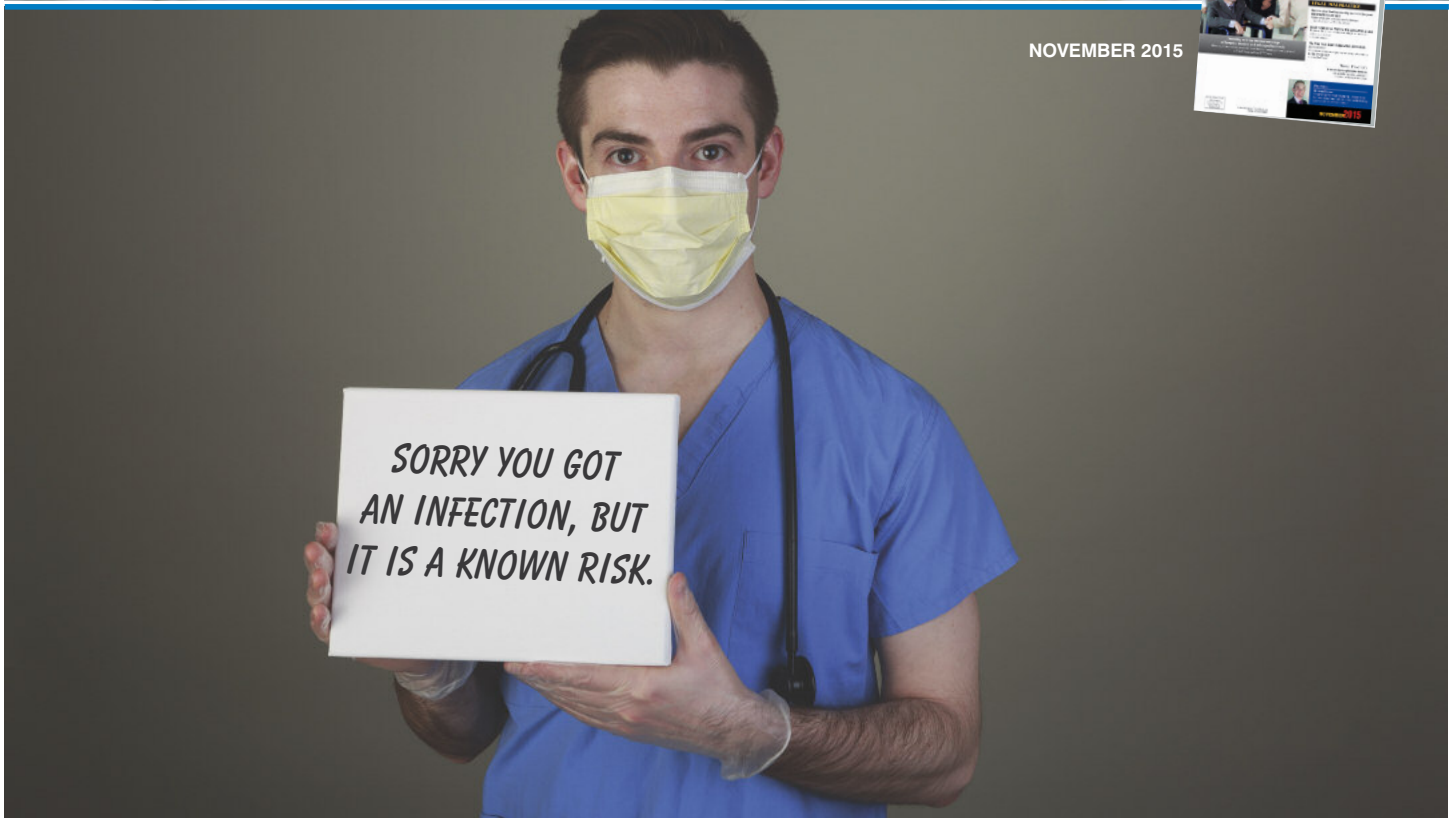


Handling medical-malpractice cases arising out of post-operative infections

Attacking defenses based on "accepted risks"

By Loren Schwartz

Hospitals and ambulatory surgery facilities are breeding grounds for viruses and bacteria. According to the Centers for Disease Control and Prevention, there were an estimated 721,800 healthcare-associated infections (HAI) in U.S. hospitals in the year 2011 alone. (*Multistate Point-Prevalence Survey of Health Care-Associated Infections* (2014), New England Journal of Medicine 370; 13, p. 1198.) Without doubt, many such infections – if not most (depending on who you ask) – were the result of accepted inherent risks of treatments or procedures for which a health-care provider cannot, and should not, be held liable. Hence, the traditional refrain from the defense bar in cases involving post-operative infections is that such infections are an accepted risk of whatever procedure your client underwent, your client understood and consented to the procedure despite being advised of the risk, and therefore he can have no recourse just because this known risk – i.e., infection – ultimately materialized.

