

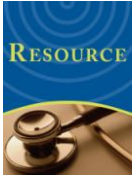
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Introduction

Hospitals and ambulatory sites learn how Toyota's obsession with eliminating waste and defects can make patient care processes safer.

And...a look at the legal ins and outs of curbside consults in the digital age.

These stories... and more, on "Resource", a news program with the latest issues in patient safety and health care risk management. Now available online, at RMF.HARVARD.EDU. "Resource" is produced six times a year by CRICO/RMF in the Harvard medical system. Information about receiving automatic podcasts and risk management CME is at the end of this program.



Legal Report **Curbside Consults in the Digital Age**

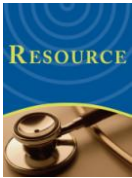
When it comes to curbside consults, patient care still benefits from the informal interaction, and physicians still face some liability risk that they should manage. But as Boston defense attorney Ellen Epstein Cohen, of Adler, Cohen, Harvey, Wakeman, Guekguezian tells us in this month's legal report: the risk has changed. Managing Editor Tom Augello recently interviewed Epstein-Cohen about curbside consults...in the digital age.

Q: Ellen thank you for joining us. Let's start by saying what we mean when we talk about curbside consults.

A: Okay, the general understanding of a curbside consult is that it is an informal interaction between physicians or other healthcare providers in which one physician asks for advice or input on how to handle a particular patient issue where they are not in the presence of the patient, where the person who the doctor is speaking to doesn't necessarily know or has never met the patient. It's just an informal exchange between colleagues trying to help make treatment decisions.

Q: So what are some of the special considerations when this interaction takes place electronically.

A: I think that's perhaps the most important question on this issue right now in the electronic age where doctors communicate with each other by e-mail so much, and there are really good reasons for doing it. At the same time, if you receive an e-mail that asks you a specific medical question, if you want to protect yourself, the best way to do it is to make clear that your answer is a general answer that is not intended to apply to any particular patient because you have a limited amount of information that is presented to you and you're providing a general answer in response without meeting a patient, seeing a patient, examining a patient, having the necessary medical history, and additional details and information about that patient. So if you choose to answer a general question with a general answer and you qualify it that way, you will be much better off than if you just give an answer to a question and if the person who is asking it then makes the decision to write into his or her chart, 'consulted with Dr. Smith.' Once your name gets into a particular patient's chart as a consultant or someone that advised the treating clinician about the care and the decisions involved in the care, then you've gotten yourself an invitation into a later lawsuit.



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Q: What if someone does give advice during a curbside consult and is not terribly explicit with the physician that they are giving it to, and then that particular physician writes it down in the medical record, and lo and behold two years later, they are both found in the midst of a lawsuit. Is there anything that the requesting physician can do after that suit has already be filed so they don't throw their colleagues under the bus?

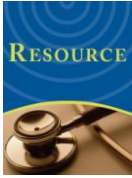
A: Once they make the ill-advised decision to put their colleague's name in the chart, there isn't a whole they can do to un-ring that bell, if you will. The important thing to understand is that for a plaintiff—a patient in a civil suit is the plaintiff—for a plaintiff to succeed in bringing any medical negligence claim, they first have to prove the first element of negligence, which is a doctor/patient relationship. So the defense of the doctor who was consulted informally would be, 'I never met this patient. I never saw this patient. I never examined this patient. I never made a note in this patient's chart. I never had any information about who this patient even was. I didn't know this patient's name.'

Q: In terms of specific communication about this whole issue, you mentioned in a general way you want to tell the doctor 'this is general and not specific to a patient; please don't put my name in the chart.' How would you advise to have that conversation?

