Why would Constellation, a company that strives to be a thought leader, devote an issue of Brink to a seemingly mundane issue like informed consent?

The answer is simple: Based on our data, breakdowns in communication continue to be a major contributing factor in claims and suits. And informed consent — which is largely about communication — is central to many legal complaints.

Most physicians, clinics and hospitals do an excellent job of obtaining signed agreements for the procedures they perform. So what’s the problem? The problem is that the signed document is just one part of achieving informed consent. True informed consent is more than a form — it’s a process.

As an ethical concept, informed consent evolved to ensure that patients understand the potential consequences of proposed care. Legal precedent in the United States dates to 1914. In Schloendorff v. Society of New York Hospital, a woman who had agreed to an examination under ether anesthesia, but not to surgery, filed suit after surgery was performed to remove a tumor and she subsequently developed a gangrenous infection.

While the plaintiff’s suit was not ultimately successful, Justice Benjamin Cardozo of the New York Court of Appeals wrote in the Court’s opinion, “In the case at hand, the wrong complained of is not merely negligence. It is trespass. Every human being of adult years and sound mind has a right to determine what shall be done with his own body.”

Case law in this area did not begin to develop until the 1950s, and even today, laws vary widely from state to state. Complex questions are involved, as you well know:

- How much should I, the physician, disclose to my patient?
- How can I be sure my patient understands what’s involved in the treatment I’m proposing?
- How can a single form cover all possible situations?
- Are blanket disclosures better or worse?

None of these questions are simple. Most breed further questions. In this issue of Brink, we provide assistance in navigating the informed consent landscape. We look at factors — like fear — that can interfere with understanding. We examine cases where lack of informed consent played a key role in a legal decision. And we explore emerging digital solutions that could be helpful to you and your patients, enabling patients to view animations of their proposed procedure ahead of time … and detailed follow-up instructions afterward, from the comfort of home. Some of these tools can also help you digitally document consent conversations.

While there are no easy answers, we are here to help. We have consultants you can talk with, educational presentations you can view, extensive online resources, and now, this issue of Brink, which we hope will help you more fully appreciate the value of truly informed consent.

Thank you for your continued support, and please don’t hesitate to write or call. We’d love to hear your ideas on how we can bring greater value to you.

All the best,
Bill McDonough, President and CEO, Constellation

---

Brink® is published quarterly by Constellation. Constellation is a growing partnership of mutual liability insurers and health organizations that unite to provide solutions and support to physicians and other health care providers. Formed in 2012 as a response to an increasingly challenging market, Constellation is guided by its own board of directors comprised of physicians, medical liability professionals and health care leaders. MMIC is a founding member company; UMIA joined Constellation in 2013, Arkansas Mutual in 2015. More partners will be joining soon and, as we grow, our partnerships will extend beyond medical liability insurers to include provider support and consulting solutions.

To download Brink, visit MMICgroup.com. To contact the editor, please send an email to Liz.Lacey-Goetz@ConstellationMutual.com.
NO MAGIC WORDS
Truly informed consent isn’t just a signature on a perfectly worded form.

DIGITALLY ENHANCED
Innovative approaches to informed consent.

LIFE STORIES
Keep detailed notes on conversations with patients.

A SHIFT IN PERSPECTIVE
Patient and Family Advisory Councils.

BREAKING POINTS
Where breakdowns in communication can harm patients most.

UNDER THE MICROSCOPE
Preparing for a surveyor visit.

ETC.
Stats and facts on informed consent.

ALL SYSTEMS GO
Reducing risks associated with your EHR.

CORRECTION: In “Belly & Bones” on p. 15 of the Winter 2016 issue of Brink, a chart was mislabeled. Injury severity related to musculoskeletal surgery should have been labeled “High – 29%” and “Medium – 71%.”
COPY AND PASTE TOOLTIP HELPS ENSURE SAFE EHR USE

To help minimize the possibility of errors or adverse patient safety events caused by copying and pasting in the electronic health record (EHR), the ECRI Patient Safety Organization’s (PSO’s) Partnership for Health IT Patient Safety, convened by ECRI Institute, has issued safe practice recommendations and a useful Toolkit for the Safe Use of Copy and Paste. A multidisciplinary group of stakeholders — providers, expert advisors and collaborating organizations, including our experts at Constellation — came together to agree upon and support these safe practice recommendations.

While copying and pasting can lead to issues, most agree that the time-saving and other benefits are too significant to suggest eliminating the practice altogether. According to multiple studies, the number of physicians and medical students using copy and paste ranges from 66 to 90 percent — a number too high to let the practice go unchecked. Another study reported that 80 percent of physicians agree that copy and paste has improved documentation overall, and 82 percent think it should continue.
OPERATING ROOM ERRORS TAKE A TOLL ON SURGEONS

When medical errors happen, many surgeons feel emotionally affected and want more support, both personally and professionally. These doctors are more likely to suffer fatigue and depression, and can even experience a lower quality of life.

Of 27 general and vascular surgeons interviewed in a recent study, 15 reported feelings of guilt, eight had confidence issues and concerns about their reputation, and six expressed worry for their patients. More than two-thirds of the surgeons said their behavior was impacted, and 18 reported noticing an impact on their surgical practice.


READ THE FULL STUDY HERE: HTTP://ONLINELIBRARY.WILEY.COM/DOI/10.1002/BJS.9308/FULL

Factors contributing to copy and paste problems

The toolkit helps health care organizations and clinicians understand their risks and create an action plan for implementing safe copy and paste recommendations. The kit also includes sample policies and procedures, as well as tools for education and training. Four key recommendations are outlined for the safe and effective use of copy and paste:

1. Provide a mechanism to make copy and paste material easily identifiable
2. Ensure that the provenance of copy and paste material is readily available
3. Ensure adequate staff training and education regarding the appropriate and safe use of copy and paste
4. Ensure that copy and paste practices are regularly monitored, measured and assessed

Resources


Compiled by Liz Lacey-Gotz
Brink Editor
Liz.Lacey-Gotz@ConstellationMutual.com

TIME CONSTRAINTS

COMPLEX DOCUMENTATION REQUIREMENTS

LIMITATIONS TO CURRENT EHR PLATFORMS

INCREASED DATA COLLECTION FOR QUALITY IMPROVEMENT INITIATIVES

Increased copy and paste

DECREASED TIME FOR CLINICAL SYNTHESIS

PROBLEMATIC EFFECTS ON THE MEDICAL CHART

- Note bloat
- Internal inconsistencies
- Propagation of errors
- Copying into the wrong patient’s chart

Source: Partnership for Health IT Patient Safety
NEARLY ALL HOSPITALS NOW USE CERTIFIED EHR TECHNOLOGY

In 2015, 96 percent of all U.S. hospitals used electronic health record (EHR) technology.* This represents a ninefold increase since 2008, prior to the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 that called for the adoption and meaningful use of EHRs.

On a state basis, EHR adoption rates have climbed from 22 percent or lower in 2008 to 80 percent or higher for 35 states in 2015.

* Does not include federal acute care hospitals.


Basic EHR adoption increased while certified EHR adoption remained high

PERCENT OF NON-FEDERAL ACUTE CARE HOSPITALS WITH ADOPTION OF AT LEAST A BASIC EHR WITH NOTES SYSTEM AND POSSESSION OF A CERTIFIED EHR: 2008-2015

NOTE: Basic EHR adoption requires the EHR system to have a set of EHR functions defined in Table A1 (http://dashboard.healthit.gov/evaluations/data-briefs/non-federal-acute-care-hospital-ehr-adoption-2008-2015.php#appendix). A certified EHR is EHR technology that meets the technological capability, functionality and security requirements adopted by the Department of Health and Human Services. Possession means that the hospital has a legal agreement with the EHR vendor, but is not equivalent to adoption. * Significantly different from previous year (p<0.05).
JULY
ANTIMICROBIAL STEWARDSHIP: A NATIONAL PRIORITY
Presenter: Jeff Brock, PharmD, MBA, BCPS-AQ ID, Pharmacy Specialist – Infectious Diseases, Mercy Medical Center

According to the CDC, antimicrobial agents (antibiotics and similar drugs) have been used so widely and for so long that the infectious organisms they are designed to kill have adapted to them, making the drugs less effective. Antibiotic-resistant infections affect 2 million people and are associated with 23,000 deaths annually in the United States. Current evidence demonstrates that Antimicrobial Stewardship Programs can both optimize the treatment of infections and reduce adverse events associated with antibiotic use.