If you have ever handled a case alleging that a health-care provider negligently caused your client to develop a post-operative infection, you almost assuredly have witnessed defense counsel, at the time of your client's deposition, pull out the consent form signed by your client, mark it as an Exhibit, and (often somewhat smugly) begin questioning your client about it:

Q: Now sir, do you see the form in front of you?
A: Yes.
Q: You see, it's entitled "Surgical Consent Form"?
A: Yes.
Q: Now do you see this paragraph which specifically states that the risks of the procedure which you underwent include infection and that you accept these risks?
A: Yes, I see it.
Q: And did you read it?
A: Well, I may have. I don't really remember. I was really anxious that day and…
Q: Sir, whose signature is that on the bottom of the form?
A: That's mine.

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Q: You signed it?
A: Correct. Yes. I signed it. It's just…
Q: Sir, I just want to be clear [as if it wasn't clear already] – You, did, in fact sign the Surgical Consent Form in front of you which specifically provides that you accept the risks of the procedure, including the risk of infection?

You get the point. From the defense perspective, your client signed a form in which he specifically acknowledged and agreed that the procedure which he underwent carries a risk of infection and that risk materialized. This is unfortunate, argues defense counsel, but not the basis for a medical negligence claim. Additionally, defense counsel has an expert in the wings who will testify that in fact, the procedure – like pretty much any invasive surgical procedure – carries a risk of infection and that these infections readily occur even where all involved health-care providers have acted with the utmost care and diligence.

As much as defendants may try to use the concept of "accepted risk" to insulate them from liability in cases involving post-operative infections, always know that simply because something may be an accepted risk does not end the analysis. The fact that an infection is an accepted risk of pretty much any invasive surgical procedure does not somehow magically relieve health-care providers of the obligation to otherwise comply with the standard of care.

Anytime you have a case involving the development of a post-operative infection, ask yourself two critical questions:

(1) Was the infection preventable? and

(2) Regardless of whether the infection was preventable, was it timely and properly diagnosed and treated?

Was the infection preventable?

Just because an infection is an accepted risk and may materialize in the absence of negligence does not mean that in your particular case it, in fact, materialized in the absence of negligence. Of the estimated 721,800 healthcare-associated infections in acute care hospitals in 2011, approximately 22 percent of these represented infections which developed at a patient's surgical site. (*Multistate Point-Prevalence Survey of Health Care-Associated Infections* (2014), New England Journal of Medicine 370;13, p.1204.)

Such surgical site infections inevitably beg the question – What was done to sterilize the equipment used in the procedure and what was done to otherwise provide for a hygienic and sterile operating environment?

Oftentimes, it is simply assumed that the equipment was properly sterilized. Don't be so quick to make this assumption. Put the onus on the defense to show you that they had proper sterilization protocols in place and that these protocols were in fact followed.

Surgical equipment is often sterilized using an autoclave – a machine which sterilizes surgical instruments and supplies by subjecting them to high-pressure saturated steam. Request that defendant produce all of its policies and procedures related to sterilizing equipment prior to use, including any policies or procedures pertaining to use of the autoclave. Find out who the manufacturer is of the autoclave used by defendant and obtain (by subpoena if necessary) whatever instructions are included by the machine's manufacturer and which are intended to be followed by the user.

In order to make sure an autoclave is operating properly – and therefore properly sterilizing the equipment placed inside of it – testing needs to be performed of the machine at regular intervals – often with 24 or 48 hours separating the start time from the end time. The manufacturer of the autoclave often provides pre-printed sterilization logs which allow the user of the autoclave to document the testing, including both the start and end times. Ask defendant to produce the sterilization logs which it ostensibly kept contemporaneously as the tests were performed and take a close look at these logs. You may end up surprised by what you find.

For example, take a close look at the start and end times for the test. How close are the start and end times to the times recommended by the manufacturer? If the times deviate only slightly, then you may not have much to go on. However, if the start and end times deviate substantially from the times recommended by the manufacturer, you may have an argument that the autoclave was not properly calibrated, and that, therefore, the entire sterilization process was compromised. Of course, you will need to consult with an expert in this regard. On the other end of the spectrum, your curiosity should be piqued if the start/end times match precisely, without exception, to the start/end times recommended by the manufacturer. If it appears too pristine to be true, it may in fact represent after-the-fact entries which were made in order to appear in strict compliance with the manufacturer's specifications.