A: The first most important thing would be to say, 'if you would like me to see your patient and evaluate your patient and give advice, send me a referral. In other words, make this go through the formal route of getting me involved in the patient's care. And also I think there are very practical reasons for doing that. It can't hurt in the verbal face-to-face interchange or telephone interchange to say, you know, 'I'm not giving advice on this particular patient and please don't include me in the patient's chart. I don't know this patient.' In an e-mail certainly you would have it clear. You could use your standard language, your disclaimer language that says, you know, 'this is just a general answer to your general question and please don't construe this as medical advice for any particular patient.'

Q: What about someone responding to a request or a question when the other physician is out of state, maybe you were good friends and one person moved to Michigan now and says oh I know who I can contact. I am going to contact Joe in Massachusetts. Is there anything different that they should be taking into consideration?

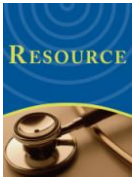
A: Well absolutely, and the question is if you give medical advice with regard to a particular patient over the Internet to a patient who is not in your state, the



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question becomes are you practicing medicine without a license in that state. So if you make clear that you're not giving patient advice or treatment; you're just trying to answer a general medical question, that would tend to make it clearer that you're not practicing medicine in that forum.

- Q: Anecdotally, any trends you have identified, more use of curbside consults or more aggressive action by plaintiffs to bring that into a case against a doctor?
- A: I actually haven't seen it increasing. I would say I have seen it decreasing and that's because of education and awareness. So the lawsuits that I've seen are there when the doctor's name gets into the record. I know that sounds overly simplistic, but if we can educate providers it's good to get consultation from your colleagues, but it's not only unfair but really not good medicine to include a doctor's name in a chart where you've never made a formal referral, then we will have gotten really far in trying to eradicate this as a basis for liability for the informal curbside consultant.



MDs Override Prescribing Alarms, Safety Value Persists

Medical facilities continue to feel pressure to incorporate electronic information tools to improve efficiency and reduce risks in clinical processes. To help prevent drug errors, for example, electronic prescribing is increasingly available, even in ambulatory care settings.

The federal government is providing incentives to providers to begin electronic prescribing in ambulatory care, where most prescriptions are written. Manufacturers of prescribing systems have sought to meet market demand to add software that goes beyond just automating a process—to incorporate intelligence that actually helps prescribers make better decisions.

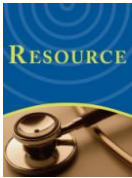
This can mean an audio alert when a clinician attempts to prescribe an unconventional dose or a combination of drugs that is usually and widely contraindicated. When confronted with a noisy bell or unpleasant alarm, a prescriber can usually override these alerts.

Dr. Saul Weingart is Vice President of Quality Improvement and Patient Safety at Dana Farber Cancer Institute in Boston. Dr. Weingart recently co-authored a study in the *Archives of Internal Medicine* that looked at the rate at which clinicians overrode alarms that go off when using electronic prescribing.

“There is a widespread perception among clinicians that alerts occur too much. There is this concept of alert fatigue. There is this concept of alert overload. The idea is that when you turn on these electronic systems they bombard the clinician with information that may not be clinically useful or relevant and that rather than doing good, they are actually intruding on clinical care and getting in the way of efficient practice.”

Dr. Weingart’s research showed that physicians overrode the alerts nine out of 10 times. But Dr. Weingart says that’s not the end of the story.

“The question that that begs is if docs override 90% of the alerts and accept only 9% or 10%, are we getting any benefit from that. In other words, what is the cost utilization and patient safety benefit of a relatively small number of cases where the docs change their perspective? So we have done some work on that and we have tried to model that.... and what we found is that in fact there is a patient safety benefit, that we do prevent injuries, that we do reduce utilization and in turn cost, principally from hospitalizations.”



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The question is whether that benefit is worth the cost, both in dollars and in physician time and mental distraction. Dr. Weingart's team is also looking at whether medical professionals who reject a prescribing alert do something differently to improve safety as a result, after they override the alarm.

