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# FORUM

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## Communicating with Patients

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by Martha Byington and Annette Bender

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Good communication is essential to medical care. Conversely, miscommunication greatly impacts both individuals' health status and collective health care dollars, including malpractice losses. Inadequate communication was the second most frequent<sup>1</sup> risk management issue identified in the CRICO<sup>2</sup> claims made from 1995-99. Of all 1,218 claims filed during those five years, nearly one-third (381) had serious, underlying communication problems (*Figure 1*). While deficient interactions among clinicians can certainly lead to health care mishaps (*see p. 15*), the bulk of this *Forum* addresses the portion of claims (251) related to clinician-patient communication.

The clinician-patient communication cases represent incurred losses of \$52 million and many unsatisfied patients. One definition of a dissatisfied patient is one whose outcome fell below his or her expectations. The decision about whether such a patient pursues a malpractice action often relates to the communication with his or her caregivers before, during, and after the events that triggered the dissatisfaction. Likewise, poor communication between a patient and physician can lead an already angry patient to believe care was poor, even when it was entirely appropriate. Lessons taken from both situations can help you avoid communication-related claims.

## An Uneven Exchange

Patient communication is a difficult task, particularly for the patient. For physicians who communicate with dozens of patients during the day, each *individual* encounter may lack the personal import that it has for the patient. Additionally, in a busy environment with multiple caregivers, the communication hand-offs between clinicians can easily be fumbled. Each caregiver makes assumptions about the roles of the rest of the team, often leaving the patient and his or her family out of the loop.

In the arena of patient safety and physician liability, the burden for "successful" physician-patient communication lies with the physicians. That's not to say patients don't have any responsibility, but society and the courts have deemed that physicians have the ultimate responsibility for initiating, facilitating, clarifying, documenting, and reinforcing discussions related to their patient's condition, treatment, and prognosis.

Patients vary in how much information they need and in how involved they want to be in making decisions. This ranges from "letting the physician decide" to multiple second opinions and exhaustive Internet searches. Because patients see and use technology (e.g., e-mail) in other parts of their lives, many expect to use these same tools to communicate with their physicians (including the

transmission of personal medical information). However, they may need guidance to understand the potential risks of faceless encounters via vulnerable media such as e-mail (*see p. 12*).

Among clinicians striving to communicate as best they can, *specific* suggestions for improvement are more likely to help than generalities. Thus, we believe that our authors' detailed advice (e.g., White and Keller, Page 4) is more enduring than the oft repeated "Be nice to your patients, and you won't get sued."

While the communication challenges facing health care providers are often explored in *Forum*, logic dictated that, for this issue, we consult patients. Thus, much of this issue reflects their needs and expectations. The key lesson we drew from such interviews was that listening to a patient's needs is well worth the time taken.

## CRICO Claims Data

The most frequent risk management issues in CRICO's physician-patient communication claims related to informed consent for surgical procedures. Among the 252 physician defendants in the claims reviewed, 144 (57 percent) were from surgical specialties (*Figure 2*).

These surgical cases comprise a range of communication levels. Some plaintiff patients were engaged in thorough consent discussions, but did not retain the relevant information: difficult for them to prove if the process was properly documented. Other patients, however, were treated by physicians who failed to adequately discuss (or document) the risks or options: a difficult allegation for the physicians to defend.

Because surgical cases alleging inadequate consent often hinge on specific clinical issues, most of the cases in this subset probably fall somewhere in between those two extremes. A common example involves an unexpected finding during surgery necessitating a procedure different from the one addressed in the consent discussion.

Patients encountering such outcomes may be motivated to allege that they were caught unaware because the provider did not explain the procedure-specific ramifications of the proposed surgery.

Figure 1

21 Percent of CRICO Cases Cite Clinician-Patient Miscommunication			
Year	All CRICO Cases	All Comm. Cases	Clinician-Pt. Communication Cases/Losses*
1995	245	75	46 / \$10,000,000
1996	214	74	53 / \$9,300,000
1997	227	73	48 / \$9,200,000
1998	228	78	48 / \$8,700,000
1999	304	81	56 / \$14,900,000
Total	1,218	381	251 / \$52,100,000

\* Total incurred losses includes payments for closed claims and reserves for open claims.

### One example from CRICO's closed claims:

Suit was brought against a surgeon by a 28-year-old woman who underwent a laparoscopic cholecystectomy that engendered complications and a later resection. The claimant alleged that the consent process—conducted by a third-year resident—was not procedure specific. No documentation in her record alluded to any discussion specific to this procedure, or of alternatives based on her history of hepatitis. When the physician opted for an open procedure, postoperative complications required additional surgery. Lack of documentation about the content of the consent discussion weakened the defensibility of this malpractice claim.

**Closely allied with consent for procedures was the complaint that patients were not given enough details about how *effective* the procedure might or might not be. The absence of clear documentation of informed consent discussions, and lack of written evidence that patients received information specific to surgical procedures, can compromise defense of such claims. For example:**

A patient complaining of breathing difficulties was diagnosed as having a nasal obstruction associated with a deviated septum and collapsed bilateral nasal valves. A septoplasty and open nasal reconstruction with repair of nasal valves were performed. The patient's breathing problems continued, but were subsequently relieved with steroid treatment. He sued the surgeon, alleging unnecessary and improperly performed surgery, and claiming that his decision to undergo surgery would have been different had he been informed that the surgical procedure would not cure his breathing problems.

### Triggering Dissatisfaction

**Poor clinician-patient rapport was the second most frequent risk management issue cited (Figure 3). For example:**

A patient who underwent a postpartum D&C for a retained placenta repeatedly complained to her physician of pain and cramping. She reported that the physician responded that the cramping was to be expected and that "two other D&C patients had already gone home." Her symptoms continued and later included more severe abdominal pain and ringing in her ears when she stood up. Her physician prescribed a pain reliever and an increase in fluids. Later that evening, after having spent the full day in the outpatient unit, the patient was hospitalized with a postpartum hemorrhage and endometritis complicated by DIC. A total hysterectomy was performed the next day.

