slip through all the defenses and result in either a near miss (if no harm occurs) or an adverse event.



This concept of the causal web of events leading to an accident has been immortalized by James Reason as the “Swiss cheese” model of accident causation (*Figure 2*).<sup>1</sup> In this model, the holes that represent active and latent failures are continually appearing, enlarging, shrinking, and closing. An infortuitous alignment of faults is what leads to an accident. The emphasis here is on the dynamic nature of the systems of care; because each system is continually changing its state, assuring safety is a dynamic, active process.<sup>12,13</sup> We can never state that a system “is safe.” Rather, we can only say that we are actively and continually managing the systems in an attempt to keep them in a safe condition. The following (non-CRICO) case illustrates several systems that needed more of this kind of attention.

### Case Study

During the late evening hours, a 29-year-old woman with a history of asthma, hypertension, congestive heart failure, chronic renal failure requiring hemodialysis, and human immunodeficiency virus (HIV) infection presented to the emergency department (ED) complaining of shortness of breath. After some time in the ED, she became acutely agitated, diaphoretic, and had marked tachypnea and tachycardia. Her O<sub>2</sub> saturation by pulse oximeter was 90 percent while breathing 100% FiO<sub>2</sub> by mask. Intravenous access was obtained and continuous beta-agonist nebulization with albuterol, subcutaneous terbutaline, intravenous corticosteroids, and intravenous magnesium sulphate were ordered.

The resuscitation nurse went to obtain medications from an automated dispensing unit (ADU), part of a computer-based dispensing system in use throughout the hospital. He found an uninformative error message on the computer screen (“Printer not available”) and an unresponsive keyboard. The system did not respond to any commands and would not dispense the required medications.

The patient was well known to the ED staff. On a recent visit, she had deteriorated rapidly to cardiac arrest and had been successfully resuscitated. With this history fresh in mind, the primary ED nurse abandoned efforts to get the ADU to work and asked the unit clerk to notify the main pharmacy that the ADU was “down” and emergency medications were needed. He asked another nurse to try other ADUs in the ED. Other ED staff became aware of the problem and began to search for albuterol and magnesium sulphate ampoules in other treatment areas in the ED. Some of the ordered medications were discovered on top of another ADU, apparently waiting to be returned to stock.

Anticipating the patient’s clinical deterioration, the ED physicians opened the resuscitation cart and prepared to intubate the patient, using the medications and equipment stored there. A pharmacist came to the ED and examined the unresponsive ADU. He decided not to use the bypass key for downtime access because that required specific information that could not be obtained from a non-functioning unit. Instead, he arranged for the pharmacy staff to use runners to run medications to the ED in response to telephone requests. The patient eventually received the requested medications. She survived and was later discharged from the hospital.<sup>14</sup>

The systems model, in contrast, assumes that providers, no matter how conscientious, well-motivated, and well-trained, will sometimes make errors in spite of themselves. For health care systems to be safe, they must account for these occasional errors.

Investigation of this near miss revealed a complex chain of events leading to a near disaster. The hospital had installed (and regularly upgraded) a popular computer-controlled automated dispensing system for drugs and supplies. At the time of this incident, 40 ADUs were linked to two centrally-located computers by a general-purpose computer network that also connected to the hospital information system (HIS).

To enhance safety, ADUs deny access to a drug unless a current, valid, pharmacist-approved order for it coexists in the HIS pharmacy subsystem. This safety feature is implemented by a software interlock between the HIS, the pharmacy computer, and the ADUs. By design, this feature is not used in the ED because of the time constraints associated with ED drug orders.

About two weeks prior to the incident, the hospital began a major HIS software upgrade that was complicated by a sudden, unexpected hardware failure resulting in the complete loss of all HIS functions. In response, operators in the pharmacy disabled the safety interlock feature that required order checking before dispensing medications so that nursing staff could obtain drugs. As the HIS came back on line, the pharmacy operators enabled this feature in order to restore normal operations. However, the HIS crashed repeatedly during this process, again prompting the pharmacy operators to disable the safety interlock.

When this procedure was started on the day of the incident, it created a storm of messages to and from the dispensing units. This message storm slowed the system response such that the individual units appeared to be unresponsive to keyboard commands from users. The pharmacy operators initially thought that network communication problems were causing the outage, but gradually came to realize that the network was functioning normally and the units were overwhelmed with messages. Eventually most of the ADUs appeared to resume normal operation. The operators had assumed that ED units would not be affected by this procedure because they did not use order checking. The specific reason why the ED unit did not resume normal operation could not be determined, leaving a residual and unremovable mystery about the system.

