Standard of Care

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I HAVE OCCASIONALLY moonlighted as an expert consultant for legal cases. I am often asked about "standard of care." Malpractice cases rest on harm resulting from substandard care, where the acceptable standard is variably defined. "Standard of care" is the term invoked to determine that benchmark. In Rhode Island, "a physician is bound to exercise the same degree of diligence and skill as physicians in good standing engaged in the same type of practice." (Perry v. Alessi, 890 A.2d 463, 467 (R.I. 2006)). I found another definition of standard of care on the Internet: "the level at which the average, prudent provider in a given community would practice."

I have some difficulty with these definitions because there is such a wide variation in how care is rendered within one community, and certainly between communities. Would one reasonably expect that the level of care in a rural town to be the same as that of a university hospital in a large city? Is the care in Manhattan, New York City, likely to be the same as that in Manhattan, Kansas? But, even within a single community, there is a large variation in how the same problem may be perceived. Yet, the standard of care is considered as a national benchmark. How does one determine an average prudent provider for one community, let alone the whole country?

The data in support of epidural injections of steroids for spinal column pain is woefully thin. If most of my peers nevertheless routinely recommend the treatment, and I do not, is my practice substandard? More challenging, perhaps, if I advised against the treatment but another physician recommended it, and, through some rare mishap, the injection caused harm, would that other physician have practiced substandard care? And what is an "average prudent provider?" Doctors, like the children in Lake Wobegone, are all, at least in their own and their patients' minds, above average.

Physicians in good standing may not practice good medicine. My own view of what the standard of care should mean, knowing that legal definitions often vary considerably from common sense definitions, is the lowest acceptable level of care in a community. Thus the average practitioner in the U.S. should recognize that care below a certain level increases the risk of harm to an unacceptable degree.

I began wondering about the meaning of standard of care when I started thinking about legal experts. We are asked if the patient had been treated in a manner that was below the standard of care, meaning, in fact, would a competent American physician have acted in the same way as the defendant. If one stops to think, it becomes obvious that asking an expert in the field if an average provider is practicing at the acceptable level in the provider's community makes little sense. I can say that the training of neurology house staff would have taught the proper treatment, but some experts are far removed from training house staff. The true expert in determining the standard of care in such a situation is the "average prudent practitioner," and not the expert. What the expert thinks should be routine knowledge may be quite erudite in another field.

The medical expert can attest that the care was suboptimal, that a different medication or a different procedure or diagnostic test administered at the appropriate time would have produced a better outcome, but is unlikely to be a reliable reporter of what constitutes a true standard of care.

I find the distinction between what one considers a term to mean and how the term is legally defined is often unnerving. The omnipresent legalese term in medico-legal issues is, "to a reasonable degree of medical certainty." One states that harm occurred, "to a reasonable degree of medical certainty," because the doctor did or did not do something. In a case I've seen, an expert not only opines with that degree of medico-legal certainty that harm would have been avoided if identified sooner, but also that the patient will, "with a

reasonable degree of medical certainty" have to stop working within 10 years based on studies in which 50% of people with similar problems needed to stop working after 10 years. While I have no problem with giving an opinion that the likelihood of being able to continue working is 50% at 10 years, more or less, depending on the severity of the current condition, what does it mean to have a "reasonable degree" of certainty? Is 50% a "reasonable degree?"

When I consider what "standard of care" means, I ponder the remark made by a United States senator, when considering the credentials of a nominee to the U.S. Supreme Court. The nominee was thought by most to be a rather average thinker and jurist, a person of no particular distinction or merit, chosen, perhaps, because of his blandness. The senator, himself of pedestrian knowledge and accomplishments, supported the nomination by noting that average people need to be represented on the Supreme Court, too.

Using actual experts may sway a jury or a mediator, but it may be a more accurate interpretation of the law to use the testimony of an average, prudent physician, an expert without expertise. ❖

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Filming in the ED: A Cautionary Tale

NY hospital settles $2.2M claim over patient-privacy violations suit

HERBERT RAKATANSKY, MD

Lots of people are fascinated by reality TV, including shows recorded live in emergency units (EU). The future of such shows now is in jeopardy. New York-Presbyterian Hospital recently settled a claim for $2.2 million in a suit alleging that an identifiable image of a patient in the EU was broadcast without permission.