Figure 2  
59 Percent of Defendants From Surgical Specialties

Specialty	Defendants*
Anesthesiology	7
Cardiac Surgery	4
Cardiology	7
Dentistry	4
Dermatology	4
Emergency Medicine	4
ENT	6
Family Practice	3
Gastroenterology	3
General Medicine	23
General Surgery	29
Hematology/Oncology	9
Nephrology	3
Neurology	2
Neurosurgery	10
Obstetrics/Gynecology	56
Ophthalmology	5
Oral Surgery	5
Orthopedic Surgery	11
Pathology	3
Pediatrics	9
Plastic Surgery	3
Psychiatry	3
Radiology/Imaging	18
Thoracic Surgery	3
Urology	7
Vascular Surgery	5
Other	6
All Surgical Specialties	144
All Specialties	252

\*Physician defendants named in CRICO claims (1995-99) alleging inadequate physician-patient communication.

Patients with unanticipated outcomes become more unhappy with their care if they bear poor perceptions of the providers who have attended them. The physician in this case *might* have mitigated the outcome by communicating better. He may have been able to gain the patient's assistance as a diagnostic ally. He might also have avoided the adversarial relationship engendered by the patient's perception of his impatient response to her.

### Family Matters

Thirteen percent of the risk management issues identified in clinician-patient communications claims involved education of the patient and/or family. These include discharge and follow up instruction, or education about the use of medications. For example:

A steroid-dependent patient with a history of rheumatoid arthritis and asthma who was under the care of a primary care provider (PCP) and a rheumatologist was instructed to stop taking Prednisone in preparation for knee surgery. After her surgery, she received no instructions as to when to resume her (steroid) medications. When she experienced flu-like symptoms that did not abate after the hospital discharge, she contacted her rheumatologist and her PCP for advice; they referred her to the orthopedist. The patient—after receiving no response from the orthopedist—presented at the hospital emergency department where a prescription was written and instructions for restarting her medications was given. The patient suffered acute failure of her adrenal gland. All of her caretakers reported being unaware that she had stopped taking the medication.

### Summary

Establishing a mutually agreeable level of participation and collaboration for diagnosis and treatment planning is the infrastructure for patient compliance. Developing and confirming reasonable expectations for the outcome of pending treatment at the outset of that treatment enhances the ability of both parties to address disappointing results in a cooperative, rather than a contentious, manner. ■

Figure 3  
Consent Process Often Cited in CRICO's Clinician-Patient Miscommunication Cases

Risk Management Issue	Percent (1995-99)
Inadequate consent process for surgical procedure	23%
Poor patient rapport	15%
Insufficient patient/family education re: follow-up instructions	13%
Inadequate consent process for treatment options	8%
Language barrier	7%
Inadequate consent process re: identity of provider	6%

#### Notes

- 1 The *most* frequent risk management issues were related to clinical judgment.
- 2 Controlled Risk Insurance Company (CRICO) provides professional liability insurance to health care institutions, their employees, and affiliated physicians.

# Negotiating an effective physician-patient relationship

## FORUM

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**W**e negotiate all the time. At first glance, most physicians assume that negotiation involves merely the tangibles of medical practice: space, reimbursement, contracts, equipment, and staff. In fact, negotiation encompasses more than that. Negotiation also affects intangibles: information, respect, reputation, participation, and expertise. In its most basic form, negotiation occurs with each interaction among colleagues, other providers, insurers, and other health professionals. Whenever we are involved in a decision or action that affects or involves someone else, and in which one party does not have complete control, the interaction can be defined as a negotiation.

As patients become better educated health care consumers, negotiation becomes a natural framework for guiding the physician-patient relationship. Every interaction requires an exchange of information, confidence, hope, and credibility: the “negotiation intangibles” necessary for constructing the diagnosis and treatment plan. Ultimately, both patient and physician derive benefit when each is part of a constructive process and a satisfying outcome.

Consider this situation taken from a CRICO<sup>1</sup> claim:

A 34-year-old woman had seen her internist with complaints of a pea-sized right breast lump that would decrease in size following her period. Her history included a maternal grandmother with breast cancer. At a repeat examination after her menstrual cycle, the internist documented that the lump had decreased in size. The physician instructed this patient to schedule a mammogram, but she did not follow up. Eighteen months later, a biopsy revealed a poorly differentiated tumor with lymphatic involvement. A suit against the internist was settled in the high range.

In this example, a broader discussion may have first revealed the depth of the physician’s concern with the patient’s family history as well as the gravity of the persistent lump and need for further investigation. It may have uncovered the patient’s fears of a positive finding coupled with doubts about payment issues. The physician and patient could then have worked to-

gether to identify emotional and financial support leading toward a clear diagnosis and treatment plan.

### Exchanging Useful Information

In the give-and-get of the physician-patient interactions, you want to exchange useful information with your patients; you want them to become invested in their care plan. If patients have concerns or reservations, you want to know what those are. This is the only way that you can obviate their worries and make them feel invested in and comfortable with the plan. The more information you have, and the more accurate and timely it is, the better you are able to combine your expertise with their experience to devise a responsive, balanced plan with which they’ll comply.

Good negotiation requires good communication skills. Patients want their physician’s attention, expertise, and ongoing concern. Patients want a doctor in whom they can have confidence: someone who will be their advocate.

Steps in the negotiation process include:

- 1 identifying the common and divergent interests, articulating their importance—both objective and symbolic—for each;
- 2 identifying an enlarged range of options incorporating each party’s most important goals; and
- 3 making a commitment by each side to the mutually developed plan.

If the exchanges between physician and patient are honest, forthright, and respectful, then the chances of having a constructive clinical relationship that reaps mutually beneficial goals are enhanced. Both you and your patients will find greater satisfaction by the range of measures that ascertain success: quality and cost effectiveness along with personal and professional accomplishment. ■

<sup>1</sup> Controlled Risk Insurance Company (CRICO) provides professional liability insurance to health care institutions, their employees, and affiliated physicians.



# Difficult Clinician-Patient Relationships

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*The following is adapted from an article<sup>1</sup> which originally appeared in the Journal of Clinical Outcomes Management and is used with permission from Turner White Communications, Inc. Copyright 1998. All rights reserved.*

All clinicians encounter patients whom they regard as difficult.<sup>2-18</sup> Clinicians diverge, however, on who merits this label.<sup>9,19</sup> We have shown videotapes of “difficult” patients to more than 1,000 clinicians from a variety of geographic and practice settings. The clinicians are shown five sets of patients with three patients in each set and are asked to name the patient in each set who they would find the most challenging. Consistently, each of the 15 patients is judged both “most difficult” and “least difficult” by different clinicians. The exercise demonstrates that interpersonal perceptions and relationships are covariates rather than objective attributes of the patient.