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### Understanding an Organizational Accident

The person model of error is completely inadequate to explain this case. While it clearly involved personal failures and violations, a search for the “perpetrator”, i.e., the responsible, accountable party, would be fruitless. This, like most accidents and adverse events, was truly an organizational accident, involving both active and latent failures.

#### Active Failures

- Staff initially failed to recognize the severity of the patient’s condition.
- The nurse may have triggered the complete failure of the ED ADU by an erroneous keyboard entry.
- The ADU failed completely at a critical moment.
- Staff had failed to return unused drugs to ADU in another area. Paradoxically, this violation assisted in the successful recovery from ADU failure.

#### Latent Failures

- An unrecognized tight coupling among ED the drug system, pharmacy, and HIS—ironically induced by the safety interlock—caused a failure in one system to be propagated to another.
- The hospital had no predefined, well-understood system for obtaining drugs during ADU failure.
- Drug storage in the ADU was by bin number: specific drugs could not be quickly located in a non-functioning ADU, even if it could be opened.
- When the ADU was installed, “crash cart” lists were not modified to include drugs not used in cardiac arrest, but nonetheless needed quickly.
- The ADU software runs on a popular, but unstable operating system.
- The software upgrade to the HIS was implemented on a less than adequate hardware platform.
- Staff had no mechanism by which to open or restart a failed ADU.
- The ADUs had no power failure or surge protection.

While this case involves technical failures as well as human failure, it illustrates the complexity revealed by a thorough investigation of critical incidents. A deep understanding of the multifactorial nature of these events provides multiple opportunities for systems improvement.

### Summary

The systems model of accidents, near misses, and adverse events provides greater understanding and more avenues for improvement than does the person model. Human errors (active faults) are generally the last and least manageable links in the chain of events leading to an incident. Because they involve states of mind (distraction, forgetting) that stem from adaptive properties of the mind, they are both ubiquitous and impossible to predict or control.<sup>9</sup>

On the other hand, latent failures are present in the system for long periods of time prior to an incident and more amenable to identification and control. Effective safety systems should thus consist of simultaneous efforts aimed at reducing, eliminating, or at least making visible latent flaws. These efforts should be directed at many levels of the system, not just the individual but also the task, team, work environment, and the organization as a whole. ■

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# Toward a user friendly health care environment: The case of alarms

By Yan Xiao, Ph.D. and F. Jacob Seagull, Ph.D.

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Is the health care environment in hospitals and clinics friendly to the health care providers? Are devices designed with considerations of how they should improve patient safety? If answers to these two questions are negative, how should we make the health care environment more user friendly? We can examine these questions using auditory alarms as a case in point.

Designers in many fields of science have long adopted the practice of attaching alarms of various types to displays and devices. Such practice is well-intentioned: it aims at well-known limitations in human performance, such as attention spans and difficulties in tracking many parameters. Power plant control room operators can be warned of leaking valves; anesthesiologists can be warned of disconnected circuits; airplane pilots can be warned of low fuel levels; train operators can be warned of over-heated engines. On the flip side, however, almost every work setting in which alarm equipment is deployed reports instances of inappropriate alarms.

## Alarms for Patient Monitoring

Within the past 30 years, the status of patient monitoring has evolved into a profusion of monitoring devices and alarm systems. The status of alarms in today's patient care is itself, alarming.

### False Alarms

The high rates of false alarms or low positive predictive values of alarms have been shown to degrade the performance of human-machine systems.<sup>1</sup> Several factors contribute to this problem. Interference and reliability are among the more significant contributors (e.g., cautery machines producing artifacts in electrocardiograms). Other significant factors are connections and calibrations.

### Nuisance or "Wrong Context" Alarms

Nuisance alarms are those indicating state changes that are potentially dangerous to system integrity, but not in the context in which they are set off. For example, when the ventilating circuit to a patient is disconnected intentionally (as in suctioning the patient's breathing airway), the disconnection alarm goes off. In general, human operators often need to change (or maneuver) process profiles (as in landing of an aircraft, anesthetizing a patient, shutting down a power plant). Alarms designed to indicate abnormal system states often go off due to insensitivity to the context of operation.