AUGUST
PATIENT AND FAMILY SHADOWING: A SAFETY SOLUTION
Presenter: Michelle Bulger, Training Coordinator, PFCC Innovation Center

Shadowing is a low cost, high impact approach that enables care providers and health care organizations of all types and sizes to continuously improve care experiences by viewing and understanding care through the eyes of the patient and family. By following along in the patient’s and family’s footsteps, noting the details of the experience and recording their observations, shadowers get a real-time view of what patients and families encounter along their health care journey, which creates an urgency to drive change.
THE COST OF MISUNDERSTANDINGS

Informed consent shows up both formally and informally in malpractice claims. And there’s a lot to be learned from looking at the data about the role played by informed consent factors in such cases.

In a five-year span from 2010 to 2014, MMIC had nine cases representing $3.2 million in total incurred costs where “failure to obtain consent” was formally alleged as a major or minor (secondary) allegation.

However, as an informal factor that contributed to other allegations across 99 claims and suits, the effects of mismanaged or inadequate informed consent practices elevated total incurred costs to $11 million.

What are informed consent factors?

Whether informally or formally identified, these allegations include factors such as inadequate informed consent (whether for treatment options, surgical procedures or provider identity [e.g., resident vs. staff]), lack of any consent, and insufficient or absent documentation of consent.

Of the cases analyzed, we found that approximately half (52 percent) were attributed to surgical treatment allegations (Fig. 1). In the case of OB-related and anesthesia-related cases, the proportion of total costs incurred exceeded the proportion of occurrence, which is indicative of higher injury severity outcomes.

So where do we see informed consent playing a major role?

In allegations where informed consent factors played a role, it isn’t surprising that the majority (67 percent) involved specialties performing invasive surgical procedures (Fig. 2).

### CASES WITH INFORMED CONSENT FACTORS ACCOUNT FOR $11 MILLION IN COSTS OVER A FIVE-YEAR PERIOD.

### What are informed consent factors?

Whether informally or formally identified, these allegations include factors such as inadequate informed consent (whether for treatment options, surgical procedures or provider identity [e.g., resident vs. staff]), lack of any consent, and insufficient or absent documentation of consent.

Of the cases analyzed, we found that approximately half (52 percent) were attributed to surgical treatment allegations (Fig. 1). In the case of OB-related and anesthesia-related cases, the proportion of total costs incurred exceeded the proportion of occurrence, which is indicative of higher injury severity outcomes.

### FIG. 2

**TOP RESPONSIBLE SERVICES WITH INFORMED CONSENT CASES**

<table>
<thead>
<tr>
<th>Services</th>
<th>Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical Specialties</td>
<td>23%</td>
</tr>
<tr>
<td>Including plastic surgery, ENT, ophthalmology, colorectal, urology, podiatry, bariatric and cardiac surgery</td>
<td></td>
</tr>
<tr>
<td>OB/GYN</td>
<td>22%</td>
</tr>
<tr>
<td>General Surgery</td>
<td>12%</td>
</tr>
<tr>
<td>Orthopedics</td>
<td>10%</td>
</tr>
<tr>
<td>Medical Subspecialties</td>
<td>8%</td>
</tr>
<tr>
<td>Including cardiology, gastroenterology and physical medicine/rehabilitation</td>
<td></td>
</tr>
<tr>
<td>Radiology</td>
<td>7%</td>
</tr>
</tbody>
</table>

An analysis of MMIC malpractice claims: N=99 open and closed medical professional liability claims and suits (“cases”) asserted 2010-2014 with informed consent factors.
Fig. 3 further defines the grouping of procedures involved more often in these informed consent-related allegations.

Because these findings span across many specialties and procedures, our insights call for improvement of the informed consent processes, communication skill-building for providers, and the need for better patient education — rather than the need for improving providers’ technical skills.

What insights can we draw from this analysis?
The combinations of factors contributing to allegations where informed consent issues played a role are significantly different from all other MMIC cases.

The biggest insight into these cases is that while documentation of informed consent remains important (found in 43 percent of these cases), inadequate communication between provider and patient carries almost double the impact in the informed consent process.

Communication problems were present in 82 percent of cases with informed consent factors — significantly higher than the cases without informed consent factors at 30 percent (Fig. 4). A deeper look behind the numbers shows many cases where patients claimed they didn’t understand what to expect from a procedure, or didn’t understand what other treatment options were available.

In these cases, misunderstandings, miscommunications or lack of communication between provider and patient significantly superseded the role of the provider’s clinical judgment as a factor, which is often medically sound. This might also explain why undesirable outcomes that are known risks of a procedure still show up in a claim or suit, indicated within the technical skill factors at 65 percent (Fig. 4).

Overall, our analysis underscores the opportunity to improve the informed consent process overall. And while documentation continues to be important, the human connection — conversations between the patient and provider — prove to be most crucial in ensuring a clear understanding about treatments, procedures, known risks, alternatives and realistic outcomes.

TRISH LUGTU, BS, CPHIMS, CHP
Associate Director, Research, MMIC
Trish.Lugtu@MMICgroup.com
According to David H. Newman, MD, author of Hippocrates’ Shadow, there’s a simple explanation for the remarkable failure rate (above 90 percent) of CPR to achieve resuscitation. “CPR is performed only on the dead,” he writes.

Less easy to explain, Dr. Newman says, is the “nearly religious zeal” with which medical professionals have practiced Advanced Cardiac Life Support (ACLS) for the past 30 years, “in light of a vast body of evidence that all leads to the same conclusion: it doesn’t work.”

These are among the inconvenient truths Dr. Newman explores in his book, which looks at the pernicious effect of secrets on the relationship between physicians and their patients. Dr. Newman characterizes this secrecy as “a massive coping mechanism, desperately erected and collectively maintained,” that “guarantees the widening of [the] patient-doctor chasm.”

The book is engagingly organized “by secret,” with chapter titles like We Don’t Know, It Doesn’t Work, We Don’t Talk, We Don’t Agree, We Prefer Tests and You’re a Number.

Sharing example after interesting example, Dr. Newman argues that poor communication is at the root of problems in modern medicine. “We don’t value communication, we don’t appreciate its healing potential, and we don’t seriously teach or encourage it,” he says. This despite the well-known fact that the quality of doctor-patient communication is a prime factor in psychological adjustment for patients and families — even when the news is bad. It also appears to be crucial for the psychological well-being of physicians. Dr. Newman cites a British study that found significantly higher levels of job dissatisfaction, distress and burnout in physician participants insufficiently trained in communication skills.

Dr. Newman observes how patients’ desire that physicians know all can lead to a kind of perverse collusion that further complicates communication. But here he finds a ray of hope. “The public’s misplaced faith that we have answers to all or even most questions may be flattering, but it has also been quietly corrosive,” he writes. “Recognizing that we’re incapable of curing or even understanding many conditions may allow patients to reclaim domain and personal control over their wellness, their illness, and their bodies.”

Such a restoration of partnership could have other benefits, such as lessening patient disillusionment. One consequence of the mindset that physicians know all the answers is that when a diagnosis is unknown (an entirely common and reasonable occurrence, given the state of our science), he notes, “people become angry. And in America, anger is often followed by lawsuits.”