Clinicians can often list demographic characteristics or personality traits that they associate with “difficult” patients. A perspective that identifies the locus of dysfunction in the patient, however, oversimplifies the clinician-patient relationship, overlooks the tremendous variety of experiences that occur in the medical care setting, and runs the risk of becoming a self-fulfilling prophecy. We have developed a model that recognizes four scores of difficulty: the patient, the clinician, the illness, and the system.

## Hot Buttons

All of us, clinician and patients both, find ourselves in situations in which we catch ourselves reacting in ways we would prefer not to act. A statement, a request, or a tone of voice pushes our hot button, triggering an immediate intense reaction. Afterward, we may recognize our automatic responses and wish we had behaved differently. Later, we often think of better responses. Although we may try to justify our behavior, a nagging feeling of regret about how we responded is a reliable indicator that our hot button was activated. Our hot buttons may lead to difficulties in relationships.

Another source of difficulty may be the illness itself. It may be one that the clinician and the patient are unable to clearly communicate about due to anxiety, fear of failure, or even boredom. The health system, too, may be a source of difficulty, such as when an insurance benefit plan does not cover certain tests or treatments. A social system that lacks adequate resources to support healthy lifestyles also may pose difficulties.

Rather than label certain patients “difficult,” we believe it is more useful to speak out about “difficult relationships” and to focus on ways of interacting in these relationships with the goal of achieving more satisfying outcomes.

## Why Difficult Clinician-Patient Relationships Occur

We have identified three core problems associated with difficult clinician-patient relationships: frustrated success, inflexibility, and misaligned expectations.

### Frustrated Success

Clinicians seek success, and success most often is defined as effective clinical problem solving or “cure.”<sup>20</sup> When success is unlikely or threatened, clinicians may use negative labels to describe patients. For example, a patient whose asthma is difficult to control due to socioeconomic or psychological stressors may frustrate the clinician.

Patients also want success. Patients may become depressed, angry, or demanding when treatment does not work or if they perceive that the clinician is blaming them for their illness. At the same time, clinicians may feel that the patient is blaming them for the lack of progress. These clinician and patient frustrations and blaming attitudes can contribute to mutual dissatisfaction.

### Inflexibility

Clinicians and patients may have a low tolerance for diversity, such as differences in language, ethnicity, socioeconomic status, values, gender, or health beliefs and practices. For example, in one study, the “least troubling” patients were described by male physicians to be middle-aged, “hard working” men with illnesses that quickly resolved or with which they came to terms quickly.<sup>19</sup>

Allopathic clinicians may be inflexible in their rejection of alternative treatments such as acupuncture or chiropractic care. Patients also may be inflexible. They may have strong preferences to be treated by a male or a female clinician, to see a specialist or a generalist, or to participate little or extensively in health care decisions. When clinicians or patients “dig in their heels” and insist on getting their way, they are likely to be regarded as difficult.

### Misaligned Expectations

Clinicians and patients frequently differ on the expectations they hold for one another.<sup>16,21,22</sup> Patients may enter treatment with a specific expectation, such as obtaining a prescription for a narcotic or getting an MRI for a headache. Physicians may have a different expectation, such as expecting the patient to learn to live with the chronic pain or to attend physical therapy and follow an exercise regimen. When expectations for treatment or the roles that each will take differ, either ~~Continued on next page~~ other as “difficult.”

*Continued from Page 4*

### Example

All three core relationship problems are illustrated in the following monologue. The patient is a 27-year-old highway construction worker presenting to his primary care physician stooped over with his hand on his lower back:

**Patient:** Don't mind me with these positions. It's my back. It's like before. I will be talking and then all of a sudden I'll move and it will just lock up on me. It's like someone is twisting a knife in my back. I know it's the disk. I don't want to see a surgeon and I don't want to have any type of extensive work done on it. At work they're making noises about me and about this particular injury, so I think its time that we claim this as a disability. I brought these papers for you to sign.

In this scenario, the clinician's chance to succeed is limited by the patient diagnosing his own problem and prescribing his own treatment plan: which is no treatment. For the patient, success may be frustrated if his goal is to obtain disability papers. This also is an example of expectations being misaligned. The clinician may have the expectation that the patient will seek information, participate in a discussion of the available treatment options, and follow through with the appropriate medical treatment. At the same time, the patient may have the expectation that nothing will help him medically and he is entitled to go on disability, especially in light of his chronic pain.

Finally, inflexibility may be a factor. The clinician may not feel comfortable signing disability papers when it is clear to him or her that there are more appropriate options. The patient also appears to be inflexible in his willingness to explore other options. If these differences are not handled appropriately, both parties may leave the encounter feeling angry or dissatisfied.

### A Three Zone Model: Comfort, Get Help, Challenge

Although stress is normal in the medical setting, interpersonal stress usually is minimal and the relationship between clinician and patient is not in jeopardy. Such interactions take place in what we call the "comfort zone." In the comfort zone, conventional interviewing techniques, such as Cohen-Cole's three-function approach (gathering information, building a relationship, and motivating adherence)<sup>14</sup> and the Bayer Institute's 4E approach (engage, empathize, educate, enlist),<sup>23-26</sup> are useful for obtaining information and furthering the relationship. However, when a core relationship problem exists, interactions move out of the comfort zone into more challenging zones of interaction. The boundaries of these zones are idiosyncratic to the clinician and the nature of the practice.

Sometimes the clinician-patient dyad does not have the resources to accomplish the medical or relationship tasks at hand, and the relationship moves into the "get help" zone. For example, with a diabetic patient who needs to make lifestyle changes, the clinician might extend the system to include a dietitian, behavioral therapists, and other family members.

When a patient or clinician is in the challenge zone, the person may have a global sense of distress accompanied by an interior monologue such as, "I wish I was somewhere else." But recognizing that a relationship is in trouble is not always easy. Feelings of distress may not be clear at the outset. Fortunately, there are three other clues that signal a difficult relationship. We refer to these clues as the IRS: either the patient or the doctor frequently Interrupts the other, frequently Repeats their statements (getting louder with each repetition), or uses Stereotypical responses that promote disengagement (responses that are too pat or general to be meaningful). These clues indicate that the relationship needs attention.

Although a large body of literature describing difficult clinician-patient interactions is available, empirical studies of techniques for dealing with these relationships are limited.<sup>26</sup> We do know, however, that the problems of difficult relationships do not respond to conventional interviewing techniques and are not likely to disappear.