### Inopportune or "Wrong Time" Alarms

During major disturbances, alarms associated with many parameters are set off simultaneously. Most indicate minor deviations that otherwise are of interest to the operators

during normal operation, but not during major disturbances. The sheer number of alarms can overwhelm the operators, even though only one or a few of them are worthy of immediate consideration.

### Unidentifiable Alarms

In several studies, health care providers were asked to listen to recordings of alarm sounds and then to identify the machine that generated the alarm. Participants could correctly identify only 40 percent of the machines that produced a given alarm.<sup>2</sup>

### Limits on Value

The pervasive nature of these aforementioned problems with alarms is demonstrated in the results of a study reviewing 47 videotaped cases of airway management.<sup>3-4</sup> In 46 cases, auditory alarms occurred from one or more of the three studied devices (blood pressure/heart-rate monitor, end-tidal CO<sub>2</sub>/pulse oximetry monitor, and ventilators). The three monitoring devices often sounded alarms multiple times during airway management, particularly the ventilator (2.7 times each case). The majority of all alarms from the three monitoring devices were superfluous: 85 percent of the ventilator alarms, 56 percent of the BP/HR monitor alarms, and 72 percent of the ET/CO<sub>2</sub>/S<sub>p</sub>O<sub>2</sub> alarms were of no clinical value to the care providers.

At the same time, care providers silenced a large portion of the alarms. Ninety percent of the ventilator alarms, 66 percent of the BP/HR monitor alarms, and 18 percent of the ET/CO<sub>2</sub>/S<sub>p</sub>O<sub>2</sub> alarms were silenced. People silenced loud alarms (ventilator) more often and more quickly than softer alarms. In one case, the ventilator alarms were silenced within 0.9 seconds of sounding. One must question whether any useful information was transmitted by alarms to the operators, or whether responses to alarms venture far beyond knee-jerk reactions to loud sounds.

The above mentioned, and their associated problems (e.g., staff burnout due to alarm noises), have cast doubt on the value of alarms.<sup>5-7</sup> One wonders whether the design of alarms is driven by what is technically possible and by legal concerns, as opposed to by the requirements for providing relevant and timely information to human operators. On one hand, a surfeit of auditory alarms with dubious informational value in many settings has raised the concern of true alarms being ignored or discounted and has been associated with noisy and stressful working environments. On the other hand, auditory channels are an important means for human operators to extract information and to monitor the underlying processes. These channels have not been effectively exploited.

*Continued on the next page*

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## Creating a User Friendly Environment

The International Standards Organization (ISO) medical alarm standards workgroup has written guidelines for producing more distinct and identifiable warning sounds which are also less disruptive.<sup>8</sup> In addition, the ISO standards also address the issue of classifying the significance of the signals from patient care monitors and codifying presentation methods. Adopting these standards in design of medical devices is a first step in improving patient safety.

Yet the acoustic aspect of auditory alarms is only part of the problem. Designing informative alarms requires a broader, systems approach. The role of alarms must be considered as an integral part of delivering monitoring and diagnostic information to the care providers.

For example, not only do alarms serve to indicate possible deviation or drift of monitored parameters, they can also:

- support or disconfirm one or more hypotheses about the source of a problem;
- act as a cue to generate more reasonable hypotheses; or
- indicate that the plan is not working as expected.

The need to understand the value of alarms—and how they should be designed to improve patient safety—indicates a critical role of human factors engineering in helping solve this problem. In one pilot study, an ambulatory eye-tracking device was shown to be feasible in surgical operating rooms.<sup>9</sup> Such devices can be useful in comparing different designs of patient monitors, evaluating different monitoring strategies that may be used by care providers, and determining best placement of patient monitors.