Dr. Newman encourages his fellow practitioners to “show our cards. Disagreements can become open points of discussion rather than hidden points of controversy debated quietly among physicians. The uncertainty suggested by the presence of disagreement can be acknowledged. … In most cases, where there is no clear right answer, the values of the patient — the one ostensibly being benefited — should be driving decisions.”

The book also includes interesting forays into the placebo paradox and the statistical concept of “Number Needed to Treat” (NNT), before wrapping up with a provocative consideration of the limits of the scientific method, a caution not to use our encumbered health care system as a scapegoat for physician distance and secrecy, and an impassioned call for a “new old paradigm” that honors — and builds on — Hippocratic ideals.

“WHILE COMPLETE AGREEMENT IS RARELY POSSIBLE, COMPLETE HONESTY ALMOST ALWAYS IS.”
— DAVID NEWMAN

LYNN WELCH
Senior Communications Consultant
Constellation
Lynn.Welch@ConstellationMutual.com
Informed consent means more than simply securing a patient’s permission for a treatment or procedure. Optimally, it is a meaningful dialogue in which you offer your knowledge and judgment while learning a patient’s values and preferences — the necessary foundation for shared decision-making. In this issue of *Brink*, we examine the factors that can adversely affect communication, and suggest ways to ensure that your patients’ decisions are truly informed.
Quick, do you know which magic words must be said during an informed consent discussion? Trick question.

According to Emily Clegg, senior risk and patient safety consultant for UMIA Insurance, Inc., there are no magic words at all. “Many providers are still clinging to the notion that all they need to do is recite a few key phrases, conduct an information dump and get a signature on a form,” she says. In reality, informed consent requires more time, and more genuine human interaction, than the common conception. There’s nothing magic about it.

Several months ago, Clegg began to notice an uptick in calls she received from providers who wanted her to review their informed consent forms. She recalls: “I would say, ‘Can we first talk about your process, the cycle and the conversations that are occurring between people?’” Spurred by what she saw as a growing over-reliance on form over function, she created an educational workshop, “Informed Consent: More Than a Signature,” that she has now delivered to numerous administrators and providers.

The program stresses the need to offer patients understandable information, respect their autonomy, allow for a discussion of shared expectations, and arrive at a mutual understanding of what is about to happen.

The Four Cs
As part of her presentation, Clegg outlines four distinct stages in the cycle of informed consent, which she calls the Four Cs.

CAPACITY
“People can’t truly agree to something they can’t understand,” Clegg says. For this reason, providers need to be especially sensitive to the increased needs of those who have diminished capacity or a language barrier. For minors, state laws vary, but the status of the minor and the care needed should guide the discussion.

COMMUNICATION
Many providers hide behind jargon, legalese and long lists of every possible risk. Clegg suggests a more thoughtful approach to the process and to the language used. “Ask yourself, ‘What’s important to the person in front of me? What do they value? How is what you’re proposing going to change their life? What are they afraid of?’”

Words to avoid during the informed consent process include terms that might seem innocuous, but that could lead to confusion or disappointment. “Don’t say ‘better’ unless you are clear about ‘better compared to what,’” Clegg says. “Telling someone ‘scarring will be minimal’ doesn’t take their own tolerance into account. And promising ‘you’ll be back to work’ needs to include a provider’s understanding of whether the patient is a laborer or a desk-bound accountant.”

What to talk about
Every informed consent conversation should include these basics:

- Diagnosis
- Purpose of procedure
- Nature of procedure
- Material risks
- Anticipated benefits
- Possible alternatives
- Risks of doing nothing

Before and during the informed consent discussion, Emily Clegg suggests that providers should ask themselves: What are patients worried about? What aren’t they understanding? What do they expect? How do they see life after the procedure? What is most meaningful in their lives?

Clegg offers an example of a surgeon who told two parents that their child’s surgery had been “textbook.” But, Clegg says, “What does that mean to the parents, who have no idea what a ‘textbook’ surgery is? Should they expect zero complications, no pain and a complete recovery for their child? Telling them ‘textbook’ doesn’t mean anything.”
COMPREHENSION

While talking with a patient about the upcoming procedure, the patient’s head will often nod like a bobblehead. But have you achieved comprehension? Don’t bet on it.

Clegg recommends the teach-back technique developed by the National Quality Forum. “Ask patients to verbalize plans themselves,” she explains. “You can say something like, ‘It’s important for me to know we’re on same page, so can you tell me how you’d describe this plan to your friends and family?’ Asking them to do this gives you a gauge of their comprehension, and also helps cement it in their minds, since it was formulated in their own words.”

Another useful method to ensure comprehension is to introduce educational tools. “You can watch a video together, or you can provide drawings or models,” Clegg says. “You might even share vignettes of other patients who have gone through the procedure.” A team approach often characterizes this model, with a provider doing an initial consult, and another team member following up with educational supplementation.

CONSENT

Informed consent is an ongoing journey, not a race that finishes the moment the patient signs a form. Reaching consent is not a one-time moment, Clegg says. “It can be withdrawn at any time, or can change from complete to partial consent. We must respect the autonomy of patients, and understand their choices today may not be their choices tomorrow.”

Finding and fixing the gaps

HOW ONE FACILITY MAINTAINS COMPLIANCE FOR INFORMED CONSENT.

Sally Yungtum, RN, is manager for risk, quality and occupational health at Community Memorial Hospital, part of UnityPoint Health and located in Sumner, Iowa (population 2,100). The 3-year-old facility has 12 beds for critical access and four pre/post-surgical rooms. With a 96-person staff, Community Memorial provides emergency care, inpatient care, outpatient care, physical, speech and occupational therapy, and cardiac and pulmonary rehab.

When the facility conducted an early assessment in radiology, it was discovered that patients having invasive radiology procedures were often arriving in the Radiology Department without having completed the informed consent process. “We launched a continuous quality improvement (CQI) project for our clinic, ensuring that the conversation was conducted and the discussion was documented,” Yungtum says.

This project has been monitored for the past three years, and one of the milestones in improvement was their request to meet with Michelle Kinneer, senior risk and patient safety consultant at MMIC. “Michelle had a productive session with the team leaders of all our departments, and she shared some very valuable information,” Yungtum says. “Even better, our leaders asked great questions.”

Kinneer’s session included several “what ifs” and other scenarios, and explored the concept of time outs when appropriate. Yungtum says, “We’re doing many more time outs for invasive procedures in our clinic now, so that’s one area that’s definitely improved as a result of Michelle’s visit. More than anything, it was an awareness builder. I can tell [our staff] this information, but when they hear it from the liability insurance company, with examples of what has gone to court, I think our staff pay closer attention.”

Yungtum’s facility is surveyed by the Iowa Department of Inspections and Appeals, which closely mirrors the standards of The Joint Commission (TJC). “We were last surveyed in 2013, so we’re ready anytime for the next one,” she says. “I feel more prepared when it comes to documentation of informed consent, and I’m proud of our providers and staff for getting on board with it.”

However, Clegg says, providers must remember that the final responsibility for the process of informed consent is non-delegable. “Sometimes patients hold it together when talking to the provider, then share their tears, questions and fears with a staff member, once the provider has left the room,” Clegg says. Those are valuable pieces of information for the provider, who should be looking for cues to unrealistic expectations or lingering questions.

So … time-stressed providers might feel as if this is one process that can be handled by others in the practice, but Clegg warns against that. “Ultimate responsibility is with the provider. Teams can help you communicate, but this is your job and the buck stops with you.”