As we all know, federal law protects the confidentiality of personal health information (PHI) outside the context of medical care of the patient. HIPAA makes an exception when release of limited PHI is used to identify an unknown patient or to locate family members.

Filming EU reality shows (with permission of the hospital) often occurs without the prior consent of the patient. There may be no time to get consent or the nature of the presentation may make prior consent impossible. Consent is required, however, before identifiable images are used. There are a number of problems with this process.

If post-facto consent is not granted, the film crew still has been privy to the PHI. Additionally, the hospital has granted the crew permission to be in the EU, thus becoming a partner in illegally divulging PHI. What then happens to the recorded images? Who owns them? Are they destroyed? Are they preserved in an "archive" somewhere? If so, who has access?

Absent prior permission, the filming crew should not even be in an area where they might acquire PHI.

Is the patient offered the opportunity to share in the profits from the commercial use of the images? This seems highly unlikely. But what about the hospital? Does it share in the profits? If so, does that motivate it to grant permission for the filming? Does the publicity and resulting renown motivate the hospital to allow this activity?

Permission to record and use images can be granted by an adult patient with the capacity to make decisions. But can a proxy give permission if the patient is unable to do so? Surrogate medical decision-makers have authority to consent to medical treatment. They do not have civil authority however. They may not make financial decisions, for example. Since filming is not a medical issue, designated medical proxies do not have authority to grant permission for it. Only a surrogate with full civil power of attorney, not the limited medical power of attorney, may grant permission for filming. Parents of minor children have such power as do court or personally appointed legal guardians, who specifically have been given such authority.

Even if prior permission is granted by patients to be filmed as part of a reality TV show or as part of a public relations video, HIPAA rules state the media organization would need to be a HIPAA-compliant business associate. It is doubtful that a media company would agree to that.

Though not a HIPAA issue, the health care workers in the EU may feel uncomfortable being recorded by "outside" production crews. Should doctors and others be required to agree?

Images of the patient that are incorporated into the medical record or, with patient permission, are made for training and educational purposes are subject to the same rules applicable to all medical information. Such pictures should be taken only on devices owned or controlled by the institution. These devices should not be capable of directly forwarding the images by text or email. Images belong to the owner of the device. Thus images recorded on devices owned by the institution (or professionals working for the institution) belong to the institution while images recorded on personal devices belong to the individual owner.

However, there is another potential scenario for image recording. Most of us, particularly in the younger (purposely left undefined) generation own a smart phone with a camera. It is very easy for health care workers to take pictures in hospitals and capture images that inadvertently reveal the identity of patients and PHI (a respirator, an IV, a catheter, etc.). Health care professionals and staff

should not create mages containing PHI on personal devices. Both intentional and inadvertent disclosure is a HIPAA violation. Doctors have gotten into trouble for posting supposedly de-identified images in social media, only to find that certain features remained recognizable.

Employees of governmental agencies and private corporations that deal with high security information may not be permitted to use cell phones with cameras in the workplace and in some situations may not even bring them onto the premises. There is thus a small market for cell phones without cameras. This approach is not necessary in the medical environment. But employers and employees should be aware of the risks of taking photos in the medical workplace.

What about families and visitors? We want parents and relatives to be able to photograph newly arrived babies, beloved relatives, etc. A recognizable patient face in the background, however, is a HIPAA violation. Visitors should be informed by appropriate signage of the necessity of confining photos strictly to family and friends.

Additionally, there have been reports of rare surreptitious audio recordings by patients, including instances where the recordings were made while the patient was under anesthesia (recorder hidden in the hair, clothes stored under the stretcher during a colonoscopy, etc.). What if during the procedure, PHI of another patient was revealed? For example, the surgeon might have discussed "Mrs. Jones" who had a condition similar to the patient. The surgeon has every reason to believe that an anesthetized patient cannot hear what is being said. When the patient awakens and hears the recording however, that PHI will be revealed.