Examining the possibilities for improvement requires studying how clinicians make use of information and how the information should be presented. As an example of one potential improvement, the auditory channel may be used not for auditory warning signals, but rather for “display” of additional patient vital-sign values (such as is the case for pulse oximeter tones). As another example, auditory signals can serve as scheduled interrupts which might act as reminders to check or act on a system.<sup>10</sup>

A more fundamental approach to the goal of a user-friendly work environment is total redesign of monitoring interfaces. Instead of fine-tuning specific components of a general information display, an entirely new display can be developed based on so-called “ecological principles” of perception.<sup>10</sup> These ecological interfaces analyze the underlying relationships between the parameters whose values are being displayed, and map those relationships onto the physical form or format of the new display. This new mapping allows the users of the interface to read not

only the individual values of the parameters displayed, but also to perceive easily the relationships among the parameters, and thus the overall state of the system (i.e., the health status of the patient being monitored).<sup>12</sup>

An immediate step that care providers could take in building a user-friendly environment is to demand better patient monitors. Ask relevant questions during selection and purchase of devices. These questions should address issues of user-friendliness and patient safety, such as:

- Are the auditory signals (e.g. alarms), color coding, visual displays and control layout compatible with the targeted environment?
- Are industry and international standards on displays met?
- What are the results of human factors evaluation and analysis?
- In what ways can a user make a mistake?
- How can a user find out if a mistake is made? How can one recover from a use error?
- Are the monitors tested for frequent artifacts?
- Are the alarm sounds designed according to international standards?

Request a human factors engineer to perform a careful evaluation and ask these questions—the answers to which in many ways affect patient safety. ■

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## Multiple Systems Breakdowns

Following several days of care in various settings, a patient with history of abdominal pain dies while being intubated.

By Kathleen Dwyer, M.S.

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### Clinical Sequence

A 47-year-old obese woman presented to the emergency department (ED) with severe abdominal pain, vomiting, and chills. She described six previous episodes and an extensive diagnostic work-up that included a small bowel series, CT scans, colonoscopy and laparotomy, none of which identified a definite cause of her pain.

The ED physician's interpretation of the KUB (kidney, ureter, and bladder X-ray) was that the patient did not have a small-bowel obstruction. After receiving pain medication and intravenous fluids, the patient was instructed to see her internist, if her symptoms persisted. The ED physician informed the patient's internist who, (as a result of a recent insurance change) had not yet seen this patient. The internist dictated a note for the patient's medical record.

The next day, the patient presented to the internist's office with continued nausea. The physician on duty (who was not the internist contacted the night before) had a copy of the ED report faxed to her office. Relying on the report that the KUB was normal, she neither ordered further X-rays nor obtained a surgical consult. Simultaneously, however, the hospital radiologist dictated his report on the KUB stating "Several moderately distended loops of small bowel in the right upper quadrant which may represent a small bowel obstruction; follow-up films recommended." This report by the radiologist went directly to the patient's record instead of to the ED for follow-up.

Over the next two days, two physicians and a physician assistant (PA) examined the patient. Multiple tests and exams failed to fully identify the source of her abdominal pain; palliative treatments provided temporary relief. The PA was able to find out that a laparotomy done several years prior showed this patient had sarcoid adhesive disease. The PA included this finding in his note.

Early the next morning, the patient, now acutely ill, was rushed to the ED with abdominal pain, nausea, vomiting, and a new problem—shortness of breath. The surgeon obtained the chronology of events over the past four days, as described by the patient. But, unaware of the patient's history of sarcoid adhesive disease, the surgeon elected to rule out a pulmonary embolism and ordered a VQ scan followed by an abdominal CT scan.

Assuming that all the diagnostic testing would get done in the morning, and that the ICU staff would keep him informed of significant changes in the patient's status, the surgeon began operating on another patient. Complications delayed his return to the first patient's bedside.

Later that night, the surgeon returned to the first patient and became aware of an earlier hypotensive episode, abnormal blood work, and the CT scan performed in the late afternoon. The patient was finally taken to surgery, but during intubation, she experienced a brief run of ventricular tachycardia followed by atrial fibrillation. Resuscitative measures were unsuccessful.

### Claim Sequence

Suit was filed against the internists, the surgeon, the PA, and the hospital.

### Disposition

This case, which included non CRICO-insured defendants, was settled for more than \$1 million.

### Discussion Points

Fragmentation of the health care system is increasing and patients frequently require medical services across multiple sites of care. As a result, about one third of the time, providers lack critical information when making treatment decisions. In the office practice setting, the paper record covers care provided there, but contains little information pertaining to care outside the office practice (e.g., ED visits, or discharge summaries).

*A computer-based patient record can bridge current medical information needs at any site. This reduces the potential for incorrect decisions and improves health care in general.*

Lag times in getting clinical information into the medical record or computer can cause injury. Failures of systems in the radiology and emergency departments in the transmission and follow-up of abnormal test results are perilous.