Pay attention to dates

One other thing to be mindful of when examining sterilization logs are the start and end *dates*. Let's say that you have identified the individual responsible for operating and testing the autoclave and you notice his deposition. You start by obtaining some background on him, where he works, how long he has worked there, what his schedule is like, etc. You learn that he is a registered nurse and an employee at the ambulatory surgery center where your client developed a massive post-operative infection. He has worked there for six years. He is salaried and works five days per week, Monday through Friday.

You obtain the logs maintained by him, and sure enough, the testing appears to be done in the 48-hour intervals recommended by the manufacturer. Sometimes, it's a little more than 48 hours; sometimes it's a little less, but nothing of any clinical (or legal) significance. The deponent's initials are right there next to both the start and end times. As he explains to you, he is diligent in initialing the document both at the start and end times of the test. You think you may not have much to go on but then during a break, you decide to

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check the days of the week which the start/end dates fall on.

You pull out your iPhone to determine what days of the week the testing was being performed. Usually, the testing is started on a Monday at 7 a.m. and completed on a Wednesday, also around 7 a.m. However, there are several instances in which the start time for the test is Thursday at 7 a.m. This means that the end date must be…Saturday – a day of the week which the deponent has indicated to you he does not work. How could he be at work checking the autoclave on a Saturday at 7 a.m. when he only works Monday through Friday? Sure enough, there are the deponent's initials, in several instances, right next to a day of the week which he has already indicated to you he doesn't work. Now, you're on to something.

Certainly, it is the rare case where you will catch the defendant falsifying sterilization records. However, the point is that in the face of arguments about how infection is an accepted risk of surgery, it is important to look critically at whether the infection was, in fact, an unavoidable risk, or is there evidence to suggest that someone did something (or failed to do something) which resulted in the risk being needlessly increased. Consider and explore the following:

- Were there protocols in place for the sterilization of equipment?
- If these protocols were in place, were they being followed? How is that documented?
- Were prophylactic antibiotics indicated and properly administered prior to surgery?
- For prolonged surgical procedures, were these antibiotics properly re-dosed intraoperatively?
- What safeguards were in place to seek to ensure that the bandages and dressings applied post-surgery were sterile and were properly changed?

In short, put the onus on defendant to demonstrate that they had reasonable procedures in place to fight the risk of infection and that these procedures were followed. If you can show that the policies in place were inadequate and/or that these policies were not properly followed, you have now called into question the integrity of the entire sterilization process. Under the right circumstances through the use of expert testimony, you can then show how the infection which your client developed was more likely the result of poor sterilization as opposed to the materialization of some inherent risk.

Keep in mind that even if you are ultimately able to call into question the integrity of the sterilization process, Defendant may still choose to fight you on the issue of causation. Let them. You have put them in the unenviable position of having to acknowledge that they screwed up but that somehow their screw-up did not cause your client's resultant harms. They may do whatever they can to try to explain away their actions and/or the causal connection. Again, let them. As the saying goes, "If you're explaining, you're losing."

Timely and proper diagnosis and treatment

Regardless of whether the infection which your client developed was preventable or not, his health-care providers have an obligation to exercise reasonable care in the diagnosis and treatment of that infection. Again, the "accepted risk" argument does not somehow immunize health-care providers from the duty to continue to exercise reasonable care in the treatment of your client.

In these cases, look for signs and symptoms of infection which your client may have presented with following his surgical procedure and that were not adequately investigated. This would include things such as fever, warmth at the wound site, increases in redness or swelling at the wound site, and abnormal sweating. All of these represent signs and symptoms that the patient may have developed an infection. If these are not timely and properly investigated, the infection may spread and cause further harm.

Meanwhile, once the infection is discovered, what steps were taken to treat the infection? On one hand, a physician, subject to certain parameters, must be entitled to exercise a certain degree of clinical discretion with respect to how he/she approaches each particular patient. The key then is figuring out what those parameters are. Again, you will need to consult with an expert in this regard.

Keep in mind that you don't get to play Monday Morning quarterback. At trial, the defendant will almost assuredly ask that the judge read an instruction to the jury which speaks to the right of the physician to exercise his/her best medical judgment under the circumstances and furthermore that just because the result ends up being worse than it may have been had he chosen a different course of action does not mean that the physician was negligent. California Civil Jury Instruction [CACI] 506 regarding alternative methods, as approved by the Judicial Council reads: "[A health-care provider] is not necessarily negligent just because [he/she] chooses one medically accepted method of treatment or diagnosis and it turns out that another medically accepted method would have been a better choice."

