Firsthand Experiences: The Impact of Informed Consent

James A.M. Smith, DO, discusses how an informed consent form proved to be the deciding factor in a malpractice arbitration case against his group.

Endovascular Today: What has been your worst experience in the malpractice arena?

Dr. Smith: The most poignant was a 61-year-old woman who came to me from an internist for a second opinion because she was going to have an aortobifemoral bypass graft procedure. She had had an iliac stent that was placed, and she had brought her films from 3 months previously. The stent was a little proximal in the aorta, more than it should have been. I thought that maybe the stent wasn't fully expanded and a good treatment option would be catheter-directed thrombolysis, and I talked to her about the options. She didn't want surgery, and her internist didn't want her to have surgery. Because she had brought her films, I knew exactly what was wrong and I was able to recommend thrombolysis as an alternative. It was actually a late add-on case, and she came over shortly before 5 PM. I saw her by myself, she was by herself, and I explained to her the options. I explicitly talked to her about complications of thrombolysis because I always mention the complication risks for any vascular procedure. I told her that the risk of bleeding and even death from the procedure was about 1%, but obviously patients hear that number and think "99% likelihood of success." She agreed to the procedure, and we scheduled it for the next day.

I documented everything meticulously in the chart. Even after she left, I continued to write details of her history and physical. I wrote the permit for pelvic angiogram, possible thrombolysis, possible angioplasty, and possible stent placement. The next day at 11:30 AM, she went for the procedure. I looked at the pelvic film and saw exactly what I thought we would find: a soft clot in the left iliac stent. I gave her a small bolus of tPA (5 mg) into the clot. I then positioned the catheter and gave her tPA at 1 mg/h, which at the time was considered standard therapy and probably still is. I also put her on a small amount of heparin (400 U/h), which was standard therapy for most people at the time. This was and still is a fuzzy area. The catheter went in at 11:30 AM. I scheduled her for a recheck 6 hours later, which is standard. But 6 hours later, the cath lab was busy and I wasn't able to get her into the lab until 8:30 that night. So, I saw her in the ICU at 5 PM and again documented that her pulse had reappeared and improved, but I still thought that clinically she had residual clot and we should continue to give the infusion. At this time, I was able to see her family—I saw them immediately after the procedure also—and I told them what was going on and that everything looked good, but there was probably still clot there. I said we were trying to get back into the lab, but there might be a chance we would just infuse over the night and check her the next morning.

I was still at the hospital at 7:30 at night, but I still could not get her into the cath lab because they were so busy. I checked on her again; she was doing better and her pulse had improved, but I felt that clinically the clot was still present and we still needed to give the infusion. Her coagulation profile was in-range, exactly where I wanted it, and we continued a low dose of heparin (400 U/h) along with the infusion of tPA (1 mg/h). At 8 PM, I wrote in the chart that the leg was warm, the pulse had reappeared but was not quite normal, she was tolerating it well, and that we would continue to give her tPA and recheck her at 7:30 the next morning. At that point, I went home.

At 1:10 AM, I got a call from the ICU nurse who said there had been a change in the patient's status. She was unresponsive and had a blown pupil, which translated into brain hemorrhage. I was at the hospital in 15 minutes. By then, she was comatose, unresponsive, with a blown pupil. I called another hospital's neurosurgery service because we did not have a neurosurgeon on staff. The neurosurgery resident

called me back within the hour, accepted the patient on transfer, and by 4 AM the patient was transferred to the other hospital. I thought they were going to take her to surgery for intracranial bleeding, but they decided that her brain stem had already herniated and that she would not survive surgery. She died later that morning at the other hospital.

Six weeks later, her family filed a complaint and I got a letter from an attorney requesting all of my records, all of which had been meticulously documented. The night of the history and physical was well-documented. The next day, I had put three progress notes on the chart. Three months after I sent them the records, I was subpoenaed for a deposition. I was completely up-front. I never considered doing anything to alter the records. I know that this was an extremely unfortunate event. This was a 61-year-old woman who had smoked, who had vascular disease, for whom I was doing everything possible to try to avoid surgery. I thought that it was a clean case. Everything was very well-documented, including risk of bleeding, hematoma, and death—everything.

Two years later, I was still dealing with her family's malpractice attorney, who said I had deviated from the standard of care. He had two radiology experts who were professors who had testified that by giving 5 mg of tPA early on to infiltrate the clot, I had deviated from standard because that was not the standard of care at the time. The radiologists also said that I deviated because I should have sent the patient back to the lab to recheck progress at 6 hours; it would have shown whether the clot had moved or dissolved, and sometimes that requires that you move the catheter farther downstream to chase the clot. Clinically, my notes said that the situation had improved; although the patient's foot was warm, it was not normal, and that I thought we were making progress but should forge ahead.

Endovascular Today: Would the hemorrhaging in the brain be affected by whether the clot had dissolved?

Dr. Smith: No. The only thing that would have changed was we would have discontinued giving tPA if the clot had completely dissolved.

Endovascular Today: They were simply speculating that maybe the clot had dissolved, but your other clinical indications were that it had not.

Dr. Smith: Correct, my clinical impression was that it had not. After the first contact when they requested the records, I began to call around to various "friends" who were experts in the field and asked if they would review the case on my behalf. I called up a radiology professor who is a very high-profile guy whose catheter I used. He said that he was very sorry, but he had actually published on the fact that he did not advocate giving heparin because of an increased likelihood of bleeding. He said that, although it is controversial, he had published several articles that took a stand against giving heparin. I had given heparin to prevent the catheter from clotting. In addition to heparin, I had given clopidogrel because it is well-known that fresh clots are platelet-activated events. So, I was giving clopidogrel, aspirin, heparin, and tPA. The attorney's expert radiologists' contention was that clopidogrel and aspirin were not indicated either. So, my friend said that he cannot be my advocate because he had published papers to the contrary.