### Clinical Approach for Difficult Relationships

In the following scenario, a 28-year-old woman who had been taking Clomaphine has had ovarian hemorrhage and intractable uterine bleeding leading to unexpected oophorectomy. Although this rare complication of fertility medication was noted and documented during the informed consent discussion, the patient decided to accept the risks in hopes of having a child. Neither party expected this outcome.

**Patient:** I can't believe this is happening. This replacement therapy is driving me crazy. I've tried very hard to go along with you. I never thought that this could happen. Three months ago I was thinking I would have a child! You told me you didn't think you'd take my ovaries. You quoted me statistics. You said you were sure that I'd be fine. Now I'll never have a child. I'm a wreck. It's impossible to have sex. You act as though you could care less that you've left me totally worthless without anything to live for. You have ruined my life and you promised me that I would be fine. I can't believe the way you are acting. You just don't care!

Some techniques for facilitating this relationship are outlined below.

## Facilitating Techniques

**The first step in resolving a difficult situation is an internal cognitive and affective review in which the clinician recognizes the tension, controls his or her own affective response, assesses the source and the nature of the difficulty, and commits to working on the relationship.**

## By Yourself

### 1) Recognize tensions

(Oh no, I'm in for it here! I'm feeling defensive and afraid this woman is going to sue me. I want to pull out the chart and show her what we went over before.)

### 2) Don't just do something, stand there<sup>11</sup>

(I need a second to think. What if I acknowledge that she is upset and let her vent a while and pull my thoughts together.)

### 3) Assess the source of the difficulty

(Is the root of her anger me? herself? her illness? the health care system?)

### 4) Identify the nature of the difficulty

(This patient had an expectation that the surgery would go fine and she'd have at least one healthy ovary. Meanwhile, my expectation was that, while I also hoped for that outcome, I did what was necessary to save her life. This woman also is frustrated because she has defined success as being able to get pregnant. My guess is she needs to grieve the terrible losses she feels. Also the medication may be playing a role in the degree of her agitation.)

### 5) Make a decision to work on the relationship in addition to addressing the medical problem

(I need to empathize with her and find out what this outcome and loss mean for her. OK, I'm ready to go.)

## With the Patient

### 6) Acknowledge the difficulty and offer a problem-solving approach

Doctor: Mrs. Jones, I hear that you are very troubled by this outcome, I see that you have suffered a terrible loss. I'd like to find out more about what this means to you and to find a way to deal with this together: if you are willing to talk to me about it.

Patient: What do you mean?

### 7) Discover the meaning of the illness

Doctor: You said that you feel totally worthless and have nothing to live for. That sounds awful.

Patient: Well it is. I've always dreamed of having children of my own. We put it off for a while so that we could establish ourselves and be able to provide the kind of life we wanted for our children. My husband is very upset and doesn't understand how this has happened to him. He wants a child very badly and now I can't give him that. I'm afraid he may leave me.

Doctor: That sounds like a tragedy for you both.

Patient: Yeah. I just feel so angry.

Doctor: It's totally natural given what you've just been through. It's going to take some time for you to absorb all that's happened. I can imagine that you also can't see any solutions at this point.

Patient: No, I just feel so terrible and frightened and alone.

### 8) Show compassion

Doctor: Mrs. Jones, is there something I could do for you at this point, anything you need from me?

Patient: No. I want to be angry at you, but I know you didn't really have a choice.

### 9) Set boundaries

Doctor: Well, I imagine you have many questions about what happened and why. I'll be glad to cover those when you feel up to it. We also may need to adjust your replacement therapy.

Patient: Thanks, but you're right. I couldn't concentrate just now. I think I just need to be sad.

Doctor: I don't want to rush you. I know this is a difficult time and you need to grieve. Would it be OK if I step out and attend to other patients? You can stay here as long as you need and I'll check back in a few minutes.

Patient: No, that's OK. I think I'll wash my face and go home.

Doctor: Will you be OK to drive yourself or can I call someone?

Patient: No, really, I'll be fine.

### 10) Extend the system

Doctor: Just one other thing. Would it be helpful if we talked with your husband? Or, is there anyone else who can be a support for you?

Patient: That may be helpful later, but he's pretty angry at you also.

Doctor: Well, I'm available to talk to him at anytime it would be helpful.

Patient: Thanks. So, I'll be back in two weeks.

Doctor: Please call me if anything changes or if you have any questions.

**Continued**

### *Continued from Page 6*

#### Conclusion

Because the art of dealing with difficult interpersonal relationships is still quite primitive, these suggestions for working with difficult clinician-patient relationships are far from definitive. Although drawn from research findings in several disciplines, a great deal remains unknown. Thus, we must approach the use of these techniques from the perspective of the clinical trial, or what Donald Schon<sup>28</sup> calls “reflective practice.” Reflective practice calls upon the clinician to consider how effective a particular action was in achieving the goal that prompted the action: “I said X to him because I thought that he would respond Y. Did he? If he didn’t, what else could I have said?” ■

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By Carol Levine, M.A.

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As difficult as communication about medical care is to navigate when its between just two parties—a health care professional and a patient—it becomes even more complicated when the patient’s family members join in. Not surprisingly, health care providers are often wary of family members’ involvement in decision making.<sup>1</sup> Yet family members play a critical role in the health care system: an estimated 25 million Americans provide unpaid care worth nearly \$200 billion annually.<sup>2</sup>

Quality care depends not only on what happens in the hospital or physician’s office, but is significantly affected by what happens at home. Even where limited home nursing care is available, the family provides or pays for most care. They also provide stability. Home care workers are frequently shifted from case to case: one family caregiver said her mother had 23 different home care aides in 11 months.<sup>3</sup> In such cases—and they are common—family caregivers are the constant factor.

Family caregivers are also surrogate risk managers, the equivalent of an early warning system. They can bring to the physician’s attention post-surgical complications or medication side effects. Early intervention can often prevent costly hospital admissions or readmissions.

The family’s caregiving role is too important to leave to chance. No matter how willing and devoted they may be, untrained family members cannot provide quality care without strong support and training from health care professionals. That process begins with information and communication.