CONSENT

Informed consent is an ongoing journey, not a race that finishes the moment the patient signs a form. Reaching consent is not a one-time moment, Clegg says. “It can be withdrawn at any time, or can change from complete to partial consent. We must respect the autonomy of patients, and understand their choices today may not be their choices tomorrow.”

JULIE KENDRICK

Freelance medical and science journalist in Minneapolis, Minn.
"It sends chills up your spine," says John Fialkov, MD, describing an experience he believes most physicians who perform surgery have had. "A patient comes in for surgery, and is all prepped and ready to go, and he or a family member asks, 'So what exactly are we doing today?'"

"I’m about to change someone’s life forever," he marvels, "and they don’t know what I’m doing!"

It’s not that consent wasn’t obtained. Or that the procedure wasn’t discussed. It’s more about how patients sometimes process information in stressful situations.

Dr. Fialkov, who practices urology at the Iowa Clinic, credits a different kind of practice — the combat/defense training system called Krav Maga, developed to help users quickly neutralize threats in "street situations" — for many of his insights into what his patients experience.

Krav Maga training involves learning to counteract the body’s instinctive physiological responses to high-stress encounters, such as tunnel vision, auditory exclusion (not hearing things) and "brain freeze."

Not unlike the way you might react upon being told you have cancer.

According to Dr. Fialkov, there is a process people go through when they receive bad news. "The first question is, ‘Am I going to live or die?’ Next is, ‘Okay, I can live. What do I need to do?’ And only then, ‘What’s involved? What are the risks? What are the side effects?’"

But many patients, Dr. Fialkov says, never reach that third stage in their discussions with doctors, in part because of the time pressures on clinic visits.

A digital assist
Dr. Fialkov is out to change that. For the past several months, he’s been beta-testing a new digital informed consent process — one he designed — in his practice.

The Rati-Fi Informed Consent System is an iPad-based system that improves patient education and comprehension, pre- and post-treatment. It uses high-quality medical animations to explain treatment options, a survey to test for comprehension, and a video-based informed consent process that records the conversation with the doctor and stores that video and a PDF of the signed file securely in the cloud.

Dr. Fialkov’s system is one of a small but growing breed of innovative approaches to informed consent that harnesses emerging digital technologies to create more robust educational experiences for patients, while also ideally freeing
time-strapped physicians to address individual patient concerns more effectively.

“Our patients have embraced it,” says Dr. Fialkov, who has used the tool with some 200 patients to date. “It’s a less threatening way of getting information.”

Patients can watch the videos from the comfort of home, with family members, multiple times, day or night. “They come back with good questions,” he says, “which makes for better conversations.”

Managing patient expectations

Dr. Fialkov has seen other benefits of his system, too, including the ability to better manage patient expectations, which can be challenging in a field like urology, yet important in minimizing the risk of litigation.

“It’s a whole new era,” he says. “Patients are out there looking for information on YouTube.” And sometimes, what they find are inflated claims. “They’ll hear that with robot-assisted prostatectomy, 90 percent of patients achieve full function within 30 days. Well, many don’t. Many never do.” But if that’s what a patient is comparing his own experience to, he says, the risk of dissatisfaction is greater.

It’s not about the form

Dr. Fialkov and other experts in the field encourage practice leaders to think beyond the form (that is, the physical document that patients sign), and beyond informed consent as simply a tool to avoid lawsuits.

“The form is the least important part of the process,” he says. “It’s important to get the patient’s signature, yes, but that’s the icing on the cake. The cake is the communication, the conversation, the connection you have with patients.”

Doing it right

Many excellent resources exist to help you improve your practice’s informed consent process (see Resources section at right). For example, Temple Health publishes an especially comprehensive online toolkit that can help you gain organizational consensus for change, address barriers to effective consent and incorporate best practices.

As you refine your own approach, keep in mind the following expansive definition of informed consent to ensure that you are focusing on the right things and choosing methods, tools and strategies that will result in better overall communication with your patients:

**Informed Consent** is the method by which patients and their physicians incorporate a patient’s values, preferences, expectations and fears in treatment decision-making.1

Resources

MMIC On-demand Webinars


HRSA - Culture, Language and Health Literacy www.hrsa.gov/culturalcompetence/index.html

Informed Medical Decisions Foundation - Shared Decision Making www.informedmedicaldecisions.org/what-is-shared-decision-making

Minnesota Alliance for Patient Safety (MAPS) www.mnpatientsafety.org/Our-Work/Past-Work/Informed-Consent

References


LYNN WELCH
Senior Communications Consultant Constellation Lynn.Welch@ConstellationMutual.com
CONSENT & COMMUNICATION

Keep detailed notes on conversations with patients to make your informed consent process more robust.

Caring for patients involves communication. Providers, team members and patients exchange information all day long. We communicate to deliver care, but also to understand fears, solve ambiguities, reach mutual decisions and improve life.

Any page in any medical record will show a collection of data: dates, vitals, labs, codes and dosages. What’s more difficult to find, however, is the human story of that patient on that day. The communication surrounding the data — the back-and-forth between real people — is not written down as frequently, or nearly as thoroughly. But a medical record is more than data points. It is a chronicle for someone else to open and understand the story of your patient.

In a malpractice lawsuit, the medical record is what we rely on to defend good care. As memories fade, the medical record is our best evidence of what transpired.

The following are three case examples (from the files of UMIA Insurance, Inc.) where the communication between patient and provider was excellent. The care was attentive and comprehensive, and mutual expectations were clear. The documentation, however, was lacking. When memories dimmed and relationships soured, the story of what happened between two people was nowhere to be found in the medical record.

Informed consent

A young woman told her ENT about the nasal allergies and sinus infections she had endured since adolescence. Together they discussed a septoplasty to correct her deviated septum and enlarged turbinates.

In pre-op conversations, the surgeon shared what the woman could expect and what could happen. They discussed the risks, they looked at an enlarged model of the nasal structures, and the patient asked several questions. The ENT also told the patient about an online video that would show the procedure and what to expect.

Then the ENT shared the story of his own brother, who had experienced uncommon breathing struggles after a similar surgery. The brother had lost sensation in his nose, leaving him constantly feeling obstructed, a rare

by Emily Clegg, JD
Two weeks later, the patient canceled his follow-up, admitting he had not obtained the colonoscopy. The internist personally returned the call and again expressed her concerns. Despite more phone calls, the patient never returned.

Years later, the physician learned that the man was in his third round of chemotherapy for a rectal tumor that would likely take his life. The patient brought a claim, arguing that if he had been told of the danger of not undergoing a colonoscopy, he would have sought earlier treatment and perhaps had a better prognosis.

In defending this ENT, we looked to the medical record for evidence of the informed consent conversation. All we found was a generic consent form. There was no note about looking at a model together, answering questions, providing online education or sharing a personal story. Thus the physician’s defense was made much more difficult, and the patient was ultimately awarded a settlement.

Care recommendations and noncompliance
A middle-aged man complained to his internist about abdominal pain and pencil-thin stools that were often tinged with blood. Alarm bells went off in the internist’s mind, warning of a colorectal tumor.

The internist expressed her fears to the patient and recommended a colonoscopy as soon as possible. While still in the exam room, she looked up clinic locations and offered to call personally to set up a quick appointment. The patient declined, promising he would arrange for the colonoscopy himself.

Two weeks later, the patient canceled his follow-up, admitting he had not obtained the colonoscopy. The internist personally returned the call and again expressed her concerns. Despite more phone calls, the patient never returned.

In defending this physician, we looked to the medical record for evidence of the conversation at discharge. All we found was the pre-printed discharge sheet given to every ED patient. There was no note about the specific instructions, the list of warnings, the phone number given or the overall concern for the child.

Write it down!
In each of these cases, our attorneys zealously defended the compassionate and attentive care provided by the physicians. But that job was more difficult because the details of doctor-patient communication were nowhere in the records. Even a quick note like “talked with patient about X” could have solidified the defense and made the evidence of good care irrefutable.