This is the law. Don't waste your energy trying to fight it. Rather, embrace it and work within its parameters. Keep in mind that whether a method of treatment is "medically accepted" depends, in substantial part, on the circumstances under which the decision to pursue that method is made. You cannot properly make your case based on circumstances which only came to fruition later on (i.e., your client's bad outcome). You *can,* however, make your case based on the circumstances as they existed at the time the medical decision was made.

Focus on what the physician knew

Let's say your client undergoes surgery to repair torn ligaments in his knee. The surgery appears to go well. Your client is in a considerable amount of pain following the surgery and there is a decent amount of swelling around the knee, but nothing which would otherwise be unexpected. However, during the ensuing

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week, your client develops a fever. He also begins to notice blistering around the area of his knee.

Concerned, he goes directly to the Emergency Room. Upon admission, the Emergency Room physician examines the knee. He notes the blistering which at this point has become considerable and which has begun to spread up the knee toward the thigh. On palpation of the knee, he reports "positive for crepitus." Finally, he notes that your client is positive for tachycardia (elevated heart rate) and fever. Your client has classic symptoms of an infection and so the physician puts in an order to have your client placed on IV antibiotics.

He remains on antibiotics for two days with virtually no improvement. In fact, the infection appears to be spreading. Finally, on the third day, after the blistering has spread almost toward your client's groin, a separate physician orders that a tissue sample be sent to the lab for testing. The results come back and it is determined that your client is not suffering from just a regular infection, but instead has been suffering from necrotizing fasciitis (referred to in some circles as "flesh-eating disease") – a relatively rare infection of the deeper layers of skin and subcutaneous tissue which, if untreated, can result in death. Your client lives but is left with significant scarring from the knee up his thigh.

You consult with an expert who advises you that in cases of necrotizing fasciitis, immediate surgical intervention is key in order to stop the infection from spreading. As you later find, defendant's expert actually agrees that the standard of care for treatment of necrotizing fasciitis generally requires emergent surgical intervention. However, defendant defends the case on the grounds that your client presented with signs of an infection and that, under the circumstances, it was reasonable to treat the infection with IV antibiotics. If they knew it was necrotizing fasciitis, well then sure, they might have acted differently, but, relying on CACI 506, they argue that they can't be held responsible.

Remember, in prosecuting your case, you cannot prevail based on circumstances which only come to fruition later on (i.e., the diagnosis of necrotizing fasciitis, spread of infection, and unsightly scarring). You *can*, however, make your case based on the circumstances as they existed at the time the medical decision was made. So focus on the information that was available to the physician at the time the decision was made to provide IV antibiotics rather than refer your client to surgery.

Yes, your client exhibited signs and symptoms of infection, and yes, prescribing IV antibiotics is a reasonable course of action for dealing with an infection. But, in evaluating the information available to the physician at the time, as it turns out, he actually had information available which should have alerted him to the possibility of necrotizing fasciitis. The blistering, in particular, which had begun to spread up toward your client's thigh represents an indication that your client was suffering from necrotizing fasciitis. Crepitus is also associated with this diagnosis.

Finally, if the physician had taken a proper history, he would have known that your client had diabetes and was a smoker, both traits which increase his risk of developing necrotizing fasciitis. As part of the physician's obligation to perform a differential diagnosis, it was incumbent upon him, at the time the patient presented, to rule out necrotizing fasciitis before moving forward. Had he done so, he would have recognized that your client was, in fact, suffering from necrotizing fasciitis at the time he presented, timely surgical intervention could have commenced, and the spread of the infection could have been stemmed.

In short, by focusing your analysis on why the physician's decision was wrong *at the time it was made*, you can effectively neutralize the impact of CACI 506 and demonstrate why the defendant's conduct did, in fact, fall below the standard of care.

Conclusion

Cases involving post-operative infections can be tricky and challenging. Without a doubt, post-operative infections *are* an accepted risk of pretty much any invasive surgical procedure. However, the fact that infection is an accepted risk should never end the analysis.

Stay on the lookout for evidence suggesting that the health-care provider did something or failed to do something which increased the risk of infection beyond the otherwise inherent risks in the procedure. In such cases, thorough discovery into the defendant's sterilization practices are often key.

In other cases where defendant may have failed to timely and appropriately treat and diagnose the infection, take a close look at the information which was available to the physician at the time treatment choices were made. Use the health-care provider's obligation to perform a differential diagnosis to show that he had an obligation to rule out more serious conditions before embarking on a certain treatment path.

By appropriately vetting and thoroughly investigating the circumstances surrounding your client's post-operative infection, you may discover that your client's untoward outcome was not just the materialization of an "accepted risk" but rather the result of medical negligence which warrants legal recourse.


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