Another interventionist I'd contacted responded that he would testify on my behalf. Next, I got a platelet expert. He was very excited about the case. He said, "Are you kidding, of course you treat the platelets. You did exactly the right thing, and I can give you a reference saying that the reason thrombolysis fails is because platelets are not treated actively; you need to be giving clopidogrel and antiplatelet drugs."

So, now that each side had two experts, the case went to arbitration. My insurance company's defense lawyer was a very experienced malpractice defense lawyer. Their lawyer was a very affable guy, likely one of the kindest, nicest guys you'll ever meet. He told us that they were suing for $1.5 million for lost affection, lost companionship, grieving, etc. They were suing on behalf of the two daughters for deviation of standard of care, for giving the bolus up front, not checking back into the cath lab 6 hours later—which their two expert radiology professors said I needed to do—and giving too many platelet drugs in addition to heparin and thrombolytics.

We were back and forth all day presenting our sides. We said that we do not believe that we deviated—the progress notes said that there is 1% chance of hemorrhage and even death. Their side said that I had misquoted the literature, that the possibility of hemorrhage was 4% or 5%. I said that even so, there is a 95% or 96% chance of success, although that risk is still highly variable and still is quoted at 1% to 3%.

Endovascular Today: So, they were going with the "informed consent" theory as opposed to negligent performance?

Dr. Smith: For the most part. I said, "Here it is, here's the explanation in the progress note, from that morning. I recall specifically on the morning of the procedure that I went in to tell her that things are going to be okay; we know that there are risks but we think this is the safest thing to do." The patient said to me, "I'll probably be the one who gets a brain hemorrhage." She said that to me, almost jokingly. I said, "No, things will be okay, I have been

doing this since 1982. I had never had that happen." The plaintiff's attorneys were saying that I hadn't explained the risks, so I brought this conversation up anecdotally, to show that I had explained the complication percentage and the patient understood. We made them an offer, but they wanted considerably more. We debated and negotiated back and forth for a while, but still there was little progress. I tell my lawyer that I haven't changed my mind, that I didn't do anything wrong, and I think this is ridiculous. The points of the case continued to be debated; their lawyers said, "You didn't take her back to the lab because it was inconvenient for you—because you couldn't fit it into your schedule." I said, "That's absolutely incorrect, in the progress note I saw her at 4 PM, and again at 7:30 PM. I was still at the hospital—it had nothing to do with convenience on my part."

When they presented their final offer, they said, "We have also found that the permit for this case said nothing about catheter-directed therapy or thrombolysis. The informed consent from the cath lab personnel only said 'Aortogram,' which is a diagnostic procedure." But I had written the order as "Aortogram," and then listed the possible therapies to follow. The plaintiff's attorney produced this document that says "Aortogram," but did not say anything about catheter-directed therapy. What this means is that the technician who filled out the informed consent and got the signature was just sloppy (this hospital had not done a lot of peripheral work). They did not list specifically list this type of procedure and instead simply said, "Aortogram" and nothing about intervention.

Endovascular Today: Who generated the informed consent?

Dr. Smith: The circulating registered nurse in the cath lab. The plaintiff's attorney said to me, "Doctor, you always review the informed consent before the procedure, don't you?" I said, "Frankly, I don't know of any doctor who looks at the consent form and watches the patient sign it. I do not read the informed consent, it's not the standard in our hospital, and I do not do that." That was quite a blow to our case, despite the fact that I was very verbose in describing the procedure and the risks.

We just can't believe that the consent was not filled out properly. The arbitrator came in and said, "This is a deal-breaker. There's no way you'll win this case in court. My recommendation is that you settle. If I were you, I'd pick a number halfway in between. My impression is that they will settle." So, we made them and offer, and they took the money and ran.

In closing, their lawyer said to me, "Doctor, I have great respect for you. I have reviewed your credentials. Initially, I was advised that you were not qualified to deliver this kind of treatment, but after doing my homework, I found that not only were you qualified, but that you were eminently qualified. This was a matter of miscommunication between your staff and the patient. The family tells me that they were never personally informed of the possibility of death. There's no question in my mind that you were qualified."

At this point, I was so depressed. It was awful. I was already upset because the woman died, but all of this made it much worse. The plaintiff's attorney asked me, "Will this change the way you practice?" I said, "Yes, I will be very reluctant to give thrombolytic therapy by catheter direction again because it is not worth the risk. I documented everything, but because of policies and procedures—a flaw in the system—I basically lost the case. I got caught on a technicality." The attorney pleaded with me to not stop doing this type of work. He said, "The good that you do far exceeds a blip like this." At the end, the two daughters both shook my hand, gave me hugs, and thanked me for my compassion, and walked away with $330,000.

I have a letter saying I was released—there was no malpractice on my part; the event went against my group malpractice, but not me personally. However, every time I fill out an application for hospital privileges and insurance, I have to go into great detail on this case.

Endovascular Today: Do you do anything differently today with respect to your informed consent procedures?

Dr. Smith: Yes. Now, I specifically look at the informed consent ahead of time to ensure that it is filled out properly.

Endovascular Today: Do you perform thrombolysis today? If you saw an iliac clot, how would you prefer to treat it?

Dr. Smith: I perform thrombolysis, but very rarely. If I encountered a case like that, I would treat it with thrombolysis, but everything would have to be in place. For instance, I'd have to be darn sure that the hospital would have a time slot open in the cath lab for follow-up. It is not often the case that everything is in place for me to be able to recheck at the end of the day. The cath labs today are so inundated that it's very hard to place the catheter in the morning and then get the patient in 6 hours later for a recheck. If were not sure I could do this, I would send the patient to surgery. ■

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