#### Communication Gaps

The most common complaint from family caregivers in the focus groups convened by the United Hospital Fund’s Families and Health Care Project and in subsequent hospital-organized focus groups was lack of information.<sup>4</sup> These anecdotal reports were borne out in a random telephone survey of New York City family caregivers. Nearly 60 percent reported that health care professionals did not give them the training needed to carry out challenging tasks for their loved ones.<sup>5</sup>

“I wasn’t prepared,” was a common theme. “Nobody told me what to expect when I brought [my relative] home.” Sometimes caregivers meant they lacked technical training on how to operate feeding tubes or other machinery. Often, however, they meant simply that they did not understand their relative’s disease,



how to handle common problems, and what symptoms require immediate attention. Discharge planning—where such information might be effectively conveyed—was devoted solely to paperwork.

Interviews and focus groups with hospital staff confirmed the family caregivers' perceptions. Of the many reasons given for limiting instructions to family members, three stood out: concerns about confidentiality, lack of time, and unrealistic expectations on the part of family members.

### Concerns about Confidentiality

Many professionals are reluctant to talk to family members because they fear violating patient confidentiality. On the other hand, family members may beseech professionals not to tell the patient bad news. These dilemmas can be reduced by defining at the outset (or as soon as the situation permits) what information will be shared and with whom. Some patients may defer to family decision making, others fiercely guard their privacy. As a general rule, family members need to know everything that is important to fulfilling the responsibility of care that is expected of them.

Before surgery, for example, a family meeting can allow various members to ask questions and to voice their concerns about the procedure and its aftermath. The family can be encouraged to designate one or more members as primary representatives. Professional team members who speak with family members should take care to offer consistent information, albeit emphasizing their particular expertise. Perhaps the hardest part is sharing uncertainty, which is inherently unsettling for professionals. But family members are usually less troubled by honest discussions of risks and probabilities than they are by difficulties in obtaining accurate information. Family members may assume that providers who are less than forthcoming in communications have something to hide.

### Lack of Time

Lack of time is clearly a major hurdle, but it also can become a convenient excuse for the admittedly difficult job of talking to upset and anxious family members. Professionals sometimes try to skirt the emotional aspects of illness by talking to family members in a highly technical way. A brief but sincere acknowledgment of a family member's concern and fear can help clear the way for the more factual discussion to follow.

Family members need specific instructions on care at home, in language they can understand. The language that professionals use amongst themselves can distance them from family members. Families should neither feel

excluded nor patronized. The use of language that is simple and clear is key to gaining their trust and cooperation. In some cases that may require limiting talk to very basic concepts; in others, the discussions may address more sophisticated details.

When the family's primary language is not English, a skilled interpreter should be involved. Using a family member to serve as translator risks misunderstandings on both sides. Written material should be at appropriate reading levels; mechanisms for follow-up questions and clarifications, such as phone numbers, hotlines, names of office personnel, etc. also improve clarity.

### Unrealistic Expectations

Finally, family members do sometimes have unrealistic expectations and hopes. While denial may play a part, another possible reason for misguided expectations is that no one has ever explained the patient's situation fully to his or her family.

Communication involves listening as well as talking. Does the family understand the patient's condition? If this is a chronic illness, how have they adapted to earlier crises? What concerns do they express? What issues lie just below the surface? Have the messages from various members of the health care team been consistent?

In many cases, it takes time for family members to absorb the reality of an impending death or dire prognosis. This is not "dysfunctional," it is part of a process of grief and acceptance.

### The Benefits of a Well-informed Family

Is all this effort worthwhile? Absolutely. Well-informed, confident, and trusting family members are more likely to understand and implement home care instructions. They are less likely to bring the patient back to the Emergency Department for unnecessary reasons. They are more likely to follow medication orders appropriately and to be alert to post-surgical complications.

And they are more likely to see professionals as partners rather than adversaries. ■

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# Health Literacy: Can Your Patient Read, Understand, and Act Upon Your Instruction?

By Joanne G. Schwartzberg, M.D.

Director, Aging and Community Health, American Medical Association

**A**t the start of the 21st century in one of the wealthiest and most sophisticated societies on earth, we have discovered a most unpalatable truth: approximately half of Americans have reading and computational skill deficiencies that could impede their participation and compliance in health care (*see sidebar*). This problem raises serious concerns about how well patients with low or marginal literacy are navigating the current health care system. Among the basic concerns:

- How well do patients understand instructions on appointment slips or prescription bottles?
- Can they follow directions for preparations for diagnostic tests?
- Do they understand the informed consent documents they are asked to sign?

## The Risks of Low Literacy Patients

Patients with low literacy are at much higher risk of errors and poorer than expected outcomes in the modern health care delivery system than they would have been 30 years ago. For example, a patient with an acute myocardial infarction 30 years ago would have been hospitalized for six weeks, surrounded by skilled professionals who took care

of every need. With new medical knowledge, drugs, and treatments (as well as cost containment pressures), a similar patient today will be out of the hospital in less than a week. Today's patients are quickly on their own, with long lists of instructions, medications, appointments, and very little support from skilled professionals. We expect patients to learn to care for themselves. How much of their "compliance" problems are our responsibility for failing to properly educate and ensure their understanding and ability to carry out the needed care?

Another problematic area is the process of obtaining informed consent. The complexity and high reading level of consent forms has been well described.<sup>10,11</sup> The legal implications of patients signing informed consent documents they do not understand is obvious. There is ample evidence in case law that health providers may be held responsible for adverse outcomes of low-literate patients who do not understand written consent forms and have not been verbally informed about the risks of medical treatments or surgical procedures.<sup>12</sup>

In a report examining the scope of the problem of health literacy, the American Medical Association's (AMA) Council on Scientific Affairs found that "limited literacy is a barrier to effective medical diagnosis and treatment."<sup>13</sup>

## Health Care Literacy: The Numbers

In 1992, the U.S. Department of Education conducted the **National Adult Literacy Survey (NALS)**, to examine literacy in terms of everyday functional tasks.<sup>1</sup> Of the 26,000 American adults interviewed, 15 percent were born outside the United States; the majority with low literacy were white and native born. Among the NALS findings:

- 22 percent of adult Americans are functionally illiterate (they cannot read the front page of a newspaper).
- Another 25 percent have difficulty with tasks involving words and numbers (they cannot read a bus schedule).
- Approximately 50 percent of Americans have reading and computational skills that are inadequate for them to fully function in our modern society.