Surreptitious recordings should be banned. If a recording is to be made, it should be known to all present. Whether the consent of the doctor is needed is another (controversial) question.

Medical institutions and physician practices should have specific enforceable policies about the confidentiality of images and recordings created in the medical workplace. These rules should be reinforced repeatedly with employees and visibly posted for visitors. As New York-Presbyterian Hospital learned, the consequences of not doing so are costly. ❖

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High Tech Tach: A New Era of Patient-Generated Data

KENNETH S. KORR, MD

As an interventional cardiologist for most of my career, I have become accustomed to a steady stream of new and more improved technologies and therapies – from balloons to stents and atherectomy devices and the ongoing evolution in dual antiplatelet therapy (DAPT) and the newer oral anticoagulants (NOACs). And I have seen similar trends throughout cardiology, in electrophysiology and echocardiography and in other areas of medicine as well. This technology revolution has always been industry-driven and physician-directed. Recently, however, I had the unique experience of the patient bringing me data downloaded from a device via his smart-phone app.

JB has been a long-standing patient of mine since his MI and stent 10 years ago. We have also been in the same tennis group for more than 20 years. He is now 80 and remains robust and active and is a real tech junkie. He has complained of intermittent palpitations for the past year but has had unremarkable EKG, Holter monitor and several event monitor readings. He has been frustrated with our inability to make a more precise diagnosis.

Last week he brought a new tech toy to our tennis session – AliveCor, an FDA-approved, hand-held device about the size of a tongue depressor with metal electrode plates on both ends. When held between the thumbs and forefingers it will record a single-lead EKG that can be downloaded to an iPhone or other smart phone via an app. We all tried it out and got reasonably good quality EKG tracings with variable degrees of baseline artifact, but easily discernible rhythms.

The next morning I received an email from JB with an attachment. At first I thought, well he's just sending me another example of his EKG. But when I opened it, there was an EKG strip of rapid afib @ 130bpm recorded at 11:30 p.m., a few hours after our tennis session and when he was feeling his palpitations. I got another email a few minutes later with another attachment showing afib @ 100 bpm recorded at 6 a.m.

By the time we got JB into the office later that day, he was back in sinus rhythm, but he had brought along several more strips of afib which finally reverted to sinus rhythm at noon. So now, thanks to this device, we had established a firm diagnosis and were able to discuss treatment options. Keeping the tech theme going, I opened up the CHADS2-VASC calculator and took him through the various elements allowing him to calculate his score of 6. This corresponds to a 9.7% annual stroke risk, an obviously high thromboembolic risk and one that warrants long-term anticoagulation.

We moved on to a discussion of the relative risk and benefits of the different anticoagulants. We decided on a once-a-day preparation which I proudly e-prescribed right in front of him. Within a minute he got a text message from his pharmacy stating that his physician had prescribed a new medication but that it would require pre-authorization, a paper and pen process that would take at least a few days. So much for e-prescribing, and certainly not ideal when therapy needs to be initiated immediately. Fortunately my office staff had a first-time, 30-day free drug coupon card and we were able to get him started.

All in all, I was fairly impressed with this simple $100 device which was quickly able to demonstrate an arrhythmia that I had been trying to capture for months and one with significant clinical and therapeutic implications for this patient. I had to ask myself why I was not aware of this device, but it may not be marketed to physicians directly and does not have an easily billable component. In fact, it is more appropriate for the tech-savvy patient with paroxysmal arrhythmias, especially if they travel or are away from conventional medical facilities. Think of it as a more sophisticated extension of patient-generated data, like home pregnancy testing or monitoring of blood glucose or INR levels.

Anyway, I remained very satisfied with the outcome, at least until the next morning when I got another EKG download from JB, just checking in. Fortunately he was in sinus rhythm but he also sent all his recent blood pressure measurements. And today I got a download of his wife's EKG. Patient-generated data and personalized telemedicine here we come! ❖

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Disclosures

None