“So, for example, if I get an alert and it tells me there is an interaction between two drugs, but both of them are needed—for example, a blood thinner and an antibiotic—then I might still go ahead and prescribe the medications because they are needed and at the same time arrange for the patient to come back a little earlier for follow-up or arrange for early blood tests or provide some counseling of some kind or another. Our preliminary research suggests that in fact . . . those alerts are triggering actions by clinicians that is above and beyond what would be expected from the override rates themselves.”

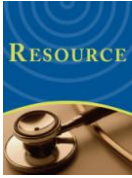
Dr. Weingart doesn't want doctors and manufacturers of electronic prescribing devices to throw the baby out with the bathwater. Given the existence of some patient safety and utilization benefit, an effort to make alerts work for doctors is worthwhile. Especially considering the risks that lurk behind the alarms.

“We know that the rate of adverse drug events in ambulatory care is about one in four. That means about one in four patients over the course of three months who receives a prescription will have some symptom related to the medication. Not that many of them are serious, and a minority of them are preventable, but many of them are ameliorable, meaning that the severity and duration of the symptom could be reduced if something was done differently, if the doctor made a better decision or if the doctor acted on patient information or if the patient communicated the information.”

Despite growing federal pressure, electronic prescribing is not widespread in ambulatory care. Massachusetts has one of the highest penetration rates, but it's well under 30 percent.

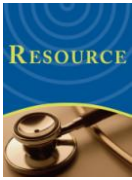
Organizations that have shown the most success in balancing the number of alerts and the benefits tend to be large academic hospitals and their affiliated ambulatory sites. Dr. Weingart says that Boston's Brigham and Women's Hospital, for example, was able to tweak its proprietary software systems to suppress some alerts and drive the override rate down to 70 percent or so. They did this by creating a tiered system of alarms, with only the most serious problems triggering an alert.

“Ultimately, what we would really like to do is to be able to tie these electronic alerts into more information that is in an electronic health record. So, for example, if a patient is on an aspirin and an ACE inhibitor, that will fire an alert because those drugs can both have an effect on the kidney. However, if you have



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heart failure or heart disease, those are two indicated drugs that you want to have together. In fact, it improves clinical outcomes if you have those drugs on board at the same time. So if we could design an alert system that would suppress alerts when those drugs are used in combination in patients who have on their problem list heart failure, then we would be much further along.”



Closed Case Abstract
Sent Home Twice Before Baby Born Sick

The following case abstract is based on closed claims in the Harvard system. Some details have been changed to protect identities.

A 21-year-old female presented to the emergency department about an hour after a spontaneous rupture of membranes at 39 weeks. She was evaluated in the Labor and Delivery unit by the nurse midwife on-call and sent home with the advice to return when her contractions were closer together.

About two hours later, the patient returned to Labor and Delivery and was re-evaluated by the same obstetrical provider. The patient's cervix was 1 cm dilated, 90% effaced, and the fetal head at -1 station. The fetus was evaluated with electronic fetal heart monitor (EFM) for 13 minutes. The nurse midwife sent her home early in the afternoon with instructions to return if her contractions did not increase by 7:00 p.m.

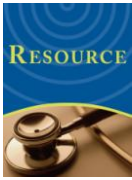
The patient returned by wheelchair to L&D at 6:45 p.m., grunting and bearing down. Her cervix was 9 cm dilated, 100% effaced and fetal head at +1 station. EFM revealed a fetal heart tracing with marked variability in the baseline heart rate, fluctuating between 120-180, and notable for repeated decelerations to 90 bpm. The patient labored for about two more hours before delivery occurred, during which time there were persistent, recurrent deep variable decelerations to 80-90bpm.

The nurse midwife delivered a baby boy at 9:01 p.m. with Apgars of 1 at one minute and 3 at five minutes. The baby was transferred to a tertiary care facility where he experienced seizure activity. A brain MRI confirmed findings consistent with hypoxic-ischemic encephalopathy. The baby developed additional symptoms of profound, permanent neurological deficits, including blindness and a severe seizure disorder. The patient's parents sued the nurse midwife and two Labor and Delivery nurses alleging that mismanagement of labor and delivery and the aftermath led to profound neurologic defects of the baby. The legal defense was compromised by the loss of the EFM strips, and the case was settled against the nurse midwife for more than \$1 million.