A 1995 study by **Williams, et al** of 2,659 public hospital patients<sup>2</sup> found that:

- 26 percent could not read their appointment slips,
- 47 percent could not understand written directions to take medicine on an empty stomach,
- 60 percent did not understand the standard consent form,
- 21 percent could not understand instructions (for a GI series) written at the 4th grade reading level.
- 81 percent of English speaking patients age 60 or older had inadequate health literacy.<sup>2</sup>

A recent study of **3,260 new Medicare enrollees in a national managed care organization** found that inadequate health literacy increased steadily with age, from 16 percent of those age 65-69, to 58 percent of those over age 85.<sup>3</sup>

**Baker, et al** found that individuals with low literacy are twice as likely to report their health as poor and twice as likely to be hospitalized.<sup>4,5</sup>

**A study of Medicaid participants** found that those reading at the lowest grade levels (0-2) had average annual health care costs of \$13,000 compared with the average for the population studied of \$3,000.<sup>6,7</sup>

**The American Academy for an Aging Society** estimates that excess health care costs generated by patients with inadequate health literacy (primarily from extra and longer hospitalizations) is \$73 billion dollars per year.<sup>8</sup>

Among **patients who had attended diabetic education classes**, less than 50 percent of those with inadequate literacy knew the symptoms of hypoglycemia compared to 94 percent of the patients with adequate literacy.<sup>9</sup>

There is ample evidence in case law that health providers may be held responsible for adverse outcomes of low-literate patients who do not understand written consent forms and have not been verbally informed about the risks of medical treatments or surgical procedures.

The AMA report stresses the importance of physicians and other health professionals increasing their awareness of the widespread incidence of low literacy and the barriers it raises throughout the health care system.

Although research instruments can help screen for levels of literacy, these may not be appropriate for use in a clinical encounter. Most people with low literacy skills are deeply ashamed and have struggled to keep their difficulties hidden. One study found that 67 percent of patients with low literacy had never even told their *spouse*.<sup>14</sup>

### Making Efforts Toward Comprehension

Since approximately half the population will have difficulty with health care information, it makes sense to move to a more accessible approach for all patients. That means consciously leaving time in the discussion with the patient to ensure his or her understanding of the information. One recent study found that physicians assess patients' understanding of their instruction only two percent of the time. This is clearly an area with room for improvement.

The AMA report states that physicians can learn effective communication strategies, such as making their instructions interactive by having patients do, write, say, or show something to demonstrate their understanding: this is sometimes referred to as having the patient "teach back" the information. Another technique is to show a patient a pill bottle and ask "If this were your medicine, tell me how would you take it?" which provides a rough measure of health literacy and a good introduction to discussing the instructions in a meaningful way.

Most important is to create a "shame-free environment" where patients with low literacy skills feel they can ask for help.<sup>15</sup> All staff, clinical and administrative, need to be sensitized to the prevalence of the problem and learn to take a non-judgmental, gentle approach to offering assistance.

Written materials, from forms and questionnaires through patient education brochures, can be revised to 4th to 5th grade reading level (currently most are written at 10th grade level or higher). Pictures, diagrams, videotapes help communicate where written words may fail.

### Above All, Repetition

**We know adult learners need repetition to remember. But in the physicians' office or health care setting, adults get information without the opportunity for repetition. We can change that.**

We can arrange for office systems where nurses review and reinforce the physician's instructions before the patients leave. We can provide instructions written at a 4th grade level that are reviewed orally with the patient (including a "teach back" step). We can make telephone calls within a day or two of the visit to find out how the patient is doing in following the instructions, etc.

While we wait for more research to illuminate the causes of health illiteracy and identify the "best practices" for diminishing and compensating for it, we can do a great deal within our own environments to improve communication and give all patients their best chance at good health outcomes. ■

*For more information on the AMA Foundation's health literacy education materials and initiatives, contact the author at 312-464-5355, or via e-mail to [joanne\\_schwartzberg@ama-assn.org](mailto:joanne_schwartzberg@ama-assn.org)*

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# Women's Understanding of the Mammography Screening Debate

By Steven Woloshin, M.D., M.S. and Lisa M. Schwartz, M.D.

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*The following is excerpted, with permission, from the Archives of Internal Medicine, Volume 160, May 22, 2000.*

**T**he fractious debate among experts over mammography screening recommendations for women aged 40-49 years has received extensive attention in medical journals and the popular press. It is well known that the public may interpret the scientific process differently than medical experts, and how women understood the debate may have important implications for physicians providing primary breast care. We conducted a national survey of 767 American women to answer the following questions

***Did women pay attention to the debate?***

***What did they think was the underlying source of the debate?***

***What was their reaction to the public disagreement among screening experts?***

***When did women think they should begin having mammograms?***

## Results [N=503 respondents]

- 95 percent of the respondents said they paid at least some attention to the discussion about screening mammography; 42 percent said they paid a lot of attention.
- 83 percent (and 92 percent of those who “paid a lot of attention”) believed that screening mammograms were a proven benefit for women aged 40-49 years.
- 68 percent reported that the debate did not change their understanding of issues related to mammography.
- 49 percent of respondents (and 53 percent of those who “paid a lot of attention” to the issue) believed that the mammography debate was really about money. Many made general statements suggesting that the controversy was about the financial cost of mammography, such as “the cost to the insurance company.”
- 38 percent believed that mammography had proven benefit for women younger than 40 years.
- About one third of the comments about costs asserted that insurers opposed mammography screening in order to save money (e.g., “because of the cost of the procedure, insurance companies want to reduce the number that are done;” “HMOs are interested in paying the least money. If they considered early detection more profitable, they would be for early mammograms”).
- 15 percent said the debate has left them “more confused.”
- 13 percent reported that the debate lessened their confidence in the recommendations of such experts.
- 10 percent cited “questions of benefit” as the source of the controversy.

## Comment

The high level of interest about mammography among women was reflected in both the high response rate to our survey and the frequency with which the respondents answered the open-ended question. However, despite the attention to the debate, few women recognized that it was about whether mammography screening reduces breast cancer mortality for women aged 40-49 years. In fact, most thought mammography had proven benefit for women in this age group.

One reason that few women correctly identified the source of the debate may be that so many women have a strong belief that the benefit of mammography has been scientifically proven. Women did not distinguish between the relatively weak evidence supporting mammography screening for women aged 40-49 years<sup>1-3</sup> and the strong evidence for mammography screening for older women.<sup>4</sup> In addition, almost half of women believed that proof of benefit existed for women aged 18-39 years, a position not supported by any findings in the scientific literature. Consistent with this finding, more than half believed mammography screening should begin before age 40 years.