Writing down the communication side of caring is just as critical as the forms, data points and values in the medical record. Your medical record is the evidence of your care — the story of what happened between two people. Be sure you’re not leaving out the most important parts.

EMILY CLEGG, JD, MBA, CPHRM
Senior Risk and
Patient Safety Consultant
UMIA
eclegg@umia.com
CONSENT & COMMUNICATION

A SHIFT IN PERSPECTIVE

How Patient and Family Advisory Councils (PFACs) can improve provider-patient communication.

If only she’d known what was about to happen to her dad — was there anything she could have done to stop it? Sandi Swenson continues to ask herself “what if” questions regarding two failed surgeries that contributed to her father’s untimely death, a tragedy in which lack of informed consent played a prominent role.

During his first hip replacement, it is suspected that her father’s femur was cracked, which went undetected. “We were never told that was even a possibility,” she says. When her father fell again, it caused a re-break and prompted another surgery; the bindings from the first surgery ended up coming loose, another situation Swenson says she was never cautioned about as a possible outcome.

Finally, the family ended up at Mayo Clinic in Rochester, Minn. Swenson praises Mayo Clinic for providing genuine concern and excellent treatment. “Finally, at Mayo, we were listened to. Every single thing was explained to us. But it was too late by that point, and my dad died.”

This is the type of situation that Lisa Juliar tries to help patients avoid. Juliar is the patient and family engagement consultant for the Minnesota Hospital Association, and she believes that adverse situations can be reduced by bringing the patient perspective to the forefront. To this end, she has championed the creation of Patient and Family Advisory Councils (PFACs) in all hospitals, nursing homes and clinics in Minnesota.

A PFAC is an established council within a health care practice or medical facility. This council is usually comprised of patients and family caregivers who have received care at the facility, and who are joined by representatives from the staff, including providers, clinicians, office staff and leadership. The group reviews improvements in care and processes as well as ways to improve outcomes and patient experiences. According to Juliar, the PFAC model is most successful when patients and family caregivers are viewed as respected partners and essential resources for the improvement of care.

When Juliar herself suffered an adverse event as the result of a medical procedure, she was asked to join the board of the Minnesota Alliance for Patient Safety. This led to a career in the area of patient advocacy, in particular with PFACs. “PFACs help transform the role of the patients into one that’s an integral part of the care team,” she says. “These groups are created with the belief that patients are experts about themselves, and having them in place helps shift the mindset of both patients and providers, creating a true partnership.”

The process of informed consent is one that could realize a significant improvement through increased patient and family input, Juliar says: “Patients and their families need to be a part of shared decision-making, especially at this crucial point of care.”

“Successful PFACs should be actively pursued to give input on safety and quality from the patient or family perspective,” Juliar adds. “Health care providers are frequently surprised that they ‘hadn’t looked at things that way before’ after hearing recommendations from the council. And even more importantly, innovative recommendations from PFACs may make a direct impact on quality and safety.”

Positive results

Juliar is a strong advocate for the growing trend of including PFACs in hospital and clinical practices. “These councils help to increase the trust level for all patients, because changes are made that directly impact quality of care,” she says. “There is a considerable body of research showing that these councils can have a positive impact on outcomes.”

JULIE KENDRICK
Freelance medical and science journalist in Minneapolis, Minn.
In the contentious arena of politics, tort reform has often been framed as a contest between those opposing malpractice litigation and those advocating for legal recourse for injured patients.

On one side are physicians lining up to support more protection from litigation. They also claim that their exposure to excessive liability leads them to practice defensive medicine — at times performing tests and procedures that aren’t needed and avoiding high-risk specialties because of the potential for legal action.

On the other side are patients and their legal advocates, i.e., plaintiff attorneys, who point to patient harm and allegations of incompetence or negligence. Without such advocacy, they contend, patients would not receive adequate compensation, nor would their doctors be held accountable.

In the midst of this fray, patient safety experts have suggested that much of the energy spent advocating for tort reform would be better invested upstream — on preventing the adverse outcomes that can lead to allegations of malpractice.

This new thinking was the driving force behind a four-year research grant from the Agency for Healthcare Research and Quality (AHRQ), which funded the PROMISES (Proactive Reduction of Outpatient Malpractice: Improving Safety, Efficiency and Satisfaction) project. PROMISES sought to teach improvement skills to small- and medium-sized primary care practices across Massachusetts.

Among the experts leading this project was Gordon Schiff, MD, an internist and associate director of the Brigham Center for Patient Safety Research and Practice at Brigham and Women’s Hospital in Boston, Mass.

Recognizing that lawsuits often occur as a result of breakdowns in communication, Dr. Schiff and his PROMISES colleagues identified and targeted five ambulatory care areas at high risk for errors that could lead to patient harm.
The Five Domains for Communication

1. COMMUNICATION RELATED TO THREE KEY RISK-PRONE PROCESSES
Experience with ambulatory malpractice claims points to several high-risk areas, with recurring problems showing up in three processes: (1) test results, (2) referrals and (3) medication instructions/warnings/indications. In each of these areas, communication issues play a major role.

It’s easy to imagine how a patient might be harmed through errors in explaining test results and how to properly use medications. But referrals? What are the communication issues that make them risky?

Take colonoscopies, Dr. Schiff explains. Alluding to one of the health systems he’s consulting with, he says, “Only 50 percent of referrals [in this system] actually result in a completed procedure. Maybe the patient is afraid and doesn’t want to go, but they don’t tell that to their doctor. Is that the patient’s fault or the doctor’s? We need to be able to talk to patients and know their concerns and fears.”

Even when the patient does want the test, who schedules it — the doctor or the patient? It is often unclear. How does the patient get prepped? What happens after their prep if they don’t show up? Does the lab call the doctor? Or is it the doctor’s responsibility to follow up and make sure the patient had the procedure?

Communication should be a closed loop, Dr. Schiff says. And the physician must know in a timely manner — not a year or two later — if the referral took place or failed.

2. COMMUNICATION AMONG CARE TEAM MEMBERS
Every clinic needs a culture of safety that encourages employees to voice concerns — including admitting when something has gone wrong — without fear of retribution. In a recent survey, only 44 percent of health care providers described the response to error at their organization as “nonpunitive.”

“Even if it’s your stated intent not to blame, how is it working in practice?” Dr. Schiff asks. “You need to be proactive and have a positive climate that allows people to feel they are being respected and their concerns are being heard.”

3. COMMUNICATION WITH PATIENTS DURING AND BETWEEN ENCOUNTERS
Overall risk can be reduced by fostering effective, respectful listening and shared decision-making, and by ensuring that doctors are attuned to their patients’ health literacy. Dr. Schiff recommends the teach-back method. “Give patients instructions in a number of ways, verbally and in writing,” he says. “Then ask them to repeat back to you what they understand.”

Also, identify the patients most at risk for not understanding, such as non-English speakers or people who have low health literacy. Understand that they will need more time with you, and book accordingly.

4. COMMUNICATION RELATED TO HEARING PATIENTS’ CONCERNS AND IDEAS
Does your clinic ask for feedback from patients? “Every defect is a treasure,” Dr. Schiff says, quoting quality guru W. Edwards Deming. “The more we can dig, each time something goes wrong, the more we can learn to both figure out the real story of what happened and help our organizations learn lessons. Our organizations need these ‘squeaky wheels’ to be the voices of things we can improve in our practices.”

5. COMMUNICATING WITH DISSATISFIED PATIENTS/FAMILIES
When something goes seriously wrong, patients need extra attention immediately. They may have a serious adverse reaction to a medication, or kidney failure from a contrast procedure, or any number of predictable or unpredicted negative outcomes. “Be there for the patient first of all,” Dr. Schiff advises. “Continue to think like a doctor, not the potential victim of a lawsuit.”