To discuss the risk management and patient safety aspects of this case, Dr. David Acker joins us now. Dr. Acker is Chief of Obstetrics at Brigham and Women's Hospital in Boston.

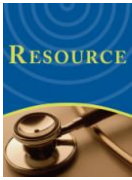
Q: Dr. Acker, thank you for joining us.

A: It's a pleasure.



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- Q: Where do we first start to see problems in this case?
- A: A variety of questions comes to mind. First, in whatever community hospital this is, is there a policy that clearly states what fetal heart rate abnormalities mandate consultation with a physician? Second, in whichever community hospital this is, has there been adequate and recurring educational processes so that people can recognize “repeated decelerations to 90 beats per minute,” etc. Third, is there a backup for the midwives in the hospital?
- Q: So let me interrupt there. When we talk about those kind of communication and collaboration issues, what are we looking for in sort of an ideal setup, including if there had been nurses or anyone else who did recognize those problems, activating a chain of command?
- A: Okay, well you bring up actually two different problems. Let’s take an easy one first. It’s the situation where everyone is actually in agreement that something is wrong and something should be done. Well, all of those policies and protocols need to be put in place by the leadership of the midwifery program, the leadership of the obstetrics program, and the leadership of the administrative program that is devoted to maternal and child health. So there is a regularly reviewed physician midwife guidelines and policies, and they are aimed primarily at patient safety, not pride in being a midwife or autonomy of the physician to stay home as long as possible.
- Human beings being human beings, there is not always going to be agreement, and there needs to be a corollary policy that deals with discord. And discord means discord amongst any person who is on the labor and delivery floor. That person could be the most junior nurse, and her opinion counts on an equal level with the most senior midwife or physician. The team must be concordant or the discordant policy needs to be operationalized and things move up the chain of command.
- Q: Let’s talk about the fetal monitoring strips. They ended up being an issue in the defensibility of the case.
- A: They end up as far as I’m concerned being an issue for two reasons. Let’s take the least controversial. So turning to the current clinical guidelines for obstetric providers, page 5, Institutional Responsibility. “Each institution shall accommodate for preserving all electronic fetal monitoring tracing with special consideration and allocation of resources to assure permanent and secure preservation of fetal monitor tracings for all babies born with a 5 minute Apgar score of 4 or less.” In my experience in medical/legal situations in Massachusetts,



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the statement that I have heard made in court by the judge is chilling because my impression is most of the time these things are lost just due to carelessness. However, that's not what the judge tells the jury. The judge specifically tells the jury that if they lost it, you can assume that would be the proof that they were negligent.

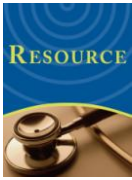
The second issue with the fetal monitor interpretation is obviously made difficult for me because I don't have the fetal monitor to look it, but nonetheless, looking at the description of the tracing, one could conclude it is definitely not a normal tracing. And if there were appropriate guidelines, the guidelines would state that this is the type of fetal monitor tracing for which consultation is necessary.

So either there is no guideline in this hospital and they should have it or there is a guideline and it's been violated. Then you just leave this up to the individual hospital and the professional discipline within the system. Or in my experience a very common problem, which I can call the 'one more push' attitude. All the professionals know something wrong is going on, but they feel for whatever reason one more push and the baby will be delivered, and so people encourage the patient to push and the baby is not delivered with the next push. So then people say it's just one more push.

As amazing as this is, people can keep on saying this for a half hour to 45 minutes, always thinking the next push will be the delivery. That is a trap that I have seen good people get into and for which I don't have an immediate solution. It's almost human nature and we have to devise systems that counteract human nature.