Patients may have a bias to believe in the efficacy of screening, a predisposition that might lead them to an uncritical acceptance of screening at any age. To make sense of the debate, women who assumed that mammography has proven benefit must look elsewhere for the source of the controversy.

## What do Women Think the Debate is About?

Many of their perceptions about the source of the mammography debate are troubling. The National Institutes of Health consensus panel was explicitly charged to examine the evidence for mammography screening without considering financial costs.<sup>5</sup> Nonetheless, most women thought the debate was about money. In particular, they believed that the arguments against routine mammography were motivated by a desire to control costs (and enhance the profits of payors) rather than by scientific questions about benefit. Despite the concern about the financial motives of those questioning routine mammography for women aged 40-49 years, few questioned the financial motives of *supporters* of mammography screening. Additionally, while most experts report that there is negligible radiation risk with mammography,<sup>5</sup> 13 percent of women thought concerns about radiation exposure stimulated the debate.

Women's beliefs about mammography may reflect confusion or nonacceptance of guidelines. Many women and perhaps their physicians may be recalling earlier recommendations (i.e., those of the American Cancer Society<sup>6</sup>



and the National Cancer Institute<sup>7</sup>) to obtain a baseline mammogram between ages 35-40 years. Physicians may have trouble explaining why recommendations have shifted in the direction of greater caution when recommending routine mammography for younger women. Also possible is that physicians may not know or have confidence in the current recommendations of national organizations.<sup>8</sup> Alternatively, women or their physicians may not accept current recommendations if they contradict strongly held beliefs. ■

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#### Editor's Comments:

The findings reported by Drs. Woloshin and Schwartz may help explain why *failure to diagnose breast cancer* is a leading allegation in office-based claims against all physicians.

Clearly, women have an unrealistic attitude about the efficacy of the mammogram as a diagnostic tool for detecting breast cancer. Almost four out of 10 of the women surveyed believed that mammography had proven benefit for women younger than 40 years. This indicates that physicians have a difficult role in educating their female patients about what a mammogram can and cannot show in the breast of younger women with dense breast tissue.

For physicians and others providing primary breast care to women, the survey's results offer (at least) two important lessons:

- 1) When ordering a mammogram (or if the decision is made not to order a mammogram), clinicians need to help patients understand the clinical basis for the decision—and, that it is not economically driven. One aid available for providers in primary care settings is written information about the value of the mammogram, and its limitations. Several of the newsletters directed at women patients, including the *Harvard Women's Health Watch* and the *Women's Health Advisor* (published by the Center for Women's Healthcare at the Weill Medical College of Cornell) stay current in issues surrounding women's health, including breast care. *WebMD* also offers a good explanation about breast care.

As always, the reasons for ordering or not ordering diagnostic tests, along with the patient's response, should be documented in the patient's medical record.

- 2) This article also emphasizes a danger of the medical community blaming "managed care" for decisions not to order particular diagnostic tests or other services.

"Managed care" can easily become a thick gray cloud obscuring clinical rationale. When a physician blames "managed care" for some perceived limitation on offering care, the patient may perceive "managed care" and the physician as one. This impression may lead to a physician getting blamed for withholding "necessary care" when a diagnostic test such as a mammogram is not ordered for sound clinical reasons.

Similarly, if the mammogram result is inconclusive—as it may well be for a woman younger than 40 years—patients may be angry if a cancer is later discovered.

While we do not want to discourage screening mammograms, patients benefit from knowing that the mammogram is not a perfect diagnostic tool—especially for patients under age 40, and to some extent for patients ages 40-49.

-Martha Byington, Issue Editor

## Help in Handling Patient E-mail

Clinicians and hospitals are increasingly concerned about risks associated with e-mail messages to and from patients. Tools such as e-mail may begin to change patient expectations about the delivery of quality care as an estimated half to three-fourths of the U.S. population will be using e-mail by 2001.

"The adoption rate of e-mail, now as common as the fax machine in business settings, has been extraordinary," writes Dr. Daniel Sands,<sup>1</sup> who works at the Center for Clinical Computing for Boston's Beth Israel Deaconess Medical Center. Sands also points out that some of e-mail's advantages are also sources of perceived risk. For example, ease of transmitting messages leads to concerns about confidentiality and verification of identities.

Dr. Sands hands his patients a business card with his e-mail address only after the patient has read and agreed with the following guidance stamped on the back of his card:

- E-mail is not entirely secure.
- Employers may view e-mail sent via a work-provided e-mail system.
- E-mail should not be used for emergencies or time-sensitive issues.
- If a response is not timely, the patient should escalate.
- Patients should keep copies of e-mails they receive from the provider.
- The provider may (or will) keep copies of e-mail that a patient sends.

1 Daniel Sands, M.D., M.P.H., in *Guidelines for the Use of Patient-Centered E-mail*, published by Massachusetts Health Data Consortium, Inc.

## Tips for Managing an Upset Caller

Compiled by Suzanne O'Connor, R.N., and Diane Hanscom

Suzanne O'Connor is president of Healthcare Satisfaction, a consulting firm.

Diane Hanscom is Senior Project Manager of Massachusetts General Hospital's Customer Service Department.

**I**n an era when telephone encounters with patients are often contentious, the people on the front (phone) lines need the skills necessary to diffuse an angry caller. While your office staff may be the ones who take the brunt of patient complaints on the phone, the patient-clinician relationship can suffer if such calls are mishandled or unresolved. To reduce negative outcomes of phone calls involving upset patients, MGH recently compiled recommendations from practice staff for successfully handling angry callers.

### Keep Your Goals in Mind

Concentrate on two goals when you take a call from someone who is irate. First, preserve the relationship between the patient and the practice. Second, maintain your own professional demeanor. Think of these calls as an opportunity to hone your skills.

### Use Names

Get the caller's name and use it throughout the conversation. Let the caller know who you are. Callers respond better when they feel they are talking to a real person instead of a faceless organization.

### Use the Human-Business-Human Model

Don't jump to solving the problem right away. Connect with the upset caller first as a person. Listen and let him or her vent. Acknowledge what he or she has said and express sincere concern. After the caller starts to calm down, you can move to the business of solving the problem. Finally, close the call with a personal touch and try to end on a personal note.

### Offer a Blameless Apology

Often, what the caller is upset about wasn't *your* fault. Offering a brief, blameless apology allows you to acknowledge the caller's frustration and the inconvenience suffered, without taking any personal responsibility. For example: "I'm sorry that you had such a frustrating experience."