Dr. Schiff personally understands how it feels to make a mistake resulting in harm. “I overlooked a nodeule on a patient’s chest CT report, resulting in a five-month delay in treatment.” After the event, he sat down with the family, apologized and candidly told them the truth.

“The patient ended up attending the hospital’s outpatient morbidity and mortality (M&M) conference when the case was presented” Dr. Schiff recalls. “At the conference she expressed her appreciation for the honest apology and corrective efforts, and also provided a list of additional ways the care could have been improved.”

When the patient later died, the family asked for donations in the patient’s name to benefit the hospital’s patient safety center where Dr. Schiff works.

“This is an example of the kind of culture we want to create that emphasizes honesty, sharing, learning and improvement, rather than adversarial relationships,” Dr. Schiff says. “We owe it to patients and their families to make sure it doesn’t happen again, so they feel that their loved one’s death has not been in vain.”

Resources
The PROMISES Project
Massachusetts Department of Public Health, funded by the Agency for Healthcare Research and Quality. Available at 1.usa.gov/1MZAs1v

Evaluating Ambulatory Practice Safety: The PROMISES Project Administrators and Practice Staff Surveys
Available at 1.usa.gov/1rMHWeC

When Things Go Wrong in the Ambulatory Setting
Brigham and Women’s Hospital. PDF available at bit.ly/1iuZsR

Doing Right by Our Patients When Things Go Wrong in the Ambulatory Setting
The Joint Commission. Available at bit.ly/1pNGqrP

References
Every hospital administrator knows the feeling. You’ve prepared, discussed and made corrections, but now it’s the moment of truth: The surveyors are here. How will your facility stand up to several days of probing questions about the way you handle every aspect of patient care, including informed consent?

Michelle Kinneer is a senior risk and patient safety consultant at MMIC. She works directly with care facilities to give workshops, offer education and help them ensure that their policies — and their practice — meet the requirements for best patient safety practices.

The first step in ensuring compliance, Kinneer says, is understanding the purpose of informed consent standards. “Those standards are in place to ensure there’s an authentic and two-way discussion between the provider who will be performing the service and the patient who is going to receive that service,” she says. “We’ve moved away from the jargon-laden discussions and the ‘you wouldn’t understand’ attitudes. Patient care begins with the acceptance that the patient and physician are working together to understand the risks, benefits and alternative options.”

Kinneer adds, “Standards are in place to make sure we are having those communications with every patient. No matter who the deeming authority is, they’ll want to see your understanding that informed consent is a process, not a piece of paper.”

**CMS: A well-designed process**

When surveyors from the Centers for Medicare and Medicaid Services (CMS) are at your facility, they will be looking for evidence of a well-designed informed consent process. “You’ll need to include a name and description of the procedure that is being proposed, who will perform it and at what facility, why it’s needed, likely benefits, alternative courses of action, possible consequences for not having the procedure, and the material risk with high degree of likelihood,” Kinneer says.

Kinneer stresses that not every single possible adverse outcome needs to be enumerated. “Just outline the most likely issues that could arise,” she says. Quoting an obstetrician friend, she adds, “If mothers-to-be knew every possible thing that could go wrong, no one would ever consent to deliver a baby.”

**TJC: Include patient goals**

While there are many similarities between CMS and The Joint Commission (TJC) standards for informed consent, TJC also requires an evaluation of the likelihood that patients will achieve their surgery goals. “This puts things into the patient’s viewpoint,” Kinneer says. “For example, a patient may have a knee or hip replacement that goes perfectly well from a surgical standpoint — no infection, appropriate healing — but may be a failure from a patient viewpoint. If a 70-year-old is expecting a new hip to allow mobility and strenuous exercise at the level enjoyed by most 20-year-olds, then there is a gap between physician goals and patient goals.”

**The surveyors are coming!**

Michelle Kinneer often consults with medical practices on the best ways to prepare — and the best ways to conduct yourself — during a surveyor visit. Here are some of her top tips.

“Think of how your house looks on a weekday, when there are baskets of laundry, miscellaneous papers and general family detritus,” Kinneer says. “Then think of how the house looks on a Saturday night when you’re expecting company for a dinner party. You want Saturday night for the surveyors, not Wednesday evening.”

And it’s fine to let your employees know when surveyors are present. Kinneer suggests that you work with your IT team in advance, so that when surveyors arrive, a “Welcome Surveyors” pop-up message appears whenever anyone logs into the EHR.

It’s also a good idea to share the news during shift huddles, just so every employee is informed.

Lastly, Kinneer suggests assigning a scribe from your facility’s employees. “A note-taker should accompany the surveyors to document areas where follow-up is required, and to flag areas the surveyors are making comments on,” she says.
Emily Clegg, senior risk and patient safety consultant at UMIA, experienced a similar situation with a relative, who received a life-saving lung transplant a few years ago. “She told everyone, including her surgeon, that to her this surgery meant she was ‘getting her life back,’” Clegg says. But her relative’s outcome has been different than her expectations; since surgery, she has experienced digestive problems and numerous hospitalizations.

“From a medical perspective, her transplant team would tell you that she’s had an expected course and normal complications from anti-rejection drugs and major surgery,” Clegg says. “But from her perspective, she feels she was deceived, and she’s angry every time she walks through the doors of the hospital. She’s now hypercritical of her care providers.”

Kinneer’s takeaway from this anecdote? “It’s important to identify the gap between patient expectations and likely reality, or you could do everything correctly from a medical perspective, and still have a dissatisfied patient.”

JULIE KENDRICK
Freelance medical and science journalist in Minneapolis, Minn.

Literacy and comprehension
If your informed consent forms are not written at a grade school level, then they need to be rewritten. Further, if a patient can’t comprehend English, you must ask for a medical interpreter to be present.

It’s challenging — sometimes uncomfortable — to determine at what level a patient can read. So Kinneer suggests, “Read the form aloud to every patient, every time, and check for patient understanding.”
Facts of the case
A family physician referred a 44-year-old woman with a past medical history of appendectomy, cholecystectomy, C-section, pancreas transplant, COPD, thyroid disease and hepatitis C to a gynecologist for evaluation of severe uterine bleeding. During the exam, she expressed a desire to have a hysterectomy. The gynecologist performed an endometrial biopsy.

At her next visit, the gynecologist reported that her ultrasound showed uterine fibroid changes, and the biopsy report showed weakly proliferative endometrium with no evidence of hyperplasia, atypia or malignancy. She again requested a hysterectomy and after a discussion of the risks and benefits, the gynecologist scheduled her for a total abdominal hysterectomy and bilateral salpingo-oophorectomy.

During the procedure, the gynecologist noted that there were significant adhesions throughout the pelvic cavity reflective of her previous surgeries. She was discharged home without complications. The surgical pathology report noted no diagnostic abnormality of the cervix, an endometrium that was active without hyperplasia or carcinoma, both fallopian tubes and left ovary without abnormality, and a right ovary with heterotopic pancreatic tissue on the ovarian capsule.

Three days later, she called the gynecologist’s office complaining of cramping pain. She reported that she was examined in the emergency room the previous night and received a “pain shot.” The gynecology staff advised her to come to the office to be examined, but she declined. The staff recommended that she go to the emergency room if she did not feel better.

The patient returned to the emergency room the next day complaining of abdominal pain and fever. She was readmitted and a general surgeon was consulted. An abdominal CT revealed a right lower quadrant pancreas allograft with enteric drainage. She underwent multiple surgeries over the next several weeks and had a rough post-operative course complicated by sepsis, acute renal failure, respiratory failure and a determination
that her pancreas allograft was not salvageable. Eventually she underwent a transplant pancreatectomy with segmental small bowel resection and side to side primary small anastomosis.