So the monitor tracings' absence dooms the whole thing. The controversy—and there must have been controversy in interpreting and consulting—almost dooms it, and in the end sadly we're not talking about a case that is doomed, we're talking about a baby who is doomed and that's what makes this really tragic.

Q: Thank you, Dr. David Acker, Chief of Obstetrics at Brigham & Women's Hospital in Boston. For Resource, I'm Tom Augello.



Making Care Systems Leaner and Safer

At Brigham & Women's Hospital in Boston, Dorothy Goulart works year-round to help departments and clinical units do more and less at the same time. Taking a page from Toyota's manufacturing model, Goulart is among a growing army of health care professionals working to drive out waste and inefficiency in the health care industry—using Lean Processes.

“Lean” is a method for fixing system flaws by using some key concepts: first, the front-line people at the point of care are involved to identify problems and potential solutions, or “counter-measures”; then, they examine every step in a single process—or pathway—across multiple settings and professional disciplines, called a “value stream”; select specific metrics to measure success; assess the intervention against the metrics; and repeat the process routinely to continue to root out inefficiency and waste. Standardizing processes is also an important Lean concept.

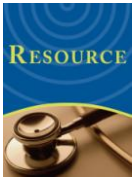
According to advocates, “Lean” promises to cut costs, add to staff satisfaction, and reduce medical errors at the same time. Dorothy Goulart:

“We can improve the way that we provide care. Toyota talks about error proofing processes so that errors don't occur in the first place. So it's really very applicable to looking at various processes proactively to see ways that we can keep errors from ever occurring in the first place or trapping them, you know, actually identifying them, seeing them before they ever reach the patient.”

As the Director of Performance Improvement at Brigham and Women's Center for Clinical Excellence, Goulart has overseen the use of Lean for a variety of projects. Driving out waste and improving efficiency frees clinicians to do more of what they are uniquely trained for. Goulart says these principles that increase efficiency can also mean reduced nosocomial infections, fewer drug errors and other patient safety benefits.

“We've done similar work using Lean principles looking at medication reconciliation. So how might a physician at the end of an office visit with a patient actually have a process of making sure of what the patient says they are taking for medicines match the list of medications that is in the patient's medical record so that everyone is aware and is on the same page as to what medicines the patient is actually taking?”

At LDS Hospital in Salt Lake City, Dr. Terry Clemmer is Director of Critical Care Medicine. Dr. Clemmer was part of a research project that applied “Lean” to his ICU. They still use Lean principles...but he identified some challenges.



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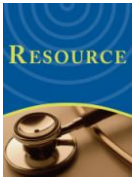
“Some things are very successful. The routine task of delivering potassium or running a ventilator, ambulating patients according to protocols and things. Those have been very successful. We struggled more with things that cross into other departments, although we are making good strides right now. But for sepsis, for example, where you have to coordinate the emergency department, which is an integral part of this, along with the laboratory and the pharmacy and everybody to get it done, those have been much, much more difficult because we cross into territories where they are not as committed.”

A key concept in Lean is that the process is embedded throughout the organization. In addition to the jobs they were hired to do, staff get trained in identifying problems in real time, designing metrics for improvement, coming up with countermeasures, and repeating the process. Dr. Zeev Neuwirth is Vice President of Quality and Innovation for Atrius Health, a multi-group primary care practice network in the Boston area. Dr. Neuwirth was able to use some early small-scale successes with “Lean” to show senior leadership the value. Now it’s starting to spread at Atrius.

“You can just keep on doing process improvement after process improvement, but if it’s not connected to your middle management level and those goals and if it’s not connected to your senior management level and the goals that are there, it’s really not going to do much good. And so what we’ve done is we’ve created an entire kind of operating platform, if you will, that goes from the top of the organization to the frontline of care and at each level there are metrics, the so-called five true north metrics, and there’s literally a cascade and a linking of the metrics and to make sure that we’re all working in alignment. That is a radically different approach which very, very few places are aware of, much less doing.”