### Focus on the Problem

Don't take the call personally. Stay focused on the problem and try to find an area of agreement. Involve the patient in coming up with solutions.

### Offer Choices

"Would you prefer to have us send the referral in the mail, or fax it to you?" Giving the caller a choice helps them feel more in control.

### Work on Your Tone

To the caller, your tone of voice is vastly more telling than your words. When you start to feel upset, slow down and lower your voice when speaking. A calm tone builds the caller's confidence, and that will help you both.

### Focus on What You Can Do

Always offer to help. Don't tell your patients you'll *try* to do something. Clearly state what you *can* do in a positive manner. "I assure you I will give the doctor your message as soon as she comes out of the exam room." Remember: *Under-promise* and *Over-deliver*.

### Don't Get Hooked

When you feel yourself starting to lose control, ask the caller if you can place him on hold for a moment. Use this time to calm down; often the caller will do the same. Another option is to ask a colleague or supervisor to take the call. He or she can start fresh and, will usually, achieve a better rapport with the caller.

### Know Your Hooks

Take a few minutes to identify the types of calls that tend to make you upset, and think about how you can best handle those calls when they happen.

### Abusive Callers

Seek mutually agreeable terms for continuing the call: "I'd like to be able to help you, but I can't when you're screaming/swearing." If that doesn't work, give one warning. "I really would like to help you with your problem, but I am going to have to end this conversation if you can not stop screaming." If the caller persists abusively, say, "I am hanging up now. When you are ready to discuss this, you can call me or my supervisor back." Then hang up. You have ended an abusive conversation in a way that is professional and appropriate.

### Reduce Stress

Knowing and practicing these techniques can help keep your stress level down and your energy level up. That combination is a benefit to anyone who calls with a problem. ■

# CLOSED CASE ABSTRACT

## Communication Among Providers

By Annette Bender

Annette Bender is Education Coordinator for Risk Management Foundation

A patient with prostate cancer sustained a cardiac arrest and brain damage following insertion of an ureteral stent.

### Clinical Sequence

Over Easter weekend, a 74-year-old retired businessman with metastatic prostate cancer had a ureteral stent placed to relieve obstruction. The staff urologist who performed the procedure signed off at its conclusion.

The patient had significant pain following the procedure and was admitted overnight for observation. The resident on duty consulted by phone with the urologist. Subsequently, two radiology residents reviewed the post-procedure KUB (kidneys, ureter, bladder X-ray) to check the placement of the stent and (mistakenly) judged it to be properly placed. The next afternoon, a radiology fellow confirmed the residents' (incorrect) judgment and the patient was discharged home.

On Monday morning, after two days of pain, the patient went to the hospital Emergency Department (ED). A repeat KUB suggested that the stent was *not* in proper position, and an abdominal CT scan was ordered to check the placement. Before the test was performed, the patient was assigned to a bed in the inpatient unit, but was kept in the ED to await his CT. During a nine-hour wait, the patient's wife repeatedly complained to the ED staff that her husband was in severe pain. The patient received analgesics in response. No explanation was given to the patient or his wife for the delay.

At 6 p.m., the ED resident who had ordered the CT checked on the status of this patient. He discovered that the patient had been removed from the CT schedule because another patient with the same name had received a scan and been discharged. He informed the patient that this name mix up was the cause of the delay and scheduled an immediate CT scan.

The scan showed that the stent had perforated the patient's ureter. A percutaneous nephrostomy was performed urgently under conscious sedation and a drain placed. Despite the sedation, the patient's pain made positioning difficult, and he needed to be restrained. Near the conclusion of the procedure, the patient suffered a respiratory and then a cardiac arrest. He sustained severe brain damage.

At the request of the family, a conference was convened several days later to review the event. The radiology and urology residents presented their part of his care but could not agree on the chain of responsibility.

The patient died four months later. Although his prognosis had been poor prior to the perforation, his death was attributed to the complications related to his conscious sedation.

### Claim Sequence

Suit was brought against the hospital, six physicians, and a nurse. Two prominent complaints expressed by the patient's wife in her deposition were that 1) her husband was kept waiting while in extreme pain and 2) that her family received no explanation of what had occurred during the family conference after the event.

### Disposition

The suit was settled in the high range (\$500,000-\$999,999) with the majority of the payment allocated against the hospital, the urology resident, and the radiology fellow.

### Discussion Points

With the patient's report of pain, the urology resident alerted the attending, observed the patient overnight, and reviewed the KUB before discharging him.

Patients can provide early warning of problems when they are instructed how to collaborate in their care by reporting unexpected side effects of treatment.

Better systems for following up on patient care in the ED were needed to avoid "losing" this patient. Repeated requests for pain control medications were cues to staff to re-evaluate this patient's status.

Physician and nursing staff are responsible for tracking orders written for patients. Older patients are traditionally less assertive about getting their needs met in a medical setting. Patient service systems may need to provide flags to alert staff to heighten vigilance for patients who may not be able to advocate for themselves.

Plaintiffs in professional liability cases often cite feelings of abandonment by their providers as a factor in their claim. In this case, the patient's long wait for the diagnostic procedure while in "significant pain" was a prominent point in the plaintiff's complaint.

Patients can tolerate unavoidable delays better when the hospital staff or provider routinely updates the patient as to reasons for the delay.

The "same name" delay in obtaining diagnostic services in the ED pointed to the need for changes both in staffing systems and in physician follow-up, but the excuse didn't appease the patient's dissatisfaction.

Reprobating the hospital system in front of the patient may only serve to undermine the credibility of care providers. Instead, a response that objectively analyzes what went wrong may help to assuage frustrations.

The family in this case requested a meeting to help them understand what had occurred, but it may not have helped.

A patient/family conference following an adverse event may contribute to averting a claim when it is well planned and carried out using good communication methods. To help both sides benefit from such a meeting, consider:

- involving your risk manager,
- selecting a single spokesperson from the care team,
- reviewing and reaching consensus among the care team about the chain of events,
- allowing time for the patient/family to express their concerns,
- acknowledging and apologizing for the patient or family's distress without pointing fingers or affixing blame, and
- offering emotional support.

A helpful guide for handling the aftermath of an adverse medical event is available on the RMF web site at [www.harvard.edu/rmlibrary/legal-claims/adverse-event](http://www.harvard.edu/rmlibrary/legal-claims/adverse-event).