She later filed a malpractice claim against the gynecologist alleging improper performance of the procedure and failure to obtain informed consent. She testified that if she had been aware of her status as high risk for complications due to her numerous previous surgeries and immunosuppression, she would not have had the elective hysterectomy.

Disposition of case
The case was settled against the gynecologist.

Patient safety and risk management perspective
The experts were critical of the gynecologist for not informing the patient of alternative nonsurgical treatments and about her high risk for surgical complications given her previous surgeries, pancreas allograft and immunosuppression. They also criticized the gynecologist’s documentation of the informed consent conversation, calling it “sparse.”

Surgical malpractice claims
Allegations involving surgical treatment are the most prevalent and costly cases overall, both for MMIC policyholders and for medical practitioners nationwide. Allegations of improper performance of surgery occur in 66 percent of MMIC cases analyzed, and allegations of improper management of surgical patients occur in 18 percent of cases. Many of the cases alleging improper performance of a procedure involve known risks and complications. Preoperative communication and expectation setting are key challenges identified in these cases.

Informed consent
The principle of informed consent is based on the patient’s right to be fully informed of the consequences of a proposed medical procedure. Informed consent is no longer founded on the physician’s decision about what is best, but on the patient’s decision about what is best based on their values and preferences. According to the Stanford Encyclopedia of Philosophy, “Consent is considered fully informed when a capacitated (or “competent”) patient or research subject to whom full disclosures have been made and who understands fully all that has been disclosed, voluntarily consents to treatment or participation on this basis.”

Obtaining informed consent for treatments and procedures is a process, not a single event of signing a form. The process begins preoperatively with a discussion of the patient’s condition, the treatments available — surgical and nonsurgical alternatives — as well as any risks, benefits and complications of the proposed treatment or procedure. The process involves communicating realistic expectations in words a patient can understand and continues throughout the post-operative period.

Resources
Center for Shared Decision Making
http://med.dartmouth-hitchcock.org/csdm_toolkits.html
Informed Medical Decisions Foundation
www.informedmedicaldecisions.org/
Mayo Shared Decision Making National Resource Center
http://shareddecisions.mayoclinic.org/

References

TJC Quick Safety Alert, Issue 21 - Informed consent: More than getting a signature
www.jointcommission.org/issues/detail.aspx?Issue=GvsxQHW218axl3%2hfLZT28Mz1lRQeU7sN4mlUu6eFu00%3d

PATIENT SAFETY AND RISK MANAGEMENT TIPS

- Practice medicine with an awareness of surgical judgment vulnerabilities
- Understand the importance of accurate patient expectation setting
- Use a patient-centered, shared decision-making model for obtaining informed consent
- Consider health literacy when communicating with patients
- Employ the teach-back technique (tell me, show me) to verify patient understanding
- Supplement informed consent discussions with web-based educational programs, written materials and visual diagrams
- Invest in evidence-based empathy training to communicate more effectively with patients and families (For more information go to www.empathetics.com)
- Document informed consent discussions thoroughly in the patient’s medical record
CONSENT & COMMUNICATION

Nearly a third of prospective subjects will be unable to read an informed consent document, even when written at a 6th-grade level.\(^2\)

Missing consent forms dropped from 4.5% in 2005 to only 0.5% in 2013.\(^1\)

Apologize & explain

Patient advocates say that when patients feel listened to and understood, they are more likely to negotiate a settlement than launch a lawsuit that could end up costing their provider millions of dollars.\(^4\)

65% of adult patients perceived the top reason for informed consent was to “help patient decide,” followed by “make sure patient understands” and “inform patient.”\(^5\)

48% of medical in-patients with acute conditions are unable to consent to medical treatment.\(^3\)

---

With all the benefits that an electronic health record (EHR) system brings to health care, it is hard to imagine how we ever managed before this technology. But as transformative as EHRs have been, they have also introduced risks to patient safety. Be sure your practice effectively monitors and manages these hot spots associated with an EHR.

Communication with patients
Electronic communications may not be the best way to interact with every patient. You can help reduce patient frustrations by letting them choose how they would like to hear from you. Based on the kind of information you need to deliver — such as a troubling test result — an office consultation or phone call might be a better approach.

If a patient visit results in orders, make sure there’s a process for follow-through. Otherwise, you risk multiple fall-outs, including possibly compromising your patient’s safety because they did not receive the test or treatment you ordered.

Communication with care team members and other physicians
Communication gaps can happen if some providers in your practice are not fully utilizing the EHR while other providers are. Some providers may not be as familiar with the system, or they may use a slightly different workflow than their peers. In such cases, they may miss information they need for diagnosis and decision-making. Make sure that all providers in your practice train periodically and know where to find the pertinent information to guide them in EHR usage, decision-making and treatment.

How well do you communicate with referring providers? Do you review and sign off on your final documentation, even if you haven’t really read it? If so, you could be putting patients at risk by supplying information to another provider that is not completely accurate.

Be sure to consistently review workflows with new and existing employees to ensure that everyone is following processes appropriately. If there are necessary deviations, they should be documented and everyone should know what they are and when they’re needed. And whenever your EHR software is upgraded or enhanced, it is a good practice to re-train, provide documentation and test user knowledge.

Interfaces
Electronic communication can break down, too. When information is not passed or orders are not processed due to an interruption or error with an EHR interface, potential problems can arise. Periodically confirm that your system is set to immediately alert the clinic if an interface goes down. For STAT labs, radiology results or any potentially high-risk result in your practice, put a procedure in place to ensure that results are responded to in accordance with your policies.

Process audits
Processes aren’t something you can “set and forget.” Consider the most common risks, such as inconsistent or undocumented workflows, result notifications and overall communication. Regular audits will reveal if your processes have flaws, identify if training is needed and help you develop a risk remediation plan moving forward.

Downtime and backup
What happens if your EHR goes down? Every clinic should be able to back up and restore EHR data. Otherwise you risk losing critical information to continue to treat your patients. A downtime policy indicating how to access data from your redundant system, a testing schedule and a restoration plan should be a part of this process.

SUSAN FISHER
Health IT Clinical Apps Consultant
MMC
Susan.Fisher@MMICgroup.com

MICHELE ROOF
Health IT Implementation Supervisor
MMC
Michele.Roof@MMICgroup.com

JESSICA BUSCH
Health IT Support Manager
MMC
Jessica.Busch@MMICgroup.com
A pulmonologist misses an abnormal CT report in the EHR, which contributes to a deadly delay in the diagnosis of lung cancer.

### Facts of the case
A family physician referred a 78-year-old man with a history of emphysema to a pulmonologist for a prolonged productive cough and other respiratory symptoms that were not responsive to treatment. The pulmonologist ordered a chest X-ray that showed worsening interstitial primarily bibasilar infiltrates that had been present for a year. The pulmonologist felt the cough was likely related to active airway disease and recommended the man to follow up as needed. The report of the chest CT done that day revealed an indeterminate 1.5 cm left lower lobe pleural-based soft tissue mass. The radiologist commented that lung carcinoma was not able to be excluded and recommended a dedicated enhanced chest CT and biopsy sampling be done. The pulmonologist did not see the abnormal chest CT report.

Four months later, the patient returned to see the pulmonologist after having the chest CT done. The patient reported he was doing better. The pulmonologist diagnosed mild interstitial fibrosis and instructed the man to follow up as needed. The report of the chest CT done that day revealed an indeterminate 1.5 cm left lower lobe pleural-based soft tissue mass. The radiologist commented that lung carcinoma was not able to be excluded and recommended a dedicated enhanced chest CT and biopsy sampling be done. The pulmonologist did not see the abnormal chest CT report.