Dr. Neuwirth has used Lean for a number of safety projects at Atrius. He says that clinicians can be skeptical, but they quickly learn that Lean is more than a flavor of the month. Dr. Neuwirth says the highest use of “Lean” will often lead to dramatic changes in work-life, that actually make providing care more rewarding. He points to efforts in the Orthopedics Department at one of his practice sites.

“When you walk into Orthopedics now at our Kenmore practice, you’ll see in the Orthopedics Department two or three white boards up on the wall. If you come at 8:30 in the morning and at 3:30 in the afternoon, every single day, Monday through Friday, you’ll walk into a team huddle. So every morning and every afternoon, they have a team huddle, and every morning and every afternoon their review of the metrics, these balance score card metrics, and they go over each one of them to see how they’ve done that day and then they go and review the week, and see how they’re trending in terms of over time if they’re getting better or worse or staying the same with these metrics. They also then move to a problem board. So if they are not getting the metrics or if they are not improving on any



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metrics, they actually do a root cause analysis and they figure out what's going wrong and how to fix it quickly. And so you're walking into a work environment that is a real learning organization.”

Goulart says that at the Brigham, a number of skeptics have become converts to Lean—and even its strongest advocates—after being involved. They see that their own ideas for what's wrong and how to fix it are respected, that they get to set the goals and implement their own changes and are supported by leadership.

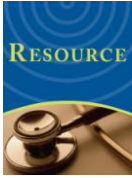
Goulart and the Brigham use a healthcare consulting arm of General Electric—GE Healthcare—for help implementing Lean at the hospital. Linda Bacelis-Bush is the consulting manager for GE Healthcare Performance Solutions, which has worked with institutions across the country and the UK. At the Brigham, Lean takes the form of 4-day, rapid-cycle style improvements, one-day “work-outs” for a specific problem, and Lean training classes for individual leaders. But the long-term goal is for as many people to use Lean as often as possible.

“Especially with Lean, it's not something you can just learn in the classroom. You can learn some of the fundamentals, theories of it, but there's no match for actually going out, participating in a project, and seeing the results of the staff being involved, identifying what the problems are, identifying what the potential solutions are, trying them out right away, seeing the result.”

According to Bacelis-Bush, those victories are important to show management and clinical leaders that the benefits of Lean process improvement is worth the cost in staff time. Leadership buy-in is a critical success factor to bring down the work silos that allow process breakdowns to go unnoticed.

“In Lean they talk about value streams. So a value stream could be the service that is provided to a patient, and this patient could go through several different departments in their whole journeys through to get this one health care service. To get the attitude or the collaboration between the different departments within a hospital to see that there is a bigger picture here is a big challenge. It's a huge challenge, and I think Lean is a good way to address that though because there are many ways to be able to come up and look and for anyone whose done any kind of value stream mapping, it's a way to look at the services that are delivered across all of the departments and be able to see the interactions, and then eventually identify the waste and how to make it better across all of those.”

That's been the experience of Dr. Neuwirth's work at Atrius as well. After introducing the Lean methodology, residents began asking to stay and establish their careers there. Dr. Neuwirth says that hadn't happened in 30 years.



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“There were probably multiple factors, but the biggest thing we did and the thing that distinguished it from everywhere else we were working was implementing Toyota Lean. One of the Toyota masters that I had been speaking to about this and mentioning it to him, said, you know, the way you improve people’s morale is that you allow them to have a goal, you set a target and you set a goal, and you give them the skills and the tools to actually reach that goal. There’s probably nothing more satisfying for a human being to actually create a goal and achieve it. There’s something just fundamentally wonderful about that. Again, it’s kind of our core to be creative and to set a vision and set a goal and to achieve it. It’s really kind of what makes us tick in some respect, and that for me is really at the heart of the Toyota Lean methodology.”