*Examination of "near-misses" alerts managers of the need for new methods to ensure that results of tests are correctly directed, received, and acted upon to prevent harm to patients.*

When a patient is admitted to the hospital, communication between the surgeon and the ambulatory care providers is vitally important.

*The ideal health care setting, where all disciplines work together in a coordinated fashion, is difficult to achieve in reality because patient care involves hand-offs to multiple departments or specialists. As a result, coordination of care is absent, resulting in a lack of accountability for the patient.*

This case demonstrates multiple failure points in the system, including the incomplete record, poor communication among the team, and administrative delays in obtaining CT scans which had come to be tolerated over time.

*Diagnostic delays need to be reviewed at a systemic level and improvement efforts structured according to the primary source of the delay.*



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## LIABILITY IN SURGERY

Both individuals and systems contribute to surgery-related claims. By looking at the cracks in the systems, as well as educational opportunities for the individuals working within them, significant progress can be made in reducing adverse events in surgery. Surgeons who take this course will be able to:

- describe common characteristics of malpractice claims involving surgeons,
- understand why competent physicians make mistakes and the need to learn from them,
- examine an adverse event from a systems perspective, and
- identify ways to improve documentation.

## THE RISKS OF POOR COMMUNICATIONS

Nearly 400 malpractice claims filed in the past five years against CRICO-insured clinicians involved serious underlying communication problems, especially between a provider and their patient or the patient's family. Clinicians who take this course will be able to:

- describe some of the pitfalls and remedies in communication in the out patient setting,
- review the interplay between individual providers and hospital systems in managing inpatient care,
- describe good documentation practices for the inpatient setting, and
- develop a plan for discussing an adverse event with a patient/family.

## EFM IN THE INTRAPARTUM PERIOD

Because electronic fetal monitoring (EFM) is the primary tool for establishing fetal well-being during the intrapartum period, its use and interpretation is often pivotal in malpractice claims. Clinicians who take this course will be able to:

- describe the use of EFM to help establish fetal well-being,
- describe critical actions when a non-reassuring EFM pattern is noted,
- identify common pitfalls in the management of patients on continuous EFM, and
- outline critical components of documenting care for patients on EFM.

## LIABILITY IN BREAST CARE

Failure to diagnose breast cancer is one of the most common malpractice claims physicians face. Learn the factors that most often lead to lawsuits and some specific patient care strategies to address them. Clinicians who take this course will examine:

- contributing factors that lead to the allegation of failure to diagnose breast cancer,
- limitations of the mammogram as a diagnostic tool,
- effective risk strategies to mitigate risk exposures, and
- appropriate documentation as a valuable defense tool.

## LIABILITY IN SHOULDER DYSTOCIA

Review the risk factors for this obstetrical emergency and examine some procedures that may prevent both injury and malpractice claims. Clinicians who take this course will review:

- risk factors for shoulder dystocia in the pre- and perinatal periods,
- documentation in the prenatal period,
- liability issues during shoulder dystocia management, and
- communication with patients and family members following a traumatic delivery.

## LIABILITY IN MEDICATION

Medication-related claims represent 10 percent of all CRICO claims with payments made. Clinicians who take this course will examine:

- which prescribing issues pose the greatest liability risk,
- techniques for enhancing communications when prescribing medications,
- methods for optimizing management for patients on long-term therapies, and
- the vital role communication among providers plays in reducing medication errors for patients receiving treatment from multiple providers.

## LIABILITY IN LAPAROSCOPIC CHOLECYSTECTOMY

Significant patient safety issues associated with laparoscopic surgery have been identified in malpractice claims. Examine the potential liability of delayed diagnosis of post-op complications with this type of minimally invasive procedure, and recognize strategies for defense when they occur. Clinicians who take this course will review:

- potential liability issues associated with laparoscopies,
- elements of informed consent,
- elements of negligence, and
- loss prevention strategies when performing laparoscopies.

## SAFE PRESCRIBING PRACTICES

More than half of U.S. residents take more than one medication daily. CRICO medication-related claims represent 11 percent of CRICO's losses over the recent 10-year period. Clinicians who takes this course will be able to:

- recognize common causes for error in the prescribing process,
- list methods for improving medication efficacy through patient communication,
- describe the risks and benefits of prescribing medications for unapproved uses, and
- understand the potential for computer technology to reduce medication errors.

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