Eight months later, the patient returned to see the pulmonologist for complaints of increasing shortness of breath. When the pulmonologist went into the EHR to order a chest X-ray, he noticed the previous abnormal chest CT results. The pulmonologist discussed the results with the patient, noting the concern for malignancy. He ordered a thoracentesis and repeat chest CT, which showed a primary lung malignancy with combined small cell and non-small cell features. The patient chose not to have chemotherapy and hospice care was ordered.

Several months later, the man was found unresponsive at home and died later that afternoon. The cause of death was determined to be metastatic adenocarcinoma of the lung. The family filed a malpractice claim against the pulmonologist alleging failure to timely diagnose and treat lung cancer.

### Consent & Communication

<table>
<thead>
<tr>
<th>SPECIALTY</th>
<th>ALLEGATION</th>
<th>PATIENT SAFETY &amp; RISK MANAGEMENT FOCUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulmonology</td>
<td>Delay in diagnosis of lung cancer</td>
<td>Managing orders and test results in the EHR</td>
</tr>
</tbody>
</table>
Disposition of the case
The case was settled with payment against the pulmonologist.

Patient safety and risk management perspective
The experts who reviewed this case argued whether or not the delay in diagnosis resulted in any lost chance of survival for this man. However, they could not support the pulmonologist clearly missing an abnormal chest CT report that recommended further testing to rule out malignancy. The pulmonologist testified that he did not know how he missed the patient’s abnormal chest CT report in the EHR, but that his clinic had just implemented a new lab module that may have failed to trigger the result notification. He testified that after a root cause analysis of this adverse event, his clinic changed the workflow process for test result management.

When EHRs cause patient harm
In an analysis of EHR-related malpractice claims submitted to the claims database at CRICO Strategies/Risk Management Foundation of the Harvard Medical Institutions, researchers found that 59 percent of these cases originated in an ambulatory care setting, and that most cases were the result of an error involving medications (31 percent), a diagnosis error (28 percent) or a complication of treatment (31 percent). In many cases, more than one contributing factor was identified, with 63 percent of cases involving user-related issues and 58 percent involving technology-related issues. User-related issues included incorrect information, pre-populating/copy-and-paste, or training and education. System-related issues involved technology and software design, routing of electronic data, system malfunction, integration problems, or failure of alerts/decision support. The researchers suggested that strategies to reduce patient harm should target the settings most at risk (ambulatory care) and the processes that account for the most errors (medication and diagnosis).

PATIENT SAFETY AND RISK MANAGEMENT TIPS

1. Build a common language using an eight-dimensional socio-technical model (see webinar list below) to address the challenges involved in design, development, implementation, use and evaluation of health information technology.

2. Establish clinician-oriented “professional rights” that represent important EHR features, functions and user privileges that clinicians need in order to provide safe, high-quality care. For each right, include the corresponding “clinician responsibility.”

3. Implement a simplified approach for conducting EHR-related surveillance activities, using “red flags” to reduce the risks associated with EHR implementation and use.

Resources
Managing Electronic Health Risk, Bundled Solution
Multiple resources including the SAFER Guide assessments, toolkits, guidance and on-demand webinars, including “When EHRs Cause Patient Harm” presented by Trish Lugtu, available at Login > Risk Management > Bundled Solutions at MMICgroup.com and UMIA.com

PATIENT SAFETY AND RISK MANAGEMENT TIPS
1. Build a common language using an eight-dimensional socio-technical model (see webinar list below) to address the challenges involved in design, development, implementation, use and evaluation of health information technology.

2. Establish clinician-oriented “professional rights” that represent important EHR features, functions and user privileges that clinicians need in order to provide safe, high-quality care. For each right, include the corresponding “clinician responsibility.”

3. Implement a simplified approach for conducting EHR-related surveillance activities, using “red flags” to reduce the risks associated with EHR implementation and use.

VIEW THE THREE ON-DEMAND WEBINARS
PRESENTED BY DR. DEAN F. SITTING AT LOGIN > RISK MANAGEMENT > BUNDLED SOLUTIONS > MANAGING ELECTRONIC RISK AT MMICGROUP.COM AND UMIA.COM

1. AN OVERVIEW OF AN EIGHT-DIMENSIONAL SOCIO-TECHNICAL MODEL FOR SAFE AND EFFECTIVE EHR IMPLEMENTATION AND USE
2. RIGHTS AND RESPONSIBILITIES OF PHYSICIAN USERS OF EHR
3. A “RED FLAGS” APPROACH TO IDENTIFYING EHR-RELATED ERRORS

LORI ATKINSON, RN, BSN, CPHRM, CPPS
Research, Development & Education Manager, MMIC
Lori.Atkinson@MMICgroup.com

References

Brink / Summer 2016 / 27
Norman, Gertrude, Betty Ann and Cutter, Bud and Flossie, Mary, Dave, Chilly and Dody … these are the names of people and their loved ones for whom I have cared in the emergency room — and from whom I have benefitted greatly in my medical career. There are many others.

Thinking about these important relationships leads me to wonder: Does today’s health care environment foster opportunities for relationship-building with patients? And does it help providers hone the communication skills so necessary to the development and flourishing of trust?

I think not.

In fact, many of the pressures facing physicians today — from time constraints to EHR challenges — work against their efforts to focus on their relationships with patients. I believe that this state of affairs has contributed to the rising rate of burnout among physicians. Burnout, as measured in the Maslach Burnout Inventory, includes emotional exhaustion, depersonalization and a lack of sense of personal accomplishment.

Tait Shanafelt, MD, and colleagues recently published a survey of burnout rates among U.S. physicians, comparing rates in 2014 to those in a similar survey conducted in 2011.1 Overall, the prevalence of burnout has increased significantly, rising from 45 percent to 55 percent. And in some specialties, burnout now exceeds 60 percent.

Other researchers have sought explanations for this burnout epidemic. Mark Linzer, MD, and colleagues surveyed physicians to better understand the predictors of physician burnout.2 Among the leading causes identified were lack of work control, time pressures, chaotic work environments and the lack of values alignment between physicians and administrators.

Linzer et al. have also proposed interventions to address burnout in primary care.3 In “10 Bold Steps to Prevent Burnout in General Internal Medicine,” they suggest changes to institutional metrics, work conditions, career development and self-care.

As I view the current state of the medical profession, I think it is clear that we need to restore our focus on relationships. We need to restore respect and empathy for physicians, nurses and all care providers who answered a “calling” to serve others, but who now find themselves pulled further and further away from relationships with their patients (and patients’ families). Providers need to be involved and engaged in all efforts to better structure the delivery of care. Administrators and clinician leaders need to engage the frontline of care in transforming medical care from the transaction-based experience it has increasingly become to the relationship-based experience it should be. Until we as physicians and nurses are recognized and honored for what brought us to medicine in the first place — our desire to serve others — we will continue to burn out at the current alarming rates.

References

Laurie C. Drill-Mellum, MD, MPH
Chief Medical Officer
Constellation
Laurie.Drill-Mellum@MMICgroup.com

“IT IS MUCH MORE IMPORTANT TO KNOW WHAT SORT OF A PATIENT HAS A DISEASE THAN WHAT SORT OF A DISEASE A PATIENT HAS.” — WILLIAM OSLER
FALL 2016
FEATURE SECTION:
Advanced Practice Providers
- Malpractice claims data involving APPs
- Enhancing the roles and reducing the risk for NPs and PAs
- The latest in training models for APPs
- Working toward a partnership-based culture for health care
- Claim Review: Improper follow-up treatment of a laceration delays healing, leaves scars
Informed consent means more than simply securing a patient’s permission for a treatment or procedure. Optimally, it is a meaningful dialogue in which you offer your knowledge and judgment while learning a patient’s values and preferences — the necessary foundation for shared decision-making. In this issue of Brink, we examine the factors that can adversely affect communication, and suggest ways to ensure that your patients’ decisions are truly informed.